Sponsored Programs Manual

See Policy and Procedure/Form Creation or Revision to request changes to this document.

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Introduction: Responsible Stewardship in Sponsored Programs

Overview

Requirements	This chapter provides the codes, principles, and regulations that provide the basis for all procedures to be followed for all sponsored programs. All sponsored programs must comply with all applicable US and local laws and regulations. In addition, Baylor College of Medicine (BCM) must carefully consider the terms of each sponsored program to assure appropriate stewardship of funds according to the requirements of the sponsor or funding organization. **All BCM personnel must assure that any proposed sponsored program activities are reviewed and approved by BCM before engaging in these activities.**
Definition	Sponsored Program - a project or activity funded with grants, contracts, and/or cooperative agreements, including, but not limited to, training, public service, research, and cooperative projects.
Principles	BCM as a recipient of sponsor funding has a legal and ethical responsibility to ensure that the money received is being spent appropriately. The U.S. Office of Management and Budget (OMB) provides regulatory principles on the expenditure of funds. Regardless of the funding source, these principles provide the foundation for the responsible stewardship of sponsored programs.
Delegation of authority	The BCM Board of Trustees has delegated to the President certain authorities for executing contracts and levels of expenditures. The President has re-delegated certain authorities to the Senior Vice President and Dean of Research (SVPDR) and designees to execute sponsored programs agreements on behalf of BCM and its investigators.
Proposal submission	The SVPDR and designees have the responsibility to approve sponsored project proposals, exercising appropriate judgment regarding the applicant's ability to provide the necessary scientific/technical leadership and administrative/financial management of the project. The SVPDR and designees may exercise this authority; individuals eligible to serve as principal investigators (PI) may not directly submit proposals to prospective sponsors.
Acceptance	Grants and contracts for sponsored programs are awarded to BCM rather than to individual investigators. The SVPDR and designees have the responsibility to accept sponsored programs on behalf of the BCM Board of Trustees. To be accepted, sponsored programs must adhere to applicable BCM policies and procedures, regulations and guidelines. Only the SVPDR and designees may exercise this authority. Other individuals may not accept awards or agree to terms proposed by a sponsor or funding organization.

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Overview, Continued

Related standards	BCM Sponsored Programs Policy 20.2.00 BCM Policy - 20.0.01 - Obligations of Baylor Faculty OMB Uniform Guidance 2 CFR 200 - Office of Management and Budget guidance establishes uniform administrative requirements, cost principles, and audit requirements for Federal awards to non-Federal entities. In general, replaces separate circulars below:
Resources for incoming investigators	The Office of Research maintains an internal Welcome website with updated information and links to checklists and resources for onboarding and lab start-up. Administrators can also send a pdf summary of the information prior to researchers getting their ECA login name.

Eligibility

Introduction	This section describes the requirements to apply as BCM Principal Investigator (PI) for Sponsored Programs.
Independent research	BCM requires the PI of an independent research award proposal to be a faculty member (instructor level or above) or research certified voluntary faculty by the time of award. • A letter or email from the department Chair to Sponsored Programs, indicating the applicant is expected to receive a faculty appointment by a specific date, will suffice for the application to be approved at the time of submission. • ***Note*: In no instance may a faculty appointment be contingent upon the disposition of a pending application.**
Fellowships and mentored awards	Numerous grant and fellowship mechanisms exist that would not be considered independent research grants, and therefore would not require a faculty appointment. These include, but are not limited to, most fellowships, including NIH F-awards; and NIH K-awards. However, the Mentor must be a faculty member and be listed as Key Personnel and must provide a signed Mentor Certification with any proposal agreeing to oversee the project and training of the fellow.
Other sponsored activities	Faculty members are usually the Program Director for other non-research awards such as education, public service, meetings and conferences, programming and web development, or infrastructure awards. Prior approval by the SVPDR or designee is required for any other BCM employee who may have the expertise and job role to provide the proper oversight and control in managing such programs.

Chapter 1
Sponsored Programs

Overview

Sponsored Programs	Sponsored Programs are externally funded activities, most typically research or educational activities, in which a formal written agreement, i.e., a grant, contract, or cooperative agreement, is entered into by BCM and by the funding source. A sponsored program may be thought of as a transaction in which there is a specified statement of work with a related, reciprocal transfer of something of value.
Structure and organization	The responsibility for the review and approval of such activities rests with the SVPDR and is delegated to the Office of Research (OOR), the Sponsored Programs Office (SPO), Baylor College of Medicine Ventures (BCM Ventures), and the Office of Clinical Research (OCR).

Roles and Responsibilities

Introduction	The proposal and acceptance of sponsored program awards and contracts relies on an interdependence of the following roles.
Principal investigator (PI)	• Timely, accurate, and complete submissions • Prepares and submits all required pre-award proposal documents using the Biomedical Research and Assurance Information Network (BRAIN) system certifying his or her understanding of, and compliance with, all laws, policies, regulations, and other terms and conditions associated with the submission • Updating financial conflict of interest disclosures for all investigators involved with the research project
Department Chair/Center Director and designees	• Section Chiefs/Department Chairs have the overall responsibility of determining the appropriateness of the project and project changes on behalf of the Department and College • Reviews and approves grant applications, progress reports (including verification of time and effort, salary, COI), and all associated budgetary and financial information • Ensures all application information is accurate and complete before approving and forwarding to Sponsored Programs, including: – Eligibility – Effort – Salary support – Budget and budget justification – Forms and format • Reviews, approves, and submits BRAIN proposal routing summaries on behalf of the department chair. See additional information in Section 5B Departmental Review.
Office of Research functions	The Office of Research (OOR) is comprised of the following offices: • Research Oversight Administration, including the: – Human Research Protection Program including the Institutional Review Boards (IRB) – Institutional Animal Care and Use Committee (IACUC) – Institutional Biosafety Committee (IBC) – Research Compliance Services (RCS) – Committee on Scientific Integrity (COSI) – Research Conflict of Interest (RCOI) • Research Support Office (RSO) • Sponsored Programs (SPO) • Office of Clinical Research (OCR) • Office of Research Information Technology (ORIT) • Center for Comparative Medicine (CCM) • Specific functions of the OOR are referenced throughout this handbook. The OOR Contact List provides contact names, functions, telephone numbers, and locations of individuals or offices to contact for assistance.

Continued on next page

Roles and Responsibilities, Continued

Sponsored Programs Office

Sponsored Programs is responsible for the pre-award phase of research proposals for:

- Grants
- Non-industry contracts, such as federal, state and foundation funded contracts
- Subawards
- Material Transfer Agreements (MTAs)
- Data Use or Data Transfer Agreements (DUAs)
- Collaboration Agreements with academic or non-profit partners
- Confidentiality non-disclosure agreements (CDAs) for basic research (not clinical research)

Sponsored Programs personnel:

- Are delegated the responsibility to serve as institutional officials for BCM, ensuring compliance with applicable laws, regulations, and policies governing research
- Review for compliance with sponsors' guidelines and policies, the terms and conditions of awards, electronic submission requirements, and College policies and procedures, by conducting assessments of both:
- For-cause concerns of noncompliance
- Routine monitoring as part of ongoing quality improvement activities

  Note: Assessments and monitoring may be conducted with support from Research Compliance Services (RCS) personnel.
- Guarantee completed grant applications received five working days prior to the sponsor's deadline will be submitted on time (this assumes departmentally approved BRAIN proposal routing summary has been received)

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Roles and Responsibilities, Continued

Sponsored Programs Office (cont.)

Additionally, Sponsored Programs:

- Counsels investigators and administrative staff regarding:
  - Research funding opportunities
  - Proposal preparation
  - Contract negotiation
  - Subaward implementation
  - Interpretation of guidelines
  - Applicable policies and regulations
- Negotiates with funding agencies, collaborators, and subawardees to reach agreements satisfactory to the sponsor, faculty, and BCM.
- Reviews, revises, and approves proposals to:
  - Comply with BCM and sponsor policies
  - Verify resource commitments, budget accuracy, and faculty appointments
- Reviews final award documents and revisions of existing awards to ensure the agreements conform with BCM policy
- Maintains pre-award proposal documents using the Biomedical Research and Assurance Information Network (BRAIN) system
- Provides management information regarding:
  - Pending and awarded grants, contracts, and cooperative agreements
  - Federal budgetary and administrative rule changes

BCM Ventures

BCM Ventures assists with processing the following types of agreements:

- Outgoing Material Transfer to a for-profit company that requires a license
- Industry sponsored Testing and Service Agreements

Office of Clinical Research

The Office of Clinical Research (OCR) is delegated the responsibility for:

- Confidentiality/Non-disclosure agreements (CDAs) for clinical research
- Clinical trial agreements (CTAs) with for-profit industry sponsors
- Sponsored Research Agreements with for-profit industry sponsors
- Research Collaboration Agreements with for-profit industry sponsors

OCR reviews and revises agreements ensuring compliance with applicable laws, regulations, and policies governing clinical research. The Clinical Trial Agreement System works in conjunction with the Biomedical Research and Assurance Information Network (BRAIN) system to provide real time tracking of the negotiation process.

Helpful Hints

See the table below for responses to common questions:

Question	Response
How to communicate with Sponsored Programs or the Office of Clinical Research	• Email spo@bcm.edu for grant-related submissions, renewals, and extensions; federal contracts; basic science contracts; and general questions • Email cta@bcm.edu for clinical trial agreements (CTAs) and confidentiality non-disclosure agreements (CDAs), and industry sponsored basic research agreements • Email mta@bcm.edu for material transfer agreements (MTAs) and data use agreements (DUAs) • Email subaward@bcm.edu for subcontracts and subgrants • Call 713-798-1297
Where to find information	Office of Research website: Sponsored Programs
What to submit to the Sponsored Programs Office (SPO)	• Requests for external research support (fellowship applications, grant applications, federal contracts, etc.) • Any federal or state program contracts (including federal symposia and conference grants, CPRIT, Texas DSHS, etc.) • Award notices, award letters, or any other type of award acceptance documents for research support (some award documents require review and negotiation prior to acceptance) • Non-monetary research support agreements for equipment or software, or for access to the NIH Genotypes and Phenotypes Database (dbGaP) • Subawards (incoming and outgoing) • Progress reports • No-cost extension requests • Requests that require sponsor prior approval prior to implementation such as PI change or effort reduction • Confidentiality non-disclosure agreements (CDAs) with other academic collaborators or non-profit sponsors • Confidentiality non-disclosure agreements (CDAs) for basic research with industry sponsors • Material transfer agreements (MTAs) - e.g., incoming or outgoing requests for research materials such as cell lines, animal models, etc. • Data use agreements (DUAs) – e.g., incoming or outgoing requests to share limited data set information. If Protected health information (PHI) is to be shared, then an additional Business Associate Agreement (BAA) may need to be negotiated as well

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Helpful Hints, Continued

Office of Clinical Research (cont.)

See the table below for responses to common questions (continued):

Question	Response
What to submit to the BCM Ventures	• Outgoing Material Transfer to a for-profit company that requires a License • Industry sponsored Testing and Service Agreements
What to submit to the Office of Clinical Research (OCR)	• Confidentiality non-disclosure agreements (CDAs) for clinical research with industry sponsors • Industry funded clinical trial agreements (CTAs), amendments, and other clinical trial related documents • Sponsored Research Agreements with for-profit industry sponsors • Research Collaboration Agreements with for-profit industry sponsors
What NOT to submit to Sponsored Programs (where to submit instead)	• Non-research agreements (e.g., service agreements, clinical service, visiting scientist, or non-grant funding for symposia and conferences) should be directed to the Office of the General Counsel • Gifts (not for specific research projects) should be directed to the office of Advancement and Alumni Affairs • Final Invention Statements should be submitted to BCM Ventures • Applications for NIH Certificates of Confidentiality should be submitted to the IRB office, contact irb@bcm.edu • Consulting agreements must be disclosed and approved by the department chair in the DOI system. No BCM confidential or proprietary information should be shared. • The following should be directed to Sponsored Programs Finance post-award accounting office, post_award@bcm.edu: – Accounting questions, including the status of a new account – Financial reporting questions – Relinquishing requests – Carry forward requests – Financial Status Reports (FSRs)
When to submit to Sponsored Programs	• At least **five working days** PRIOR to the sponsor's deadline • Application and BRAIN proposal routing summary must be complete and approved by the department chair (or his/her designee) • Each Academic department may have an earlier deadline – check with the departmental grants administrator

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Helpful Hints, Continued

How to submit to Sponsored Programs

A proposal routing summary is required to be submitted to Sponsored Programs through BRAIN ESP2 for the following:

- Grant applications and proposals, including resubmissions, amendments, progress reports, renewals, no cost extensions, and changes of PI
- Research contracts, agreements, and amendments
- Clinical trial agreements and amendments
- Incoming subawards and subcontracts

***Note*:** Only the PI may submit under his/her unique BCM username and password. The BRAIN proposal reflects the certification and understanding of the PI's responsibilities to BCM, to the sponsor and to governmental oversight agencies.

When the BRAIN proposal routing summary is NOT required

A BRAIN proposal routing summary is NOT required for the following items but must still be reviewed by the appropriate office:

Item	Action to take
Material transfer agreements (incoming and outgoing)	• Email mta@bcm.edu • See MTAs on the OOR website • If from another academic institution or industry, forward the agreement to mta@bcm.edu for review • If to another academic institution, use the Uniform Biological Materials Transfer Agreement (UBMTA) • If to a company, email bcmventures@bcm.edu – a license is required for BCM materials going to a company
Carry-forward requests	• Check the Notice of Grant Award to determine if this is automatic • If not automatic, prepare a letter to the sponsor (to Grants Management Specialist if NIH) including the following: – Explain reason for remaining funds – Provide expected amount in direct and total costs – Briefly describe how the carry forward funds will be used – Have the PI sign with second signature line for BCM Authorized Signature • Scan and email the attachment to Sponsored Programs Finance at post_award@bcm.edu

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Helpful Hints, Continued

When the BRAIN proposal routing summary is NOT required (cont.)

A BRAIN proposal routing summary is NOT required for the following items but must still be reviewed by the appropriate office (continued):

Item	Action to take
Pre-award spending requests	Email Sponsored Programs Finance, post_award@bcm.edu, providing grant number and an unrestricted account number to serve as a back-up in the email. Complete an online Pending Account Request form, which is located on the Finance website. Provide a justification and an unrestricted account number.
Pending account requests	• Department fills in an online intranet form with: – A backup cost center number – BRAIN number – Grant number (if available) – PI – Admin contact/e-mail – And a reason for the delay • A request should only be submitted if the proposals have been approved and all associated protocols are current and have been approved, and research conflict of interest assurance has been approved in BRAIN • The request can be accessed through Request for Pending Accounts
Outgoing subawards	• While incoming subawards are processed through BRAIN, outgoing subawards are tracked using the Subaward System • Additional information, instructions and handbook are available on the SPO intranet site for Subawards • Contact subaward@bcm.edu for questions or use of accounts not tracked by BRAIN proposals

Flow chart

Below is a process flow chart for proposal submissions through BCM's Sponsored Programs Office:

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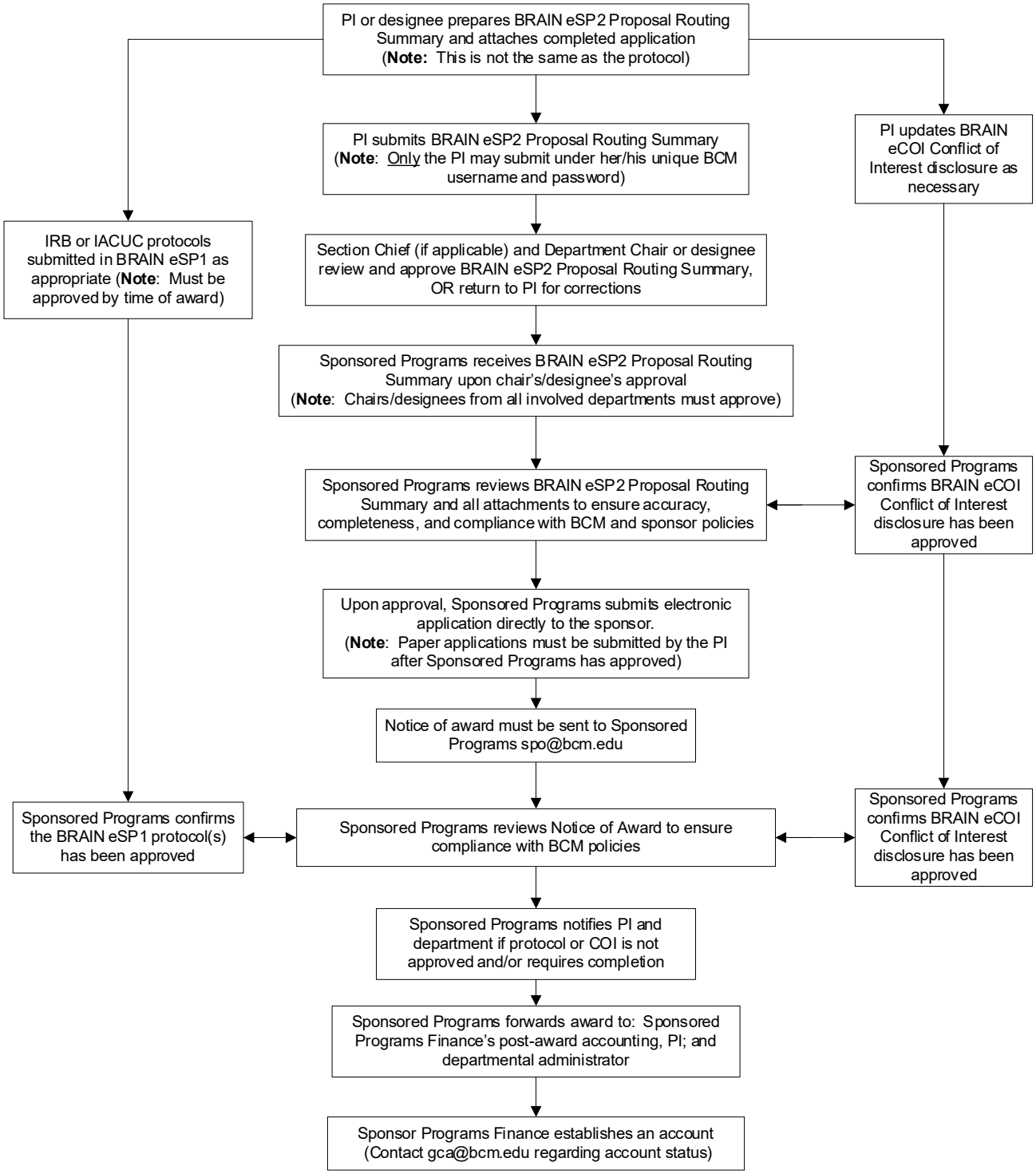
Sponsored Programs Proposal Review, Approval, and Submission



Chapter 2
Research Funding Types

Overview

Introduction	Principal Investigators must identify sources of funding outside of the College to help support their research. These external sources are referred to as sponsors. Sponsors include federal agencies (e.g., the National Institutes of Health), state agencies (e.g., Texas Department of State Health Services), non-profit organizations (e.g., American Cancer Society); and for-profit corporations (e.g., Merck).
In this chapter	This chapter covers the following sections: Section 2A: Research Agreements Section 2B: Identifying Potential Funding Sources Section 2C: Helpful Resources for Preparing Grant Applications

Section 2A
Research Agreements

Overview

Introduction	This section describes how proposals and awards are handled.
In this section	This section covers the following topics: • Types of Proposals and Their Unique Requirements • Types of Awards

Types of Proposals and Their Unique Requirements

RFAs

Requests for Applications (RFAs) are targeted, stand-alone solicitations for applications for:

- A well-defined scientific area
- A one-time competition
- Construction grants or
- Cooperative agreements

Each RFA provides sufficient information to allow prospective applicants to determine whether or not to apply, including the:

- Amount of funding available
- Number of awards anticipated
- Deadline date for receipt of applications
- Nature of effort desired
- Eligibility requirements
- Obligations of recipients

For cooperative agreements, the RFA describes the responsibilities and obligations of the:

- Awarding Agency
- Awardees (Recipient Institutions with Investigators)
- Agency and awardees jointly

***Note*:** Occasionally, RFAs limit the number of proposals that an institution may submit, necessitating an internal selection process through the Faculty Committee on Awards as described below.

Continued on next page

Types of Proposals and Their Unique Requirements, Continued

RFPs

Requests for proposals (RFPs) are issued by federal agencies supporting specific research through a federal **contract** instead of through a grant. The following provides more information about RFPs:

- RFPs describe the specific program interests of the sponsor, and include submission requirements such as:
  - Format
  - Scope of Work
  - Budget
  - Receipt Deadlines
- RFPs generally are open to bidding by any qualified research institution
- The submission typically comprises two parts – the technical (research) proposal; and the business (financial) proposal
- A Small Business Subcontracting Plan must be included either in the initial business proposal or a subsequent iteration. Contact BCM's Supply Chain Management well in advance to prepare the Small Business Subcontracting Plan
- Deadlines are specified in the announcement and must be observed. The deadlines are **receipt** deadlines, not postmark deadlines
- A revision period, often including a conference call between the federal sponsor and key personnel, culminates in a Best and Final Offer
- The final award is issued as a contract between the federal agency and the institution. The institution and investigator must strictly adhere to the terms and conditions of the contract. The contract is not as flexible as most grant awards, eliminating or limiting the ability to re-budget or adjust the scope of work without prior written authorization from the federal sponsor.

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Types of Proposals and Their Unique Requirements, Continued

Unsolicited proposals

Unsolicited proposals are submitted to a potential sponsor in accordance with general guidelines rather than as a result of a topic-specific solicitation. Most grant applications are considered unsolicited. If awarded, the funding mechanism may be a grant, contract, or cooperative agreement. For more information, see below:

- Most National Institutes of Health (NIH) awards result from unsolicited proposals using generic applications called Parent Announcements (PAs)
- Industry (for-profit) funding typically is through a contract
- Most sponsors have well-established deadlines for submission of unsolicited proposals as well as published schedules for review and notification
- The Sponsored Programs website lists the major NIH deadlines throughout the year. Regardless of sponsor, all applications must be complete and submitted to Sponsored Programs FIVE WORKING DAYS PRIOR to the sponsor's deadline.

Limited submission proposals

Some sponsors limit the number of proposals an institution may submit, necessitating an internal selection process. When a researcher wants to apply to an opportunity with eligibility restrictions on the number of applicants allowed per institution, then they need to contact BCM's Intramural Funding and Awards to request review as soon as they identify the restriction.

- Email awards@bcm.edu with a copy of the opportunity instructions to inquire whether any other parties are interested.
- An internal RFA will be issued to the Research listserv providing a specific amount of time to respond, usually 2-3 weeks. Requests to join the listserv should be sent to awards@bcm.edu.
- Researchers interested in the opportunity will typically be asked by the Intramural Funding and Awards office to submit a one-page summary proposal for review. Internal review will *only* take place if more than one party indicates interest in submission to a limited submission opportunity.
- Faculty Committee on Awards (FCA) reviews submissions and chooses the nominee for the Institution, usually 10-14 days. Sometimes the full FCA review process cannot be followed due to deadline or other restrictions. If this is the case, a mini-version or alternative faculty review occurs.
- Depending on a particular award or sponsor the submissions may be reviewed and managed by designated Centers or Departments.

All of this should happen before the BRAIN proposal gets submitted, so it is helpful to be aware of interested parties and also be mindful of deadlines.

Please email awards@bcm.edu for further information regarding solicitations which limit the number of allowable applications.

Types of Awards

Introduction

Awards may be issued through various mechanisms. Regardless of mechanism, the PI and the College must comply with the specific terms and conditions of each award. A few of the most common mechanisms are listed below:

- Contracts
- Cooperative agreements
- Grants
- Subawards
- Fellowships
- Donations/gifts

Contracts

Contracts are legal agreements used for procuring a specific service or product. Detailed descriptions of material transfer agreements, sponsored research agreements, clinical trial agreements, and other contracts are in Chapter 5, Section 5E.

The following describes broad contract categories:

Contract Type	Description
Fixed price	A set lump-sum payment is established in advance for performance of a specified set of tasks or delivery of a certain service. Overhead expenses, indirect costs, are included in the lump-sum and/or per unit cost. • Payment is limited to a price multiplied by the number of units performed. ***Example*:** $/completed lab test per patient. • BCM also will negotiate the terms and conditions of the sponsor's contract, if one is provided
Cost-reimbursement	Provides for payment of actual costs incurred, including overhead/indirect costs, up to a ceiling amount equal to the total cost stated in the contract.

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Types of Awards, Continued

Cooperative agreements	This form of federal assistance involves both the federal government and the grantee (e.g., BCM) sharing responsibility for the program management of the project. • Cooperative agreements anticipate substantial federal involvement with the recipient during performance of the contemplated activity • Specific terms of collaboration are spelled out in individual agreements, which Sponsored Programs will review carefully with the investigator • In all other respects, cooperative agreements follow the policies applicable to grant awards
Grants	Grants and cooperative agreements are usually awarded to support or assist investigator-initiated projects whereas contracts procure a pre-defined service or product. • Grants are less restrictive than contracts, although technical and financial reports are generally required • Grants may be awarded by foundations, corporations, or agencies of the local, state, or federal government • Award amounts, types of awards, and terms and conditions vary from sponsor to sponsor • Most agencies offer a variety of grant opportunities Among the grants available from the NIH, the major mechanisms include: • Research Project Grant (R01) • Small Grant (R03) • Exploratory/Developmental Research Grant (R21) • Program Project Grant (P01) • Career Development Grants (K series) • National Research Service Awards for Institutional Training Grants (Institutional NRSA) (T32)
Subawards	Subawards may be incoming or outgoing: • Incoming subgrants or subcontracts result when another organization, typically another academic institution, receives an award from an external sponsor and asks BCM to perform part of the work on their behalf • Outgoing subawards are issued by BCM when BCM has received an externally sponsored award and another organization, typically another academic institution, will perform part of the work on behalf of BCM

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Types of Awards, Continued

Fellowships	Individual fellowships may be awarded to support training at both the pre-doctoral and post-doctoral levels. • Fellowships are available from a broad range of sponsors, including foundations, other non-profit organizations, governmental agencies, and professional societies • NIH offers individual fellowships for: – Predoctoral – Postdoctoral – MD/PhD candidates – Senior fellows (changing research careers) • NIH's F-Kiosk provides detailed information regarding NIH's Individual Fellowships (F series)
Donations/gifts	Donations and gifts are provided to the College with no benefit to the donor. No strings are attached to a gift. The donor requires no detailed technical reporting, no review prior to publication, and no rights to intellectual property which may result from research supported through the gift. If such terms and conditions are attached to a gift, the gift is treated as a research grant and, if from industry, charged the appropriate indirect cost rate. BCM requires 25% of gift funds be set aside toward the Strategic Fund to help further the mission of the College such as providing seed funds for faculty recruitment. See below for additional information: • The donor may stipulate that her/his contribution is to be used for a designated purpose, although a detailed research plan usually is not included • Detailed expenditure or technical reports are generally not required as a condition of the gift • Ownership of, or granting other rights to, intellectual property is not included • Progress report letters are an expected courtesy – confidential or proprietary information should not be disclosed • Contact the office of Advancement and Alumni Affairs to identify a Development Officer assigned to the recipient department for assistance with the gift stewardship process.
Research agreement decision tree	BCM manages over 30 different types of research agreements. OOR maintains a Decision Tree with guidance and documentation to help determine the type of agreement and how to route it for the most efficient review process.

Section 2B
Identifying Potential Funding Sources

Overview

Introduction

This section focuses on the tools used by investigators to identify potential sources of funding for their research.

In this section

This section covers the following topics:

- General Search Tools
- Federal Agency Funding Websites
- Private, Non-Profit Funding Websites
- BCM Intramural Funding and Awards

General Search Tools

Introduction	The following describes popular websites for locating funding sources for research purposes.
Funding websites	• Grants.gov - Lists all current discretionary funding opportunities from 26 agencies of the United States government, including the National Institutes of Health, the National Science Foundation, the Department of Energy, and many others -- in other words, all the most important public funders of research in the United States. • The National Institutes of Health (NIH) Office of Extramural Research - The largest funder of biomedical research in the world, NIH funds research in just about every area that's remotely related to human health and disease. This page includes extensive information about NIH grants, as well as a place to search NIH funding programs. NIH also has an advanced search page, which offers a wide range of search options. • The National Science Foundation (NSF) - An independent federal agency, the U.S. National Science Foundation funds approximately 20 percent of all federally supported basic research conducted at America's colleges and universities. This is the place to search for NSF funding programs.

Federal Agency Funding Websites

Assistance Listings

Assistance Listings, formerly known as the Catalog of Federal Domestic Assistance (CFDA), is compiled by the US General Services Administration. The list provides the user with access to all assistance and benefit programs of federal departments and agencies. Links to Grants.gov are included in the Listing.

Program information may be searched many ways, such as by:

- Program number
- Keyword
- Grant only
- Advanced search
- Programs listed numerically
- Top 10 percent of programs

Federal Contract Opportunities

Federal Contract Opportunities, formerly known as FedBizOpps, is the official listing of all federal government contracting opportunities and awards over $25,000. Opportunities include pre-solicitation notices, solicitation notices, award notices, and sole source notices.

Federal Digital System

The Government Printing Office's Federal Digital System (FDsys) provides free online access to official publications from all three branches of the Federal Government. FDsys allows users to:

- Search for documents and publications - Provides advanced search capabilities and the ability to refine and narrow searches for quick access to the needed information
- Browse for documents and publications - Offers browsing by collection, Congressional committee, and date
- Access metadata about documents and publications - Provides information about Government publications in standard XML formats
- Download documents and publications in multiple renditions or file formats - Users can download a single file or download content and metadata packaged together in a compressed file

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Federal Agency Funding Websites, Continued

Department of Health and Human Services

The Department of Health and Human Services (DHHS) is the federal government's principal agency for protecting the health of all Americans and providing essential human services.

Most DHHS grant applications must be submitted electronically through the federal-wide Grants.gov system.

The following are DHHS agencies which provide significant research funding:

DHHS Agencies	Description
National Institutes of Health (NIH)	NIH is the primary federal agency for conducting and supporting medical and biomedical research.
Administration on Aging (AOA)	Supports a nationwide aging network that provides services to the elderly, especially those enabling them to remain independent.
Agency for Healthcare Research & Quality (AHRQ)	Supports research designed to improve the outcomes and quality of health care, reduce its costs, address patient safety and medical errors, and broaden access to effective services.
Agency for Toxic Substances & Disease Registry (ATSDR)	The agency conducts public health assessments, health studies, surveillance activities, and health education training in communities around waste sites on the U.S. Environmental Protection Agency's National Priorities List.
Centers for Disease Control & Prevention (CDC)	With the assistance of states and other partners, CDC guards against international disease transmission, maintains national health statistics, provides for immunization services, and supports research into disease and injury prevention.
Administration for Children & Families (ACF)	Responsible for programs which provide services and assistance to needy children and families.
Food & Drug Administration (FDA)	Assures the safety of foods and cosmetics, and the safety and efficacy of pharmaceuticals, biological products and medical devices.
Health Resources & Services Administration (HRSA)	Helps provide health resources for medically underserved populations. HRSA supports a nationwide network of community and migrant health centers, and primary care programs for the homeless and residents of public housing.

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Federal Agency Funding Websites, Continued

Department of Health and Human Services (cont.)

The following are agencies of the DHHS that are sources of funding for research (continued).

DHHS Agencies	Description
Indian Health Service (IHS)	Supports a network of hospitals, health centers, school health centers, health stations and urban Indian health centers to provide services to American Indians and Alaska Natives of federally recognized tribes.
Centers for Medicare & Medicaid Services (CMS)	Administers the Medicare and Medicaid programs, which provide health care to America's aged and indigent populations.
Substance Abuse & Mental Health Services Administration (SAMHSA)	Works to improve the quality and availability of substance abuse prevention, addiction treatment, and mental health services.

National Science Foundation

The National Science Foundation (NSF) is a funding source for basic research conducted by U.S. colleges and universities. In many fields such as mathematics, computer science, and the social sciences, NSF is the major source of federal research support.

NSF does not fund as much in the biomedical arena as in the hard sciences, since NIH typically funds biomedical research. However, many BCM investigators have successfully applied for NSF funding. Contact SPO to get a login for NSF.

Department of Defense

The Department of the Defense (DOD), through its Congressionally Directed Medical Research Programs (CDMRP), supports research in areas such as autism; breast, ovarian, and prostate cancer; tuberous sclerosis complex; neurofibromatosis; PTSD; and TBI. The CDMRP offers pre- and postdoctoral research support as well as research support for faculty at all levels. Opportunities and online applications are managed at the Electronic Biomedical Research Application Portal (eBRAP).

National Aeronautics and Space Administration

National Aeronautics and Space Administration (NASA) provides information on how to identify and apply for NASA funding. The Translational Research Institute for Space Health (TRISH) is funded through NASA and housed at BCM. TRISH funds transformative human health technologies to predict, protect, and preserve astronaut physical and mental wellness during deep space exploration missions.

If looking for grant and cooperative agreement funding opportunities with NASA, please refer to Grants.gov or NASA's NSPIRES website. Contact SPO concerning Affiliation Requests for NSPIRES.

Private, Non-profit Funding Websites

Introduction	The following are examples of private (non-federal) non-profit organizations that provide funding for researchers in disease- or condition-specific areas. Please note that these non-profit sponsors typically cap indirect costs. BCM honors these non-profit indirect cost caps, but does require applicants to request indirect costs up to the cap. A copy of the organization's policies on indirect costs should be attached to the BRAIN proposal; often this is part of the opportunity instructions. All proposals to any of these non-profits must be entered into BRAIN to be reviewed and approved by Sponsored Programs. Most of these non-profit foundations also follow the PHS regulations concerning financial conflict of interest reporting.
Alzheimer's Association	The Alzheimer's Association has a strong commitment to direct funding of research grants, in addition to a commitment to increase federal funding for Alzheimer research through public policy efforts.
American Cancer Society	The American Cancer Society (ACS) focuses its funding on investigator-initiated, peer-reviewed proposals. This process ensures that scientists propose projects that they believe are ready to be tackled with the available knowledge and techniques.
American Diabetes Association	The American Diabetes Association (ADA) research program supports basic and clinical diabetes research aimed at preventing, treating, and curing diabetes. The diabetes research projects cover the spectrum from islet cell biology and transplantation techniques to studies in education and behavioral issues.
American Heart Association	The American Heart Association (AHA) has many different types of funding. The AHA has a very broad definition of what it considers related to heart disease or stroke.
American Lung Association	The American Lung Association (ALA) supports basic and clinical research through training and "seed" grants for researchers who are at the early stage of their careers. ALA also created the Asthma Clinical Research Centers Network (ACRC), which seeks to conduct large clinical trials that will provide useful information about asthma and benefit patients directly.
Cancer Prevention and Research Institute of Texas	The Cancer Prevention and Research Institute of Texas (CPRIT) goal is to expedite innovation and commercialization in the area of cancer research and to enhance access to evidence-based prevention programs and services throughout the state. CPRIT accepts applications and awards grants for a wide variety of cancer-related research and for the delivery of cancer prevention programs and services by public and private entities located in Texas. CPRIT also requires financial conflict of interest reporting throughout the term of the award.
March of Dimes	Research subjects appropriate for support by the March of Dimes (MOD) include basic biological processes governing development, genetics, clinical studies, studies of reproductive health, environmental toxicology, and social and behavioral studies.

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Private, Non-profit Funding Websites, Continued

Muscular Dystrophy Association	The Muscular Dystrophy Association (MDA) is the world's largest non-governmental sponsor of research seeking the causes of and effective treatments for neuromuscular diseases.
National Kidney Foundation	The National Kidney Foundation (NKF) has embarked upon an initiative to increase the support of clinical research through its Postdoctoral Fellowship, Young Investigator Grants and Clinical Scientist programs.
Proposal Central	The Proposal Central website hosts over 200 funding organizations and provides a common grants management platform for application, award and management. Researchers can search for funding opportunities, prepare applications and work with institutional signing and financial officials to complete submissions and reports.
Robert Wood Johnson Foundation	Robert Wood Johnson Foundation (RWJF) issues special calls for proposals as well as accepts unsolicited proposals. The calls for proposals describe the specific problem to be addressed, who is eligible to apply, what the proposal should include, how the selection process will work, and how to apply. Unsolicited proposals - good ideas that come from the field – are accepted throughout the year. There are no specific application forms or deadlines, but the investigator must coordinate any unsolicited proposal with BCM's Office of Development.
Susan G. Komen for the Cure	Susan G. Komen for the Cure supports breast cancer research. Komen funds research to find the causes and cures of breast cancer and focuses on speeding the translation of research discoveries to reduce breast cancer mortality and/or incidence.
Welch Foundation	The Welch Foundation, based in Houston, Texas, is one of the oldest and largest private funding sources for basic chemical research in the United States.
W. M. Keck Foundation	The W. M. Keck Foundation makes grants to research institutions and accredited institutions of higher learning primarily in the areas of Science and Engineering, Medical Research and Liberal Arts.
World Health Organization	The World Health Organization (WHO) has grant opportunities available through the Special Programme for Research and Training in Tropical Diseases (TDR). This program aims to help coordinate, support, and influence global efforts to combat many of the major diseases of the poor and disadvantaged.

BCM Intramural Funding and Awards

Introduction

BCM's Intramural Funding and Awards oversees:

- Faculty Committee on Awards
- Basic and Clinical Collaborative Research
- Interim (Bridge) Funding
- Junior Faculty Seed Funding
- Michael E. DeBakey, MD, Excellence in Research Awards
- Mrs. Clifford Elder White Graham Endowed Research Fund
- Privately Funded Internal Awards

Award opportunities are sent out to the BCM community through the Office of Research Listserv. To join the Listserv, please send an email to awards@bcm.edu.

Faculty Committee on Awards

The Faculty Committee on Awards coordinates the selection of BCM investigators allowed to apply to a given opportunity when the sponsor limits the number of applicants from each institution. The BCM committee reviews potential nominees and selects the most outstanding nominee(s) to apply for the funding.

Only nominees selected by the Faculty Committee on Awards may submit an application to the sponsor. Once selected by the committee, an applicant should proceed as with any other application – submitting the proposal through BRAIN, obtaining signatures through Sponsored Programs, etc. See additional information in Section 2A Types of Proposals.

Basic and clinical collaborative research

The Basic and Clinical Collaborative Research Program supports research between established independent investigators in the basic and clinical sciences to more closely integrate research and patient care.

The program is open to all BCM tenured and tenure-track faculty. Applications are reviewed by the Faculty Research and Fellowship Support Committee.

Interim funding

The Interim Funding Program provides short-term relief funding for established laboratories that have experienced a lapse in funding. Rules apply as follows:

- For competitive renewals only
- All BCM tenured and tenure-track faculty are eligible
- New grant applications that are not funded are not eligible
- Any given application may receive interim funding only once, and investigators may apply only once per three years
- The Interim Funding Advisory Committee makes the award decision

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BCM Intramural Funding and Awards, Continued

Junior faculty seed funding	The Seed Funding Program helps prepare and support new investigators at the Assistant Professor level as they begin their careers as independent researchers. Rules apply as follows: • Applicants must be full-time, tenure-track Assistant Professors appointed during the past three years • Previous recipients of other BCM seed funding programs are not eligible for funding • Applications are accepted once a year in the spring, date posted on the website.
Michael E. DeBakey, MD, Excellence in Research Awards	The Michael E. DeBakey, MD, Excellence in Research Awards are given annually to BCM faculty who have made the most significant published scientific contribution to clinical or basic biomedical research during the past three years. Applications are accepted once a year, generally in the spring, date posted on the website.
Mrs. Clifford Elder White Graham Endowed Research Fund	The purpose of the Mrs. Clifford Elder White Graham Endowed Research Fund is to support annual pilot project awards for BCM faculty who are studying muscular dystrophy or related disorders. Please visit the webpage above for more details.

Section 2C

Helpful Resources for Preparing Grant Applications

Grant application basics	NIH provides an excellent starting point through its Grant Application Basics page. Information includes: • What Does NIH Look For? • Who Is Eligible for an NIH Grant? • Finding a Funding Opportunity
NIH RePORTER	The NIH RePORTER (formerly CRISP), is a database of NIH-funded projects. Abstracts of funded research projects, along with the institutions and PI names, are posted on NIH RePORTER. Investigators may search using keywords, institution name, PI's name, or other specific criteria.
General Grant Application Writer's Handbook	The Grant Application Writer's Handbook by Liane Reif-Lehrer, Ph.D., Jones and Bartlett Publishers, Inc. includes helpful information on: • Writing: – Research plans – Summary statements – Rebuttals – Revisions • Submitting and tracking grant applications • NIH and NSF • Applying to foundations This handbook is available at the Houston Academy of Medicine/Texas Medical Center Library.
BioScience Writers	BioScience Writers is a for-profit company that provides a number of technical writing services. They have an office at BCM that provides convenient on-site editing and proofreading services for a fee.

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Helpful Resources for Preparing Grant Applications, Continued

Career development awards (K-awards)	The following link contains information on NIH Career Development (K) Awards, K-Kiosk.
Fellowship awards (F grants)	The following link contains information on NIH NRSA Individual Fellowship Funding Opportunities, F-Kiosk.
NIH Biosketch	The format of the NIH Biosketch is exactly specified with both instructions and a sample available. The format should be followed carefully so the NIH application will not be administratively withdrawn. It is important to list all current positions held to accurately report relevant affiliations (domestic and foreign). The NIH Office of Extramural Research has suggested that the easiest way to navigate the biosketch changes is to use the Science Experts Network Curriculum Vitae (SciENcv). SciENcv serves as an interagency system designed to create biosketches for multiple federal agencies. The SciENcv home page has plenty of resources to get started, including: FAQs, YouTube tutorial and support documentation.
Sponsored programs workshops	The Sponsored Programs Office offers workshops throughout the year with detailed instructions and specific information for some of the most popular types of applications such as NIH Research (R01), NIH Fellowship (F31), and DOD CDMRP. See the Workshops page on the Sponsored Programs website for sample applications and the PowerPoint presentations. Send email requests to spo@bcm.edu to be added to the SPO Listserv for Announcements and be added to the calendar invite for the monthly Sponsored Programs Office Knowledge Exchange (SPOKE) Program for Researchers and Administrators.

Chapter 3
Applications/Forms for Funding

Overview

Introduction

Organizations have many different methods for investigators to apply for funding. This chapter focuses attention on some of the more widely used applications/forms.

In this chapter

This chapter covers the following sections:

- Section 3A: Government Agencies
- Section 3B: Non-Government Agencies

Section 3A
Government Agencies

Overview

Introduction

Instructions are provided to investigators on how to locate application forms for various types of government funding.

In this section

This section covers the following topics:

- Grants and Cooperative Agreements
- Contracts
- Subawards - Both Subgrants and Subcontracts

Grants and Cooperative Agreements

Introduction

Explanations of the types of grant applications required by various government agencies are provided herein. All of the forms below are accessible through the sponsor's website as indicated.

***Note*:** Prior to using an application previously saved, make sure that:

- The application form is not out-of-date
- It is the correct form for the type of award desired

NIH

National Institutes of Health (NIH) forms in general may be accessed online. For weekly email notices of NIH funding opportunities, sign up for the NIH Guide Listserv.

Investigators are responsible for the completing the following steps before applying for funding:

- **All** NIH applicants from BCM must have an NIH eRA Commons username set up by the BCM Sponsored Programs Office. This enables the PI to take advantage of electronic submission and retrieval of grant information.
- To obtain an eRA Commons username, please email Sponsored Programs at spo@bcm.edu. Provide full name, BCM email address and the role needed. The types of user roles allowed are:
  - PI
  - Postdoc
  - Graduate student
  - Trainee
  - Assistant
  - Sponsor (mentor for Fellowships)
  - Project personnel
- All NIH grant applications must be submitted electronically. ASSIST is NIH's web-based service for the preparation, submission and tracking of grant applications. Specific opportunity instructions and obtaining the opportunity reference number can be downloaded from the federal-wide Grants.gov system:
  - Login to the NIH Commons system and go to the ASSIST link
  - Initiate the application in ASSIST by entering the Opportunity Announcement Number
  - Complete and save the application online. When finished, change the status from "Work in Progress" to "Ready for Submission"
  - View and save a pdf copy and attach that to the BRAIN ESP2 proposal
  - Following review, SPO submits the application not the investigator/designee
  - Individuals do not need to have log in names for Grants.gov. BCM is already registered.

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Grants and Cooperative Agreements, Continued

NIH Progress Reports

The Office of Management and Budget (OMB) has mandated that federal agencies implement a federal-wide research performance progress report (RPPR). This is for submission of required annual or other interim performance reporting on research grant and cooperative agreement awards to standardize recipient reporting on federally funded research projects.

NIH requires all annual reports to be submitted in the Commons using the RPPR tab to complete information and then submit online:

- Complete and Route the RPPR to the BCM Signing Official, or to a departmental reviewer if directed by the department or section.
- Attach pdf copy to the BRAIN ESP2 non-competing proposal
- Following review, SPO submits the RPPR not the investigator/designee

Paper forms

Links to paper style forms that are generally not used any longer except for grant transfers or by specific instruction by the NIH Program officer:

Type	Description
New/renewal	Form PHS 398 – The PHS 398 form is used for paper submission of new or supplemental applications.
Non-competing continuation	Form PHS 2590 – This form is used for paper submission of non-competing continuations (progress reports).

Continued on next page

NRSA

National Research Service Awards (NRSA) postdoctoral fellowship forms are available online as follows:

- Individual Fellowship applications are all submitted electronically. See the SF424 (R&R) Individual Fellowship Application Guide for use by NIH and AHRQ applicants.
- For links to all the current opportunities, see the F-Kiosk. The application is prepared using the ASSIST system:
  - Attach the pdf copy of the completed application to the ESP2 BRAIN proposal and route for approvals
  - SPO will submit to the sponsor not the investigator/designee
- Form PHS 416-1 – This is the old paper individual fellowship application to be USED ONLY FOR A CHANGE OF SPONSORING INSTITUTION APPLICATION IF DIRECTED BY PROGRAM OFFICER
- Form PHS 416-9 – This is the old paper application for continuation (progress report). All Noncompeting – Individual Fellowship Progress Reports for Continuation Support must be submitted using the Research Performance Progress Report (RPPR) in the Commons.

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Grants and Cooperative Agreements, Continued

NSF

The table below is description of useful websites for applying for funding with the National Science Foundation (NSF):

Websites	Description
NSF FastLane	Research account management has been moved from FastLane to the new Management System called Research.gov. Previous login ID can be used but SPO must approve the request to be affiliated with BCM and the role requested.
Proposal & Award Policies & Procedures Guide (PAPPG)	The Proposal & Award Policies & Procedures Guide provides guidance for the preparation and submission of proposals to NSF. Contact with NSF program personnel prior to proposal preparation is encouraged.
NSF E-Bulletin	Active funding opportunities are updated daily to provide the most accurate and timely information possible.
Research.gov	NSF uses a grant management system called Research.gov which will include other federal agencies partnering with NSF. Current partners are NASA, USDA and NIFA. It provides services for the research community and support transparency in research. Currently, all functions are performed at Research.gov and no longer in FastLane: • Provide authorized user access • Create, submit, track, and update proposals • Project Reports System for annual and final progress reports • Project Outcomes Report for the General Public • Federal Financial Report • Grants Application Status • Institution and User Management – FastLane and Research.gov login accounts are the same

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Grants and Cooperative Agreements, Continued

DOD	Most applicants for Department of the Defense (DOD) funding go through Congressionally Directed Medical Research Programs (CDMRP): • Individual program announcements and some required forms can also be found on this website • Award mechanisms requiring Pre-Applications including Letters of Intent (LOIs), Pre-proposals and/or Nominations are submitted through the Electronic Biomedical Research Application Portal (eBRAP) website. Typically, the DOD Pre-Applications do not include a budget or approval from SPO, so a BRAIN ESP2 proposal is not required in this instance. • Full proposals requesting funding from DOD are submitted through Grants.gov and will require a BRAIN ESP2 proposal. Investigators must register in Grants.gov in order to use the WorkSpace grants submission system. SPO must approve your request to affiliate and give you the role of Workspace Owner to be able to initiate an application. • All proposal information must be submitted electronically as a PDF document • The due date may be found in the guidelines for the specific funding opportunity • Save a pdf copy of the completed application and attach to the BRAIN ESP2 proposal. Following review, SPO submits the application not the investigator/designee. • The PI then verifies the content of the application online in eBRAP
Grants.gov Workspace	All Federal agencies use the Grants.gov Workspace system and all applications must be submitted electronically. The PI and Administrator prepare the application, its status is changed to Ready to Submit and a pdf copy is attached to the BRAIN ESP2 proposal. SPO reviews and submits the application and approves the proposal.
Other state and non-profit agencies	Certain agencies withhold forms distribution until the applicant has prepared specific proposals. Therefore, Sponsored Programs does not carry a supply of these applications. Many agencies use their own unique online portals for grant application preparation and processing. Obtain the particular agency's instructions through the sponsor's website. See Identifying Potential Funding Sources for examples of websites.

Contracts

Introduction

Contracts are usually solicited by government agencies in the form of RFPs (Requests for Proposals), which describe the:

- Work to be performed
- Application format

Announcements

Announcements of federal RFPs are publicized in Grants.gov and in the NIH Guide for Grants and Contracts. See NIH in this Section.

Notify Sponsored Programs office

Investigators who intend to submit federal contract proposals (including continuation and/or renewal proposals) should:

- Notify the Sponsored Programs Office (SPO) at spo@bcm.edu
- Notifying SPO of the intent to submit a contract proposal early in the process will save time
- Forward a copy of the RFP as soon as it is available

Sponsored Programs duties

Sponsored Programs staff:

- Complete the Representations and Certifications section
- Review the RFP to assist in negotiating favorable terms
- Assist in avoiding potential problems

Supply Chain Management duties

Federal contractors are required to maintain an acceptable subcontracting plan if they are a large business (including all affiliates), and the estimated dollar value of the base contract and all option periods exceeds, or is expected to exceed, $700,000. A Small Business Subcontracting Plan will need to be developed with the help of the BCM Supply Chain Management personnel.

Contractors that meet the above criteria **must** establish a subcontracting plan with specific dollar and percent goals for subcontracting to small, HUBZone small, small disadvantaged, small women-owned, veteran-owned small, and service-disabled veteran-owned small business firms. This plan must be in place prior to contract award and is updated annually.

The requirement to submit a subcontracting plan **does not** apply to:

- Small businesses
- Contracts under the prescribed dollar amounts
- Prime contracts not offering subcontracting possibilities
- Contracts to be performed entirely outside the United States

Subawards – Both Subgrants and Subcontracts

Introduction

Other organizations may request a subaward proposal for purposes of collaboration on their research grants or contracts.

BRAIN

Such proposals must be submitted through Biomedical Research and Assurance Information Network, or BRAIN using the (ESP2 Proposal Summary) routing sheet.

The proposal must include the following **even if the is to be in modular format**:

- An application Face Page pertinent to BCM as the subaward institution, or a letter of intent/consortium letter, including direct and indirect costs
- A budget specifying both direct and indirect costs (expressed as dollar amounts, not just percentages)
- A description of the work scope
- Other Support, Resources and Environment, and a Letter of Support from PI to prime award PI

DHHS agencies

For NIH and other DHHS agencies, the Principal Investigator (PI) needs to express her/his willingness to collaborate on the project by including a consortium letter (signed by the BCM Institutional Official) with the direct and indirect costs and the following required wording:

> "The appropriate programmatic and administrative personnel of each institution involved in this grant application are aware of the NIH consortium grant policy and are prepared to establish the necessary inter-institutional agreement(s) consistent with that policy."

A template for this Consortium Letter or Letter of Intent is available on the SPO website.

Section 3B
Non-Government Agencies

Overview

Introduction

Although most funding at BCM is from governmental sources, non-governmental agencies are an increasing source of research support.

In this section

This section covers the following topics:

- Commercial/Industrial (For-Profit) Sponsors
- Biomedically-Specific Granting Organizations
- Foundations

Commercial/Industrial (For-Profit) Sponsors

Introduction	Commercial/industrial (for-profit) organizations continue to be an important source of research funding.
PI and sponsor discussions	Some research support is given as a result of a relatively informal technical discussion between the investigator and sponsor. This type of technical exchange is encouraged. However, there are important points to keep in mind with these exchanges: • If a commercial or industrial organization initiates contact regarding support of ongoing research, discuss the potential agreement with BCM Ventures staff (or email bcmventures@bcm.edu) before any formal documents or oral understandings have been formulated • Be familiar with BCM Policy on Patents and Other Intellectual Property and related policies before developing any relationships with commercial organizations • ***Note*****:** A Confidentiality/Non-Disclosure Agreement must be in place if any confidential or proprietary information is being discussed. • Only BCM can enter into a contract with the sponsor. The Principal Investigator may not sign on behalf of the College.
Contract negotiations	The appropriate personnel in the Office of Research must negotiate the contractual and administrative functions of any agreements made between the PI and sponsor as follows: • Avoid discussion of financial or other contractual aspects of the proposal or the agreement (i.e., budget, inventions, patents) until after consultation with staff from SPO or OCR depending on the type of research: – Basic Science Research email mta@bcm.edu – Clinical Trial Research email cta@bcm.edu • All proposals must be approved by the PI's primary department and the Office of Research via BRAIN ESP2 before they are submitted to the potential sponsor
Confidentiality/ Non-disclosure agreement	Some sponsors may request that a Confidentiality/Non-Disclosure Agreement (CDA) be signed before they will allow information to be reviewed by BCM staff. These agreements require review by the appropriate office. • If the CDA is a preliminary step for a Clinical Trial, attach the agreement to be reviewed in the OCR CTA/CDA System. Contact cta@bcm.edu for further information. • If the CDA is preliminary for a basic research sponsored agreement, then send email requests to mta@bcm.edu and attach the agreement to be reviewed

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Commercial/Industrial (For-Profit) Sponsors, Continued

Applications	Most commercial and industrial sponsors do not have specific application formats. However, to reduce the potential for misunderstandings, it is recommended that investigator-initiated proposals to these sponsors be spelled out clearly, including at least the following elements: • BRAIN (ESP2 Proposal Summary) routing sheet • Cover page or cover letter with a block for institutional endorsement • Statement of work to be performed • Budget: – Most industrial sponsors would prefer to negotiate a fee per completed unit of service, such as per completed patient subject, rather than an expense budget – In such cases, an internal expenditure budget needs to be developed to document that all costs are included – ***Note*:** The budget must include full direct costs and indirect costs recovery at the approved rate, (60% for basic research and 35% for clinical trials) • Provide a copy of any written response to the proposal to the PI's Department Administrator and Sponsored Programs staff
Testing agreements	Industry sponsored Testing or Service Agreements (non-clinical) will be reviewed by BCM Ventures. A BRAIN proposal should be prepared and full indirects included in the total amount quoted to the sponsor. Consult with BCM Ventures staff at the start of negotiations by emailing bcmventures@bcm.edu.
Consulting	Commercial organizations often ask faculty to consult with them as an outside activity, in addition to providing sponsored projects support. Any such agreements must be disclosed at the proposal stage to ensure that they comply with College policies. See the BCM Compliance and Audit Services website for more information about disclosure of outside activities and the Research Conflict of Interest h website for disclosure of significant financial interests.
Consulting agreement vs. contract	Work for a commercial sponsor performed using institutional facilities should be negotiated via a contract between the College and the commercial organization, **not** a consulting agreement between the faculty member and the commercial organization. Contact the Office of Corporate Compliance and Audit Services for more information regarding outside activities.

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Commercial/Industrial (For-Profit) Sponsors, Continued

Clinical trials

Most contracts with For-Profit Sponsors are for Clinical Trial Agreements. Investigator-Initiated agreements are when the BCM investigator approaches the sponsor and are most often for Phase 1 trials. The sponsor approaches the investigator or puts out a call for site participants for most of the more advanced Phase 2-4 trials.

- The process often starts with signing a Confidentiality Disclosure Agreement between the sponsor and BCM on the behalf of the investigator. After proprietary or confidential information about the trial is shared, the investigator is able to decide whether to participate.
- In order to process a Clinical Trial, all of the following needs to be initiated by the Principal Investigator:
  - ESP1 human protocol submitted to IRB
  - ESP2 contract proposal with Word version of the CTA attached, keep in draft
  - CTA Pre-Review Form submitted in the CTA System.
  - Access to the system is available directly or through the ESP2 proposal (choose Industry Clinical Trial Agreement from the 'What would you like to do?' drop down menu).
- OCR negotiates the agreement and helps finalize the budget while the IRB reviews the protocol. Then the PI will be advised when to submit the ESP2 contract proposal.
- Trials involving therapeutic intent may also be deemed a Qualifying Clinical Trial (QCT) and require additional approval of a Billing Grid in order to allow Medicare/Medicaid payments. Approval must be completed before the agreement can be signed.
- Once the human protocol is approved by the IRB, then the agreement can be signed and the proposal marked as funded.
- The process of negotiating a clinical trial has many steps and can take several months. The CTA System allows for real time tracking of where the agreement is in the review and negotiation process.
- Further information, including a Process Flow chart, Feasibility Assessment, Budget Analysis tools, and the Instruction Manual for the required Pre-Review Form are available at the SPO website.

Additional questions should be directed to cta@bcm.edu.

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Commercial/Industrial (For-Profit) Sponsors, Continued

Registering clinical trials

ClinicalTrials.gov is an online registry of clinical trials conducted around the world. The Food and Drug Administration Amendments Act of 2007 (FDAAA or US Public Law 110-85) requires that certain clinical trials be registered and results of those clinical trials be made available to the public.

Usually, the for-profit sponsor registers the trial, but for Investigator-Initiated trials the PI may need to be the Responsible Party.

The principal investigator of the clinical trial can serve as the "Responsible Party" if she/he has:

- The responsibility to conduct the trial
- Access to and control over the data from the clinical trial
- The right to publish the results of the trial

The Responsible Party is:

- Allowed to certify the information entered into the protocol record and release the information to the public
- Required to update the record annually by reporting on outcomes and status of the trial being open or closed

For more information on whether a trial needs to be registered, see General Requirements. NIH encourages registration of ALL trials.

The Protocol Registration System (PRS) allows registration of clinical trials. BCM has an organization account and the BCM Office of Clinical Research, as a PRS Administrator, can create individual accounts for investigators and their staff. Send a request for an account to ocr_regulatory@bcm.edu. Through its website the Office of Clinical Research provides guidance and registration information.

Qualifying Clinical Trial (QCT)

Medicare covers the routine costs of "qualifying clinical trials" as well as reasonable and necessary items and services used to diagnose and treat complications arising from participation in all clinical trials. A qualifying clinical trial (QCT) is a trial that meets the requirements set forth in Clinical Trial Policy (NCD 310.1) by the Center for Medicare and Medicaid Services (CMS).

Trials with therapeutic intent must have an objective/aim that assesses the effects of the intervention on patient outcome (i.e., prolongation of life, shrinkage of tumor or improvements in quality of life) and must not be exclusively designed to test toxicity or disease pathophysiology.

Once a trial has been determined to be a QCT, the routine costs associated with it are billable to and reimbursable by Medicare. Therefore, the researcher needs to complete a Billing Grid. The billing grid facilitates billing compliance and enables coordinators and research administration to correctly identify those items and services that are for research purposes only from those that are part of routine care and therefore billable to Medicare or the patient's provider.

Further information is available on the OCR website.

Biomedically-Specific Granting Organizations

Introduction	Biomedically-specific granting organizations are agencies that concentrate their research funding in specific areas to reduce human suffering in these areas. Such examples include: • American Cancer Society • Muscular Dystrophy Association • American Lung Association
Applications	Many of these organizations have official application forms that are available upon registration with their websites. Many utilize online submission processes. Even though the Principal Investigator is able to submit online, the application should not be submitted until officially approved by the College. A pdf copy or summary documents should be submitted for approval in the BRAIN ESP2 system first in case any revisions need to be made before sending to the sponsor. See Private, Non-Profit Funding Websites for a few examples of these websites.
Indirect cost rates	BCM honors the published indirect cost rates for these sponsors. Each sponsor's rate is available through their website. A copy of the sponsor's policies on indirect cost rates (often this is found in the opportunity instructions) should be attached to the BRAIN proposal.

Foundations

Introduction	There are many different kinds of Foundations that will fund BCM projects. Some have application forms that require institutional signature, while others allow an investigator to submit directly to them. In either case, when funding is solicited from an external source to fund projects at BCM, a BRAIN ESP2 proposal should be submitted. Following approval, the investigator can submit directly to the sponsor.
Advertised applications	Applications to biomedically-specific foundation grant programs may require institutional clearance through BCM's Faculty Committee on Awards. Many of these advertised foundation programs limit the number of applications per institution for each grant cycle (i.e., Pfizer Scholar Program, Searle Scholars Program). Please contact Intramural Funding for more information.
Uninvited project applications	Uninvited project applications to foundations usually require institution-wide coordination in order to avoid flooding a particular foundation with competing applications. To avoid potential conflicts, the PI must coordinate such submissions with the office of Advancement and Alumni Affairs.

Chapter 4
Proposal Preparation

Overview

Introduction

Requirements for the proposal preparation portion of grants and contracts vary considerably according to project, sponsor, and type of funding instrument.

Always review the sponsor's most current (on-line) guidelines. See Applications/Forms for Funding in this handbook for further information.

In this chapter

The Sponsored Programs Office provides the following general instructions for preparation of proposals:

- Section 4A: Technical/Scientific Aspects
- Section 4B: Budget/Financial Considerations
- Section 4C: Certifications and Assurances

Section 4A
Technical/Scientific Aspects

Overview

Introduction

Requirements for the technical/scientific portion of grants and contracts vary considerably according to project, sponsor, and type of funding instrument.

Always review the sponsor's most current (on-line) guidelines.

In this section

The Sponsored Programs office provides the following general instructions for preparation of proposals:

- Tips for Preparing a Successful Grant Application
- Additional Tips for NIH Applications
- Drafting Abstracts and Program Narratives

Tips for Preparing a Successful Grant Application

Introduction

The following are useful tips for preparing a successful grant application.

Sponsor instructions

Heed sponsor instructions carefully, especially as they relate to:

- Page limitations
- Font
- Type size
- Requirements for human subjects
- Biohazards, etc.

For NIH Grants in particular:

- Format instructions must be followed on all pages, especially the:
  - Margins
  - Font size
  - Spacing
- NIH rejects all proposals which do not conform to the specific instructions provided
- Arial 11-point is the NIH-suggested font. NIH does not allow color font except in graphs and figures.

Work scope statements

Work scope statements and abstract summaries should be clear, concise and understandable as follows:

- While the majority of applications will be assessed by scientific peer review bodies, reviewers in some organizations may not be totally familiar with an investigator's area of specialization
- Therefore, it is usually advisable to write for both a general scientific audience and for the technical expert in the field
- Always have a draft proposal reviewed by at least one expert in the project area and one senior faculty member in the same general field who is less conversant with the specific area of the project
- Their comments can help adjust the text to the needs of both types of reviewers

Workshops

Sponsored Programs offers lectures and workshops throughout the year so students, faculty, and staff may improve their grant preparation skills.

Additional Tips for NIH Applications

Introduction

In addition to the general information presented in Tips for Preparing a Successful Grant Application, specific items to consider when preparing NIH applications include the following.

Proposal assignment and review

Applicants may provide information to facilitate the assignment and review of their proposals. This can be done by in the following ways:

- In the ASSIST application, include the Optional Form called PHS Assignment Request Form where both preferences for Awarding Component and Study Section can be specified. NIH staff will consider all assignment preferences, although in some cases, the awarding component is pre-determined and assignment preferences cannot be accommodated.
- Include a cover letter with the application at the time of submission suggesting an initial review group and/or a DHHS component to which it could be appropriately assigned
- Membership of the review groups is available in the NIH Study Section Rosters website
- Review of the members' publications will often alert applicants to relevant portions of their prior work, which should be considered in light of the methods presented in the proposal. Potential competitors can be requested to not be included in the review group with proper justification.
- Identify scientific areas of expertise needed to review the application, although specific individuals cannot be requested.

Minorities

Minorities of both genders are required to be included study populations for the following NIH applications:

- Clinical research grants
- Cooperative agreements
- Proposals for contracts

This is so that research findings can be of benefit to all persons at risk of the disease or condition under study. This information should be included in the Research Plan or the Human Subjects Section of the Adobe application form.

Consistency

The human subject and vertebrate animal sections of the Research Plan **must be** congruent with the protocols reviewed by the IRB and specified in the ESP2 (Proposal Summary) routing sheet. It is the PI's responsibility to link the specific protocols with the matching application proposal in BRAIN.

The approval dates stated in the application must be the most current.

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Additional Tips for NIH Applications, Continued

Subawards	If a portion of the grant activity is being performed at a collaborating organization outside of BCM, the applicant organization's Research Plan **must** include a description of the portion(s) of the work scope being conducted at the subaward organization. This is required so that the Research Plan conforms to the summary project budget. Additionally, reviews for Human Subjects and/or Animals must be performed and certified by the subaward organization.
Individual development plans	The Individual Development Plan (IDP) is intended to be used as a tool to enable graduate students and postdoctoral researchers to identify professional goals that match their interests and values for the purpose of identifying and developing the appropriate career specific skills. NIH will be requiring this reporting for all types of grants, not just for training or fellowship grants. Additional information and forms are available on the SPO intranet site.

Drafting Abstracts and the Research Strategy

Abstracts

While an abstract is not required by all sponsors, it is a highly effective means of presenting a project to a reviewer or review committee. Factors to consider when designing an abstract are as follows:

- Should be approximately 250-300 words and should outline the proposed project, including its objectives and the methods of meeting them
- Special care and attention should be given to the construction of the abstract, since it can be a very important element in an application
- Many agencies appreciate a project abstract since it facilitates the initial review of the proposal
- Abstracts often help a sponsor in developing statistical profiles of their programs
- Sponsors and other parties search for key words within the Abstract to identify potential collaborators or research groups

Research strategy

The research strategy or program narrative, the body of the proposal, should have the following information, written in layman's language:

Information	Description
Project Objectives	• Start with a discussion of the need for the project • State the questions which the proposed project is designed to answer • Provide information that convinces reviewers that the questions are important and worth answering, and that the approach is sound • Prepare a statement of: – The problem – Purposes (goals) – Objectives – Specific activities – Present the status of work related to the project
Literature Review	This should not be an annotated bibliography, but rather a concise and scholarly critique: • This demonstrates that the proposer is aware of the overall significant and current research in the field • It also shows how the proposed project will extend the state of knowledge about the field

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Drafting Abstracts and the Research Strategy Continued

Research strategy (continued)

The research strategy or program narrative, the body of the proposal, should have the following information, written in layman's language (continued):

Information	Description
Project Activities	Indicate what activities will be undertaken: • Who will do them? • When they will be done? • How these activities will assist in meeting program objectives • What criteria will indicate that program objectives have been met • Give precise information on project arrangements and materials which are to be developed • It is very important to include a timeline and discuss evaluation procedures
Project Methodology	The precise methods to carry out the study should be detailed: • This section is probably the one the reviewers will study most carefully • This section should assure reviewers that the investigators: – Are conversant with the methodology in the field – Have the expertise and skills necessary to successfully complete the project
Findings/ Conclusions	Discuss the contributions the successful project will make to knowledge in the discipline. If applicable, note how the results can be replicated and disseminated.

Section 4B
Budget/Financial Considerations

Overview

Introduction

Peer reviewers on Study Sections or other committees are asked to determine whether all items of the budget are realistic and justified in terms of the aims and methods of the project and currently available resources.

Presuming that the reviewers are enthusiastic about the work scope, the ideal budget justification should relate the costs to the work so closely and thoroughly that no decrease in the budget could be recommended without a corresponding change in the work scope.

Carefully read the directions provided by the sponsor and the guidelines provided in this section. Consult with the PI's Departmental Administrators and/or the Sponsored Programs Office for additional clarification as needed.

In general, the Federal guidelines for reasonable, allowable and allocable costs found in the Code of Federal Regulation should be followed as detailed in CFR200 Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards.

In this section

A typical budget includes:

- Project Personnel
- Personnel Salaries
- Fringe Benefits
- Consultant Costs
- Equipment
- Supplies
- Travel
- Alterations and Renovations
- Other Expenses
- Subawards (Consortium Agreements)
- Trainee Costs
- Indirect/Facilities & Administrative Costs

Project Personnel

Introduction

Full-time faculty are expected to generate an appropriate share of their support from grants and contracts for which they have academic responsibility.

Project personnel

Project personnel are customarily listed in the following order:

- Principal Investigator – except for fellowships, the Principal Investigator must be a faculty member
- Co-Investigator
  ***Note*:** NIH does not use the position "Co-Principal Investigator" or "Co-PD/PI"
- Other professional personnel
- Non-professional staff

Additional items to note regarding project personnel:

- Be sure that all project positions are enumerated even though the specific individuals who will fill the positions may not yet have been identified
- All participating faculty must have consented to be included as project participants
- In order to protect the objectivity of covered personnel who are engaged in research activities, and to preserve the integrity of the College, all covered personnel must manage any apparent conflict and avoid any actual Conflict of Interest
- Use titles appropriate to the project (e.g., PI, Co-Investigator, Technicians, etc.) Avoid using faculty titles (e.g., Research Associate) for personnel who do not or will not hold faculty appointments at the time of the award

Inter-divisional/ departmental personnel

Personnel of the College or departments other than the applicants are not to be listed as project personnel without the full knowledge and consent of the department or division in which she/he holds a primary appointment.

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Effort and salary cost sharing

The time which each individual devotes to the project should be expressed in terms of a percentage, or calendar months in the case of the NIH.

The reporting of professional effort in terms of hours is unacceptable because it is difficult to reflect and measure scientific contribution by hour, and because of the burdensome recordkeeping mechanism which would have to be established for this kind of system.

Tips for effective effort and salary cost sharing are as follows:

Tip	Description
1	Do not promise more effort than is feasible
2	Be sure that reimbursement is requested for full percent of effort/calendar months indicated
3	Minimum Effort of 1% is required for all Principal Investigators. *Note*: There are a few exceptions when zero effort is allowable such as equipment grants, supplement applications, and when the PI is acting as a mentor for a fellowship application.
4	Salary cost sharing is not permitted unless approved by the Department Chair. Failure to request full salary recovery constitutes voluntary cost sharing which results in the College's paying for salary and benefits as well as indirect costs for the contributed effort.
5	Faculty should generally not have more than 95% effort on sponsored projects: • Exceptions to this rule are junior faculty on career development awards who otherwise do/will not have teaching, patient care, and/or institutional/departmental committee responsibilities • Deviations from this guideline should be discussed with the faculty member's Departmental Chair or Administrator/Director
6	Investigators should not propose more than the minimum effort stated in the PHS K award guidelines (e.g., K08, K23). Effort that exceeds the minimum will not improve priority scores and further limits the applicant's potential effort and salary support from other grants and contracts.

Personnel Salaries

Introduction

Wages/salaries on grants or contracts are payments for time and effort devoted to funded projects. List actual and projected salaries according to each budget period within the project period.

No salary charges to federal grants may exceed the federal salary cap, updated annually.

***Important*: Obtaining a grant does not result in a raise.**

Obtain current salary figures

If the budget includes faculty from other departments, check with appropriate Departmental Administrative personnel to make sure that projections for that faculty member are adequate.

Especially if new positions are contemplated, check with Departmental Administrators to determine whether salary shifts are planned which will cause increased minimal salaries.

Prorating salary

If a budget period does not correspond to the College's fiscal year, prorate the salary.

For instance, if the grant period is April 1 through March 31, calculate three months at the old salary rate and nine months at the new rate (assuming a salary increase on or around July 1).

For future years

Project salary increases based on the latest guidelines available from Department Administration. Most sponsors allow up to a 3% increase per year.

When calculating future year salary projections on the budget for the entire project period, consider that professional staff involved on the project:

- May not be requesting salary support until Year 2 or 3 of the grant because they are the current recipient of a research career award which restricts salary supplementation from other federal sources
- There may be circumstances where personnel begin participating on the research project after the initial 12-month budget period

NIH research career awards

Certain NIH research career awards (K-series e.g., Mentored Research Scientist Development Award {K01}, Mentored Clinical Scientist Development Awards {K08}, etc.) specify in their program guidelines that salary supplementation is not permitted from federal funds, unless explicitly authorized under the terms and guidelines of the program.

- Faculty and staff should carefully review the specific program guidelines and consult with the Department Administrator and/or Sponsored Programs staff for additional clarification
- Review the section above on Effort and salary cost sharing
- Reimbursement of salaries should usually be requested for the full percent of effort indicated

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Personnel Salaries, Continued

Salary cap	The salary cap for federal grants, cooperative agreements, and contracts is a limitation to the salary level based on the federal government's Executive Level II salary. If an investigator's salary exceeds the federal cap, the investigator may only charge the appropriate percentage of her/his salary against the cap. The department cost-shares the difference.
Administrative and secretarial salaries	For federal grants and contracts, CFR 200 Subpart E – Cost Principles states that the salaries of administrative and clerical staff should normally be treated as Facilities and Administrative Costs as follows: • Direct charging of these costs may be appropriate only where a major project or activity explicitly budgets for administrative or clerical services and the individuals involved can be specifically identified with the project or activity • This provision is intended to establish the principle that the salaries of administrative and clerical staff should usually be treated as Facilities and Administrative Costs • However, direct charging of these costs may be appropriate where the nature of the work performed under a particular project requires an extensive amount of administrative or clerical support which is significantly greater than the routine level of such services provided by academic departments • The special circumstances requiring direct charging of the services would need to be justified to the satisfaction of the awarding agency in the grant application or contract proposal

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Personnel Salaries, Continued

Examples of direct charging clerical staff salaries	The following examples illustrate circumstances where direct charging of administrative or clerical staff salaries **may** be appropriate: • Large, complex programs, such as: – General Clinical Research Centers – Program Projects – Other grants and contracts that entail assembling and managing teams of investigators from a number of institutions • Projects such as epidemiological studies, clinical trials, and retrospective clinical records studies which involve: – Extensive data accumulation – Analysis and entry – Surveying and tabulation – Cataloging – Searching literature – Reporting • Projects that require making travel and meeting arrangements for large numbers of participants, such as conferences and seminars • Projects whose principal focus is the preparation and production of manuals and large reports, books and monographs (excluding routine progress and technical reports)
Stipends/ fellowships	Unlike salaries, stipends/fellowships are living allowances to further the education and training of the recipient for which no services are rendered. The College receives no benefit from the activities.
Graduate students (degree candidates)	The Graduate School publishes guidelines for the graduate education stipends. In order to equate net salary to stipend and/or fellowship levels, salaries may need to be higher than stipend levels to adjust for income tax and/or tuition responsibility.
Postdoctoral fellows	Approved maximum salary levels for postdoctoral fellows are published by the Office of Graduate Medical Education. Combined stipend and salary support for any postdoctoral fellow may not exceed these levels. Do not confuse these levels with the rates set by various sponsors, including NIH, for training grants and fellowships.

Fringe Benefits

Definition	Fringe benefits are the College's contribution to Social Security, group insurance plans and retirement programs. These contributions are expressed in terms of a percentage of salary. They are re-stated at the beginning of each fiscal year and posted on the Office of Research website under Salary and Fringe Benefit Information.
Prorating	In calculating fringe benefits, please note that fringe benefits for most personnel change at the beginning of the new fiscal year (July 1) and should be prorated in the same manner as salaries.
Student wages	Student wages (OE, OW, OH, OG) are exempt from FICA taxes only while the student is enrolled full-time and attending classes. Other items to note: • Overseas salaries (OS) are also exempt from any personnel benefit changes • No benefits are assessed to object code OV, wages paid to non-resident postdoctoral fellows • The costs for applicable health, life and disability insurance should be budgeted under "Other Expenses" • Some types of awards do not allow fringe benefits. However, it is important to recover fringe benefits (as well as full salaries) whenever possible.

Consultant Costs

Introduction

Refer to the policy guidelines of the sponsoring agency to determine when project funds may be used for consultant costs.

Definitions

The following definitions have been provided to clarify the difference between consulting and other types of agreements:

- Advising - is advice and one-time assistance, with no salary requested. NIH designation for such people is "Other Significant Contributor"
- Consulting – is limited assistance by persons outside of BCM who charge a specific fee for the advice or assistance they provide
- Collaborative research – is proposed as a subaward and budgeted under "Consortium/Contractual Costs" in which part of the work scope is actually being performed by another investigator at another institution
- Service agreements – in general, do not involve work scope design and modification and should be budgeted under the categories of "Other Expenses" or "Patient Care" if appropriate

NIH

The NIH will approve consultant fees only if:

- The services to be provided are essential and cannot be provided by persons receiving salary support under the grant
- A selection process has been documented in writing regarding the selection of the most qualified person available
- The charge is appropriate to the services rendered and the consultant's qualifications
- A letter of support is provided by the consultant that includes a brief description of the assistance and the rate to be charged

Faculty members

A salaried College faculty member may **not** serve in the capacity of a paid consultant. Instead, list her/him among the project personnel.

Consulting costs do not carry income tax and FICA deductions. The IRS does not allow the College to pay an individual consulting fees for the same professional services for which she/he is employed.

Federal employees

Federal employees are usually not allowed to be paid consultants on federal grants and contracts. Federal employees are also required to obtain written permission from their federal agency for any paid consulting.

Equipment

Definition	Equipment, as defined by federal guidelines and by the College: • Is a single article of non-expendable personal property • Has a useful life of more than one year • Has an acquisition cost of $5,000 or more per unit • Accessories, component parts, and installation costs of an item of equipment should be classified as part of the basic unit cost of the equipment. Do not list such charges separately. Items which do not meet the above criteria should be classified as "Supplies". ***Example*:** replacement parts for equipment
Other definitions of equipment	Non-federal sponsors may use other criteria for classifying equipment. In that case, use their definition to complete the budget.
Justification	For most applications, justification must be provided for requests to purchase equipment that appear to duplicate or to be equivalent to items already available in the research environment. Most sponsors will require a quote for the equipment item before approving its purchase.

Supplies

Introduction	Supplies such as chemicals, glassware, and other small laboratory equipment (under $5,000) should be itemized by category.
Animals	Costs for purchase and care of animals are usually listed under "Supplies". A written estimate of animal purchases and care costs can be obtained from the Center for Comparative Medicine (CCM). Thereafter, assume 3% annual increases. CCM reviews application information regarding proposed animal use to ensure compliance with federal law and NIH regulations.
Research supplies	In future year projections for research supplies, increase the amount budgeted per supply item by at least the rate of the current Biomedical Research and Development Price Index (BRDPI) assuming that similar volumes/types of supplies will be needed. Provide separate justification for cost items which may exceed this estimate.

Travel

Introduction	Funding agencies require full justification for travel requests.
Description	Describe the following aspects of the requested travel: • Purpose • Destination(s) • Names or titles of individuals for whom funds are requested • Frequency of repetitive trips
Costs	See Travel Services for travel cost estimations. Some sponsors limit the amount allowed for travel. Check opportunity guidelines to ensure the amount requested does not exceed that allowed.
Foreign travel	The Fly America Act, 49 U.S.C. App. 1517, requires Federal employees and their dependents, consultants, contractors, grantees, and others performing United States Government financed foreign air travel to travel by U.S. flag air carriers. Authorization from the sponsor and approval of any waiver request to use a foreign air carrier must be obtained in advance from many sponsors. See Travel Services for further information.

Alterations and Renovations

Introduction	Alterations and renovations are modifications of the interior of College buildings.
Sponsor guidelines	Carefully review the sponsor agency's guidelines to determine their policy regarding funding for this item. • In NIH research applications, construction costs are not permissible direct cost charges except in the case of specific construction grant programs • Many foundations will allow alteration/construction as direct costs even though they do not fully fund indirect costs
Approval	Before requesting funds for construction, renovation or alteration of any College facility, consult with the Department Director/Administrator, who must obtain Institutional approval, prior to submission of the proposal to a potential sponsor.
Space committee	The Space Committee of the College must approve all alterations and renovations. Cost estimates for approved alterations must be provided by Facilities.

Other Expenses

NIH applications

NIH applications include under "Other" such expenses as:

- Publication costs
- Telephone
- Facility Rental and leases
- Automatic Data Processing (ADP)/Computer services
- Patient subject costs such as, incentives, travel, or parking expenses incurred by human subjects participating in the project
- When employing students on research grants, include costs of applicable health, disability and life insurance as these costs are not a part of the College's fringe benefit rates for students. Calculate these costs proportionately to the level of support that the salary represents.

Subawards (Consortium Agreements)

Introduction	The following is an explanation of the use of the word "subaward" as a budget item in a grant or contract. For an explanation of procedures to follow when another organization is providing a subaward to BCM, see Chapter 5, Section 5E, Incoming Subawards.
Work scope	If a portion of the work scope other than the services of a consultant is to be provided by an organization outside of BCM, the costs should be budgeted under the subaward/consortium/contractual costs category.
Consortium agreement	A formal agreement is required only if the grant or contract is awarded.
Collaboration	The collaboration is ordinarily such that the Co-Investigator participates in the project on an ongoing basis and expects to be named as a co-author on publications.
Consortium letter	The following items are needed from the co-investigator at the time of proposal submission: • A consortium letter (letter of intent) from the collaborator indicating their willingness to collaborate on the project (signed by the other organization's Institutional Official) • If the proposal is to an NIH/DHHS agency, include the following required wording: "The appropriate programmatic and administrative personnel of each institution involved in this grant application are aware of the NIH consortium grant policy and will establish written inter-institutional agreement(s) to ensure compliance with all pertinent federal regulations and policies in accordance with the HHS Grants Policy Statement, PHS 398 Application for Public Health Service Grant, and the NIH Guidelines for Establishing and Operating Consortium Grants."

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Subawards (Consortium Agreements), Continued

Other required documents

Other required documents are as follows:

- A budget specifying both direct and indirect costs, and accompanying budget justification
- An abstract or description of the work scope
- Other support, if required
- Biographical sketch
- Resources and environment
- Checklist
- Many academic institutions are part of the Federal Demonstration Project and have signed the assurance online and so those institutions are listed in BRAIN as a pull-down menu when entering subaward information. If the collaborating institution is not on this list, then a Financial Conflict of Interest (FCOI) Assurance letter will be required. The consortium letter may include this assurance. The letter should include the following required wording:

  "Institution certifies that it has a conflict of interest policy that is in compliance with the requirements of all applicable regulations, including but not limited to those set forth in 45 CFR 94 and 42 CFR Part 50, Subpart F."

Templates for use with either a paid subrecipient or with a non-paid collaborator are available on the SPO intranet website.

How to include indirect costs

The total costs (direct and indirect) of the subawardee should be entered in the direct cost budget under the category "Subaward/Consortium/Contractual Costs".

Their costs are excluded from the Modified Total Direct Costs used as the base to calculate the indirect costs for BCM.

However, our rate agreement allows us to add back the first $25,000 for each subaward when calculating BCM's indirects to help offset the costs of creating and administering the subaward.

***Example*:** If $100,000 is subcontracted to University of XYZ in Year 1 BCM would charge BCM's current indirect cost rate of 58.5% on $25,000 in the first year only. This amount should be a second line item for Indirect Costs in ASSIST applications or explained on the bottom of the paper Checklist form.

Trainee Costs

Introduction	The guidelines below discuss some of the costs that are placed under trainee costs.
Stipends	Stipends are non-salary support for pre or postdoctoral fellows; no services are rendered to the college to earn this support. The Graduate School has guidelines for graduate education support. The following items to be aware of regarding stipends: • Do not confuse these parameters with the stipend rates set by various sponsors, including NIH, for training grants and fellowships • Postdoctoral stipends and salary support may not exceed the approved levels for postdoctoral fellows issued by the College • Sponsors frequently define the stipend level according to year of study • Supplementation from other sources may be restricted by the sponsor's policies
Tuition and fees	Tuition and fees for trainees are charged as follows: Predoctoral: Full tuition is charged for full-time graduate study Postdoctoral: Tuition is charged only for special courses outside of the Department
Health insurance	Health insurance costs should be recovered whenever possible. NIH allows individual (not family) coverage for each trainee under an institutional training grant. For individual NRSAs, the trainee should plan on using a portion of the institutional allowance for medical insurance.
Trainee travel	Budget as for any staff travel but include under "trainee costs".
Institutional allowances	Unlike training grants, NIH Individual Fellowships (NRSAs) provide stipend and institutional allowance only. The institutional allowance may be spent in any way desired, hence detailed budgeting on the application is not required.

Indirect/Facilities & Administrative Costs

Definition

Many of the actual services used by a sponsored project are not charged directly (per unit of use) because to do so would be too cumbersome and expensive.

Instead, the actual costs of operation are usually charged by use of indirect cost rates which include maintaining:

- Space
- Utilities
- Department administration
- Library
- General administrative services (accounting, payroll, purchasing, etc.)
- School administration
- Required institutional oversight (human subjects, biohazards, radiation safety, etc.)

NIH refers to indirect costs as Facilities and Administrative costs, or F&A.

Common questions

Below are common questions regarding indirect or F&A costs:

Question 1

How are the indirect cost rates established?

Federal accounting regulations require the following procedure for establishing federally negotiated indirect cost rates:

- Total anticipated costs for all indirect services and facilities are computed by the institution
- Modified total direct costs (direct costs less equipment, patient care, major alterations, etc.) are estimated for the three basic functions of College activity:
  - Organized research
  - Departmental research/instruction
  - Other sponsored activities
- Total indirect costs, with and without space costs, are distributed among the three basic functions above, based on:
  - Applicability to function
  - Percent of direct costs in each function
  - Functional purpose of space
- The ratios of indirect costs to modified total direct costs result in two indirect cost rates for each of the three functions:
  - On-Campus (includes space cost)
  - Off-Campus (excludes space cost)

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Indirect/Facilities & Administrative Costs, Continued

Question 2

What happens when the indirect cost rate used in a project is less than the approved rate?

Use of a lesser rate results in an under-recovery of the actual indirect costs.

- Such under-recovery must be paid from sources of general funds other than indirect cost, such as tuition and endowment earnings
- Tuition must be used to support instructional programs. Endowment income is for the most part restricted by the donors to purposes other than sponsored project support.
- Accordingly, the College:
  - Does not accept sponsored projects which do not provide full recovery of indirect costs
  - Will not waive or reduce indirect costs on federally funded or industry-funded projects
  - Does accept the published indirect cost rates established by private foundations and other non-profit entities

Question 3

When must the federally negotiated indirect cost rate be used?

The federally negotiated indirect cost rate must be used on all:

- Federal research and service grants and contracts
- On-campus for-profit corporate grants and contracts which provide service or data for the benefit of the company other than clinical trials
- Subcontracts from other institutions which are funded by federal or commercial grants or contracts
- Other sponsors who will pay the federally negotiated indirect cost rate

Question 4

When should a Total Direct Cost rate basis be used?

All on-campus and off-campus commercially funded research agreements, that do not require return of unspent funds, should use a rate based on total costs (TDC) instead of modified total direct costs.

- This TDC rate avoids confusion regarding the basis of the federal rates and what categories qualify for inclusion, thereby avoiding negotiation delays with commercial sponsors of clinical trials
- The TDC-based rate for commercially funded clinical trials is 35%, regardless of location (whether on or off campus)

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Indirect/Facilities & Administrative Costs, Continued

Question 5 **When may a rate other than the federally negotiated indirect cost rate be used?**

Less than the approved rate may be used in cases such as the following:

- Non-profit foundations and disease-specific societies which have a written policy specifying a smaller maximum indirect cost rate (e.g., American Cancer Society, American Heart Association, etc.)
- Federal training grants, fellowships, conference and construction grants which specify other rates
- State grants which limit indirect cost reimbursement
- Only the Senior Vice President and Dean of Research can waive or reduce an established indirect cost rate. A specific request should be routed via the Department Chair who must approve it first.

Question 6 **What approved rate should be used?**

See BCM Indirect Costs for rates that apply to grants, contracts, and other agreements funded by federal government agencies.

Question 7 **How are indirect costs calculated for a project budget?**

Follow the steps below to calculate indirect costs for a project budget:

Step	Action
1	Determine whether the project is: • Research • Instruction • Other sponsored activities, examples include programming, and developing web applications
2	Determine whether the project is "on" or "off" campus. • If significant parts of the project are at both "on-campus" and "off-campus" locations, the project costs should be apportioned accordingly • If the project, or part of the project, is taking place at a BCM-affiliated hospital, please use the combined rate shown in the affiliated institution table
3	Determine if the project should use a total direct cost or modified total direct cost TDC or MTDC base (TDC for industry-funded clinical trials).

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Indirect/Facilities & Administrative Costs, Continued

Question 7 (cont.) **How are indirect costs calculated for a project budget?**

Follow the steps below to calculate indirect costs for a project budget:

Step	Action
4	If MTDC based, calculate Modified Total Direct Cost as follows: • Indirect costs are NOT charged on the following direct cost items if the approved indirect cost rate is applied: – Equipment ≥ $5,000 ***Note*:** The federal standard defines equipment as those items having a useful life of more than one year and an acquisition cost of $5,000 or more per unit. – Alterations/renovations (over $5,000) – Patient care costs – Subawards of a portion of the work scope (amount in excess of $25,000 for each subaward) – Stipends and tuition payments – Space rental • Total direct costs less the above listed items = Modified Total Direct Cost • Multiply MTDC by the appropriate indirect cost rate to calculate the correct indirect cost to include in the budget
5	If less than the approved indirect cost rate is allowed, exclude only those items specifically prohibited from indirect costs by sponsor policy. For example, many non-profits allow equipment to be included in the indirect cost calculation.
6	If a College application requests funds for a subaward, the collaborating institution will include their indirect costs in accordance with their DHHS-negotiated indirect cost rate agreement. • The first $25,000 of each subaward is included in the BCM direct cost base • Amounts over $25,000 of each subcontract are excluded from the base
7	In the matter of budgeting for indirect costs, as in other areas concerning proposal preparation, please contact Sponsored Programs staff if further explanation would be helpful.

Program Income

Definition	Program income is defined as: gross income – earned by a grantee, a consortium participant, or a contractor under a grant – that was directly generated by the grant-supported activity or earned as a result of the award. Examples of program income include: • Fees earned from services performed under the grant, such as those resulting from laboratory drug testing • Rental or usage fees, such as those earned from fees charged for use of computer equipment purchased from grant funds • Third-party patient reimbursement for hospital or other medical services, such as insurance payments for patients where such reimbursement occurs because of the grant-supported activity • Funds generated by the sale of commodities, such as tissue cultures, cell lines, or research animals
Reporting	The Principal Investigator must report if s/he anticipates that program income will be generated under the subject project.

Section 4C
Certifications and Assurances

Overview

Introduction

Federal regulations require certifications and assurances that certain procedures have been followed prior to submission to the sponsor.

Since regulations may vary between sponsors and between specific opportunities, it is important to review the sponsor's most current guidelines.

In this section

The Sponsored Programs office provides the following general instructions for assuring compliance with regulations for the submission of proposals:

- Certification for Federal Sponsors
- National Historic Preservation Act
- Financial Conflict of Interest
- Joint Appointments with the Veterans Administration

Certifications for Federal Sponsors

Non-delinquency on federal debt	The applicant institution must certify that it is not delinquent in repayment of any federal debt. • On general grant and contract applications, the institution certifies on the behalf of the whole college • On DHHS applications for individual fellowships (PHS 416-1), the named fellow applicant is certifying that she/he is not delinquent on repayment of any federal debt • For individuals appointed under institutional training grants, the trainee appointed under the institutional NRSA is required to submit a Statement of Non-Delinquency on Federal Debt (PHS-T-600) along with the required forms for appointment of the trainee and payback agreement
Federal debarment of individuals	The college provides assurance to federal sponsors that all employees are not on any lists for debarment or restriction by the FDA and federal granting agencies as well as against lists for excluded/restricted parties for export control and terrorism prevention. BCM Compliance and Audit Services engages a third-party service to identify any BCM personnel who may appear on debarment, restriction, or on excluded or restricted parties lists. The OOR Sponsored Programs Office will be notified if any personnel are identified through this process for further action.
Misconduct in science	Under DHHS guidelines, Institutions must certify that administrative procedures are in place regarding dealing with and reporting possible misconduct in science. This applies to any institution which receives or applies for DHHS: • Research • Research-training • Research-related grants or cooperative agreements
Civil rights	The College has on file assurance of compliance forms with the Department of Health and Human Services, Office of Civil Rights, pertaining to: • Civil rights • Handicapped individuals • Sex discrimination • Age discrimination
Whistleblowing	The College maintains a policy to comply with 41 U.S.C. § 4712, a federal law relating to whistleblower protections for employees who make a good faith disclosure of suspected improper activity or gross mismanagement of a federal grant or contract.

National Historic Preservation Act

Background

The Roy and Lillie Cullen Building at Baylor College of Medicine was dedicated as a Texas Historic Landmark on May 1, 2015. The National Historic Preservation Act of 1966 and Archaeological and Historic Preservation Act of 1974 require that federal sponsors take into account the effect on these sites of the proposed activity before approval of a grant related activity.

If a property listed in the National Register of Historic Places or a potentially eligible historic property will be affected, the applicant must obtain clearance before submitting the application to a state or federal sponsor. During review, the federal agency evaluates the property and whether it may be harmed by the activities. See National Register of Historic Places for more information.

Adverse effect

If a project may alter characteristics that qualify a specific property for inclusion in the National Register of Historic Places in a manner that would diminish the integrity of the property, that project is considered to have an Adverse Effect. Integrity is the ability of a property to convey its significance based on its location, design, setting, materials, workmanship, feeling and association.

Adverse effects can be direct or indirect and include the following:

- Physical destruction or damage
- Alteration inconsistent with Secretary of the Interior's Standards for the Treatment of Historic Properties
- Relocation of the property
- Change in the character of the property's use or setting
- Introduction of incompatible visual, atmospheric, or audible elements
- Neglect and deterioration
- Transfer, lease or sale of a historic property out of federal control without adequate preservation restrictions

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National Historic Preservation Act, Continued

Procedures for Federal applications

Certain Federal applications for funding that use the SF424 Adobe Forms may include the following question (typically found on Other Project Info page, item 5):

- Is the research performance site designated, or eligible to be designated, as a historic place?
- Yes or No
- If yes, please explain

The following decision tree can be used:

Step	Action
1	Is the Principal Investigator's lab located in the Cullen Building, corridors A, B and C? • Choose NO for any projects that will be conducted in any other buildings • Choose YES if the project performance site is in the Cullen Building since it is eligible to be included in the National Register of Historic Places
2	Is the application for a Construction grant or large Equipment grant that could entail major remodeling of the research space located in the Cullen Building? • If NO, then a simple answer can be inserted into the text box to explain. Since the form only allows 55 characters/spaces insert the following: "Research at site will not adversely affect the property" • If YES, then consult with the Director of Sponsored Programs for further evaluation and steps to evaluate for any possible Adverse Effects

Financial Conflict of Interest

Introduction

Regulations and policies on Financial Conflicts of Interest in Research have been established to promote objectivity in research. These standards assure that there is no expectation that the design, conduct or reporting of the research will be affected by an investigator's conflicting financial interests.

NSF, DOD, PHS agencies, and many non-profit foundations require disclosures by all investigators at the time of application. Most other sponsors require reporting of any conflicts and how they are managed when an award is made.

Who needs to disclose?

BCM requires disclosures of outside financial interests (domestic and foreign) be submitted for anyone that appears to meet the definition of investigators. PIs must consider all personnel designing, conducting or reporting research. This includes at a minimum:

- All paid or unpaid key personnel
- Paid other personnel, including but not limited to:
  - Post-docs
  - Research techs
  - Study coordinators
  - Graduate students
- ***Reminder***: Investigators must consider financial interests held by spouse and dependent children

Outside financial interests submission process

Currently BCM uses the Disclosure of Outside Interests Tool and the Electronic Research Conflict of Interest (ERCOI) modules in BRAIN to manage disclosures specific to each proposal entered in ESP2. Upon notice of funding, the disclosures are reviewed, and an Assurance letter generated that can be sent to sponsors or the prime institution in the case of incoming subawards.

Additional information, forms, and details of the submission process are available on the Research Conflict of Interest (RCOI) website.

Joint Appointments with the Veterans Administration

Introduction

Investigators with joint appointments at Baylor College of Medicine (BCM) and the Michael E. DeBakey Veterans Affairs Medical Center (MEDVAMC) who receive or apply for NIH funding and/or NIH support for research must have a valid Memorandum of Understanding (MOU).

Types of appointments

BCM Appointment – A BCM appointment is employment by BCM, full-time/part-time, clinical, adjunct or research certified, tenure, non-tenured or individuals with non-paid appointments.

MEDVAMC Appointment – A MEDVAMC appointment is any of the following:

- A full-time or part-time appointment
- An Intergovernmental Personnel Agreement (IPA) appointment
- Or any other MEDVAMC appointment not mentioned

MOU-related definitions

Below is a list of definitions related to joint appointment MOUs:

MOU: Abbreviation for Memorandum of Understanding. A Memorandum of Understanding is prepared in compliance with NIH guidelines for any BCM or MEDVAMC Investigators with joint appointments to both institutions who receive or apply for NIH funding and/or NIH support through BCM.

Institution: Any domestic or foreign, public or private, entity or organization (excluding a Federal agency that: (1) is the direct and primary recipient of PHS grant funds; (2) submits an application/proposal for a research grant/contract whether in response to a solicitation from the PHS or otherwise; (3) is accountable to PHS for the performance of the research grant/contract and: the appropriate expenditure of grant/contract funds by all parties, all other obligations of the grantee/awardee, and compliance with the terms and conditions of the PHS grant/contract awards.

Investigator: Any person who is responsible for the design, conduct, or reporting of research funded by the PHS or proposed for such funding. This includes Principal Investigators (PIs always meet the definition), co-investigators, Site Investigators, research personnel, research assistants, research coordinators, sub-grantees, contractors, collaborators, sub-recipients, and sub-contractors meeting the definition of investigator; including personnel serving on a compensation basis, Without Compensation (WOC) basis, or through an Intergovernmental Personnel Act (IPA) appointment.

Intergovernmental Personnel Act (IPA) Appointment: Personnel who are being compensated through an IPA are considered federal employees without benefits and meet the definition of being dually appointed and in all cases would need a Dual Appointment MOU, if they are also on NIH awards. By definition, personnel serving on an IPA are not considered to have Without Compensation (WOC) Appointments.

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Joint Appointments with the Veterans Administration, Continued

MOU-related definitions (cont.)

Below is a list of definitions related to joint appointment MOUs (continued):

Without Compensation (WOC) Appointment: Personnel who are NOT receiving ANY compensation of any kind (whether directly, through an IPA, or other salary reimbursement agreement) from MEDVAMC do not meet the definition of a dually appointed investigators and are not required to have a Dual Appointment MOU.

Dual Compensation: Defined as payment by both BCM and the Veterans Affairs (MEDVAMC): using either VA funds directly or through an IPA or funding from another federal sponsor through any funding mechanism) to an employee for the same work effort. Receiving dual compensation is not permissible. When BCM's Authorized Organizational Representative signs an NIH proposal s/he is certifying that there is no possibility of dual compensation for the same work or of an apparent conflict of interest.

Joint Appointment: A joint appointment is a set of Total Professional Responsibilities mutually arranged by BCM and MEDVAMC. The combination of clinical, teaching, administration, and research activities at BCM and MEDVAMC comprises 100 percent of the joint appointee's Total Professional Responsibilities which are detailed in the MOU.

Significant Change: BCM defines a significant change as a 25% or greater change in the investigator's responsibilities or distribution of effort.

Memorandum of understanding (MOU)

The MOU at both BCM and MEDVAMC must specify the:

- Title of the investigator's appointment
- Distribution of compensation
- Responsibilities of the proposed investigator
- Percentage of effort available for research at each institution

The MOU must be:

- Signed by the appropriate officials at BCM and the MEDVAMC
- Updated with each significant change of the investigator's responsibilities or distribution of effort and, without a significant change, not less than annually

The joint BCM/MEDVAMC appointment of the investigator constitutes 100 percent of his or her total professional responsibilities.

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Joint Appointments with the Veterans Administration, Continued

Memorandum of understanding (MOU) (cont.)	The MOU must be valid with all applicable signatures and on file with the BCM Office of Research prior to the submission of a grant application to the NIH. When the NIH grant application is signed and/or submitted to NIH, the BCM Signatory Official is certifying the following: • The individual whose salary is included in the NIH application serves under a joint appointment documented in a formal MOU between BCM and MEDVAMC • There is no possibility of dual compensation for the same work or of an actual or apparent conflict of interest Concerns regarding the completion of the MOU should be forwarded to the Office of Research, BCM-VA Joint Appointment team at BCM-VAResearch@bcm.edu.
Forms and procedures	Additional information, forms, and details of the submission process are available on the Office of Research site MEDVAMC-BCM Dual Appointments of Investigators.
Required MOU training	A course on Joint Appointments Memorandum of Understanding (MOU) training is available through the Collaborative Institutional Training Initiative (CITI) website. MOU training in CITI is required for any: • BCM faculty member who will be or is currently listed and paid as an investigator (whether principal or co-investigator) on an NIH grant or NIH contract • Grants administrator/administrative contact who will help submit an NIH grant or NIH contract

Chapter 5
Administrative Review and Approval

Overview

Introduction

This chapter covers the various reviews and approvals needed prior to submission of a grant or contract application to any agency.

In this chapter

The Sponsored Programs Office describes the mechanisms of administrative review and approval in the following sections:

Section 5A: Assurances/Certifications

Section 5B: Submitting Sponsored Project Documents for Approval

Section 5C: Completing the Proposal Routing Sheet

Section 5D: Sponsored Programs Processes for Grants

Section 5E: Sponsored Programs Processes for Contracts

Section 5A

Assurances/Certifications

Introduction	On grants and cooperative agreements to the federal government, the College is required to certify that assurances have been filed pertaining to compliance with governmental administrative, scientific, and fiscal regulations. This certification is made by the signature of the official signing for the applicant organization on the face page of the application.
Intent of this section	The assurances summarized below are intended to provide an understanding of the policies and procedures pertinent to the grants administration process and are not a comprehensive outline of all DHHS, federal or private sponsor requirements or policies.
Signature of investigator	Each investigator certifies by signature that s/he: • Agrees to abide by BCM research policies and procedures including: – Misconduct in Research – Inventions and Patents • Acknowledges that s/he has read and understands the policy on Conflict of Interest
Proposal submission	Go to BRAIN Electronic Submission of Proposals (grants, contracts, etc.), ESP2, to complete the proposal routing sheet. This allows each PI to submit grant and contract proposals for routing through the Department and through the Office of Research for signature and budget review. Direct any questions on how to complete the routing sheet to spo@bcm.edu.
Human subjects research protocols	For information regarding human subject research, see BCM's Institutional Review Board (IRB) website. • To submit a human research protocol, go to BRAIN Electronic Submission of Protocols to IACUC, IRB (ESP1) to submit a protocol for review • Questions regarding human research protocols may be directed to irb@bcm.edu
Animal subjects research protocols	For information regarding animal subject research, see Baylor College of Medicine's Institutional Animal Care and Use Committee (IACUC) website. • To submit an animal research protocol, go to BRAIN Electronic Submission of Protocols to IACUC, IRB (ESP1) to submit a protocol for review • Questions regarding animal research protocols may be directed to iacuc@bcm.edu

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Assurances/Certifications, Continued

Research using biohazardous materials	The BCM Institutional Biosafety Committee (IBC) reviews the following by way of full review or report from subcommittees: • Recombinant or Synthetic Nucleic Acid Molecule Research • Lasers • X-ray Machines • Radioactive Materials • Irradiators To submit an IBC protocol, go to BRAIN Institutional Biosafety Committee (IBC) to submit a protocol for review. Questions regarding biosafety research protocols may be directed to ibc@bcm.edu.
Conflict of interest	Faculty and staff must disclose activities that may compromise or appear to compromise the objectivity of research results or other activities of BCM: • Additional information and details of the submission process are available on the Research Conflict of Interest (RCOI) website • Training is required and once the modules are successfully completed, the certification is good for four (4) years. Log into CITI using the Single Sign On (SSO) choice and pick Baylor College of Medicine. Log in using the BCM ECA login name and password. • If a conflict is identified,-the Department Chair or Supervisor and the Financial Conflict of Interest Committee assists in managing the potential research conflict of interest • Questions regarding these submissions may be directed to research.coi@bcm.edu
Assurances training	Go to BRAIN Electronic Certification and Training (eCAT) to access training modules for both human and animal subject research. BCM accepts transcripts from the Collaborative Institutional Training Initiative (CITI) website. Log into CITI using the Single Sign On (SSO) choice and pick Baylor College of Medicine. Log in using the BCM ECA login name and password. For more information, email the oversight committee office at iacuc@bcm.edu, irb@bcm.edu, or ibc@bcm.edu. Once the modules are successfully completed, the certification is good for three (3) years.
Inventions and patents	For additional information on inventions, patents, and licenses, Investigators may visit the BCM Ventures website.

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Assurances/Certifications, Continued

Debarment and suspension	The applicant organization is required to certify that neither it, nor its principals, officers, or investigators are presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from covered transactions by any federal agency. HHS regulations published in 2 CFR 376 implement the government-wide debarment and suspension system guidance (2 CFR 180) for HHS' non-procurement programs and activities. "Non-procurement transactions" include, among other things, grants, cooperative agreements, scholarships, fellowships, and loans. NIH implements the HHS Debarment and Suspension regulations as a term and condition of award. Accordingly, recipients of NIH grants ("primary covered transactions"), including sponsoring institutions for Kirschstein-NRSA individual fellowships, are required to determine whether it or any of its principals (as defined in 2 CFR 180.995 and 2 CFR 376.995) is excluded or disqualified from participating in a covered transaction (i.e., grant or cooperative agreement) prior to entering into the covered transaction, i.e., prior to the drawdown of funds which signals acceptance of the grant award. Grantees may decide the method and frequency by which this determination is made and may check the Exclusions lists available on www.SAM.gov, although checking is not required. Principals, officers, and investigators, as employees of the College, are automatically screened, in accordance with the BCM Office of Risk Management process, for debarment, disqualification, or suspension under Title 21 CFR 1404 and 2 CFR 376 as well as any other potential reason that an individual may not qualify as a principal, officer, or investigator for research. The appropriate institutional authority is notified when applicable.
Drug-free workplace	The Drug-Free Workplace Act of 1988 requires that the applicant institution certify that it will maintain a drug-free workplace. DHHS grant application forms have been revised to include a specific assurance from all applicants that a drug-free workplace will be provided.
Certification regarding lobbying	Recipients of federal grants are prohibited from using appropriated funds for lobbying in connection with any federal support.

Section 5B
Submitting Sponsored Project Documents for Approval

Overview

Introduction

This section describes the review process and documentation needed for institutional review and approval of proposals.

In this section

This section covers the following topics:

- Purpose of the Proposal Routing Sheet
- Departmental Review
- BRAIN ESP2 Signature/Reviewer Access Requests
- Sponsored Programs Review
- VA Research Review by BCM

Purpose of the Proposal Routing Sheet

Introduction

After compiling the grant application and associated documentation the proposal must be submitted for administrative review and approval through BRAIN ESP2.

***Important note*:** Do not submit an electronic grant submission to any agency without an approved BRAIN proposal from the Department and the Sponsored Programs Office.

BRAIN ESP2

BRAIN ESP2 allows users to:

- Create an electronic proposal routing sheet
- Attach the complete grant application or contract that will be signed or submitted to the Sponsor
- Forward the documents to all departments involved and to the Sponsored Programs Office for review and approval

Purpose

Information on the proposal routing sheet highlights relevant project issues that require compliance with other formal institutional review mechanisms.

- Accurate responses enable the College, Sponsored Programs, and departmental administration to advise the Principal Investigator regarding compliance with institutional, sponsor, and government policies and regulations
- The text of the proposal must agree with the text of any protocol supported by the proposal
- By submitting the proposal routing sheet, the PI is certifying the accuracy of the responses and the corresponding details relating to the questions
- ***Note*:** Willfully submitting false information in federal grants, cooperative agreements, and contract proposals is a criminal offense.

Application deadlines

An ESP2 BRAIN proposal routing summary and attached application must be complete and approved by the department at least 5 working days prior to the sponsor's deadline. Please check with the department grants administrator regarding any additional deadlines the department may have.

Applications:

- Are reviewed in the order received for each deadline
- Received after the 5 working day deadline may not be reviewed
- That have not been reviewed will not be submitted
- Received on the day of the deadline may not be processed by SPO unless special approval is requested by the PI from the Director of Sponsored Programs

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Purpose of the Proposal Routing Sheet, Continued

Timing	The following are major NIH application deadlines. Sponsored Programs' deadlines are always FIVE working days prior to these NIH receipt deadlines. • February 5 • March 5 • June 5 • July 5 • October 5 • November 5 The volume of work being processed just prior to these dates is extremely heavy. Sufficient lead-time is especially critical at these times.
NIH viewing window	NIH applications can be viewed online in the Commons for 48 hours after submission. Errors due to electronic processing, such as upside-down pages or blurry figures, can be corrected within the viewing window up until the deadline. Corrections after the deadline will be subject to NIH late policy and may result in the application not being accepted. Therefore, submitting an application through BRAIN early gives the most time to ensure the application is uploaded correctly and error free.

Departmental Review

Verification

Applications for funding and correspondence requiring institutional endorsement are reviewed to:

- Verify that College and sponsor requirements have been followed
- Assure that the College has the resources and facilities to carry out the project
- Assess the potential impact of the research activity on the College

Approvals

Once the proposal is entered into ESP2 and submitted by the Principal Investigator, the routing sheet is automatically sent in the following order for review and approval:

- Section Chief (if applicable)
- Department Chair (or designee)
- Sponsored Programs

Section Chiefs/Department Chairs

Section Chiefs/Department Chairs have the overall responsibility of determining the appropriateness of the project and project changes on behalf of the Department and College.

- It is expected that investigators will have discussed the scope of the project and its implications with the Department Chair before the proposal preparation has begun.
- The Chair should be fully aware of the commitments entailed by the project such as:
  - Faculty appointments
  - Personnel
  - Space
  - Facilities
- The Chair's approval of the ESP2 routing sheet signifies that these obligations have been considered
- A designee may be authorized to sign for the Chair with the Chair's permission (such as the Department Administrator)

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Departmental Review, Continued

Department Administrator

The Department Administrator's approval on the routing sheet signifies that she/he has:

- Thoroughly reviewed the document
- Approved the project's impact on the Department
- Checked the budget and the forms for accuracy
- Certified that the project is in compliance with the policies and guidelines of all institutions named in the proposal
- Carefully evaluated the project with respect to:
  - Salary recovery
  - Program income under the project
  - Cost projections
  - Patient care costs
  - Other support declaration
  - Redistribution of effort, resources and environment commitments
  - Use of human subjects or vertebrate animals

Issues such as the following require resolution and appropriate institutional approval prior to the application being submitted for review by Sponsored Programs:

- Additional space
- Significant revisions to clinical practice
- Alterations/renovations to existing facilities
- Use of biohazards and highly toxic chemicals
- Cost sharing for effort or indirect costs

Designee

The Section Chief/Department Chair may designate Signature Authority or Reviewer ability to administrators to be able to view all proposals submitted for that Section or Department. A Reviewer should provide assistance to the Signature designee. Requests to add designees are made in BRAIN using Access Request in eSP1 and eSP2.

BRAIN ESP2 Signature/Reviewer Access Requests

Introduction

Departments, Sections and Centers must delegate authority for College approval in BRAIN ESP2. Ideally each distinct group has at least two people with Signature authority to approve proposals submitted by the PI. Additional people may be added that have only Review ability over proposals under that department, section or center.

Some administrative offices such as Sponsored Programs Finance, BCM Ventures, or Business Development may request Report access for purposes of their administrative duties for the College.

Who can request

Anyone who has current ESP2 Signature authority may initiate a request to change, remove, or add additional people. If no Signature authority is listed, permission must come from the Department Chair or the Section Chief, as applicable.

How to request access

Follow these steps to request special access for BRAIN ESP2:

Step	Action
1	Log into BRAIN and choose ESP2
2	On the left side of the Welcome page click on "Access Request"
3	In the upper left of the page, click on "New"
4	Fill in the Request: • Choose the Type: Assign, Change, Replace or Delete • Choose the Menu: Reviewer, Signature or Reports • Select the type of group using the radio button: Department, Section or Center • Depending on the group selected, the Drop-down box will offer selections. Click on one and the box will auto fill. • In the "To" box, type the first 3-4 letters of the persons last name and use the binoculars to see people's names to select the person to be given privileges • Fill in an Explanation as to why this access is needed • Choose the "Submit" button
5	Send an email to spo@bcm.edu asking that the request be reviewed and approved

Sponsored Programs Review

Introduction

Grants, contracts and similar forms of funding assistance are legal agreements between the sponsor organization and the College. These agreements are formally approved only by the Institutional Official or authorized designee.

Document review

Sponsored Programs staff review documents in preparation for institutional approval, including award and post award documents.

College budget accounts will not be established until this review and approval has occurred.

What paperwork to submit

Below describes what paperwork to submit in ESP2:

Type of Agreement	Paperwork to submit
Grant and Cooperative Agreement applications	• Opportunity instructions • Copy of the online completed application for electronic federal applications that are submitted via the Grants.gov Workspace system or the NIH ASSIST system • Excel budget spreadsheet to aid internal review • Copies of relevant correspondence with the sponsor • Paper or other online application should include: – Cover page/transmittal letter – Abstract or brief work scope description – Specific Aims – Budget and budget justification pages – All pages requiring institutional endorsement – All pages specifying terms and conditions of award – All other pages containing administrative detail, for example: > Facilities and Other Resources > Other Support > Checklist from PHS applications – Relevant animal portions of applications (e.g., Section F of a new or renewal NIH grant) if applicable
Fellowship applications	Sponsored Programs must review all fellowship applications in order to ensure compliance with institutional policies and guidelines. This includes both applications awarded to the Institution, as well as those that are awarded directly to the individual fellow applicant. The fellow applicant should have her/his mentor listed as Key Personnel on the BRAIN proposal and should also attach a Mentor Certification Letter to the BRAIN proposal. See certification forms on the SPO site under Templates - Grants. Other attachments should follow instructions above depending on whether the application is an electronic or paper submission.

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Sponsored Programs Review, Continued

What paperwork to submit (continued)

Below describes what paperwork to submit in ESP2 (continued):

Type of Agreement	Paperwork to submit
Subaward proposals	Furnish a copy of the following: • Opportunity instructions • Consortium Commitment or Letter of Intent – The template should be completed and ready for institutional official signature • Budget and justification • Work scope and/or Specific Aims
Contract proposals	Sponsored Programs is responsible for working with investigators on all aspects of federal and state contract negotiations. Therefore, investigators are asked to provide the following contract-related items at the time indicated: • Notification of intent to enter into a contract and a copy of the Request for Proposal (RFP) as soon as it is decided to apply • The contract proposal • Pre- or post-award correspondence with the Contracting Officer. This correspondence must be countersigned by our institutional official Should a contract be awarded, the PI is free to discuss the progress of the research with the Program or Project Officer. • However, neither the PI, nor the Project officer is authorized to negotiate any changes in the contract • Changes in research conduct or cost must be approved by the Contracting Officer and processed through the Office of Research for institutional endorsement

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Sponsored Programs Review, Continued

What paperwork to submit (cont.)

Below describes what paperwork to submit in ESP2 (continued):

Type of Agreement	Paperwork to submit
Clinical trial agreements	The Office of Clinical Research is responsible for working with investigators on all aspects of clinical trial contract negotiations: • Investigators should begin a parallel process of creating the ESP1 Human protocol and the ESP2 proposal, containing a Word version of the contract, so the reviews proceed at the same time. • To facilitate negotiations, investigators complete and submit the CTA Pre-Review form which provides additional information for negotiation purposes • Further information, feasibility assessment and budget templates, and the link to the Pre-Review form are on the SPO website
Industry Sponsored Research Contracts	The Office of Clinical Research works with investigators on sponsored research, and collaboration agreements with for-profit sponsors. • Investigators should create the ESP2 proposal, containing a Word version of the contract, an Excel budget and include full indirects. • OCR staff reviews and approves confidentiality or non-disclosure agreements provided by commercial organizations as a precursor to sponsored research agreements. • Send a Word document version of the confidentiality agreement to be reviewed to cta@bcm.edu.
Industry Service Contracts	BCM Ventures works with investigators on Testing or Service Agreements. Depending on the scope of work they may be tracked in BRAIN or they may be processed separately. Contact bcmventures@bcm.edu to discuss.

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Sponsored Programs Review, Continued

What paperwork to submit (cont.)

Below describes what paperwork to submit in ESP2 (continued):

Type of Agreement	Paperwork to submit
Grant and Contract Awards and agreements	Authorized personnel from SPO, OCR or BCM Ventures review all awards and agreements. In any agreement or award, the following elements are considered essential: • The award is to the correct corporate entity, namely, Baylor College of Medicine • Clear definitions of work scope, award period, and responsibilities are provided in the agreement itself or by reference to the proposal or protocol • Total costs or fees and budgets are correct, and re-budgeting restrictions are not excessive • Payment terms are fair to the cash flow of the College • Progress and financial reporting requirements are reasonable • Confidentiality and publication restrictions do not violate College policy • Patent, licensing and copyright provisions comply with BCM Intellectual Property guidelines • General provisions refer to and comply with current laws and regulations • The College is granted approval on the use of its name, or any abbreviation thereof, or the name of the Principal Investigator(s), expressly or by implication, in any: – News – Publicity release – Advertisement, or – Other public disclosure by the Sponsor Only the appropriate official, not the PI, may sign agreements that require Institutional acceptance. Where the sponsor requests PI endorsement in addition to Institutional acceptance, the suggested heading is: "I have read and agree to abide by the terms of this agreement."

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Sponsored Programs Review, Continued

What paperwork to submit (cont.)

Below describes what paperwork to submit in ESP2 (continued):

Type of Agreement	Paperwork to submit
Letters of Request to sponsors	The PI should author and sign post-award letters of request which need to be sent to sponsors (including NIH) on matters such as: • Prior approval for re-budgeting or changes in effort for Key Personnel • Extensions • Supplemental funding • Subcontracting, or • Transfers Please leave space on the letter for institutional countersignature. Send the letter to be reviewed and co-signed to spo@bcm.edu.
Confidentiality/ Non-disclosure agreements (CDAs)	Commercial organizations may require that the College and/or Principal Investigator execute a confidentiality or non-disclosure agreement. These agreements are to protect the sponsor's interest when disclosing proprietary information regarding a potential sponsored project protocol. Depending on the final purpose of sharing the confidential information one of three offices may review the CDA: • SPO staff reviews and approves confidentiality or non-disclosure agreements provided by federal, state, non-profit foundation or academic collaborating institutions. Send a Word document version of the agreement to be reviewed to spo@bcm.edu. • OCR staff reviews and approves confidentiality or non-disclosure agreements provided by commercial organizations as a precursor to clinical trial agreements or industry sponsored research agreements. Send a Word document version of the agreement to be reviewed to cta@bcm.edu.

VA Research Review by BCM

Introduction	The Michael E. DeBakey Veterans Affairs Medical Center (MEDVAMC) has been affiliated with BCM since 1949. The majority of physicians at MEDVAMC are BCM faculty and in keeping with BCM policy, all United States Department of Veterans Affairs' (VA) research conducted by BCM personnel must be approved through the BCM Protocols and Proposals submission processes. This includes research projects that are routed to the: • BCM IRB (or IACUC, IBC as appropriate) • VA Central IRB (Reliance protocols) • Houston VA Research and Education Foundation (HVAREF) for industry-sponsored protocols
VA research definition	VA Research is defined as meeting any of the following criteria: • Research conducted using any property or facility of the VA, including MEDVAMC, which includes leased space and off-site waivers (partial and full) • Research conducted by or under the direction of any salaried or without compensation (WOC) employee, or Intergovernmental Personnel Agreement (IPA) appointments of the MEDVAMC during and in connection with her/his MEDVAMC responsibilities • Funds supporting the research are managed by the MEDVAMC or the Houston VA Research and Education Foundation (HVAREF) • Research which recruits VA subjects (staff, patients, volunteers) at the MEDVAMC or uses the MEDVAMC's nonpublic information (i.e., CPRS) to identify or contact human subjects or prospective subjects for research purposes • Research utilizing other MEDVAMC resources (e.g., equipment), or • Research approved by the Research and Development Committee (R&DC)
BCM investigators engaged in VA research	BCM investigators engaged in VA research are required to abide by all: • BCM policies and procedures, and • VA policies and procedures
IRB, IACUC, and IBC	The following BCM committees review protocols for the MEDVAMC as applicable: • Institutional Review Board (IRB) • Institutional Animal Care and Use Committee (IACUC) • Institutional Biosafety Committee (IBC)

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VA Research Review by BCM, Continued

QCT review

A Qualifying Clinical Trial Assessment (QCT) and Patient Care Coverage Analysis (PCCA) is required for all clinical trials that have therapeutic intent, regardless of funding or sponsor type. The QCT assessment process is used to evaluate the underlying eligibility of the study for Medicare/third-party payer coverage.

Step-by-step instructions on how to access the web-based system, how complete a QCT assessment and the process for setting privileges in the QCT Assessment System are available on the OCR website.

Review requirements for funded research

See the table below for explanations on the requirements for different types of funding:

Types of funding	Requirements
VA	Federal funding received from the Veterans Administration is called VA funding (i.e., merit and career development awards, cooperative studies, etc.). **Proposal review** • In addition to MEDVAMC requirements, BCM investigators are required to submit a proposal to BCM SPO in BRAIN for VA funded research. See Submitting Sponsored Projects Documents for Approval. VA funding for research must be requested through the VA central Office of Research and Development (ORD). • All VA funded research must have a proposal and as applicable be linked to the appropriate oversight committee. **Oversight committee review** • Certain VA funded research requires use of the VA Central IRB, otherwise the BCM IRB must be used. – VA protocols that are approved through the VA Central IRB are reliance protocols which require a Reliance Letter from the BCM IRB **before** beginning any research procedures. – Follow the Submission Process for reliance and IRB protocol approval in BRAIN ESP1. • As applicable, BCM IACUC and/or IBC review

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VA Research Review by BCM, Continued

Review requirements for funded research (cont.)

See the table below for explanations on the requirements for different types of funding (continued):

Types of funding	Requirements
Industry	Industry funding is derived from private, for-profit sponsors. **Proposal review** • When VA protocols are submitted with an Industry Sponsor the Houston VA Research and Education Foundation (HVAREF) negotiates the contracts for funding between the VA and the industry sponsor. The HVAREF also assists with budgeting and project management of VA protocols. • These VA funding contracts are called Cooperative Research and Development Agreements (CRADAs). • For ESP2 routing sheet instructions, see Submitting Sponsored Projects Documents for Approval. Be sure to include Human Research Protections fees and other BCM costs. • All industry funded research must have a proposal and as applicable be linked to the appropriate oversight committee. • Each protocol must have an associated funding proposal in BRAIN ESP2, which must be approved by BCM Sponsored Programs, in which the Industry Sponsor is given and the HVAREF is entered in the front of the title. **Oversight committee review** • There is no provision for VA Central IRB review of these protocols, the BCM IRB must be used. • As applicable, BCM IACUC and/or IBC review

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VA Research Review by BCM, Continued

Review requirements for funded research (cont.)

See the table below for explanations on the requirements for different types of funding (continued):

Types of funding	Requirements
NIH	Federal funding received from the National Institutes of Health (NIH): **Proposal review** • In addition to MEDVAMC requirements, BCM investigators are required to submit a proposal to SPO in BRAIN. For ESP2 routing sheet instructions, see Submitting Sponsored Projects Documents for Approval. • All NIH funded research must have a proposal and as applicable be linked to the appropriate oversight committee. **VA MOU requirement – Joint Appointments** Investigators with joint appointments at Baylor College of Medicine (BCM) and the MEDVAMC who receive or apply for NIH funding and/or NIH support for research must have a valid Memorandum of Understanding (MOU). See MEDVAMC - BCM Dual Appointments of Investigators for processing an MOU. **Oversight committee review** • There is no provision for VA Central IRB review, the BCM IRB must be used. • As applicable, BCM IACUC and/or IBC review
Foundation	Foundation funding is non-profit funding received from private entities. **Proposal review** • In addition to MEDVAMC requirements, BCM investigators are required to submit a proposal to SPO in BRAIN. For ESP2 routing sheet instructions, see Submitting Sponsored Projects Documents for Approval. • All foundation funded research must have a proposal and as applicable be linked to the appropriate oversight committee. **Oversight committee review** • There is no provision for VA Central IRB review, the BCM IRB must be used. • As applicable, BCM IACUC and/or IBC review

Section 5C
Completing the Proposal Routing Sheet

Overview

Introduction

BCM's Biomedical Research and Assurance Information Network (BRAIN), is an on-line system for creating, routing, reviewing, signing, and tracking both protocols and proposal routing sheets.

In this section

This section covers the following topics:

- Accessing BRAIN ESP2
- Creating a Proposal Routing Sheet
- Funding and Charging of HRP Fees for Industry Sponsors

Accessing BRAIN ESP2

Introduction

The Principal Investigator must submit grant applications or contracts for College approval in BRAIN ESP2. BRAIN may be accessed from any computer.

System requirements

BRAIN supports Internet Explorer 6-10. Internet Explorer 11 can be used in compatibility mode. The directions for configuring compatibility mode are on BRAIN's landing page when trying to access using this browser version.

Mac, IPad and IPhone users can use Safari (all browser versions). BRAIN no longer supports the use of Firefox for BRAIN access.

If there exists pop-up blocker software installed on a computer, users MUST configure the pop-up blocker software to allow pop-ups within BRAIN.

ECA ID and password

A BCM ECA ID and password is needed to access BRAIN:

- For help with email addresses, passwords, or problems logging into BRAIN, please call the IT Help Desk at (713) 798- USER (8737) during regular working hours
- Users will get a change notification through their BCM email account prior to expiration

How to access BRAIN ESP2

Follow these steps to access BRAIN ESP2:

Step	Action
1	Go to the BCM main website
2	At the top of the page, click on "Intranet". Those accessing this site outside of the BCM intranet will be prompted for their ECA ID and password.
3	In the upper right of the page, click on "Research"
4	On the left side of the Research page click on "BRAIN". ***Note*:** Click on ESP2 BRAIN Guide to learn how to perform basic functions in BRAIN. Those accessing this site outside of the BCM intranet will be prompted for their ECA ID and password.

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Accessing BRAIN ESP2, Continued

How to access BRAIN ESP2 (cont.)

Follow these steps to access BRAIN ESP2 (continued):

Step	Action
5	Users are now at the BRAIN login screen. Enter an ECA ID for the user name (the email name in front of the @ sign)
6	Tab down to enter the BCM password
7	Click on the “Login” icon or press “Enter”
8	Select ESP2 by clicking on the underlined text, “Electronic Submission of Proposals (grants, contracts, etc.)”

Creating a Proposal Routing Sheet

When to create one

A separate proposal routing sheet is required for each:

- New - Use the first time a project is entered in BRAIN
- Resubmission/Amendment – Use for major changes to the project such as:
  - Applications being resubmitted for a second review
  - Changing the BCM PI or changing the primary institution of a subcontract
  - Amendments to a Contract or Clinical Trial
- Non-Competing Renewal – Use for:
  - Progress reports or non-competing applications to get the next year of expected funding
  - Annual amendments to subcontracts
  - No Cost Extensions
- Competing Continuation – Use for renewal applications that must undergo Sponsor review before the project can be extended
- Transfer – Use for transferring an already funded grant from another institution to BCM
- Supplement – Use for additional funding requests on an already funded project such as for equipment or students who quality for diversity funding

Navigating in ESP2

ALWAYS navigate through the screens by using the BRAIN icons or the BRAIN pull-down menu selections. Do NOT use the back or forward buttons at the top of the browser screen.

- Do not double-click, only single clicks are needed
- Red bars indicate required information
- Blue bars indicate optional information
- Save the information before moving forward or closing out of BRAIN
- Log out by clicking on the "Logout" button on the left-hand sidebar
- Call the Sponsored Programs Office at 713-798-1297 for specific proposal questions

To create a proposal routing sheet

Click on the blue triangle on the left side of the screen next to "Investigator", and then click on "Create Proposal".

- Select the type of proposal to prepare by clicking on the appropriate circle. ***Example*:** Click on the circle by "New" to create a routing sheet for a new application.
- If selecting Resubmission, Non-competing renewal, Competing continuation, or Supplement, then enter the proposal number of the previously submitted proposal so the project can be linked. Most of the pertinent information will be automatically copied to facilitate the process of making the proposal.
- Move to the next screen by clicking on the "Save and Continue" icon at the bottom of the screen

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Creating a Proposal Routing Sheet, Continued

Proposal entry-Personnel

The first information gathering section is the Proposal Entry – Personnel screen. Follow these steps to complete:

Step	Action
1	The name of the individual who has primary responsibility for the project (Principal Investigator, PI) is entered here. Type in the first three letters of the last name, then use the binoculars to locate the correct person and click on their link to automatically fill in the name, ID number, email, phone and fax.
2	Enter the PI's: • Percent effort • Percent salary • Department • Section (if needed) • Research Center (if needed)
3	Double check the name of the responsible department or center. The system fills in the primary appointment listed in HR, but researchers with multiple department appointments may need to choose a different one. When the award is received, the project will be assigned to the PI in the department listed on the routing sheet.
4	Add other key personnel (co-investigators, faculty advisors) by clicking on the appropriate plus sign (BCM or non-BCM). Fill in all of the contact information for key personnel including their role.
5	Add other investigators that are not considered key personnel but are part of the project by clicking on the appropriate plus sign BCM or non-BCM). Fill in all of the contact information for other personnel including their role. **For VA Funded Research** • List all Investigators/Staff working on the project, both BCM and VA employees • Effort should represent each person's true effort on the project, but salary can be zero
6	Add the name of the administrative contact for this proposal (the name of the individual to whom questions regarding the proposal may be directed)
7	Once the required fields are completed, click the "Save and Continue" icon at the bottom or at the top of the screen

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Creating a Proposal Routing Sheet, Continued

Proposal entry – Title/Sponsor

Follow the steps below to complete the Proposal entry - Title/Sponsor section:

Step	Action
1	Enter the complete title of the proposal. The title of the proposal must agree with the title of the associated protocol. ***Note*:** For progress reports, insert "Year #" before the title. **For VA Cooperative Research and Development Agreements (CRADAs) with industry sponsors** Enter the "HVAREF" in front of the title to indicate it is negotiated by the Houston VA Research and Education Foundation.
2	Select the name of the sponsor funding the research from the small binoculars icon to the right of the "Sponsor" field. Type at least three letters of the sponsor's name before using the icon. ***Note*:** The sponsor is the name of the entity to which the proposal is being submitted, or with which a contract is being made. **For VA Funded Research** Choose the "MICHAEL E. DEBAKEY VETERAN AFFAIRS MEDICAL CENTER" **For VA Cooperative Research and Development Agreements (CRADAs) with industry sponsors** Choose the actual industry sponsor's name.
3	Leave the next field, "Primary Institution," blank, unless the proposal is a subaward. If the proposal is a subaward, select the name of the primary institution submitting the full application (including the budget portion) from the small binoculars icon to the right of the "Primary Institution" field.
4	If the sponsor or primary institution is not listed, please call or email Sponsored Programs to have the sponsor added, (713) 798-1297, or spo@bcm.edu. Send a link to the sponsor's web site in the email.
5	SPO will enter grant information when the proposal is funded. Proposals that are created from already funded proposals will copy over the grant information.

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Creating a Proposal Routing Sheet, Continued

Proposal entry – Title/Sponsor (cont.)

Follow the steps below to complete the Proposal entry - Title/Sponsor section (continued):

Step	Action
	Additional Information:
6	For all other proposals, there is additional information (red bar item) that needs to be filled out. Choose the appropriate: • Funding instrument ***Note*:** The choice for any incoming subaward is a "subcontract" • Purpose • Check if the proposal is cancer related or not • ***Note*:** The submission date is automatically filled in • Sponsor due date ***Note*:** For incoming subawards, use the date the Primary Institution requires the information back, not the sponsor's actual deadline **For VA Funded Awards** • Funding Instrument should be "Non-monetary" • Purpose should be chosen as appropriate to project **For VA CRADAs:** • Funding Instrument should be "Contract" • Purpose should be "Research – Clinical Trials"
	Foreign Component:
7	For Federal and State sponsors, additional information concerning foreign components of the project will be required. A series of Yes/No questions must be answered regarding the performance of any significant scientific element or segment of a project outside the United States, either by the recipient or by a researcher employed by a foreign organization, whether or not grant funds are expended. If any of the answers are Yes, then additional information may need to be gathered, sponsor prior approval may be required and special agreements may be needed before work with the collaborator can begin. Please call or email Sponsored Programs for help with these types of requests at (713) 798-1297, or spo@bcm.edu.
8	Click on the "Save and Continue" icon at the bottom of the screen.

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Creating a Proposal Routing Sheet, Continued

Proposal entry – Location/Budget

Follow these steps to complete the Proposal entry - Location/Budget section:

Step	Action
	Location:
1	Indicate the location of the project work being done at BCM or its affiliates. If more than one location will be used, indicate the percentage of work to be performed in each location, for a total of 100%. Select a location from the pull-down menu. Do not include subaward locations. This applies only to the proportion of work done at BCM and its affiliated institutions.
2	Enter the percentage of work to be performed at the selected location
3	Enter the appropriate F&A (indirect cost) rate for that location. To find the current F&A rate for a specific location, click on the link to BCM Indirect Costs.
4	If the work will be performed at multiple sites, click on the "plus" sign and select another location, then continue as above
5	VA Funded Research should have 100% VAMC with 0% IDC
	Account Naming Information:
	Insert in the text box the seven (7) digit number for SAP account set up that includes the codes for Department (3 digits) Section (2 digits) and PI (2 digits). If uncertain of these codes, consult with the overall Administrator for the Department.
	Project Summary (Budget):
1	Enter the requested start and end dates for the proposal's first year under "First Year"
2	Enter the direct cost and indirect cost. The total cost for the first year automatically populates.
3	Enter the same start date and the ultimate end date for the proposed project under "All Years"
4	Enter the summary direct cost and indirect cost. The total cost for all proposed years automatically populates.
5	If the opportunity has any budget limitations, the sponsor has a salary cap, or any special budget notes are needed, check "Yes" next to the budget question and enter information in the text box.

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Creating a Proposal Routing Sheet, Continued

Proposal entry – Location/Budget (cont.)

Follow these steps to complete the Proposal entry - Location/Budget section (continued):

Step	Action
	Project Summary (Budget) continued:
6	If any Cost Sharing will be provided, either required or voluntary, check "Yes" next to the question and enter information in the text box. Attach a copy of any institutional letter of support for cost sharing if needed.
7	If subcontracting some of the work to another institution, check "Yes" next to the consortium question. Then enter the name(s) of the consortium institution(s) that are planned to collaborate with to perform part of the work.
8	**VA Funded Research** • Dates: Either grant start dates or the protocol approval date, then annually thereafter • Direct and Indirect Costs can be zero • There should be no budget limitations or consortiums
9	Click on the "Save and Continue" icon at the top or bottom of the screen

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Creating a Proposal Routing Sheet, Continued

Proposal entry - Assurances

Follow these steps to complete the protocol assurances section of the proposal entry:

Step	Action
1	Check "Yes" or "No" next to: • Animal Subjects • Human Subjects • Recombinant DNA • Lasers • X-ray Machines • Radioactive Materials • Irradiators • Human Embryonic Stem Cells • Dual Use Research of Concern Materials Do not leave these fields blank.
2	If "Yes" to animal or human subjects, click on the large plus sign to attach the appropriate protocol(s). A search screen will open.
3	Enter the protocol number (e.g., 12345), OR the protocol title, OR the investigator's last name. Click on the "Go" button to the right.
4	Select the protocol that matches the proposed work by clicking in the small box to the left of the protocol title
5	Click the "Save" icon at the bottom of the screen
6	Click on the "X" icon on the BRAIN screen. Do NOT close by clicking on the x in the upper right-hand corner of the screen.
7	The Attached Protocols screen appears again. The protocol that has just been selected will appear at the bottom of the screen.
8	To add additional protocols, click on the plus sign by the protocol and repeat Steps 3-7
9	It is incumbent on the PI to ensure congruency between the proposal and any protocols that are linked to it, see Section 5D Proposals.
10	Click on the "Save and Continue" icon once all the protocols have been added

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Creating a Proposal Routing Sheet, Continued

Proposal entry – Abstract

Follow these steps to complete the Abstract section of the proposal entry:

Step	Action
1	Type or paste the abstract including key words for search purposes into the large field (8000 character limit – including spaces). For Non-competing proposals simply type in "Progress Report for Year #" or "No Cost Extension".
2	Enter a brief (1000 character limit – including spaces) description of the major goals for the project.
3	Click on the "Save and Continue" icon

Proposal entry - attachments

The department may require certain attachments (e.g., Specific Aims, complete application, budget, justification, opportunity instructions). Please contact the departmental administrator regarding department-specific requirements.

Follow these steps to complete the attachments section of the proposal entry:

Step	Action
1	Sponsored Programs requires signature pages, budget page(s), budget justification, checklist and the opportunity instructions at the minimum. Electronic applications must be complete and ready to submit and a pdf copy of the online application should be attached for departmental review.
2	When attaching a document, generate or save the document in a commonly used software program so that the recipient is able to open the attachment (e.g., Word, Excel, Adobe Acrobat) **For VA CRADAs:** If there is a budget, a Research Service Agreement from the HVAREF will have to be attached, reviewed and signed like other contracts.
3	Make sure the file name does not have any special characters (above the numbers on a keyboard) as this disables the ability to open the file later.
4	To attach a file, enter the drive, path, and file name of the file to attach, or click on the "Browse" button to access the appropriate file
5	Enter a brief description of the file being attached (e.g., Final Budget).
6	Click the "Save and Continue" icon.

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Creating a Proposal Routing Sheet, Continued

Proposal entry – Certify/Submit

The principal investigator must certify that he or she agrees to and understands both the sponsor's and BCM's policies, terms, and conditions. The principal investigator must also confirm whether or not there could be a perceived conflict of interest.

Follow these steps to Certify/Submit the proposal routing sheet:

Step	Action
1	Prior to submitting the routing sheet, the principal investigator may check the accuracy and completeness of the routing sheet by clicking on the "Review" button.
2	A form will open that summarizes the data entered into BRAIN for this proposal. If any required information is missing, a message will appear stating what needs to be completed.
3	Clicking on the "Printer" icon will produce a copy of the proposal in report format.
4	By submitting the proposal routing sheet, the principal investigator has signed the investigator certification.
5	To submit the proposal routing sheet, click the "Submit" button.

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Creating a Proposal Routing Sheet, Continued

Review and approval

The appropriate electronic signatures are required for the proposal routing sheet and are obtained in the sequence listed:

- Principal Investigator – certifies and submits
- Section Chief (if applicable) - reviews and approves
- Department Chair – reviews and approves
- Sponsored Programs – reviews and approves

Follow these steps to see where the proposal has been routed as follows:

Step	Action
1	Select "View Proposal" in the left-hand sidebar, and then click on the underlined proposal number of the routing sheet just submitted. Each of the departments, sections and/or centers it has been routed to for approvals will be listed. Identify the specific individuals in the departments and/or centers to whom the form has been routed by clicking on the underlined department or section name that will appear on the screen.
2	A small window with the individuals authorized to sign for that department or center will open on the screen
3	The PI and administrative contact will receive an automatic email message when: • A reviewer returns the proposal routing sheet and attachments to the PI for revisions • A reviewer has approved the proposal routing sheet and attachments and forwarded the information to BCM's Sponsored Programs Office • Sponsored Programs has approved the proposal
4	If a paper copy is still required by the granting agency, the electronic approval of the proposal by the Sponsored Programs Office does not mean that the application has been submitted to the sponsor
5	The PI and department are responsible for delivering the paper original, with the appropriate required signatures to the Sponsored Programs Office for signature
6	The paper original will be signed as soon as the electronic routing sheet, in BRAIN, has been approved. SPO will contact the department to pick up the original.

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Creating a Proposal Routing Sheet, Continued

Review and approval (cont.)

Follow these steps to see where the proposal has been routed as follows (continued):

Step	Action
7	After picking up the signed proposal, make the appropriate number of copies for the sponsor, and send the complete package to the sponsor
8	If this is an electronic submission, there are additional requirements by both the Department and the Sponsored Programs Office. • ***Important*:** Do not to submit an electronic grant submission to any agency without an approved BRAIN proposal from both the Department and the Sponsored Programs Office • Please contact the appropriate administrator on the proper procedure for electronic submissions • Federal applications using the Grants.gov system will be submitted by Sponsored Programs. Therefore, the complete application must be attached to the BRAIN proposal and routed for review and approvals.

Logging out

Make certain the information has been saved before logging out.

When finished with a session, log out by clicking on “Logout” in the left-hand sidebar.

Funding and Charging of HRP Fees for Industry Sponsors

Funding industry-sponsored contracts

This process begins with the Sponsor and PI working together to decide whether to collaborate on a Clinical Trial. The discussion involves the following:

- Protocol
- Budget
- Contract (Clinical Trial Agreement)

If the Sponsor and PI agree to work together, the Sponsor gives the PI a Clinical Trial Agreement for the College to review and ultimately execute.

PI responsibility

As per BCM procedures, the PI:

- Submits the Protocol in ESP1 for IRB approval
  - Sponsored Programs staff recommends that the PI start the Protocol (ESP1) and Proposal (ESP2) simultaneously and they can stay in draft status while details are negotiated. For example, once the PI has an H# (Human Protocol number) from ESP1, she/he can place it in ESP2 under "Protocol Information".
  - ***Note*:** When BRAIN ultimately generates an IRB fee email, it is based on the private, for-profit (industry) sponsor with whom we are seeking the contract
- In ESP2, completes a draft Proposal Summary which includes the following:
  - The Budget (attached) for Section/Department review
  - The Contract (attached) for Sponsored Programs staff review
  - Name and Type of Sponsor - Each Sponsor name has a default in BRAIN as to the type of sponsor
  - Fill in the H# of the Protocol
  - If no H# yet, under "Protocol Information", "Human Subjects", check "Yes" and save. Sponsored Programs staff will add the H# in later.
- Submits a Pre-Review form in the Clinical Trial Agreement System. Instructions available on the OCR website.
- Submits the Proposal Summary to the Section/Department Administrator for approval in ESP2 once the budget has been negotiated
- Section/Department Administrator reviews, corrects, approves and submits to the Office of Research via ESP2

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Funding and Charging of HRP Fees for Industry Sponsors, Continued

OCR duties prior to funding	Office of Clinical Research (OCR) staff reviews the Contract (or drafts a new one) and negotiates terms with the Sponsor. OCR staff then confirms that: • The PI's Department Administrator has approved the Budget • A Protocol H# has been provided in the Proposal (if not provided, find out which is the appropriate Protocol and enter into the Proposal in ESP2) • The IRB has approved the Protocol (an Approval Letter has been generated). If this is the case, the approval date automatically updates in ESP2 under "Protocol Information" • OCR staff has received and signed a partially executed agreement (contract) and has sent it to the Sponsor for signature • If all of the above criteria have been met, OCR staff: – Goes into ESP2 on the main page drop down box and changes the status of the Proposal to "Approved by Office of Research", and presses the Save button – ESP2 updates and automatically indicates the OOR Approval Date on the Proposal Summary
Sponsor responsibilities	The Sponsor signs and returns the Contract to OCR staff. If it goes to the PI, the PI must forward the Contract to OCR. Once OCR receives the Contract, it is considered a fully executed original.
OCR duties after funding	Once OCR has received the fully executed original Contract from the Sponsor, OCR staff changes the status of the proposal to "Funded" and routes the Award Routing Sheet to SP Finance for account set up as a Cash award.
Sponsored Programs Finance responsibilities	Once Sponsored Programs Finance (SPF) receives the original Contract, Finance staff: • Set up an account for the study for the PI in SAP • As money is received from the Sponsor, it is processed in SAP as a Cash Award for the appropriate study • Ensure that the Cash Award is applied to the correct Proposal number so that it is applied to the correct Protocol • SPF applies IRB Fee charges to accounts at the end of each month

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Funding and Charging of HRP Fees for Industry Sponsors, Continued

Criteria for charging HRP fees

In order for Human Research Protection (HRP) Fees to be charged for contracts, the following criteria have to be met:

- In ESP2 the:
  - Sponsor must be Private, For-Profit (Industry)
  - Type of Award must be either a Contract or Co-operative agreement
  - Proposal must be marked as "Funded" by OCR staff (whether or not there is money in the study account, the contract is enough for charging fees)
  - There must be an H# (Human protocol) associated with the funding (either put in by the PI or by Sponsored Programs staff)
- In ESP1, an Approval Letter must have been generated by the IRB for a new Protocol or an annual Renewal

How BRAIN communicates HRP fee charges

When HRP fees are charged BRAIN generates two emails, one to Finance (G&C) and one to the PI.

The PI email states, "An invoice has been sent to Finance (Grants and Contracts) to charge the study listed below for IRB review. Please ensure an invoice is sent to the industry sponsor for these fees", and includes the following information:

- New or Renewal
- Proposal #
- PI name
- Sponsor Name
- Protocol #
- Approval date of Protocol
- Fee amount

For information on HRP fee rates for Industry Sponsors see HRP Fees.

Section 5D
Sponsored Programs Processes for Grants

Overview

Introduction

This chapter describes Sponsored Programs processes for grants.

In this section

This section covers the following topics:

- Proposals
- Appeals of Initial Peer Review
- Annual Reports
- No Cost Extensions
- Grant Closeout

Proposals

Introduction

Below is the Sponsored Programs process for approving and funding grants.

Administrator duties

For grants, the PI and/or Departmental Administrator:

- Initiates the Proposal Routing Sheet in BRAIN ESP2:
  - Ensures all investigators for the project have been entered
  - Initiates Master RCOI list so they can provide disclosures prior to submission of the complete proposal and ensure the application can be submitted
- Attaches the following Administrative pages in ESP2 for NIH grants:
  - For electronic applications - Attach the completed application and opportunity guidelines
  - For paper applications, attach opportunity guidelines and the following:
    - > Face page
    - > Specific aims
    - > Detailed budget
    - > Overall budget
    - > Justification
    - > Checklist
- For other agencies, the attachments vary by sponsor. However, at a minimum, Sponsored Programs needs to see:
  - Opportunity guidelines
  - Specific aims
  - Budget
  - Budget justification
  - Any form requiring Institutional signature

***Note*:** For re-submissions and renewals do not create a New proposal but use the Amendment, Non-competing or Competing options so the number stays the same and only the suffix changes.

PI responsibility

The Principal Investigator (PI) must submit the routing sheet in BRAIN ESP2 for departmental review and approval in ESP2.

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Departmental review

Once the PI submits the BRAIN ESP2 routing sheet, the system automatically sends an email to the PI's department, as well as any other departments or centers listed for the Key and Other Personnel.

- Each department or center should have at least 2 reviewers who are approved in BRAIN to process the submissions in a timely manner
- Once the routing sheet has been approved by all the departments listed, BRAIN notifies Sponsored Programs by email automatically
- By providing their approval, departmental reviewers are certifying that the following items are correct at the time of submission:
  - Listed investigators are current or pending BCM employees
  - Investigator's effort is correct
  - Investigator's salary and fringe benefits are correct in the budget attachments
  - Any cost sharing has been documented and unrestricted funds are available to cover the amount being cost shared
  - Any files that contain Other Support information correctly list Current and Pending grant support including domestic and foreign research awards
  - Effort reported in progress reports for the past year on the Personnel Report is correct
  - All investigators in their department have submitted RCOI disclosures
  - The PI's department should also review the entire Application and its attachments to make sure they are complete and ready for submission
- The Departmental reviewer should return the proposal to the PI and ask for revisions as needed before approving the proposal to move forward to Sponsored Programs

Proposal approval process

Once the routing sheet has been approved by the department, BRAIN notifies Sponsored Programs by email automatically. Sponsored Programs staff proceed as follows:

Step	Action
1	• Reviews Administrative pages per funding source guidelines • Responds to the Department Administrator with any changes or requests for more information
2	• If the funding source requires a hard copy signature of the face page, staff obtains the institutional signature • If necessary, the Department Administrator prints and delivers the face page to Sponsored Programs for signature • The Department is responsible for physically mailing the application documents to the funding source, when necessary • Staff attaches a pdf copy of any signed pages to the proposal

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Proposal approval process (cont.)

Once the routing sheet has been approved by the department, BRAIN notifies Sponsored Programs by email automatically. Sponsored Programs staff proceed as follows (continued):

Step	Action
3	If the funding source requires an electronic submission: • Sponsored Programs staff approves the application and submits it to the funding source • The final revised and submitted application is attached to the proposal
4	Once everything is in order, the status of the proposal is changed to "Approved by the Office of Research"

NIH Just-in-Time (JIT) Procedures

Sometime after the reviewers have provided a score for the application, the Grants Management Specialist assigned to the grant may send an email to the PI requesting additional information. Typically, these items include:

- Approval dates for animal or human protocols that were only pending at the time of submission
- Certification of training in the use of human subjects
- Other Current and Pending Support for each of the key personnel
- Revised budget

PI communication duties when ready to submit JIT

PIs should work with their department to prepare all the requested documents. Typically, the items are uploaded in the NIH Commons under the JIT link associated with the pending grant. Once the items are saved and ready for review, the PI or department needs to forward the original NIH email to SPO and advise SPO staff that the JIT is ready to submit. The grant number, and the BRAIN proposal number that the information is associated with, need to be included in the email.

Protocol congruency

PIs must ensure grant and protocol congruency per the PHS policy and commit to conducting research activities according to approved IRB and IACUC protocols. The PI should work with SPO to ensure all related protocols have been linked with the proposal in BRAIN, and that any new protocols or amendments are submitted at JIT so the approvals will be ready when the Notice of Award is received.

JIT submission process

SPO reviews the submitted material online in the Commons and compares it to the information in BRAIN:

- In addition, the PI is asked to provide email confirmation that the Other Support lists all sources of funding (domestic and foreign), effort in calendar months, and that any potential overlap has been explained.
- After it is approved, the JIT material is submitted online.

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Timeline for funding

It takes approximately 9 months before the PI learns from the funding source whether or not the grant is funded.

PI communication duties regarding the application

Sponsored Programs staff should be notified of any communication between the PI and the funding agency regarding the application. If the application is not chosen for funding, then SPO should be informed so the proposal can be marked as "Not Funded" in BRAIN.

Depending on the funding source, the PI is notified of any award. The PI is then required to send a copy of the Notice of Award to spo@bcm.edu so that SPO can begin the funding process.

Proposal funding process

Having been notified of the Notice of Award (NOA), Sponsored Programs staff:

Step	Action
1	Notifies the PI and Department Administrator if action is needed
2	Verifies that the: • Human or animal protocol(s) have been approved • Conflict of Interest disclosure and approval has been completed • Training in Responsible Conduct of Research has been completed by the PI and Administrator. Training is required and once the modules are successfully completed, the certification is good for four (4) years. Log into CITI using the Single Sign On (SSO) choice and pick Baylor College of Medicine. Use a BCM ECA login name and password to log in to CITI. • Trainings required by sponsor (ex. CPRIT) or type of project (ex. Good Clinical Practice for NIH Clinical trials) may also be required and will be requested by SPO as needed. • If any Foreign Component questions are answered Yes, then SPO will request an Assurance form be completed and signed by the PI and his or her department Chair to ensure all approvals have been completed. If necessary, SPO will assist in sending a Prior Approval request to the sponsor as described in Section 6A, Types of Prior Approval Requests.
3	If items in Step 2 are verified, the proposal is marked "Funded" in ESP2
4	In the "Edit Awards" section of ESP2, completes the following based on the Notice of Grant Award: • Start and end date • Direct and indirect costs • Data enters grant number and other funding information

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Proposal funding process (cont.)

Having been notified of the Notice of Award (NOA), Sponsored Programs staff (continued):

Step	Action
5	Forwards the NOA to Finance (Grants and Contracts) for account set-up
6	Finance (Grants and Contracts) staff forwards the account number to the PI and the Department Administrator

Proposal not funded process

If Sponsored Programs is notified in writing by the funding source that the application was **not** funded, Sponsored Programs staff:

Step	Action
1	Notifies the PI and the Department Administrator via email and attaches the documentation
2	Marks the proposal in ESP2 as "Not funded"
3	If the Department requests that a proposal be marked "Not funded", the Department Administrator must: • Send a written request via email to spo@bcm.edu • Copy the PI on the email

Appeals of Initial Peer Review

Background

The first level of NIH review is carried out by a Scientific Review Group (SRG), a committee of scientists who have expertise in relevant scientific disciplines and current research areas, and who make recommendations concerning the scientific and technical merit of the applications. The official outcome of the initial level of review is made available to investigators, Council members and NIH staff via a written report, the NIH summary statement.

Investigators who perceive a flaw in the review process for a particular application may make an appeal under specific conditions.

NIH appeal process

PIs who wish to appeal the review of their application should reference the NIH policy as described in NOT-OD-11-064. Additional internal BCM procedures are as follows:

Step	Action
1	PI must have received an official summary statement and have discussed their concerns with the appropriate NIH Program Official (PO). Following their recommendations, the PI must write a letter that describes the flaw in the review process and explains the reasons for the appeal. The appeal must be based on one or more of the following issues: • Evidence of bias on the part of one or more peer reviewers • Conflict of interest, as specified in regulation at 42 CFR 52h.5 "Scientific Peer Review of Research Grant Applications and Research and Development Contract Projects", on the part of one or more peer reviewers • Lack of appropriate expertise within the SRG • Factual error(s) made by one or more reviewers that could have altered the outcome of review substantially
2	PI emails letter and copy of the summary statement to the Director of Sponsored Programs with a request for review and providing the BRAIN number of the submitted application
3	Director will review the documents to ensure they follow NIH and BCM criteria for appeal, and will discuss the situation and any revisions to the letter with the PI
4	If the Director concurs that the PI's basis for appeal falls into one of the categories 1.a-1.d above, then the final version of the letter will be forwarded to the Senior Vice President for Research (SVPDR) for final approval indicating concurrence with the PI that appeal information should be considered
5	Following approval by the SVPDR to send the appeal on behalf of the institution, both the PI and Director will sign the letter and SPO will email it to the PO for subsequent consideration by NIH

Appeals of initial peer review by other sponsors

PIs who wish to appeal the review of their application should contact Sponsored Programs to get help determining the appropriate process for each unique sponsor. In general, the appeal must fall into one of the categories in Item 1 listed above. Subsequent steps of review by the Director of Sponsored Programs, and by approval of the SVPDR before the appeal can be sent to the sponsor will be followed as above.

Annual Reports

Continuations – Non-NIH sponsors

For continuing years, the PI must submit an annual report of progress to the funding source based on funding source guidelines.

Below are steps for the PI to submit the progress report to the Sponsored Programs Office for approval prior to sending it to the sponsor:

Step	Action
1	Create a Non-Competing Renewal proposal in BRAIN off of the currently funded proposal so that BRAIN creates the N1 (N2, N3, etc.) proposal. • In front of the title, add what year this will be for (i.e., "Year 3:") • Since the Abstract copies over, in the Abstract (Additional Comments), type "Progress Report for Year X" • Update the Personnel list for names and effort • Create the RCOI Master list so investigators can submit annual disclosures, and then submit the Master so the Assurance letter can be generated in anticipation of the next year award notice • Update any Animal or Human Assurance numbers
2	Attach a pdf of the full report and a Word version of the face page if an authorized official signature is required
3	Submit the BRAIN proposal for review and approvals. • SPO contacts the PI and department administrator listed in BRAIN when the face page is ready to be picked up • Both the PI and administrator get an automatic email when the BRAIN proposal has been approved
4	Compile the complete report and mail or email to the sponsor in time to arrive on the deadline

Continuations – NIH awards

For continuing years, the PI must submit an annual report of progress as an electronic submission in the NIH Commons:

- All grant types have transitioned to the Research Performance Progress Report (RPPR) format
- Rarely an interim paper report is specially requested by the Program Officer and may be emailed to them or mailed to the Division of Extramural Activities Support
- Email SPO if this is requested for assistance in preparing the proper format of the report

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Annual Reports, Continued

Electronic progress reports - RPPR

Below are steps for the PI to submit an RPPR electronic progress report to the Sponsored Programs Office:

Step	Action
1	Log into the eRA Commons (if the administrative person assisting the investigator does not have an eRA Commons account, please email spo@bcm.edu to request one).
2	Search for the grant number and follow the link to "RPPR". Directions for preparing an annual progress report are in the NIH RPPR Instruction Guide.
3	Complete the required fields and when all uploads are complete, click "Save" at the bottom of the screen. On the "Manage RPPR Menu" screen, select "Validate" to check for any errors within the report and fix as needed.
4	View the completed RPPR report and save the pdf copy.
5	Route the RPPR report to the BCM signing official. Check with the department to determine whether to route to the Administrator first.
6	Create a Non-Competing Renewal proposal in BRAIN off of the currently funded proposal so that BRAIN creates the N1 (N2, N3, etc.) proposal. • In front of the title, add what year this will be for (i.e., "Year 3:") • Since the Abstract copies over, in the Abstract (Additional Comments), type "RPPR Progress Report for Year X" • Update the Personnel list for names and effort • Create the RCOI Master list so investigators can submit annual disclosures, and then submit the Master so the Assurance letter can be generated in anticipation of the next year award notice • Update any Animal or Human Assurance numbers
7	Attach the pdf of the RPPR progress report
8	Submit in BRAIN proposal for review and approvals. • The PI receives an automatic email from the Commons once the report has been submitted • Both the PI and administrator get an automatic email when the BRAIN proposal has been approved

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Annual Reports, Continued

SPO review of annual reports

Sponsored Programs staff processes the report as follows:

Step	Action
1	Checks report for completeness and reviews any budget items for accuracy
2	Confirms that the protocol and Conflict of Interest approvals are current before approving the report
3	For hard copy report submissions: • Depending on the funding source, the report may require institutional signature • Once signed, staff notifies the PI and the Department Administrator listed on the proposal that the hard copy is ready for pick-up • The Department is responsible for picking-up and mailing the report to the funding source • If a special paper report has been requested by NIH, then SPO staff emails the final complete report to the Grant Officer as required
4	For electronic reports: • The funding source may require institutional electronic approval and/or submission • Sponsored Programs staff notifies the PI and Department Administrator of submission completion
5	For sponsors that provided multiyear funding in the original award, SPO will immediately fund the proposal to add the next year of time. Otherwise, funding will occur after receipt of the Notice of Award for the next year of the grant.

RPPR monitoring procedures for SPO

Sponsored Programs is responsible for following the steps below to ensure the RPPR is submitted prior to the due date and avoid non-compliance notification by NIH:

Step	Sponsored Programs Responsibilities
1	To prevent non-compliance, SPO monitors via the Commons the status of all Pending Progress Reports: • In addition to the automatic email from the Commons, SPO sends a courtesy reminder email to all the departments and PIs on the monthly list along with links to the current instructions • SPO provides the dates for the internal deadlines in order to meet the sponsor's requirements (five working days before the sponsor deadline)

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RPPR monitoring procedures for SPO (cont.)

Sponsored Programs is responsible for following the steps below to ensure the RPPR is submitted prior to the due date and avoid non-compliance notification by NIH (continued):

Step	Sponsored Programs Responsibilities
2	• Sends a second courtesy reminder email five working days before the SPO internal deadlines • Asks if extenuating circumstances exist and if a request for an extension has been sent to the Program Officer and assists with communication if needed
3	• The day after the internal deadline or extension has passed, sends a third reminder and copies the Department Chair and Research Compliance Services (RCS) • Warns the PI they are in non-compliance with BCM OOR procedures and subject to transaction suspension, whereby SPO will not conduct any other grant-related activities until the PI has submitted the late Progress Report
4	RCS will send a non-compliance Assessment Report with BCM procedures to the PI with one week to respond.
5	Upon receipt of the RCS email, SPO: • Places the PI on transaction suspension unless the PI completes the report, or provides acceptable reason for delay and a plan for completion of the report by a specified date • Notifies the Department Chair that the Department will have to prepare the report if the PI is unable, copying all parties below: – PI and Department Administrator(s) – Research Compliance – Department Chair • SPO proactively requests an extension from the grant specific Program Officer in order to forestall non-compliance notification from the sponsor
6	Once the reporting requirements for the grant have been successfully completed, the suspension will be lifted.
7	Multiple infractions are escalated to the Senior Vice President and Dean of Research to determine how best to guide the Department in implementing procedures to ensure compliance.

No Cost Extensions

Description

Most sponsors allow a one time, 12-month extension of the grant without any additional funding to complete the project. Depending on the sponsor an email, letter or on-line request may need to be sent. In all cases, SPO should be informed so the grant end dates can be extended in the BRAIN and SAP.

NIH allows the institution to process a first-time extension in the Commons from 90 days before until the end date of the grant. The request has to be made in writing if it comes after the end date. All subsequent years' requests must be made in writing prior to the end date; most sponsors require a prior approval request at least 30 days before the end date.

PI duties for first extensions

PIs are responsible for following the steps below for first extensions:

Step	PI Responsibilities
1	Create a Non-competing renewal proposal in BRAIN off the currently funded proposal. Attach any required FCOI disclosures or Assurance letters.
2	In front of the project Title, enter "NCE:"
3	In the Abstract (Additional Comments), enter "First No Cost Extension"
4	In the budget, enter the extended dates, but put zeros for the money
5	Attach a document with a short Justification that provides programmatic not financial reasons for the extension. Attach any letters or emails from the sponsor providing approval (except for NIH).
6	Route for approvals

SPO duties for first extensions

Sponsored Programs is responsible for following the steps below for first extensions:

Step	Sponsored Programs Responsibilities
1	Extend the grant in the NIH eRA Commons
2	Attach a copy of the automatic email showing the new end date or attach sponsors approval document if not previously received
3	Ensure protocols and RCOI are approved and RCR training has been completed
4	Mark the proposal as funded
5	Send sponsor approval and funding routing sheet to Grants and Contracts to extend the end date, and copy the PI and Administrator

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No Cost Extensions, Continued

PI duties for second extensions or any thereafter

PIs are responsible for following the steps below for second extensions or any thereafter:

Step	PI Responsibilities
1	Create a Non-competing renewal proposal in BRAIN off the last NCE proposal at least 30 days prior to the end date
2	In front of the project Title, enter "NCE:"
3	In the Abstract (Additional Comments), enter "Second No Cost Extension"
4	In the Budget, enter the extended dates, but put zeros for the money
5	Ensure protocols are approved and FCOI Assurance letter is attached
6	Attach a budget on PHS 398 form for how the remaining funds will be used
7	Attach a budget justification
8	Attach a draft letter on departmental letterhead that covers the following: • Composed letter is addressed to the sponsor requesting a No-Cost extension. The letter should clearly identify the reason(s) for requesting a second no-cost extension. • In the letter, describe why additional time is required to complete the specific aims as originally proposed. Simply having funds left over is not sufficient reason to request additional time. • In the letter, include the remaining direct and indirect dollar amounts • The letter should be signed by the Principal Investigator and should include a signature area for BCM authorized Signatory
9	Submit the proposal for review and approvals

SPO duties for second extensions or any thereafter

Sponsored Programs is responsible for following the steps below for second extensions or any thereafter:

Step	Sponsored Programs Responsibilities
1	Forward the request to NIH or another federal sponsor as appropriate. ***Note*:** The sponsor responds with email approval, letter approval, or a revised Notice of Award. Any of these documents can be used for funding.
2	Attach documents to the proposal
3	Send sponsor approval and funding routing sheet to Grants and Contracts to extend the end date, and copy the PI and Administrator

Grant Closeout

Closeout reports

All sponsors, whether federal, state, non-profit or for-profit industry, require a Final Report at the end of the grant project. Many times, this is sent directly by the Investigator to the sponsor without needing an official signature.

However, since this is typically a requirement of the Terms and Conditions of the Grant, Sponsored Programs requires a copy to ensure this last obligation is met. The PI or department administrator must attach it to the BRAIN proposal or send it to SPO for help.

NIH Closeout requirements

NIH has a specific process that is described below requiring 3 reports to be submitted in the Commons. Failure to complete this final condition of award places BCM and the PI in material non-compliance with federal grants policy and may impact future funding for both the college and PI. Therefore, the PI must complete the FRPPR and initiate the Inventions within 30 days following the grant end date.

The PI must submit the final documents in the Closeout section of the Commons:

- Final Financial Report (prepared and uploaded to the Commons by Sponsored Programs Finance, SPF. The PI and Department need to work with SPF to closeout in SAP so the information can be submitted to the NIH.
- Final Progress Report: Online forms are completed by the PI, then routed to the BCM Signing Official who submits to NIH.
- Final Invention Statement: Started by PI and confirmed by the Baylor Licensing Group who submits to NIH.

***Note*:** Only the PI or those with SO (Signing Official) access can submit these documents.

NIH closeout procedures for PIs

PIs are responsible for following the steps below for closing out the grant:

Step	PI Responsibilities
1	Directions for preparing a final progress report are in the NIH RPPR Instruction Guide.
2	The PI logs in to the Commons. From the Status tab select **List of Applications/Grants.**
3	Locate grant requiring closeout; on the right hand side of the screen there will be an action item, **Requires Closeout.** This redirects to the Final RPPR forms. (The regular RPPR tab in the Commons will not link to the FRPPR; that is only for the annual reports.)

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NIH closeout procedures for PIs (cont.)

PIs are responsible for following the steps below for closing out the grant (continued):

Step	PI Responsibilities
4	The screen for the Final RPPR will display and the PI needs to **Initiate** in order to begin filling in the information. (It is similar to the annual RPPR except for the addition of a new section I which is a public summary that should be in lay terms). ***Note*:** The PI can allow administrators with the ASST role to assist in completing the information. Publications will need to have Pub Med Central ID numbers. If they are non-compliant, then the Program Officer will require a Final Report Additional Material (FRAM) update to be submitted once the publications have been cleared.
5	Once all the Report sections have been completed and saved, use the **Check for Errors** button to ensure it can be submitted and make corrections as needed.
6	The PI uses the **View** button to obtain a concatenated pdf of the Final Report to save to the desktop, and attaches the Final Report to the last funded proposal in BRAIN in case any question arises from the sponsor. ***Note*:** A new proposal is not needed since this is for the closeout.
7	Route to the Signing Official (SO) Director of Sponsored Programs: • An auto email from the Commons will be sent to SPO • SPO will complete the submission to NIH, or return to the PI if any revisions are needed
8	The Invention Statement form is also provided for the PI to enter information concerning inventions: • The PI must notify BCM Ventures that the Invention Statement has been completed • Any inventions listed on the form will be verified and the form will be certified and completed.

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NIH closeout procedures for SPO

Sponsored Programs is responsible for following the steps below to ensure grant closure occurs within 90 days after the end date of the grant:

Step	Sponsored Programs Responsibilities
1	To prevent non-compliance, SPO monitors via the Commons the closeout status of all BCM grants checking for: • Grants in renewal • Grants in no cost extension • Final reports (Final reports will not be required until all segments of the grant are complete, but the PI should communicate with SPO about the status of the grant)
2	• Follows up the original Closeout email from NIH forwarding it to the PI and Administrator listed in the BRAIN proposal with specific directions on how to complete the requirement. • Sends a second reminder email at 30 days following the grant end date.
3	• Sends a third reminder after 60 days and copies the Department Chair and Research Compliance Services (RCS) • Warns the PI they are in non-compliance with BCM OOR procedures and subject to transaction suspension, whereby SPO will not conduct any other grant-related activities until the PI has submitted the late Final Report.
4	If the PI has not successfully closed the grant, he/she will receive a non-compliance Assessment Report from RCS with one week to respond. Upon receipt of the RCS email, SPO: • Places the PI on transaction suspension unless the PI completes the closeout, or provides acceptable reason for delay by a specified date (within 5 working days) • Notifies the Department Chair that the Department will have to prepare the report if the PI is unable, copying all parties below: – PI and Department Administrator(s) – Research Compliance – Department Chair
5	Once the closeout requirements for the grant have been successfully completed, the suspension will be lifted.
6	Multiple infractions are escalated to the Senior Vice President and Dean of Research to determine how best to guide the Department in implementing procedures to ensure compliance.

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Grant Closeout, Continued

NIH closeout procedures for Departments

Departmental responsibilities for Closeout when the PI is unable to, or has already left BCM are as follows:

Step	Departmental Responsibilities
1	Obtain the final progress report from the PI.
2	Obtain new contact information for the PI and new Department Chair. If necessary, SPO sends official emails requesting help getting the report.
3	Compile previous progress reports into a Final Report without the PI's help.

Section 5E
Sponsored Programs Processes for Contracts

Overview

Introduction

This chapter describes Sponsored Programs processes for contracts.

In this section

This section covers the following topics:

- Contract Agreement Types
- Confidential Disclosure Agreement
- Clinical Trial Agreement
- Material Transfer Agreement
- Data Use Transfer Agreement
- PI and Research Personnel Responsibilities Regarding Research Materials
- Incoming Subawards
- Outgoing Subawards
- Non-Competing Years of a Subaward
- Salary Reimbursement Agreements
- Genomic Data Base Access
- Contract Closeout

Contract Agreement Types

Introduction

At BCM, authorized staff are responsible for the review, negotiation and approval of all incoming and outgoing CDAs, MTAs, DUAs, SRAs, CTAs, and TAs. However, the Principal Investigator or designee will be responsible for finalizing any study budget with the sponsor.

CDA

Confidentiality Disclosure Agreements (CDAs) are used when the owner of confidential information wishes to disclose that information to another party (either an individual or a company).

- This agreement usually occurs in the course of business negotiations when the owner wishes the information to remain confidential
- By signing a confidentiality agreement, the recipient undertakes the obligation not to disclose the confidential information as defined in the agreement
- These agreements are also referred to as:
  – Non-disclosure agreements (NDAs)
  – Secrecy agreements

Depending on the final purpose of sharing the confidential information one of three offices may review the CDA:

- **Federal, State or non-profit foundation -** SPO staff reviews and approves confidentiality or non-disclosure agreements provided by federal, state, non-profit foundation or academic collaborating institutions. Send a Word document version of the agreement to be reviewed to spo@bcm.edu.
- **Commercial entities as precursor to Clinical Trial agreements -** OCR staff review and approve confidentiality or non-disclosure agreements provided by commercial organizations as a precursor to clinical trial agreements. Submit a Word document version of the agreement to be reviewed on the OCR CTA/CDA System.
- **Commercial entities for basic research agreements -** SPO staff reviews and approves confidentiality or non-disclosure agreements provided by commercial organizations as a precursor to non-clinical sponsored research agreements. Send a Word document version of the agreement to be reviewed to mta@bcm.edu.

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Contract Agreement Types, Continued

MTA

A Material Transfer Agreement (MTA) is a contract that governs the transfer of tangible research materials between two organizations, when the recipient intends to use the materials for his or her own research purposes.

- The MTA defines the rights and obligations of the provider and the recipient with respect to the materials and any derivatives of the material
- Biological materials are the most frequently transferred materials such as:
  - Reagents
  - Cell lines
  - Plasmids
  - Mouse models
  - Mouse tissue
  - Vectors
  - Chemical compounds
  - Unpublished data
  - Human samples
  - Any software developed at BCM
- Three types of transfers are most common at academic institutions:
  - Transfer between academic or research institutions, contact mta@bcm.edu
  - Transfer from industry to academia, contact mta@bcm.edu
  - Transfer from academia to industry – Requires a license agreement, not an MTA, contact BCM Ventures, bcmventures@bcm.edu

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Contract Agreement Types, Continued

DUA

A Data Use Agreement (DUA) is needed if health information is disclosed as a *limited data set. Contact mta@bcm.edu regarding DUAs.

The purpose of a data use agreement is to make sure that data is used in ways that are consistent with research, public health, or health care operations.

The agreement must:

- Limit who can use or receive the data
- Require the data recipient to agree not to re-identify the data or contact the subject of the information
- Contain adequate assurances that the recipient will protect the data

***Definition of limited data set:**

- Information that is minimally identified by including a few selected identifiers
- It may only contain the subject's:
  - Dates of admission and/or discharge
  - Date of death (if applicable)
  - Date of birth (which can only be used as necessary)
  - Five-digit zip code or any other geographic subdivision (e.g., state, city, county)
- The subject's street address cannot be included
- Because a limited data set is not fully de-identified and could potentially be used to re-identify an individual, it is still subject to privacy protections
- Therefore, if the data is going to be released to an outside party, a data use agreement must be established between BCM and the third party

SRA

A Sponsored Research Agreement (SRA) is a legal agreement that is considered a pre-clinical or basic science research project involving investigation and discovery in the health sciences field.

The industry sponsor funds a specific project for a definite time period and in return gets certain deliverables such as:

- Research data
- Reports
- Certain rights to intellectual and tangible property

SRAs usually include a budget as the sponsor provides funding for the project. Therefore, the agreement should be routed through BRAIN ESP2 as a contract proposal for review.

After the agreement is fully signed then the proposal is marked as funded. Contact the Office of Clinical Research at cta@bcm.edu.

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Contract Agreement Types, Continued

CTA	The Clinical Trial Agreement (CTA) is an agreement between the sponsor and the College to define the scope of work required by a clinical protocol. The CTA should be routed through BRAIN ESP2 as a contract proposal, and additionally submitted through the CDA/CTA Agreement Tracking System. Industry-funded clinical trial agreements and associated documents are negotiated and executed by the Office of Clinical Research at cta@bcm.edu. The CTA may have other names such as: • Letter of Agreement • Clinical Research Agreement • Clinical Study Agreement • Study Agreement • Memorandum of Understanding • Research Agreement
TA	A Testing Agreement (TA) is when a BCM investigator: • Provides testing, or assays of a material provided by Industry, and then delivers the data to the sponsor • Or analyzes the data provided by the sponsor, in return for funding The TA should be routed through BRAIN ESP2 as a contract proposal and will be reviewed by BCM Ventures, bcmventures@bcm.edu.
Other research related agreements	Certain research related Non-Monetary Agreements should also be reviewed and negotiated by Sponsored Programs and are submitted in BRAIN for review and approvals. This includes agreements such as: • Collaboration Agreements or Memorandums of Understanding between other institutions to delineate how research will be jointly conducted • Equipment Use Agreements for items that will be loaned for a limited time in return for usage reports • Software Use Agreements in return for usage reports • Drug Donation Agreements from industry sponsors to provide free materials to be used in conjunction with a project funded by another sponsor • Master Agreements where funding will be provided by linked Task or Work Orders that are entered separately in BRAIN Each of these can have unique considerations, so consult with SPO via phone or email on what to include in the submission and review process.

Confidential Disclosure Agreement

Introduction

A Confidential Disclosure Agreement (CDA) is a legal document which precedes the sharing of ideas, information or data from one institution to another. Sponsors usually require an agreement to be in place to ensure protection of any proprietary or confidential information that they wish to share with a potential collaborator.

CDAs are often executed in advance of a clinical trial or other types of research so the potential researcher can evaluate whether they want to participate in the trial and/or research. These agreements may also be called Non-Disclosure Agreements, or Secrecy Agreements.

Who signs agreement?

BCM is always the signing party on the behalf of the faculty member acting as the lead investigator and an official signatory of BCM must sign.

The Principal Investigator (PI) must co-sign the agreement as "Read and Understood" or "Read and Acknowledged". All other staff or members of the PI's lab are included as employees under the single document for that specific project. They do not need to co-sign or sign separate documents.

Which CDA to use?

Many industry sponsors require the use of their version of the agreement, but BCM negotiates the terms as needed. Send the agreement with the request for review and assistance in signing to cta@bcm.edu.

- BCM Confidentiality Agreement template – Use when a BCM faculty member wants to initiate a CDA with another party in order to protect BCM's proprietary information that she/he would like to share with a potential sponsor or collaborator
- BCM Reciprocal Confidentiality Agreement template - Provide the sponsor/collaborator with this form when a two-way agreement is needed for the mutual exchange of confidential information. Contact cta@bcm.edu for this form.

For review, assistance in negotiations and obtaining the final authorized signature, contact cta@bcm.edu.

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Confidential Disclosure Agreement, Continued

Processing

Authorized research administration staff (Associates) implement the following standard procedures when a CDA is received from an investigator or sponsor.

Step	Action
1	• OCR monitors the shared email box cta@bcm.edu for email requests and forwards non-clinical trial related requests to SPO. CDAs for Clinical Trials should be submitted to the CDA System that allows transparent tracking as it is processed. • Within 3 business days, an assigned Associate responds to the investigator or department administrator with any changes or requests for more information
2	Associate reviews the confidentiality agreement: • Requests Word version if revisions are needed • Negotiates by email with the sponsor/other party and copies the investigator and department administrator on all emails
3	When negotiations between the Sponsor and staff are final, the signature process begins: • The PI signs the CDA either electronically or scans an ink signature and then sends the pdf back. ***Note*:** If sponsor requires, duplicate originals can be executed but the Department has to pay to mail or FedEx the documents. • The Associate has the Institutional Official sign and then emails the partly signed pdf to the sponsor • The Sponsor returns a fully signed pdf and the Associate attaches it in the CDA tracking system • If required, the Sponsor keeps one copy of the fully executed original and sends the other to the PI. The PI sends a pdf of the fully executed agreement to the Associate who attaches it.
4	When SPO negotiates the non-clinical trial CDAs, the Associate places a pdf of the fully signed agreement in the MTA database with the letters "CDA" in place of the material description.

Clinical Trial Agreement

What is a clinical trial?

Although there are many definitions of clinical trials, they are generally considered to be biomedical or health-related research studies in human beings that follow a pre-defined protocol.

Interventional studies are those in which the research subjects are assigned by the investigator to a treatment or other intervention and their outcomes are measured.

Observational studies are those in which individuals are observed and their outcomes are measured by the investigators.

Preparation of the CTA

Clinical Trials Agreements (CTAs) are considered contracts and are typically funded by for-profit sponsors such as pharmaceutical drug companies.

- In order to process a Clinical Trial, all of the following needs to be submitted by the Principal Investigator to the Office of Research:
  - ESP1 human protocol
  - ESP2 contract proposal with Word version of the CTA attached
  - CTA/Industry Sponsored Pre-Review Form
- The Office of Clinical Research negotiates the agreement and helps finalize the budget
- Once the human protocol is approved by the IRB, then the agreement can be signed, and the proposal marked as funded
- The process of negotiating a clinical trial has many steps and can take several months
- Further information, including a Process Flow chart, Feasibility Assessment, Budget Analysis tools, and the link to the instructions for submitting the Pre-Review form are available at the SPO website Clinical Trials

Additional questions should be directed to cta@bcm.edu.

Processing

Office of Clinical Research (OCR) staff review and process the agreement when a CTA is received from an investigator via the Clinical Trial Agreement (CTA) System as described on their website:

Closeout reports

All sponsors require a Final Report at the end of the contract project. Many times, this report is sent directly by the Investigator to the sponsor without needing an official signature.

- However, since this is typically a requirement of the Terms and Conditions of the Contract, Sponsored Programs requires a copy to ensure this last obligation is met.
- The PI or department administrator must attach it to the BRAIN proposal (or send it to SPO if help is needed).

Material Transfer Agreement

Introduction

A Material Transfer Agreement (MTA) is a legal document which precedes the transfer of materials from a one institution to another.

Examples of such materials are as follows:

- Biological materials such as reagents, cell lines, plasmids, and vectors
- Chemical compounds
- Transgenic animals
- Software development at BCM

Which MTA to use?

If sending out materials from BCM to a collaborator, use the UBMTA or the full BCM MTA. Templates for both incoming and outgoing UBMTAs are available on the SPO intranet under MTAs.

If we are receiving materials, use the UBMTA if possible. If a full agreement must be used, then please ensure that the MTA is from the providing institution, not BCM. If the other party does not have its own template, consult with mta@bcm.edu on adapting the BCM template.

Material Transfers-At-a-Glance:

	Academic Transfer	Industry Transfer
Outgoing	BCM to Institution: Use UBMTA and sent to collaborator first Send partially signed to mta@bcm.edu	BCM to Company: Contact BCM Ventures for a License: bcmventures@bcm.edu
Incoming	Institution to BCM: Submit their agreement for review and execution to MTA/DUA Management System	Company to BCM: Submit the company's agreement for review and execution to MTA/DUA Management System

UBMTA

Most academic institutions are signatories to the Uniform Biological Materials Transfer Agreement (UBMTA). Over 500 Institutions have signed the Master Agreement and agreed to exactly the same terms and conditions which speeds up review and signing tremendously.

In order to use this efficient method, the parties only need to enter information into the Implementing Letter: Names and addresses of institutions, respective scientists and the description of the material. After the Letter is fully signed, then the material can be exchanged. For a list of institutions that have signed the UBMTA check the AUTM website: Signatories.

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Material Transfer Agreement, Continued

Outbound academic or non-profit transfers

The process of handling a UBMTA to a non-profit or academic Collaborator from a BCM PI is as follows:

Step	Action
1	PI or Department Administrator uses the Outgoing UBMTA template and after completing the BCM information, sends the document to the recipient investigator to complete their part and start the signature process
2	When they return the partially signed Implementing letter, then the PI (a faculty member, instructor level or above) can add their signature
3	PI or Admin sends to mta@bcm.edu for the final BCM Institutional signature
4	SPO Associate will review for completeness and obtain official final signature
5	Fully signed agreement will be sent to all parties copied on the initial email
6	SPO attaches completed UBMTA in the MTA database

Inbound academic or non-profit transfers

The process of handling an UBMTA from a non-profit or academic Collaborator to a BCM PI is as follows:

Step	Action
1	When the BCM PI contacts the other scientist, the BCM PI should request the UBMTA from that institution. An Incoming UBMTA template is also available on the SPO intranet page, and can be used if allowed by that institution.
2	BCM PI or Admin completes the information in the template and, as the Receiving Scientist, would sign first
3	PI sends to mta@bcm.edu and requests institutional signature
4	SPO Associate reviews for completeness and obtains signature and returns to PI
5	PI sends the partially signed UBMTA to the Provider Scientist who then signs and sends to their institutional approver
6	After BCM PI receives copy of the fully executed UBMTA, a pdf copy is emailed to mta@bcm.edu
7	SPO attaches completed UBMTA in the MTA database

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Material Transfer Agreement, Continued

Special terms or Full MTA

The process of handling either an incoming or outgoing MTA with a collaborator requiring terms as follows:

- Is either not a signatory to the UBMTA, or
- Requires their own special template for review, or
- When special terms are added such as:
  - Requiring co-authorship
  - Adding an end date
  - Requiring confirmation of return or destruction of the materials
  - Reciprocal material exchange

Step	Action
1	PI requests material from Provider and receives a full agreement, not the simple UBMTA implementing letter, and they complete the contact information and material description, but do not sign yet
2	PI logs into the MTA/DUA Agreements Management System, answers questions about the material, provides contact information for the provider institution, scientist and admin, and submits.
3	Incoming Animals or Human materials will require approved protocols at BCM. Further information is on the SPO intranet page MTAs
4	SPO Associate reviews, negotiates terms if needed, and ensures all compliance items are complete
5	SPO Associate routes final version to PI for their final review and signature
6	PI sends pdf back in MTA System for institutional signature
7	SPO Associate emails the partially signed to Provider Contacts who complete the signature process
8	When fully executed MTA is received, SPO attaches and marks the entry complete which sends an auto-email and copy of the agreement to the PI

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Material Transfer Agreement, Continued

Inbound company or for-profit transfers

The process of handling an incoming MTA or non-exclusive "license for use" from a for-profit company to a BCM PI is as follows:

Step	Action
1	BCM PI receives agreement from the Company and completes the Material description and any contact information in the template
2	PI logs into the MTA/DUA Agreements Management System, answers questions about the material, provides contact information for the provider institution, scientist and admin, and submits
3	Incoming Animals or Human materials will require approved protocols at BCM. Further information is on the SPO intranet page MTAs.
4	SPO Associate reviews, negotiates terms if needed, and ensures all compliance items are complete
5	SPO may request additional review assistance from BCM Ventures if IP or licensing terms are especially stringent with the main purpose to allow BCM PI to be able to publish any results obtained with the use of the Material
6	SPO Associate routes final version to PI for their final review and signature
7	PI sends pdf back in MTA System for institutional signature
8	SPO Associate emails the partially signed to Provider Contacts who complete the signature process
9	When fully executed MTA is received, SPO attaches and marks the entry complete which sends an auto-email and copy of the agreement to the PI

Outbound company or for-profit transfers

The process of handling an outgoing MTA to a for-profit company from a BCM PI is as follows:

Step	Action
1	Company contacts BCM PI to receive BCM owned Material
2	PI contacts BCM Ventures to help execute a for-profit MTA or to negotiate a full License Agreement, bcmventures@bcm.edu
3	Further information is found on the BCM Ventures website

Data Use or Transfer Agreement

Introduction

The transfer of data, and materials such as samples, between organizations is common in the research community. When a larger agreement such as a Contract, Subaward, or Collaborative Agreement is in place to facilitate a shared project, then terms for data transfer and use are included in that agreement. When collaborators are listed as co-investigators on approved protocols, they are likewise approved to receive data as provided in the IRB-approved protocol as required to complete their role in the protocol. However, both institutions should enter into a data sharing agreement, and this may be required by the funding agency or by one of the institutions.

When data is considered confidential, proprietary or otherwise sensitive, then the organization providing the data "Provider" may require the organization receiving the data "Recipient" to enter into a Data Use Agreement (DUA) or Data Transfer Agreement (DTA).

Responsibilities

When data elements include information about human subjects, then specific protections need to be in place to for Protected Health Information (PHI). Both parties are responsible for ensuring procedures follow HIPAA compliance requirements.

De-identified data

Data are considered de-identified for the recipient if there is no reasonable way the data could be used to identify an individual person. When BCM researchers want to share BCM research data/information, they must receive written approval that the data to be provided is confirmed as de-identified for the recipient. The Privacy Rule provides two ways to de-identify PHI:

- One way is to remove the following identifiers of the individual and of the individual's relatives, employers, or household members:
  1. Names
  2. All geographic subdivisions smaller than a state, except for the initial three digits of the zip code if the geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people
  3. All elements of dates except year and all ages over 89
  4. Telephone numbers
  5. Fax numbers
  6. Email addresses
  7. Social security numbers
  8. Medical record numbers
  9. Health plan beneficiary numbers
  10. Account numbers
  11. Certificate or license numbers
  12. Vehicle identifiers and license plate numbers
  13. Device identifiers and serial numbers
  14. URLs

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Data Use or Transfer Agreement, Continued

De-identified data (cont.)

15. IP addresses
16. Biometric identifiers
17. Full-face photographs and any comparable images
18. Any other unique, identifying characteristic or code, except as permitted for re-identification in the Privacy Rule

In addition to removing these identifiers, the covered entity must have no actual knowledge that the remaining information could be used alone or in combination with other information to identify the individual.

- Covered entities may also use statistical methods to establish de-identification instead of removing all 18 identifiers above. The covered entity may obtain certification by "a person with appropriate knowledge of and experience with generally accepted statistical and scientific principles and methods for rendering information not individually identifiable" that there is a "very small" risk that the information could be used by the recipient to identify the individual who is the subject of the information, alone or in combination with other reasonably available information.

  The person certifying statistical de-identification must document the methods used as well as the result of the analysis that justifies the determination. A covered entity is required to keep such certification, in written or electronic format, for at least 6 years from the date of its creation or the date when it was last in effect, whichever is later.

The PI or Department must submit a request to privacycompliance@bcm.edu to obtain this approval.

Limited Data Set

Limited Data Sets (LDS) are NOT technically de-identified and may contain some, but not all, of the 18 elements that qualify as PHI.

- The data types of the 18 elements of PHI which may be provided to the recipient under an LDS are:
  - Dates of treatment, admission, discharge
  - Birth date, date of death
  - Age (including age 90 or over)
  - Geographic subdivisions such as state, country, town, city, precinct, and zip code
  - Unique codes or identifiers that are not direct identifiers or replicates of a part of direct identifiers.
- If there is a signed consent or an IRB waiver of consent, and the approved IRB explicitly covers the release of the LDS data to the recipient/other party, then no further agreement is needed.
- If the consent or waiver of consent is not in place, or the data exceed a LDS and includes directly identifying information (like name or address), then a DTA/DUA is needed.

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Data Use or Transfer Agreement, Continued

Limited Data Set (cont.)

Limited Data Sets (LDS) are NOT technically de-identified and may contain some, but not all, of the 18 elements that qualify as PHI (continued).

Step	Action
1	Whether the Data will be outgoing or incoming, the PI or Department should submit the request for creation, review, negotiation and signature in the MTA/DUA Agreement Management System
2	SPO Associate will review the answers to the online questions and contact the requestor for more information as needed to prepare the correct template or to review an agreement from another institution
3	SPO Associate sends the agreement to the other institution, negotiates terms if needed, and ensures all compliance items are complete
4	SPO Associate routes final version to PI for their final review and signature
5	PI sends pdf back in MTA/DUA System for institutional signature
6	SPO Associate emails the partially signed to collaborator Contacts who complete the signature process
7	When fully executed DUA is received, SPO attaches and marks the entry complete which sends an auto-email and copy of the agreement to the PI

PI and Research Personnel Responsibilities Regarding Research Materials

Date of Last Revision/Review: 04/29/22

What are research materials?

Research materials may include any of the following:

- Chemical compounds
- Drugs or other substances
- Tissue specimens (from humans or animals)
- Cultures of infectious substances (infectious to humans and/or animals)
- Plant pathogens and plant materials
- Genetically modified organisms
  Examples: Transgenic mice, plants, drosophila, *C. elegans*
- Cell lines, plasmids, and vectors

Responsibilities

Below are important compliance responsibilities that **may** be associated with research materials:

Step	Action
1	Work with recombinant or synthetic nucleic acid molecules, including bench, animal, plant, and human gene transfer, must be pre-approved by the Institutional Biosafety Committee (IBC) at ibc@bcm.edu or 713-798-6966
2	Work with biohazardous materials, including human blood, tissues, cells and cell lines as well as hazardous chemicals or agents may require review by the Office of Environmental Safety (OES). • For biohazardous materials questions, contact biosafety@bcm.edu or 713-798-6616 • For hazardous chemical questions, contact wdavis@bcm.edu or 713-798-3851
3	Work with human blood, tissues, cells and cell lines may require review by the BCM Institutional Review Board (IRB) at irb@bcm.edu or 713-798-6970
4	Work with live vertebrate animals must be pre-approved by the BCM Institutional Animal Care and Use Committee (IACUC) at iacuc@bcm.edu or 713-798-6966
5	Coordinate the health and well-being of research animals with the Center for Comparative Medicine (CCM) at ccm@bcm.edu or 713-798-4486

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PI and Research Personnel Responsibilities Regarding Research Materials, Continued

Responsibilities (continued)

Below are important compliance responsibilities that **may** be associated with research materials (continued):

Step	Action
6	Ensure that any BCM proprietary rights in the research materials are protected prior to shipping or transferring research materials by using a Material Transfer Agreement (MTA) when applicable. For information contact mta@bcm.edu or 713-798-1297. To determine whether an MTA is necessary, the investigator should consider whether: • There is a concern about competition in the same research area • The published material may have commercial value If the answer to one or both above is "yes", then an MTA may be appropriate. With respect to protection of potential intellectual property: • If the investigator believes that the materials generated have commercial value, the investigator should contact the BCM Ventures, bcmventures@bcm.edu or 713-798-4886, at the early stages of development and before publication • The investigator together with BCM Ventures will determine whether intellectual property protection is warranted See the table below to determine when it is needed to have an MTA in place before the transfer:

MTA is Needed	No MTA Needed	Transfer Only with Permission from the Provider
Mouse models	Reagents covered under a multi-site grant transferred within/between the grant recipients **(Excluding Mouse Models)**	Reagents that are not developed at BCM
Human derived samples	Reagents covered under a subcontract	Reagents received under an MTA or a similar contract from another institution
Unpublished materials		For the reagents not developed at BCM or by BCM investigators: Before transferring reagents to a third party, the PI and Sponsored Programs need written permission from the provider institution and the provider scientist.
Concerns with publication protection		
Concerns with intellectual property protection		
Concerns with specialized handling of the reagents		

PI and Research Personnel Responsibilities Regarding Research Materials, Continued

Responsibilities (continued)

Below are important compliance responsibilities which **may** be associated with research materials (continued):

Step	Action
7	Shipping Training must be completed by all personnel who ship or transport (see Biosafety Manual, Chapter 18 on Transportation) human or animal specimens of a research or clinical nature, biohazardous materials (including select agents) or hazardous chemicals. For information, contact the Office of Environmental Safety: • Click here to register for the class on Shipping Biological Samples • For information concerning transport or shipping of biological materials contact biosafety@bcm.edu or 713-798-6616. **Reference:** BCM IATA Manual • For information on shipping hazardous chemicals, contact wdavis@bcm.edu or 713-798-3851
8	Export control laws that regulate export of sensitive technologies, software, biological agents, and related data and services may also apply. These laws require that licenses be obtained for exports of these sensitive items unless an exemption exists. Whenever it is planned to send samples to organizations in other countries, check that both the material and the recipient are allowable. For information, contact Research Compliance Services oor-rcs@bcm.edu. Additional information can be found on federal websites such as the: • Commerce Department – Bureau of Industry and Security Export Administration Regulations (BIS EAR) • International Traffic and Arms Regulations (ITAR) • Office of Foreign Assets Control (OFAC)

Incoming Subawards

Introduction

Incoming subawards are received from other academic institutions or for-profit companies, typically off of NIH awards:

- If funded by NIH, albeit through another institution/company, the agreement must comply with current NIH policy and Federal Demonstration Project (FDP) guidelines
- Most institutions use the standard NIH FDP subcontract template, with slight variations

Awarded by sponsor

Incoming subawards are considered awards and are credited to the PI based on the sponsor, not the primary institution.

***Example*:** If the NIH awards money (sponsor) to UT and UT (primary institution) subawards to a BCM investigator, the BCM investigator gets credited as if the award came directly from the NIH.

Processing

Sponsored Programs staff implement the following standard procedures when a subaward is received from another institution:

Step	Action
1	SPO receives subawards electronically usually from the primary institution's Sponsored Program's Office or its equivalent. Sometimes the agreement may be sent to Departmental Administrator or PI and should be forwarded to subaward@bcm.edu.
2	Search BRAIN to confirm that a proposal routing sheet was submitted and approved for the specific subaward. Original agreements are on Initial or Resubmission/Amendment proposals, while amendments to incoming subawards (subins) are on Non-competing renewal proposals.
3	Confirm approval of the IRB or animal protocol that is linked to the proposal
4	Confirm PI and Administrator have completed Responsible Conduct of Research (RCR) Training in CITI
5	Request RCOI to review the submitted FCOI disclosures and generate the Assurance letter for conflict of interest.

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Processing (cont.) Sponsored Programs staff implement the following standard procedures when a subaward is received from another institution (continued):

Step	Action
6	Check indirect cost rate(s) on the routing sheet: • If there is not an ESP2 proposal, or if protocols are pending, send an email to the PI and the Departmental Administrator asking them to prepare and submit a proposal and/or forward protocol approval(s) • If a non-standard indirect cost rate is used, review the "Comments" section of BRAIN and/or contact the BCM PI and/or the primary institution to determine whether or not BCM can accept a non-standard rate • If a non-standard rate is accepted, the rationale is added to the "Comments" section of BRAIN • Attach email approval of a non-standard rate from the Sr. Vice President and Dean of Research to the BRAIN proposal or other authorized signing official
7	Upon receipt of the following approved items: • ESP2 proposal • Protocol(s) • Indirect costs • Conflict of interest assurance • Any other training or compliance items Email a copy of the subaward, including the budget and work scope, to the PI and the Departmental Administrator for review and approval.
8	Upon receipt of PI/Department approval, obtain BCM official signature ***Note*:** SPO does not execute any incoming subaward without an approved routing sheet, approved protocol(s), appropriate indirect costs, and PI's approval.
9	Return pdf of the partially executed subaward agreement or amendment to primary institution via email. ***Note*:** Hard copies are sent when the primary institution will not accept an electronic version. The originals are returned to the PI and the Departmental Administrator to FedEx or mail to the prime institution.
10	Upon receipt of the fully executed subaward: • Update BRAIN to reflect "Funded" status • Attach the fully executed agreement to the proposal • Enter funding and date information under "Awards"
11	Email scanned attachment of fully executed subaward and Awards Summary Sheet to Sponsored Programs Finance, PI and Departmental Administrator.

Outgoing Subawards

Introduction

Outgoing subawards are initiated upon receipt of an award from an external sponsor.

When a grant or cooperative agreement is the prime award, then the outgoing consortiums are called "subawards".

When a contract is the prime award, then the outgoing consortiums are called "subcontracts". Contracts are administered by a contracting officer, a government employee who is authorized to execute contractual agreements on behalf of the government. Therefore, subcontracts require approval by the contracting officer before issuing to the subcontracting organization.

FDP template

The majority of outgoing subawards are funded through NIH awards made to BCM. Sponsored Programs staff fill out applicable templates as follows:

- A standard NIH Federal Demonstration Project (FDP) template, which has been modified for a NIH Subaward Agreement, is used for all NIH subawards
- A standard Federal Demonstration Project (FDP) template, which has been modified for use for many other federal awards such as:
  - National Science Foundation, NSF Subaward Agreement
  - United States Department of Agriculture, USDA Subaward Agreement
  - Department of Defense, CDMRP Subaward Agreement
  - Center for Disease Control, CDC Subaward Agreement
- All subawards to foreign entities use the Foreign Subaward template
- In all cases, federal and non-federal, the sub-recipient is expected to comply with the terms and conditions stated in the parent award. Therefore, those terms and conditions are included in the subaward or subcontract.
- Sponsored Programs:
  - Chooses the correct template and inserts information from the Information Gathering template sent by the PI or Administrator
  - Performs subrecipient risk analysis and obtains clearance from the SAM.gov Excluded Party List System before proceeding
  - Attaches all documents to the prime award BRAIN proposal

Format

Whenever possible, Sponsored Programs staff prefers to fully execute outgoing subawards electronically. However, a few institutions still require a hard-copy original with an ink signature. The originals are returned to the PI and the Departmental Administrator to FedEx or mail to the other institution.

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Outgoing Subawards, Continued

Processing Sponsored Programs staff processes a **new** award with sub-recipients as follows:

Step	Action
1	Receives a Notice of Award (NOA) from the sponsoring agent, normally via email. ***Note*:** Departments may receive a non-NIH NOA via email or mail, in which case, they forward the NOA to Sponsored Programs.
2	The Sponsored Programs: • Funds the award • If the award includes a subaward, then BRAIN auto notifies the PI, Admin listed on the proposal, and any departmental approvers that a Subaward Request can be sent in the Subout System. • ***Note*:** A Request can be prepared prior to funding but cannot be submitted until the BRAIN proposal has status of Funded.
3	The Department Administrator or PI follows the link to the Subawards System that is on the list of menu options in ESP2 or logs in using their ECA name and password on the website Subaward System. • Additional information, information gathering template to send to the collaborator, flowchart, FAQs and complete Handbook of instructions are on the SPO intranet site Subawards. • If there are multiple subawards off of one award, the Department submits the request for each institution
4	SPO Staff reviews the request and confirms the unique tracking number
5	SPO staff performs Subrecipient Risk Analysis and Monitoring steps, and choses the correct templates to prepare the agreement
6	**Purchase Order Approvals:** • SPO sends draft of the full agreement and requests final departmental approval • Department submits draft to SAP for shopping cart review • Supply chain converts to Purchase Order and places on Hold • Supply chain notifies department of the PO number • Department enters the Purchase Order number into the Subout Request and is able to Approve the draft agreement

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Outgoing Subawards, Continued

Processing (continued)

Sponsored Programs staff processes a **new** award with sub-recipients as follows (continued):

Step	Action
7	SPO contacts subaward institution: • Emails Word version of subaward to sub-recipient institution (to Sponsored Programs Office) • Requests updates of contact information (if needed), FFATA reporting requirements (if needed), and CFR200 Subpart F Audit Requirements Assurance (if needed)
8	If the sub-recipient accepts, the sub-recipient either: • Prints, signs, scans, and returns partially executed original via email, or • Replies to BCM email requesting hard copy originals, and mails two copies of the partially executed subaward to BCM
9	If sub-recipient requires changes: • Emails are exchanged • Revised subcontract is finalized One of the items in Step 8 is followed
10	Upon receipt of the partially executed subaward, staff: • Obtains final authorizing signature • Scans subcontract if an original was required • Returns a pdf of the fully executed subaward to the contact at the other institution, or notifies the BCM PI that the originals can be picked up to be mailed back • Attaches to the Subaward System and changes status to Fully executed • The System automatically sends electronic copy to the PI and administrative designees and automatically forwards electronic copy to Supply Chain to remove Hold from Purchase Order
11	After a subaward has been fully executed, any subsequent change in the sub-recipient's key personnel or scope of work needs to be approved in writing by BCM's Sponsored Programs office.
12	Associate submits FFATA information for Federal Awards or chooses correct alternative and marks the Subout Request as Complete

Non-Competing Years of a Subaward

Definition

A typical federal grant is awarded for up to 5 years. However, funding is available in one-year increments only.

Years 2-5 of a grant are termed "non-competing" as the funding is received without additional peer review.

Non-federal awards

Subrecipients are expected to follow all terms and conditions in the original parent award. Therefore, non-federal agreements between BCM and subrecipients for non-competing years are drafted on a case-by-case basis.

Federal awards

For federal awards, there are two types of non-competing awards:

- Those that fall under expanded authority (Federal Demonstration Project, FDP)
- Those that do not fall under expanded authority but require sponsor prior approval

Automatic carry forward vs separable funding

For non-competing awards under expanded authority, a standard Subaward Amendment template is used. This allows automatic carry forward and the next year funds are incrementally added in the amendment.

For non-competing awards not under expanded authority, a different Subaward Amendment template is used that specifically disallows carry forward. This means that a second amendment may be needed later once sponsor approval for the carry forward has been obtained.

Purchase Order remains the same, but the way the funds are tracked is different within the accounting system.

Below is the process Sponsored Programs staff uses when a non-competing award is received with subrecipients:

Step	Action
1	Staff receives a notice for non-competing awards from the sponsoring agent, normally via email. ***Note*:** Departments may receive a non-NIH Notice of Award via email or mail, in which case they forward the notice to Sponsored Programs staff.
2	Sponsored Programs: • Funds the non-competing proposal in BRAIN ESP2 • If the award includes a subaward, then BRAIN automatically notifies the PI, Admin listed on the proposal, and any departmental approvers that a Subaward Request can be sent in the Subout System. • ***Note*:** A Request can be prepared prior to funding but cannot be submitted until the BRAIN proposal has status of Funded.

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Non-Competing Years of a Subaward, Continued

Automatic carry forward vs separable funding (cont.)

Below is the process Sponsored Programs staff uses when a non-competing award is received with subrecipients (continued):

Step	Action
3	The PI or her/his administrative designee log into the Subaward System and create an Amendment request so that the previous agreement and amendments all share the same unique Subout ID that enables tracking of the project over time. • Answer questions about subrecipient performance as part of the monitoring process concerning invoices, reports, and compliance • Provide the subrecipient detailed budget for additional funds, or enter zero if it is for a No Cost Extension • Confirm the purchase order number • Confirm whether or not funds will be allowed to carry-forward If there are multiple subawards off of one award, the Department must send the above for each institution.
4	SPO Associate creates the correct type of Amendment, then routes for final departmental approval of the amendment.
5	Department does not send the amendment to Supply Chain at this time but must wait until it is fully executed in order to modify the Purchase Order.
6	SPO contacts subaward institution, then emails Word version of Amendment to sub-recipient institution (to Sponsored Programs Office).
7	If the subrecipient accepts the agreement's terms, the subrecipient either: • Prints, signs, scans, and returns partially executed Amendment via email, or • Replies to the Sponsored Programs email requesting hard-copy originals, which Department mails to the subrecipient
8	If the subrecipient requires changes: • Emails are exchanged • The revised Amendment is finalized • One of the items in Step 7 is followed

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Non-Competing Years of a Subaward, Continued

Automatic carry forward vs separable funding (cont.)

Below is the process Sponsored Programs staff uses when a non-competing award is received with subrecipients (continued):

Step	Action
9	Upon receipt of the partially executed subcontract amendment, staff: • Obtains Institutional signature • Attaches amendment to the Subaward System and changes status to Fully executed • The System automatically sends electronic copy to the PI and administrative designees and informs Administrator to modify PO
10	Department submits the fully executed amendment to Supply Chain to extend dates and/or revise the amount obligated so the collaborator can continue to invoice against the account
11	Associate submits FFATA information for Federal Awards or chooses correct alternative and marks the Subout Request as Complete.

Salary Reimbursement Agreements

Introduction

Salary Reimbursement Agreements (SRAs) are used when:

- Students from other institutions come to BCM to perform work and the BCM PI needs to send funds back to their home institution to cover their stipend
- The funding source is from internal funds or from non-profit foundations

Training grants follow normal subaward out (subout) procedures.

When BCM students work at another institution and funds are coming into BCM, then the agreement is treated like a regular subaward in (subin) and must be routed through BRAIN for review and funding.

Notification

When a salary reimbursement agreement needs to be executed Sponsored Programs staff are notified by any of the following:

- PI
- PI's administrative designee
- Sponsored Programs Office of the other institution

PI duties

The PI provides the following to Sponsored Programs staff:

- Name of the student and mentor
- Funding period
- BRAIN proposal number (unless from internal funding)
- Contact information for the other institution
- Purchase order number
- Salary details

Continued on next page

Salary Reimbursement Agreements, Continued

Sponsored programs duties

SRAs are handled by Sponsored Programs staff as follows:

***Note*:** No indirect costs are charged to salary reimbursement agreements.

Step	Action
1	Complete SRA template and send to Department for review and to obtain a purchase order off the foundation grant or internal funds account
2	Request final departmental/PI approval
3	Obtain BCM signature
4	Scan partially executed SRA
5	Email pdf attachment of partially executed SRA to student's school (to their Sponsored Programs Office) and cc the department administrator
6	If staff at the collaborating institution accepts the agreement's terms, staff either: • Prints, signs, scans, and returns fully executed original via email, or • Replies to BCM email requesting hard-copy originals, which Department then mails to the sub-recipient
7	If the sub-recipient requires changes: • Emails are exchanged • The subcontract is revised • If it deals with the budget, it is finalized after the PI approves of the changes • If changes are only with the terms/conditions language, only Sponsored Programs staff needs to approve • One of the items in Step 6 is followed
8	Upon receipt of the fully executed SRA: • Scan subcontract and forward to Finance (Grants and Contracts) • Copy PI and his/her administrative designee • Forwards electronic copy to Supply Chain to remove Hold from Purchase Order
9	Attach pdf of the agreement to the BRAIN proposal if from external funding or store in shared drive for internal funding

Genomic Data Base Access

Introduction

National Institutes of Health (NIH) issued the Genomic Data Sharing (GDS) Policy that took effect for grant applications with due dates on or after January 25, 2015. It sets forth expectations that ensure the broad and responsible sharing of genomic research data.

The GDS Policy applies to all NIH-funded research that generates large-scale human or non-human genomic data as well as the use of these data for subsequent research.

Large-scale data include genome-wide association studies (GWAS), single nucleotide polymorphisms (SNP) arrays, and genome sequence, transcriptomic, metagenomic, epigenomic, and gene expression data, irrespective of funding level and funding mechanism (e.g., grant, contract, cooperative agreement, or intramural support).

- Researchers are required to submit Genomic Data Sharing Plans as part of their application
- Deposit information into secure Data Repositories in a timely manner
- For human genomic data, even though it is de-identified, the Institutional Signing Official must provide Institutional Certification that the sharing of data has been included in the consent forms and that all laws, regulations and policies have been followed
- In order to access data provided by other researchers, the investigator and the Institutional Signing Official must agree to the Data Use Certification Agreement.

Additional information available on SPO intranet site.

Access to dbGaP

Currently the largest human genomic data base is the Database of Genotypes and Phenotypes (dbGaP). In order to access the data, investigators need to follow these steps:

- PI initiates request and fills in an online template and chooses current BCM signing official with NCBI dbGaP
- PI creates a Non-monetary BRAIN proposal in order to get institutional approval and because dbGaP requires annual reports to maintain access to the data.
- The IT Director required by the Certification and any other personnel who will have access to the data must be listed in BRAIN and an email providing their Certification that they have read and understand the terms of the Data Use Certification (DUC) Agreement and the Data Security Plan must be attached.
- Any Human protocols must be approved
- Following review, Sponsored Programs will submit the online dbGaP application and approve the Non-monetary BRAIN proposal

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Genomic Data Base Access, Continued

Access to dbGaP (continued)

- When approval is received from dbGaP, then the proposal is marked as Executed. Access is valid for one year from date of approval
- Annual reports have to be submitted online and a Non-competing proposal created to ensure all investigators have provided annual certification of their agreement to the DUC
- When the use of the data is completed, and a Final Report is required, then an attestation by both the PI and the department that all copies of the data have been destroyed will be needed before SPO can co-sign on the Final Closeout Report

Contract Closeout

Closeout reports

All sponsors, without exception, require a Final Report at the end of the contract project. Many times, this report is sent directly by the Investigator to the sponsor without needing an official signature.

However, since this is typically a requirement of the Terms and Conditions of the Contract, Sponsored Programs requires a copy to ensure this last obligation is met.

The PI or department administrator must attach it to the BRAIN proposal (or send it to SPO if help is needed).

Chapter 6
Post-Award Procedures

Overview

Introduction

The following sections deal with the administrative requirements concerning post-award grant changes that require a Principal Investigator to obtain written "prior approval" from a federal awarding agency.

Additionally, this chapter covers procedures that occur post-award.

In this chapter

This chapter covers the following sections:

- Section 6A: Federal Grant Prior Approval Categories
- Section 6B: Sponsored Programs Finance
- Section 6C: Faculty Departure and Extended Absences
- Section 6D: Transferring and Relinquishing Awards

Section 6A
Federal Grant Prior Approval Categories

Overview

Introduction

For most grants, NIH and NSF provide an approved budget on the Notice of Award. This document constitutes "prior approval" for expenditure activities as specified in the grant application.

However, if at a later date the investigator wishes to re-budget to meet unanticipated requirements, she/he may need to seek approval for the change from the federal granting agency.

In this section

There are three categories of federal agency prior approval authorities for post-award grants administration:

- Federal Demonstration Project (FDP) Awards
- Types of Prior Approval Requests
- NIH Grant Awards Under FDP
- PHS Expanded Authorities for Research Activities
- Other Awards Not Eligible for FDP or Expanded Grant Authorities

Federal Demonstration Project (FDP) Awards

Features

The purpose of Federal Demonstration Projects is to increase research productivity at academic institutions by standardizing and simplifying Federal terms for the support of academic research.

The major features of FDP include:

- Elimination of requirements for prior federal approvals to project changes, except for change of:
  - Project scope
  - Foreign components
  - Principal Investigator (PI)
- Providing the College with unilateral authority to issue a one-time 12-month no-cost extension
- Allowing carryover of unobligated balances (up to 25% of current year's budget) between budget periods
- Allowing the College to authorize pre-award costs up to 90 days prior to award

Prior approval

For items requiring sponsor prior approval, the Principal Investigator needs to write a letter to the agency that includes spaces for institutional signature.

This letter is forwarded to Sponsored Programs or Post Award Sponsored Programs Finance (SPF) along with written certification of Departmental approval.

Prior approval for Carryover requests should be obtained from Sponsored Programs Finance.

Prior approval for any of the other above-mentioned items should be obtained from Sponsored Programs.

Types of requests

Below is a list of change requests:

- Re-budgeting
- Carryover
- FDP carryover
- Carryover request
- Absence of PI
- Change of effort of key personnel
- Foreign component
- Substantive changes to scope
- Pre-award costs for FDP awards
- No-cost extension for FDP awards

Types of Prior Approval Requests

Re-budgeting	Re-budgeting for FDP awards is at the discretion of the PI with Departmental approval as long as costs are allowable. It is important to note that when the re-budgeting option is used, the PI: • Must stay within the total award dollar amount, and • Full indirect cost recovery must be maintained
Carryover	Carryover is the transfer of any unobligated balance or over expenditure of funds that remains at the end of a budget period, to the next budget period (except in the final year of a grant). • NIH allows carryover between competing awards • Funds that are carried forward are expended using the indirect cost rate(s) in effect at the time of the expenditure (the date the check is cut) • Over expenditures carried forward are a debit (including the prior year's indirect cost rate) from the total funds available for the current year
FDP carryover	Automatic cumulative carryover is allowed up to 25% of the current year's total budget. • Any estimated unobligated balance (including prior year carryover) that is greater than 25% of the current year's total budget on more than $250,000 must be explained in the progress report/non-competing continuation application • To ensure carryover, the Financial Status Report (FSR) must be received by the agency no later than 90 days after the close of the budget period • This means that the PI must work with Post Award SPF to ensure that the FSR is received by the agency within the 90-day period
Carryover request	Grants that do not allow automatic carryover must have a prior approval request sent to the sponsor.
Absence of PI	NIH defines the absence of a PI as any continuous period of more than three months. A letter must be sent to the sponsor asking for approval for any absence greater than allowed that provides a justification and whether the project will be suspended or conducted under a co-investigator's supervision.

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Types of Prior Approval Requests, Continued

Change of effort of key personnel

Change of effort is considered:

- A change in key personnel or significant change in their level of effort from what was approved for this project
  ***Definition*:** A significant change of effort is defined in federal regulations as a 25% reduction in time devoted to the project compared to the original approved effort.
- Replacing or adding a key person requires all of the following:
  – The prior approval request letter
  – A copy of their biosketch
  – Current and pending other support

Foreign component

A Foreign Component is defined as the performance of any significant scientific element or segment of a project outside of the United States, either by the recipient or by a researcher employed by a foreign organization, whether or not grant funds are expended. Activities that would meet this definition include, but are not limited to:

- The involvement of human subjects or animals
- Extensive foreign travel by recipient project staff for the purpose of data collection, surveying, sampling, and similar activities
- Any activity of the recipient that may have an impact on U.S. foreign policy through involvement in the affairs or environment of a foreign country
- Collaborations with investigators at a foreign site anticipated to result in co-authorship
- Use of facilities or instrumentation at a foreign site
- Receipt of financial support or resources from a foreign entity

NIH Policy requires prior approval for all instances of a Foreign Component added to a grant to a domestic or foreign organization. If the foreign component was included in the application, then receiving the Notice of Award would indicate approval.

Depending on the scope of work of the foreign collaborator (ex. animal or human subjects, or subaward funding) additional approval from the U.S. State Department may be required.

Embargoed and Sanctioned countries on the OFAC list are prohibited from **ALL transactions** (including imports and exports) without a license authorization. Currently that list includes: Crimea, Cuba, Iran, North Korea, Sudan and Syria.

A letter must be sent to the sponsor asking for approval for any addition or changes to performance of a project outside of the United States.

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Types of Prior Approval Requests, Continued

Substantive changes to scope

This refers to changes such as: substantive re-budgeting, change of work scope, or change in research objectives.

The PI is required to seek approval the DHHS awarding component when there is a change in the scope or research objectives of the project. Examples of this are included, but are not limited to, the following:

- A change in the specific aims approved at the time of award
- Substitution of one animal model for another
- Any change from the approved use of animal or human subjects
- Shifting the emphasis of the research from one disease area to another
- Applying a new technology
  ***Example*:** Changing assays from those approved to use of a different type of assay
- Transferring the performance of substantive programmatic work to a third party by contract or any other means
- Significant re-budgeting:
  – Occurs when the cumulative amount of transfers among direct cost categories for the current budget period exceeds 25% of the total amount awarded, or $250,000, whichever is less
  – Includes (whether or not it requires approval under rules governing budget changes) the following:
    > Key personnel
    > Salary
    > Equipment, etc.
- Incurring patient care costs where the need has not previously been approved by DHHS and/or when a PI desires to re-budget funds OUT OF the patient care category

Pre-award costs for FDP awards

The PI or department administrator must send an email to SPO and Post Award SPF indicating the following:

- Identifying an unrestricted department account number for the pre-award expenditures (this is the account that will be charged if no award is made, or if the charges are not allowed)
- Requesting 90 days pre-award spending approval

Sponsored Programs and Sponsored Programs Finance must jointly-approve all pre-award spending requests.

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Types of Prior Approval Requests, Continued

No-cost extension for FDP awards

The College has unilateral authority to issue a one-time, 12-month, no-cost extension to the expiration date of the project; which means there is additional time to complete the project without additional money.

Table summarizing prior approvals

The table below summarizes when and from whom prior approval must be obtained for Federal Demonstration Project Awards:

Request	Responsibility
Re-budgeting	PI/Department/SPF
Carryover – up to 25%	Department/SPF
Carryover – over 25%	Department/SPF/Sponsor
Absence or change in PI	PI/Department/Sponsored Programs/Sponsor
Change of effort over 25%	PI/Department/Sponsored Programs/Sponsor
Substantive change in objective or scope	PI/Department/Sponsored Programs/Sponsor
Foreign component	PI/Department/Sponsored Programs/Sponsor
Pre-award costs (up to 90 days)	PI/Department/Sponsored Programs/SPF
No-cost extension (up to 12 months)	PI/Sponsored Programs
No-cost extension (second or third request)	PI/Sponsored Programs/Sponsor

NIH Grant Awards Under FDP

Notice of award

On NIH grants, the Notice of Award will include the:

- Dates of the budget period or other specified funding period
- Amount of funds authorized for obligation by the grantee during the period indicated
- If applicable, it will also indicate the:
  - Dates of the approved project period
  - Amount of support recommended for each subsequent budget period of the approved project

Remarks section

The "Remarks" section on the award notice contains special terms and conditions, restrictions, and grant management/program contacts.

In addition, each NIH award that is included in FDP will carry an explanatory footnote on the Notice of Award.

Exclusions

However, an awarding component may specifically **exclude** a grant award from the FDP when considered necessary by programmatic and/or administrative reasons.

It is also important to remember that exceptions to any policy may be stated in the "Remarks" section on award notices.

PHS Expanded Authorities for Research Activities

Introduction	Public Health Services (PHS) has implemented expanded authorities for grantee organizations, designed to "waive approval of certain actions which had previously required awarding office prior approval". These PHS expanded authorities offer many, but not all, of the Federal Demonstration Project (FDP) authorities to grants from PHS agencies other than NIH.
Exceptions	The expanded authorities mentioned above are applicable to all PHS research grants with the following exceptions: • Cooperative agreements • When an awarding component specifically excludes a grant award from the expanded authority
NIH expanded authorities	The NIH (only when awarding to non-FDP participating institutions) is applying the expanded authorities to: • R series grants (except Phase I SBIR and STIR) • Program Projects Grants (P01s) • Research Career Awards (Ks)
Notice of award	The Notice of Award issued within the covered research programs will indicate that a research grant is subject to the expanded authorities administration provision.
Questions	If uncertain whether a particular change is significant enough to require agency prior approval, consult Sponsored Programs staff at 713-798-1297 or spo@bcm.edu.

Other Awards Not Eligible for FDP or Expanded Grant Authorities

Introduction	It is important to remember that the same rules that have been in existence still apply for grants not eligible for either FDP or Expanded Authorities. These include grants from federal agencies (for example, DHHS agencies other than PHS) such as: • Centers for Medicare and Medicaid (CMS) • Excluded grant programs such as the S and T series awards of the NIH
Notice of grant award	Refer to the Notice of grant Award and the awarding agency's written grant policies for specific rules and guidelines that relate to: • Equipment • Alterations and renovations • Foreign travel • Single expenditures of $25,000 or 25% of the direct cost budget, whichever is greater
Other awards/ sponsors	For other types of awards and sponsors, consult the terms and conditions of the award agreement.
Questions	Consult the department administrator or Sponsored Programs staff for additional information.

Section 6B

Sponsored Programs Finance

Introduction

The department of Sponsored Programs Finance (SPF) is responsible for assisting, reviewing and approving many post award administrative records of sponsored project expenditures.

SPF is responsible for the central financial post award administration of all sponsored projects at the Baylor College of Medicine. They set up new award WBS accounts, prepare and submit invoices and financial reports to the sponsors, and close out expired sponsored projects.

As part of the post award life cycle, the Post Award Team also provides training and guidance on post award administration topics including allowability of cost on sponsored projects, effort certification, cost share, program income, and other compliance related topics. SPF provides support and oversight in managing sponsored projects and monitoring the financial compliance requirements of sponsors.

Functions

Some typical SPF functions relating to sponsored projects include:

- Establishing accounts and assignment account numbers
  - Method of payment (timing and billing instructions)
  - Financial reporting requirements (if any)
  - Disposition of unexpended funds
- Approval of:
  - Project budgets and budget changes
  - Faculty payroll forms
  - Cost transfers between budgets

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Sponsored Programs Finance, Continued

BRAIN use of databases

BRAIN downloads data directly from SAP and the Faculty Affairs databases. Some data is gleaned indirectly from the Effort Reporting System by SPF for use in BRAIN.

- SAP - Information from the BRAIN proposal is used by SPF to set up the account in SAP. BRAIN can pull employee contact information from SAP but does not upload data to SAP.
- Faculty Affairs:
  - BRAIN pulls appointment information directly from the Faculty Affairs database
  - Default department information is pulled from Faculty Affairs into a BRAIN proposal
  - The information can be changed in BRAIN, but that change will not affect the Faculty Affairs system
  - There must be a full-time, part-time, or research certified voluntary appointment entered into BRAIN before someone can submit as a PI
- Effort Reporting System (ERS):
  - Effort reporting should be verified with SPF using SAP and ERS
  - ERS is populated from SAP's cost and effort distributions and committed effort entered into the grant header
  - BRAIN does not interact with ERS, but the initial efforts in the BRAIN proposal are used by SPF for committed effort when creating the grant header in SAP
  - If effort has changed from time of proposal to time of funding, contact SPF post_award@bcm.edu to correct the problem

Questions

Questions related to the above and other post-award budget concerns are addressed through SPF staff, usually assigned to department administrative offices. View the current list of contacts on the SPF website. Send questions to post_award@bcm.edu.

Section 6C
Faculty Departures and Extended Absences

Overview

Introduction

Faculty leaving BCM should notify the Office of Research well before the planned departure date to ensure a smooth transition of protocols and grants/contracts.

In this section

This section covers the following topics:

- Leaves of Absence
- Time-Limited Transition
- Change of Principal Investigator on a Grant or Contract
- Subawards – Both Subgrants and Subcontracts
- Transfer of Materials - MTA with New Institution Required
- Disposition of Pending Applications

Leaves of Absence

How to handle	PIs and other key personnel may not be absent from funded research projects for **three contiguous months** or longer. Such absences require the sponsor's prior written approval. • The PI of the project should send an email to spo@bcm.edu, explaining the need for the extended absence and how the work will progress during the absence • Specify the dates of the planned absence or sabbatical and provide the sponsor's contact information, including an email address • Sponsored Programs will forward the request to the respective sponsor for the sponsor's review and approval
Absences on training grants or fellowships	Depending on the length of the absence, trainees may need to go through a formal termination and then reappointment process. Consult with SPO for the specific process and provide the grant number and dates of the planned absence.

Time-Limited Transition

Overview	If a departing faculty member requires a defined period of time, beyond the employment termination date, to ensure a smooth transition of grants, contracts, and associated protocols to her/his new institution, s/he must sign a Research-Certified Voluntary Faculty Agreement (Time-Limited Transition) form and submit as indicated on the form. • The BCM department chair and the new institution's official must sign the form as well • Forward a fully executed copy to Sponsored Programs • Adjunct appointments without this form do not allow grants, contracts, or protocols to remain in place or active at BCM • Only an approved Research-Certified Voluntary Faculty Agreement (Time-Limited Transition) form will result in an adjunct appointment that allows work to continue, subjects to be seen, or animals to remain in place, at BCM during the transition to a new institution
Time-limited transition form	The time-limited transition form is required if: • A lab or other facility will remain open for some period of time after the faculty member leaves BCM • If human or animal protocols remain active • If animals remain in BCM facilities • If human subjects need to continue in the study prior to the protocol being approved at the new institution • See Research-Certified Voluntary Faculty Agreement (Time-Limited Transition)
Protocols/lab certifications	Faculty with human protocols, animal protocols, or lab biosafety issues must coordinate the disposition of those protocols or lab certifications with the following administrators as appropriate: • Institutional Biosafety Committee at ibc@bcm.edu • Institutional Review Board at irb@bcm.edu (for human protocols) • Institutional Animal Care and Use Committee at iacuc@bcm.edu

Change of Principal Investigator on a Grant or Contract

Overview	A department chair may choose to designate a replacement Principal Investigator (PI) in lieu of relinquishing, transferring, or terminating a grant or contract. • The preferred replacement is another faculty member who has played a key role on the grant from the outset • If the replacement PI is not from the same department as the current PI, the current PI's department chair must approve of the change
Letter to sponsor	The departing faculty member should prepare a letter to the sponsor: • Explaining the reason for the change • Highlighting the qualifications of the recommended replacement • Attaching the new PI's biosketch and updated other support information to the letter
Who signs the letter	The following individuals should sign the letter to the sponsor: • Current PI • Replacement PI • Authorized Institution Official (from the Office of Research)
Sponsored programs notification	Sponsored Programs must receive a copy of the sponsor's approval upon receipt. • The approval may be sent to spo@bcm.edu • Sponsored Programs also will need a revised BRAIN proposal routing summary, identifying the new PI • The new investigator's office should contact Sponsored Programs for assistance submitting a change-of-PI proposal routing summary in BRAIN, 713-798-1297, or spo@bcm.edu
Sponsored programs responsibilities	Sponsored Programs will ensure the new PI's protocols are in place and conflict of interest disclosure is up to date. Sponsored Programs then coordinates with SPF so that Post Award establishes an account in the new PI's name.

Subaward to/from New Institution

Overview	As many research grants and contracts involve collaborations with colleagues, a subaward may need to be put in place between BCM and the new institution to ensure continued collaboration. • When the grant or contract remains at BCM, under the auspices of a new PI, part of the work may be subawarded to the former investigator's new institution • If the grant or contract is relinquished and re-awarded to the new institution, the PI may choose to subaward a portion of the work back to his or her former BCM colleagues
Grant or Contract remaining at BCM	The substantive portion of the project must remain at BCM if the grant or contract remains at BCM.
Subaward development	Sponsored Programs will work with both investigators and the new institution to develop an appropriate subaward. The respective investigators will provide the scopes of work and associated budgets.

Transfer of Materials - MTA with New Institution Required

Overview	If the departing faculty member, or non-faculty member leaving for a faculty position, plans on taking any materials (e.g., cell lines, KO mice, etc.) with her/him, a Material Transfer Agreement (MTA) must be executed with the new institution. Sponsored Programs coordinates the MTA(s). If the faculty member is moving to a for-profit company, a **licensing agreement** must be executed between BCM and the company. BCM Ventures negotiates the license agreement.
List of materials	Typically, a single MTA is negotiated, with a list of materials attached to the agreement. The list may be modified or expanded as required.
Where to send MTA	The departing faculty member should email the SPO at mta@bcm.edu to initiate the process. Include the name of the new institution, and appropriate contact information at the new institution, in the email.
Transfer of notebooks or other intellectual property	BCM Policy on Research Inventions and Patents 20.8.01 provides that all ownership and control of BCM Intellectual Property shall be in the College and applies this policy to all college members. Each College Member shall prepare, maintain, and provide to the College accurate and complete records and documentation (including, without limitation, traditional laboratory notebooks or visual, auditory, written, electronic, cloud-based, or other equivalents thereof) detailing the Development of any Intellectual Property Developed by such College Member. All such records and documentation will remain the property of, and solely owned by, the College. Requests to retain copies of such notebooks must be made to the BCM Ventures with the prior approval of the Department Chair.

Section 6D
Transferring and Relinquishing Awards

Overview

Introduction	Faculty moving to BCM may need to transfer awards from their old institution, while faculty leaving BCM can request approval to relinquish awards to their new institution.
In this section	This section covers the following topics: • Transferring a Grant to Baylor College of Medicine • Relinquishing a Grant from Baylor College of Medicine • Disposition of Pending Applications

Transferring a Grant to Baylor College of Medicine

Introduction

Faculty joining BCM may already have sponsored awards that they wish to transfer from their previous institution in order to continue the work. The basic procedures are the same as applying for a grant although special procedures may need to be followed depending on the timing of their move.

- The recruiting department should contact Sponsored Programs to notify them of the new faculty recruit and consult on procedures needed since different sponsors have different requirements in the transfer process:
  - Contracts are generally negotiated as a completely new agreement with BCM and terminated with the original institution.
  - Subawards are generally negotiated with BCM as a completely new subaward and is terminated with the original institution
  - Non-profit Foundation awards usually require a letter sent by the PI and their former institution requesting approval to move the grant before they will send an award letter to BCM
  - Federal awards have specific steps and forms that are required
- Depending on the sponsor, a new agreement, an amendment, an approval letter or a simple email of approval may be received which can be used to fund the award.
- SPO will fund the BRAIN proposal for the transferring award as described in Section 5D Proposals

During the transition

The recruiting department can choose to give the new faculty member research certified voluntary faculty status prior to their official start date at BCM. This allows them to receive an ECA ID and password to access BRAIN. The new faculty member can begin ESP1 protocols and ESP2 proposals in order to facilitate having approvals and awards in place more quickly.

ESP2 proposal submission

Grants and subawards should be submitted as Transfer proposals, not New proposals in ESP2. This avoids confusion when the Notice of Award is received that starts with later years and not year one. Contracts with industry sponsors should be submitted as New since a new agreement will have to be negotiated.

NIH specific steps

NIH has a specific set of steps that must be coordinated between the old and new institutions. Following relinquishment by the original institution, the new institution can submit an application for a "Change of Grantee Institution".

Prior to moving, the PI should first contact the Program Officer to inform them of the change, then contact the Grants Management Specialist identified on the Notice of Award and inquire what format they prefer the transfer application to be submitted to that NIH Institute/Center:

- PHS 398 or PHS 416-1 - Paper forms scanned and emailed directly
- Or via Grants.gov using the Parent Funding Opportunity Announcement with change of grantee chosen

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Transferring a Grant to Baylor College of Medicine, Continued

Paper application

The paper application from the proposed new grantee institution, BCM, should include, at a minimum, the following:

- PHS 398 Face page with "Change of Grantee Institution" typed on the top of the form
- PHS 398 Budget pages (current and future years):
  - Under awards resulting from modular applications, the application should include narrative budget information for the current budget period, including total direct cost and the basis for computing F&A costs and, if applicable, future budget periods.
  - Budgets should not exceed the direct costs (plus applicable F&A costs) previously recommended for any budget period
  - For transfers in the middle of a budget period, the budget for the initial year may be based on the total costs relinquished only if the grantee has been instructed to do so by the awarding IC
  - For these applications, grantees will also need to include the Other Project Information and the Senior/Key Personnel components
- Updated biographical sketches for the PD/PI and existing senior/key personnel and biographical sketches for any proposed new senior/key personnel
- If transferring on the anniversary date, include the progress report for the current year including a statement regarding the goals for the upcoming year. For all transfer applications include also a statement indicating whether the overall research plans/aims have changed from the original submission, and if so, provide updated information.
- Updated "other support" page(s), if necessary
- Resources page, including probable effect of the move on the project
- PHS 398 Checklist page
- Certification of IRB/IACUC approval, including OHRP and OLAW assurance numbers, if applicable
- Detailed list of any equipment purchased with grant funds to be transferred to the new organization (inclusion of this list in the transfer application from the new organization indicates its acceptance of title to that equipment)

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Transferring a Grant to Baylor College of Medicine, Continued

Electronic application

The electronic application from the proposed grantee institution should include, at a minimum, the following:

- SF 424 (R&R) Cover Component
- SF 424 (R&R) Project/Performance Site Location(s)
- SF 424 (R&R) Other Project information:
  - Certification of IRB/IACUC approval, including OHRP and OLAW assurance numbers, if applicable
  - Facilities and Other Resources, including probable effect of the move on the project
  - Detailed list of any equipment purchased with grant funds to be transferred to the new organization (inclusion of this list in the transfer application from the new organization indicates its acceptance of title to that equipment)
- SF 424 Research & Related Senior/Key Person Profile: Updated biographical sketches for the PD/PI and existing senior/key personnel and biographical sketches for any proposed new senior/key personnel, and updated "other support" page(s) as necessary
- Budget pages applicable for activity code (current and future years):
  - If the budget for the original award was submitted in a modular format, use the R&R Detailed Budget form for all electronic applications
  - Grantee may either complete all of the fields in the R&R Detailed Budget as appropriate or complete only the costs for the PD/PI (Section A) and include the remainder of the direct costs under Section F (Other Direct Costs) Item 8, and Section H (Indirect Costs).
  - For awards resulting from modular applications, include narrative budget information for the current budget period, including total direct cost and the basis for computing F&A costs and, if applicable, future budget periods.
  - Budgets should not exceed the direct costs previously recommended for direct costs (plus applicable F&A costs) for any budget period
  - For transfers during the course of a budget period, the budget for the initial year may be based on the total costs relinquished only if the grantee has been instructed to do so by the awarding IC.
- SF 424 Research Plan
- If transferring on the anniversary date, include the progress report for the current year including a statement regarding the goals for the upcoming year. For all transfer applications include also a statement indicating whether the overall research plans/aims have changed from the original submission, and if so, provide updated information.
- SF 424 Cover Page Supplement
- SF 424 Checklist

Relinquishing a Grant from Baylor College of Medicine

Approvals

The departing faculty member's Department Chair and BCM's SVPDR must approve of the disposition of all grants and contracts – both awarded and pending – in writing (email is fine).

- The departing faculty member should send an email to her/his chair providing:
  - Name of new institution
  - Last day at BCM
  - List of all grants and/or contracts the faculty member would like to have relinquished, terminated, or changed to a new PI
  - A detailed list of any equipment purchased with grant funds to be transferred to the new organization should be included in the request
- Completed projects must have all Final Closeout Reports attached in BRAIN to ensure all the sponsor's requirements have been met
- The email should request that the Department Chair forward her/his approval to the SVPDR for final review and approval
- Both Sponsored Programs, spo@bcm.edu and Sponsored Programs Finance, post_award@bcm.edu must receive copies of the Chair's and SVPDR's approval emails

Change to a new PI at BCM

Follow procedures as described in section 6C Change of Principal Investigator on a Grant or Contract.

Non-profit and for-profit sponsor notification

Non-profit sponsors (e.g., American Cancer Society) and industry sponsors (e.g., Merck) must be notified in writing of the pending departure of the faculty member upon receipt of the above-noted approvals from the Department Chair and Sr. Vice-President of Research. Terms and conditions of the award document will need to be reviewed to determine if any specific procedures are required by the sponsor:

- The faculty member is responsible for preparing all notification letters
- Notification letters are co-signed by BCM's authorized institutional signatory in the Office of Research
- Notification letters typically are sent via email, but some sponsors may require paper originals
- For-profit sponsors typically send a contract amendment, terminating the agreement with BCM. A BCM authorized institutional signatory, from the Office of Research, must sign the amendment.
- Non-profit sponsors typically send a letter or email acknowledging termination. If a signature is required, a BCM authorized institutional signatory, from the Office of Research, must sign the letter.

Subawards

Most subawards are for one-year increments and have a clear end date so a termination amendment may not be required. It is often possible to simply submit a Final Invoice for reimbursable expenses incurred up to the PI's last day at BCM. The prime institution then issues a new subaward to the PI's new institution starting after that date. The PI should consult with Sponsored Programs.

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Relinquishing a Grant from Baylor College of Medicine, Continued

Federal relinquishing forms

Federal grant funds are relinquished upon receipt of the required approvals (see above) through the following means:

- Each federal sponsor has standardized relinquishing forms that are completed by Sponsored Programs Finance in conjunction with the faculty member's departmental administrator in order to determine the remaining balance to be relinquished.
- The relinquishing forms then are signed by the authorized representatives of the Office of Research.

NIH specific steps

To transfer a grant to a new organization, the following must be submitted from the original grantee organization:

- NIH Forms and Applications are available online
- **Form PHS 3734**, "Official Statement Relinquishing Interests and Rights in a PHS Research Grant." The original grantee organization must relinquish the grant, or it cannot be transferred to another organization. The relinquishing statement should be submitted electronically via the eRA Commons.
- **Form SF 425**, "Federal Financial Report (FFR)." This is due from the original grantee within 90 days after the end of the final budget period. However, the final FFR should not be submitted until the original institution has received a revised Notice of Award for the relinquished grant. The FFR should be submitted electronically via the Payment Management System (PMS).
- **Form HHS 568**, "Final Invention Statement and Certification." This is due within 90 days after the end of the final budget period at the original organization. It should be submitted electronically via the NIH eRA Commons.

Change of institution applications for federal grants

The faculty member must submit a Change of Institution application to the federal sponsor through her/his new institution:

- For NIH grants, the faculty member should contact her/his Grants Management Specialist to determine what must be included in the Change of Institution Application
- At the very least, a new face page, signed by the new institution's authorized official; new budget and budget justification pages; new facilities and resources page; and a new checklist page should be submitted to the NIH Grant Management Specialist
- Upon receipt of BCM's relinquishing statement, and the new institution's Change of Institution application, NIH or other federal sponsor will terminate the award at BCM and issue the remainder of the award to the new institution

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Relinquishing a Grant from Baylor College of Medicine, Continued

Disposition of funds	BCM typically does not transfer funds to a new institution: • NIH monies are removed from BCM's federal letter of credit and issued to the new institution by NIH when a new Notice of Grant Award is issued. • Other sponsors may prefer unspent funds be returned to the sponsor via check or wire transfer. • Most non-profit and for-profit sponsors prefer monies to be returned directly to them. The sponsors then enter into new agreements with the new institution and fund the new institution directly • BCM does not transfer funds to the new institution unless the sponsor formally acknowledges the study will continue at the new institution and specifically requests, in writing (email is fine), for BCM to transfer the funds to the new institution.
Other off-boarding items	In addition to moving awards, there are many other aspects to closing down a lab and any protocols. While not inclusive, this Checklist for Off-Boarding Research Faculty can be used to consider whether an item is applicable and if it has been completed.

Disposition of Pending Applications

Introduction	Applications for sponsored research may have been submitted prior to the PI's decision to move, and so the award could still be Pending. Depending on the sponsor different actions may be required. SPO will assist as needed upon receipt of the required approvals (see above). The last step should be to mark the BRAIN ESP2 proposal as Not Funded.
Industry contracts	The appropriate office that is negotiating the agreement, OCR, or SPO, should be notified so that further work is not done. The PI should contact the sponsor and provide them with information about the new institution so they can begin negotiating their own agreement with the sponsor.
Subawards	The departing faculty member should contact the lead PI to inform them of the move and work with their new institution to provide revised budgets and a letter of intent so the prime can issue the subaward to the new institution.
Non-profit grants	The Sponsor should not be contacted until after the review has been completed and the proposal actually recommended for funding: • The faculty member is responsible for preparing all notification letters to request the award be made to a different institution • Notification letters are co-signed by BCM's authorized institutional signatory in the Office of Research • PI should work with new institution to provide any further documents requested by the sponsor
Federal grants	Usually, Federal sponsors request Just In Time (JIT) materials prior to funding an award: • At that time a letter can be sent by SPO to Release the application and allow the new institution to submit revised application materials. This is not the same as the Relinquishing form because there has not been an actual award. • The PI should contact their Program Officer once they know they are being considered for funding to determine the process required • NIH follows the same basic steps as in the Change of Grantee application