Baylor College of Medicine

RESEARCH

Research Investigator Workshop – Day 1

October 28, 2021

Research Compliance Services

MANAGING HUMAN SUBJECTS RESEARCH AT BAYLOR COLLEGE OF MEDICINE

Provided by:

1. Research Compliance Services

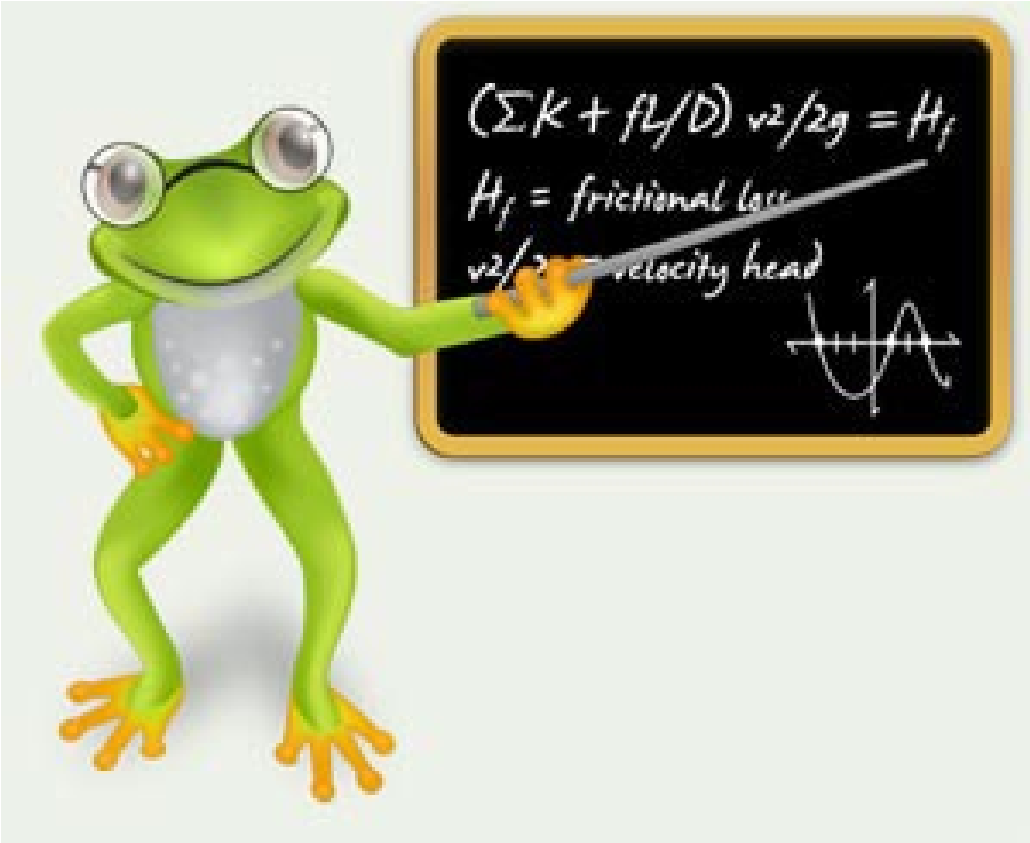
   https://intouch.bcm.edu/sites/research/SitePageModern/4129/reporting-research-compliance-concerns

AND

2. Institutional Review Board:

   https://intouch.bcm.edu/sites/research/SitePageModern/4100/institutional-review-board-for-human-subject-research

WELCOME!!



Baylor College of Medicine

RESEARCH

POLL: WHO IS IN OUR AUDIENCE?

What is your role in research?

- PI
- Coordinator (Research/Regulatory)
- Other

Baylor College of Medicine

RESEARCH

RESEARCH COMPLIANCE SERVICES (RCS): WHAT WE DO

The mission of Research Compliance Services (RCS) is to ensure BCM's compliance with federal, state, and local regulations as well as BCM's own institutional policies and procedures with regard to research.

Baylor College of Medicine

RESEARCH

RESEARCH COMPLIANCE SERVICES FOR:

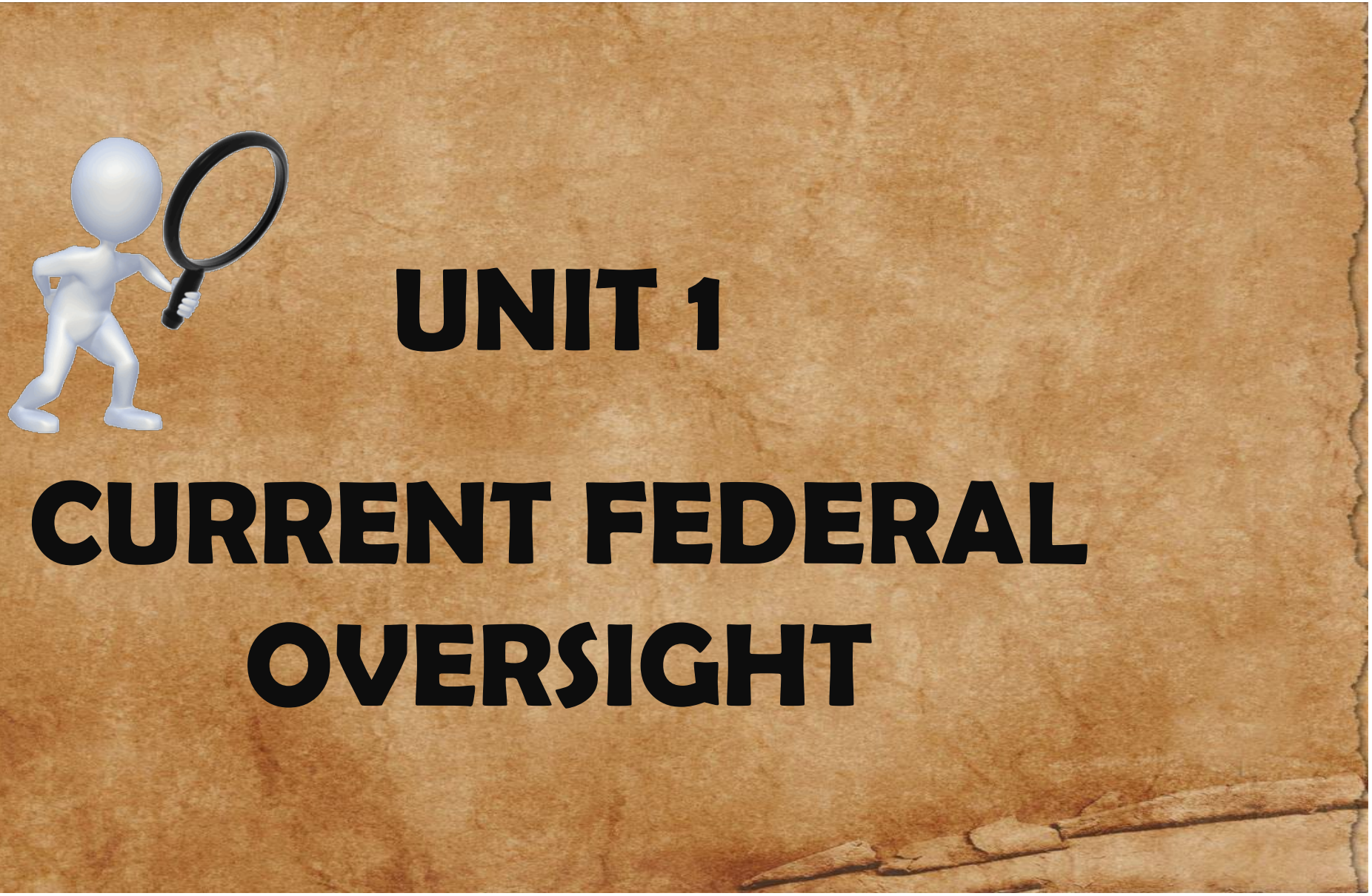
- **Institutional Review Board (IRB)**
- Institutional Animal Care and Use Committee (IACUC)
- **Committee on Scientific Integrity**
- Institutional Biosafety Committee
- Research Conflict of Interest Committee
- **BCM Investigators**

WORKSHOP AGENDA

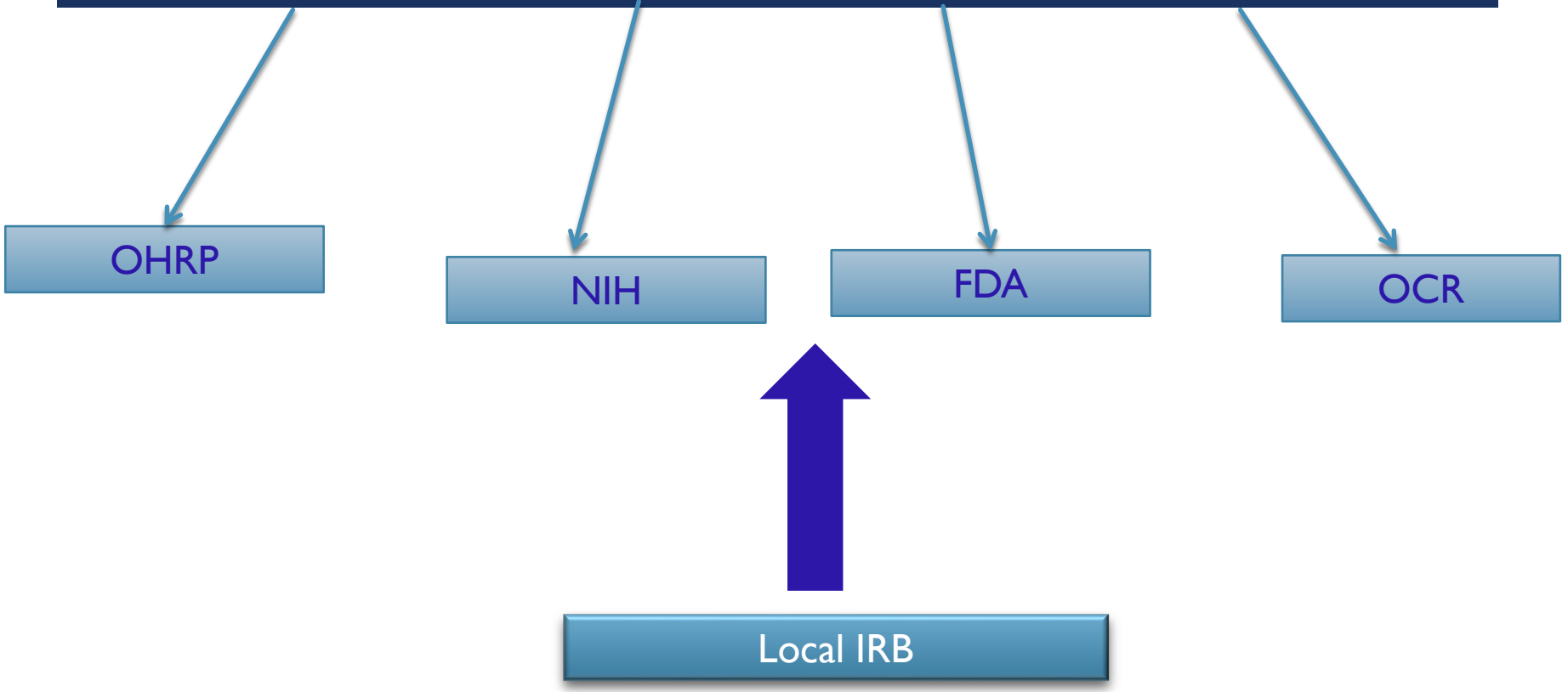
- Address regulatory and institutional requirements encountered during the conduct of a research study
- Provide training on the BCM IRB submission process (BRAIN)
- Discuss reporting requirements of investigators
- Dive into the world of reliance

Baylor College of Medicine

RESEARCH


UNIT 1
CURRENT FEDERAL OVERSIGHT

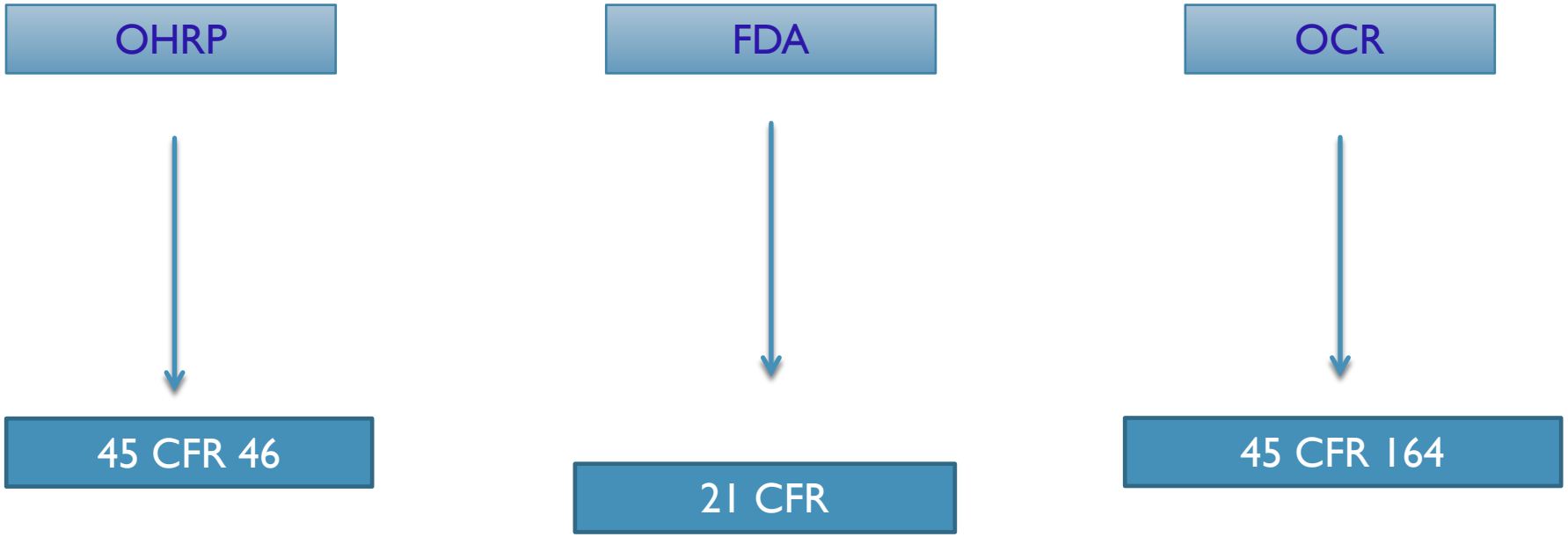
DEPARTMENT OF HEALTH AND HUMAN SERVICES (DHHS)



Baylor College of Medicine

RESEARCH

FEDERAL REGULATIONS



Baylor College of Medicine

RESEARCH

FEDERAL REGULATIONS
OFFICE FOR HUMAN RESEARCH PROTECTIONS (OHRP)

Baylor College of Medicine

RESEARCH

45 CFR 46

Code of Federal Regulations
TITLE 45
PUBLIC WELFARE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
PART 46
PROTECTION OF HUMAN SUBJECTS
***
Revised January 15, 2009
Effective July 14, 2009
* * *

Subpart A. Basic HHS Policy for Protection of Human Research Subjects

Sec.

§46.101 To what does this policy apply?

§46.102 Definitions.

§46.103 Assuring compliance with this policy--research conducted or supported by any Federal Department or Agency.

§46.104 -
§46.106 [Reserved]

§46.107 IRB membership.

§46.108 IRB functions and operations.

§46.109 IRB review of research.

- 45 CFR 46: The Common Rule –

https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html

Includes the following 4 subparts:

- Subpart A: Basic HHS policy (core requirements)
- Subpart B: Pregnant Women, Human Fetuses, and Neonates
- Subpart C: Prisoners
- Subpart D: Children

At BCM, all research, regardless of funding, must be conducted under these regulations.

FEDERAL REGULATIONS: DHHS FOOD & DRUG ADMINISTRATION (FDA)

- Title 21 CFR
- Similar to 45 CFR 46 with additional regulations regarding the use of investigational: drugs, biologic agents, devices, diagnostic tests

Even if not a <u>new</u> investigational drug, FDA regulations may still apply

Baylor College of Medicine

RESEARCH

The FDA regulates clinical investigations that are conducted on drugs, biologics, and devices

The FDA has codified these regulations that are almost identical to the DHHS regulations:

Topic	CFR Citation
General regulations	
Informed consent	21 CFR Part 50
IRB	21 CFR Part 56
Child protection	• 61 FR 20589 • 21 CFR Part 50, Subpart D
Protection of human subjects	
Investigational New Drug Applications	21 CFR Part 312
Biological Products	21 CFR Part 600
Investigational Device Exemptions	21 CFR Part 812

Baylor College of Medicine

RESEARCH

WHICH REGULATIONS APPLY?

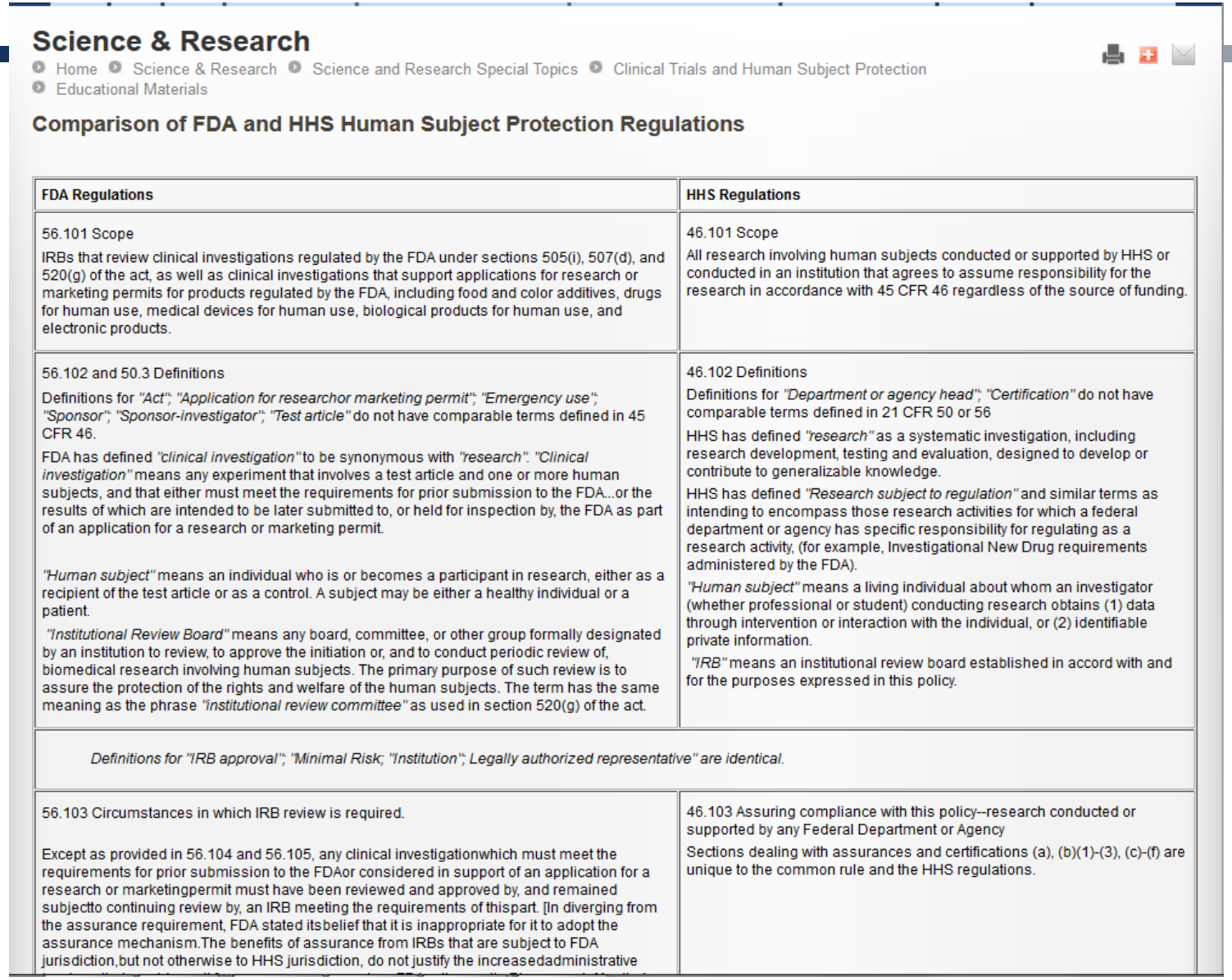
- **OHRP Regulations** – always (at BCM, and under most Assurances)

- **FDA Regulations** – when conducting research involving FDA-regulated drugs, devices, or biologics (regardless of funding source)

- In many cases, both sets of regulations must be met - be careful: some regulations are more specific than others!

- A good resource available on the web:

https://www.fda.gov/science-research/clinical-trials-and-human-subject-protection/regulations-good-clinical-practice-and-clinical-trials



Science & Research

Home › Science & Research › Science and Research Special Topics › Clinical Trials and Human Subject Protection › Educational Materials

Comparison of FDA and HHS Human Subject Protection Regulations

FDA Regulations	HHS Regulations
56.101 Scope IRBs that review clinical investigations regulated by the FDA under sections 505(i), 507(d), and 520(g) of the act, as well as clinical investigations that support applications for research or marketing permits for products regulated by the FDA, including food and color additives, drugs for human use, medical devices for human use, biological products for human use, and electronic products.	46.101 Scope All research involving human subjects conducted or supported by HHS or conducted in an institution that agrees to assume responsibility for the research in accordance with 45 CFR 46 regardless of the source of funding.
56.102 and 50.3 Definitions Definitions for *"Act"; "Application for researchor marketing permit"; "Emergency use"; "Sponsor"; "Sponsor-investigator"; "Test article"* do not have comparable terms defined in 45 CFR 46. FDA has defined *"clinical investigation"* to be synonymous with *"research"*. *"Clinical investigation"* means any experiment that involves a test article and one or more human subjects, and that either must meet the requirements for prior submission to the FDA...or the results of which are intended to be later submitted to, or held for inspection by, the FDA as part of an application for a research or marketing permit. *"Human subject"* means an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy individual or a patient. *"Institutional Review Board"* means any board, committee, or other group formally designated by an institution to review, to approve the initiation or, and to conduct periodic review of, biomedical research involving human subjects. The primary purpose of such review is to assure the protection of the rights and welfare of the human subjects. The term has the same meaning as the phrase *"institutional review committee"* as used in section 520(g) of the act.	46.102 Definitions Definitions for *"Department or agency head"; "Certification"* do not have comparable terms defined in 21 CFR 50 or 56 HHS has defined *"research"* as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. HHS has defined *"Research subject to regulation"* and similar terms as intending to encompass those research activities for which a federal department or agency has specific responsibility for regulating as a research activity, (for example, Investigational New Drug requirements administered by the FDA). *"Human subject"* means a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information. *"IRB"* means an institutional review board established in accord with and for the purposes expressed in this policy.
Definitions for "IRB approval"; "Minimal Risk; "Institution"; Legally authorized representative" are identical.	
56.103 Circumstances in which IRB review is required. Except as provided in 56.104 and 56.105, any clinical investigationwhich must meet the requirements for prior submission to the FDAor considered in support of an application for a research or marketingpermit must have been reviewed and approved by, and remained subjectto continuing review by, an IRB meeting the requirements of thispart. [In diverging from the assurance requirement, FDA stated itsbelief that it is inappropriate for it to adopt the assurance mechanism.The benefits of assurance from IRBs that are subject to FDA jurisdiction,but not otherwise to HHS jurisdiction, do not justify the increasedadministrative	46.103 Assuring compliance with this policy--research conducted or supported by any Federal Department or Agency Sections dealing with assurances and certifications (a), (b)(1)-(3), (c)-(f) are unique to the common rule and the HHS regulations.

https://www.fda.gov/scienceresearch/specialtopics/runningclinicaltrials/educationalmaterials/ucm112910.htm

HIPAA

HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT

Who must comply?

- Health care providers who transmit health information in electronic transactions, including for research purposes
- Health plans
- Health care clearinghouses

BCM is a covered entity

Protected Health Information (PHI): See Part II, 45 CFR 164.501.

HIPAA and Reserach on the BCM intranet: https://intouch.bcm.edu/sites/research/SitePageModern/4329/hipaa-and-research

HIPAA and Research (NIH pamphlet): https://privacyruleandresearch.nih.gov/

Baylor College of Medicine

RESEARCH

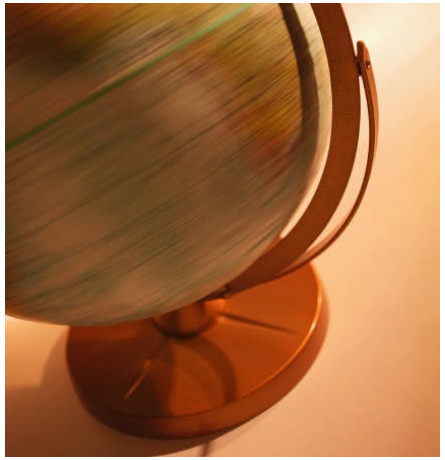
FEDERAL WIDE ASSURANCE (FWA)

- The Federal Wide Assurance (FWA) is BCM's agreement with the federal government that all research engaged in by BCM will be conducted under the Common Rule (45 CFR 46)

- The FWA recognizes the Institutional Review Boards (IRBs) officially designated to review the College's research.

- Search OHRP Database for Registered IORGs and IRBs, Approved FWAs:

- https://ohrp.cit.nih.gov/search/search.aspx?styp=bsc



UNIT 2

About the IRB

Baylor College of Medicine

RESEARCH

POLICY AND PROCEDURES

All Baylor faculty conducting research must submit their protocols and associated documents to the BCM IRB for review and determination (i.e. non-human subjects research, exemption, or approval) by the IRB prior to implementation.

Baylor College of Medicine

RESEARCH

POLICY AND PROCEDURES

- Only BCM faculty (professor, assistant/associate professor, instructor) may be principal investigators of clinical research protocols.

- Voluntary faculty (i.e. clinical, adjunct, visiting) can contact the Faculty Affairs Office and apply to become "research certified".

- Organizations at which research is conducted, including hospitals, schools and clinics, typically have their own specific processes and requirements for the conduct of research, *in addition to* BCM IRB review.*

Baylor College of Medicine

RESEARCH

Baylor College of Medicine

RESEARCH

IRB INFORMATION IS AT YOUR FINGERTIPS!

- IRB manual (Human Research Protections Manual)
- Meeting dates (includes submission schedule)
- IRB member roster
- Federal Wide Assurance
- Assurance Forms (includes templates for foreign language short consent forms)
- FAQs: Frequently Asked Questions
- Medical/Scientific lay terms

https://intouch.bcm.edu/sites/research/SitePageModern/4100/institutional-review-board-for-human-subject-research

THE IRB OFFICE

- Located on the 3rd floor of the Neurosensory Center
- 6 Federal Wide Assured Boards

- Main IRB Line: 713-798-6970
- Main IRB email: irb@bcm.edu

Baylor College of Medicine

RESEARCH

BAYLOR IRB

- **Chairs**
  - Gabriel Habib, MD (Board 1 & Board 4)
  - Julie Katkin, MD (Board 2 & Board 5)
  - Flor Munoz-Rivas, MD (Board 3 & Board 6)

- **IRB Administrator/Director of Research Compliance**
  - Amara Azobu, MS, CIP

- **Senior Associates**
  - Makenzie Maupin, (713) 798-1574
  - Priel Meir (713) 798-5308
  - Swati Bansal, (713) 798-201
  - Veronica Roberts Garrett (713) 798-5842
  - Tegan Tulloch (713) 798-9035
  - Tiffanie Morris (713)798-4233

Baylor College of Medicine

RESEARCH

GABRIEL HABIB, MD

- Chair for **Boards 1 & 4**
  - Associate Chief of Cardiology, VAMC
  - Director, Education Programs, VAMC
- Specialty:
  - Hypertension
  - Coronary Artery Disease
- VA Representative
- IRB Member since 2006

Phone: 713-794-7310
gjhabib@bcm.edu
habib.gabrielb@va.gov

Baylor College of Medicine

RESEARCH

JULIE KATKIN, MD

- Chair for **Boards 2 & 5**
  - Associate Professor of Pediatrics
- Specialty:
  - Pediatric Pulmonology
  - Pediatric Life-threatening Asthma
- Clinical Interests:
  - Pulmonary medicine, asthma, cystic fibrosis, and bronchopulmonary dysplasia
- IRB Member since 2001

Phone: 832-822-3307
jkatkin@bcm.edu
jpkatkin@texaschildrenshospital.org

Baylor College of Medicine

RESEARCH

FLOR MUNOZ-RIVAS, MD

- Chair for **Boards 3 & 6**
  - Associate Professor of Pediatrics-Infectious Disease
- Clinical Interests: Pediatric infectious Diseases
- IRB member since 2005

Phone: 832-824-4371
florm@bcm.edu

Baylor College of Medicine

RESEARCH

IRB MEMBERSHIP 45 CFR 46.107

- a) >5 members, diverse, competent
- b) gender & professional diversity
- c) 1 scientist & 1 non-scientist
- d) one non-affiliate
- e) cannot participate if conflict of interest
- f) consultants OK but cannot vote

The IRB Office

What we do

Baylor College of Medicine

RESEARCH

IRB RESPONSIBILITIES 45 CFR 46.109

- a) authority to approve, require modifications to or disapprove all research activities
- b) comply with informed consent 46.116
- c) require documentation of informed consent or may waive documentation 46.117
- d) notify investigators & institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval
- e) annual continuing review (if required)

Baylor College of Medicine

RESEARCH

THE IRB OFFICE – WHAT WE DO FOR YOU

- We make full board/expedited determinations of protocol submissions
- We provide regulatory guidance to researchers and board members
- We are the liaison between the PI and the Board Members

Baylor College of Medicine

RESEARCH

THE IRB OFFICE – WHAT WE DO

- We conduct a review of every protocol submission to ensure regulatory requirements are met
- We ensure all primary and/or team reviewer feedback is in BRAIN prior to the meeting.
- We take minutes at convened meetings and participate in the discussion
- We write and send memos of requested modifications from the Board to the investigator

Baylor College of Medicine

RESEARCH

- BCM is fully AAHRPP accredited:
  - Research at BCM exceeds federal requirements for safeguarding participants
  - Designates a quality program; ensures data are reliable and credible
  - Effective policies and procedures
  - Competitive edge for funding
  - Public trust and confidence

http://www.aahrpp.org/

Baylor College of Medicine

RESEARCH

WHAT DOES IT TAKE TO GET A STUDY STARTED?

- Submission of protocol to OOR
  - Biomedical Research Assurances Information Network (BRAIN)
- Review of protocol by IRB
  - Expedited review
  - Full board review
- Approval of protocol by IRB or
- Exemption of protocol by IRB or
- Determination that protocol is non-human subjects research

Baylor College of Medicine

RESEARCH

PROTOCOL SUBMISSION

- Principal Investigator must be BCM faculty or voluntary research certified
- Protocol must be submitted to OOR by the PI
- Protocol must receive departmental and center signatures before it is routed to the OOR in BRAIN
- Protocol arrives in the OOR

PROTOCOL IS SUBMITTED TO THE IRB. WHAT'S NEXT

- Protocols are assigned a meeting date based on the date of submission and the deadline dates for meetings
- All VA regulated research protocols go to IRB #4
- Protocol is determined to be human subjects research
- OOR Staff review protocols to route them for review
  - Routed for review by expedited procedures, or
  - Routed for review by fully convened IRB
- Protocol may be returned to PI for clarifications prior to review; protocol would need to be resubmitted

Baylor College of Medicine

RESEARCH

WHEN THE PROTOCOL GOES FOR "FULL IRB REVIEW"

- Protocols are assigned to a team of reviewers made up of members of the IRB
- Protocols are reviewed prior to the meeting date
- Protocols are discussed, deliberated upon, and voted on during the convened IRB meeting
- Decisions of the determination of the IRB are communicated to the PI within 7-10 days of the meeting

WHAT ARE THE IRB DECISIONS?

For Full Board Review:

- Approved
- Approved with modifications
- Tabled: Requires substantial changes to the research and/or the addition of important information that was lacking in the application; these items must be addressed by the investigator and be resubmitted for review and approval by the fully convened IRB before the research may proceed.
- Disapproved: The IRB has determined that the research cannot be conducted at the College or by its employees or agents. Reasons for the decision are included in the response to the investigator.
- Suspended
- Terminated

For Expedited Review:

- Approved
- Approved with modifications

Baylor College of Medicine

RESEARCH

INSTITUTIONAL RULES

- Each IRB should have a policies and procedures manual that codifies, clarifies, or expands upon federal regulations
- Includes definitions of what it means to be engaged in research, rules for dealing with non-compliance with regulations/rules and procedures related to these issues

EXPEDITED REVIEW 46.110

- May be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB

  An IRB may use the expedited review procedure to review either or both of the following:

- (1) some or all of the research appearing on the list and found by the reviewer(s) to involve no more than minimal risk,
- (2) minor changes in previously approved research during the period (of one year or less) for which approval is authorized.

Baylor College of Medicine

RESEARCH

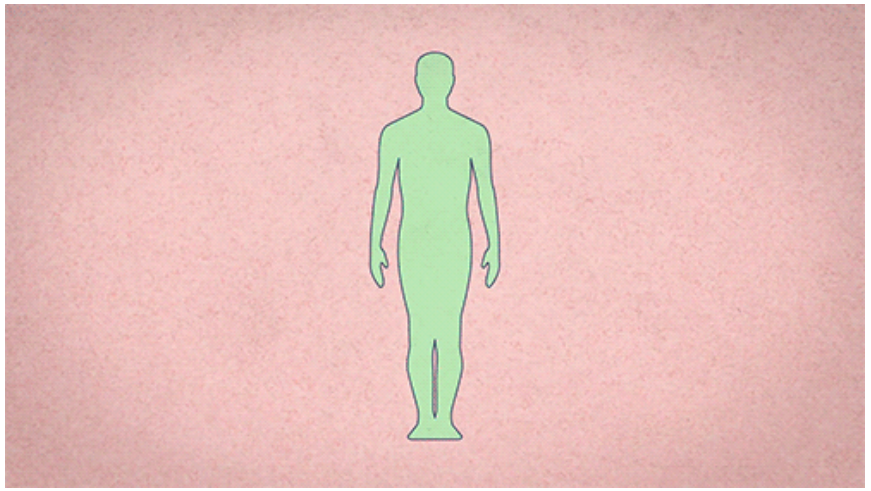
CRITERIA FOR APPROVAL 45 CFR 46.111(A)

- Risks minimized
- Reasonable risk: benefit
- Equitable selection
- Informed consent sought
- Informed consent documented
- Monitoring data for safety
- Protection of privacy/confidentiality

UNIT 3 - IS WHAT I'M DOING CONSIDERED "RESEARCH"?

A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

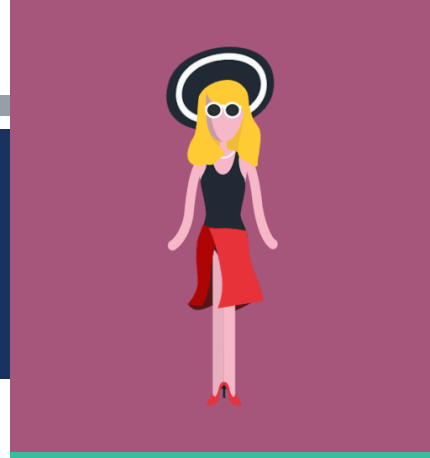
45 CFR46.102 (L)

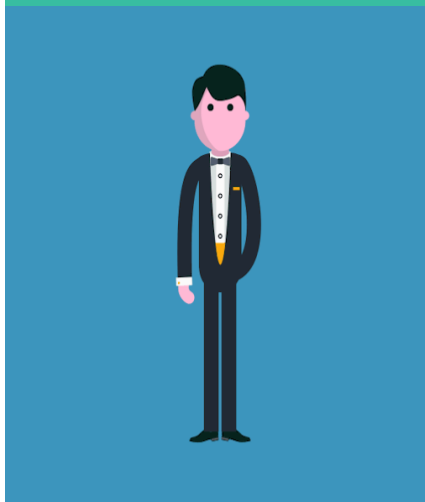


Baylor College of Medicine

RESEARCH

IS WHAT I'M DOING HUMAN SUBJECTS RESEARCH?
AS DEFINED BY OHRP & FDA





OHRP: 45 CFR 46.102 (E1)

- A living individual about whom an investigator (whether professional or student) conducting research obtains:
- Data through intervention or interaction with the individual,

OR

- Identifiable private information.

FDA: 21CFR 50.3(g)

- An individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient.

FDA: 21CFR 812.3(p)

- A human who participates in an investigation, whether as an individual on whom or on whose specimen an investigational device is used or as a normal control. A subject may be in normal health or may have a medical condition or disease.

GENERAL TERMINOLOGY

- Principal Investigator: the individual responsible for the conduct of the research and the resulting data
- Investigator: Investigator: defined as the PI, project director, and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS (e.g., NIH), including collaborators and consultants. (grants.nih.gov/grants/policy/coi/coi_faqs.htm)
- Funding Source: Provides the monetary and/or material support to conduct an investigation, but does not initiate the investigation (e.g. NIH)
- Sponsor: Initiates a clinical investigation, but does not actually conduct the investigation (usually a pharmaceutical, biotech, or medical device company
- Sponsor-Investigator: The investigator both initiates & conducts a clinical investigation.
  - must fulfill the duties of BOTH sponsors & investigators.
    - Requires extensive knowledge of regulations & a high level of bookkeeping

  See 21 CFR 50.3(f), 56.102(k), and ICH E6 1.54

Baylor College of Medicine

RESEARCH

CASE REPORTS

- Three or fewer patients: Not research. IRB does not review or approve these reports
- More than three patients is considered research and will require IRB review and approval prior to the conduct of the research.
- Even though a case series of three or fewer patients does not constitute research, it is still subject to HIPAA rules. Investigators therefore may be required to de-identify all data disclosed (as defined by HIPAA) or to obtain patient authorization to disclose private health information.

QA/QI ACTIVITIES: ARE THEY RESEARCH?

- Quality Assurance (QA) activities attempt to measure the effectiveness of programs or services
- May be used in all departments
- Sometimes may cross over into research territory

Baylor College of Medicine

RESEARCH

Quality Assurance/Quality Improvement Activities as Human Subject Research, Continued

IRB review and documentation

After reviewing applicable policy and guidance, investigators are responsible for assuring that all human subject research is prospectively reviewed by the BCM IRB.

QA/QI vs. Research

If the IRB reviews the activity, documentation of the determination consists of the reviewer's written concurrence in the IRB Research Review File that the activity described in the Investigator's Application does or does not satisfy the definition of human subject research. The investigator proposing the activities will receive a notification stating the determination.

45 CFR Part 46 defines research as: A systematic investigation including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

The following are examples of QA/QI activities that do not contribute to generalizable knowledge:

- Implementing a practice to improve the quality of patient care
- Collecting patient or provider data regarding the implementation of a practice for clinical, practical, or administrative purposes
- ***Note*:** The results of the activity may be published later but this does not in and of itself mean that the activity is research

Some QA/QI activities do meet the definition of research, for example:

Introducing an untested clinical intervention for purposes which include not only improving the quality of care but also collecting information about patient outcomes for the purpose of establishing scientific evidence to determine how well the intervention achieves its intended results

Continued on next page

QA/QI vs. Research (cont.)

The table below compares activities of research and QA/QI:

Aspects of the Activity	Research	QA/QI
Purpose	Test a formal hypothesis	Assess a process, program or system
Starting Point	A prospectively designed research hypothesis	An established set of standards
Benefits	Knowledge sought may or may not benefit subjects involved in study	Knowledge sought is intended to benefit process/program/system
Risks/burdens	May put subjects at risk	No risk, with exception of possible loss of privacy/confidentiality
Data Collection	Systematic data collection	Systematic data collection
End Point	Answer research question	Improve the program/process/system
Testing/Analysis	Determine validity of hypothesis	Compare the program/process/system to established set of standards

QA/QI ACTIVITIES: ARE THEY RESEARCH?

WHEN:

- QA activities are designed solely for internal program evaluation purposes with no external application or generalization

- They usually do not constitute human subject research

QA/QI ACTIVITIES: ARE THEY RESEARCH?

WHEN:

- QA activities are designed or intended, at least in part, to develop or contribute to generalizable knowledge
- They constitute human subject research and require IRB review.
- Information where the intended use of the research findings can be applied to populations or situations beyond that studied.

Baylor College of Medicine

RESEARCH

QA/QI ACTIVITIES: ARE THEY RESEARCH?

What is generalizable knowledge?

- Attempt to make comparisons or draw conclusions from data gathered
- Seek underlying principles that have predictive value and can be applied to other circumstances for the purpose of controlling outcomes
- Create general explanations about all that has happened in the past
- Predict the future.

QUESTION

- Who is best suited to make a determination whether something is research if it is not clear?
  - PI
  - IRB Staff

UNIT 4

General Research Responsibilities & Training

Baylor College of Medicine

RESEARCH

INVESTIGATOR & RESEARCH PERSONNEL RESPONSIBILITIES

OHRP 45 CFR 46.109, BCM HUMAN RESEARCH PROTECTIONS MANUAL

- The ethical conduct of research
- Design & implement ethical research
- Involve qualified research personnel
- Obtain IRB approval prior to initiating human subjects research
- Comply with federal & state regulations, institutional & IRB requirements, & HIPAA pertaining to research
- Implement research as approved by the IRB
- Maintain appropriate project & personnel oversight & appropriately delegate research responsibilities
- Conduct recruitment of subjects fairly & equitably while continually assessing risks/benefits to research subjects
- Obtain & document informed consent/assent & authorization
- Monitor data integrity, the rights, safety, & welfare of human subjects
- Submit progress reports at predetermined intervals
- Report unanticipated problems as soon as possible, but in all cases within 5 working days.
- Obtain prior approval from the study sponsor & IRB for modifications to research protocols

THERAPEUTIC MISCONCEPTION:

WHY IT'S SO IMPORTANT TO "WEAR 2 HATS"

- Research subjects sometimes think that the research is actually clinical care
- Sometimes the Investigator/research team think of the research subject as a clinical patient and forget that the research subject is a volunteer
- Key phrases that may indicate this problem:
  - "When should I start feeling better?"
  - "Doctors are healers. They wouldn't ask me to do this if it wouldn't help me."
  - "My doctor knows what is best for me. He/She is giving me the treatment I need."

Baylor College of Medicine

RESEARCH

AVOIDING THERAPEUTIC MISCONCEPTION

- Yourself: When speaking of individuals participating in research, use the term "subject" instead of "patient"
- Subjects: Remove therapeutic language from the consent form/discussions
  - Do not refer to experimental drugs as "treatment"
  - Make alternatives clear
- Ask the subject questions to ensure he/she understands the difference
- Be honest in that it is unknown whether this is (or isn't) in the subject's best interest
- Refer to the "investigator" instead of the "doc/physician"

Baylor College of Medicine

RESEARCH

Training Requirements

- **Everyone engaged in research** conducted under the BCM FWA must be appropriately trained prior to working on the project
- This requirement at BCM is met by taking the CITI training online modules located at **https://www.citiprogram.org/Default.asp?**
- Training is valid for 3 years
- PI responsibility to ensure all involved have up-to-date training
- Additional, position-specific training should also be provided by the PI

Baylor College of Medicine

RESEARCH

WHAT HUMAN SUBJECTS PROTECTIONS TRAINING IS REQUIRED?

Who is required to take the training?

- PIs and Co-PIs, even if those individuals will not have direct subject interaction/intervention
- Scientists
- Research Coordinators
- Administrative Contacts
- Medical students, fellows, and residents
- Summer students
- Visiting scholar
- Volunteers
- Other individuals involved in the protocol

Is CITI training mandatory?

- Yes

Baylor College of Medicine

RESEARCH

WHAT TRAINING IS REQUIRED?

- **Will I get reminders regarding expiration of CITI training?**
  - Yes
  - CITI will send a reminder to users 90 days before training is set to expire

- **Which courses are required?**

<u>For human subjects protections (one of the following):</u>

- Biomedical Research
- - Basic/Refresher
- Biomedical Refresher 101
- Biomedical Refresher 200
- Biomedical Refresher 201
- IRB Members - Basic/Refresher
- Social & Behavioral Research Refresher 101
- Social & Behavioral Research Refresher 201
- Portuguese Language Biomedical
- Spanish Language – Biomedical HS

WHAT TRAINING IS REQUIRED?

FOR HIPAA:

- The "Health Information Privacy and Security (HIPS) for Biomedical" or "Health Information Privacy and Security (HIPS) for IRB Members"

- Modules:

Basics of Health Privacy

Health Privacy Issues for Clinicians

Health Privacy Issues for Researchers

Basics of Information Security, Part 1

Basics of Information Security, Part 2

Research Privacy & Security Training (BCM & Texas)

NIH Training: Which courses are required?

All investigators and staff on NIH-funded protocols, who are involved in the conduct, oversight, or management of clinical trials should be trained in GCP, consistent with the principles of the International Conference on Harmonisation (ICH) E6 (R2).

- Good Clinical Practice (ICH focus)
- Good Clinical Practice (U.S. FDA focus)
- GCP FDA refresher

Other

- RCR Course for PI and admin contact listed in BRAIN

Baylor College of Medicine

RESEARCH

WHAT HUMAN SUBJECT PROTECTIONS TRAINING IS REQUIRED?

<u>Reminders:</u>

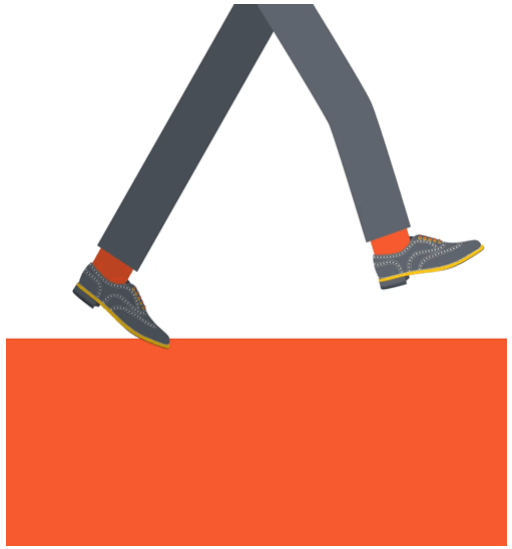
- Don't forget to affiliate with BCM inside CITI
- Need more info about CITI? Instructions on accessing the site?

  BCM Intranet < Admin Offices < Human Subject Research < Detailed IRB Information < FAQs: On-Line Training
- Contact IRB Administrator Amara Azobu for CITI questions

Baylor College of Medicine

RESEARCH

TO ASSURE THE QUICKEST REVIEW:



- Make sure you have thoroughly read the protocol prior to attempting a submission. Ask questions of the sponsor if any areas are unclear.
- Include clear, precise information; no fillers!
- Answer all questions completely
- Cutting & pasting parts from the full protocol or grant can lead to choppy, incomplete information for the reviewers.
  - Please reread the information prior to submission
  - Please remember this is a protocol summary – non-scientist members of the IRB also must be able to understand

UNIT 5:

REVIEWS AFTER INITIAL IRB APPROVAL

Baylor College of Medicine

RESEARCH

TYPES OF IRB SUBMISSIONS

- New 
- Amendment
- Renewal
- Events and Problems
- Request for closure

Baylor College of Medicine

RESEARCH

- Inform the IRB of any change to an approved research protocol (considered an amendment) regardless of how minor it is BEFORE implementing.
- Exception: true emergencies 21 CFR 56.109

Baylor College of Medicine

RESEARCH

- Include in the Amendment Description Page:

  -Brief description of amendment

  -A rationale for the amendment

- Make any resulting changes to the rest of the protocol

- All other supporting documents must be attached to section S of the protocol.

Baylor College of Medicine

RESEARCH

TYPES OF IRB SUBMISSIONS

- New 
- Amendment 
- Renewal
- Events and Problems
- Request for closure

Baylor College of Medicine

RESEARCH

FULL BOARD CONTINUING REVIEW (RENEWAL)

- IRB approval period lasts no longer than 365 days.
  - A lesser approval period can be determined
  - Consent documents in BRAIN have a time and date stamp of approval
- Continuing review must be completed prior to expiration of the protocol
  - BRAIN begins to notify the principal investigator and/or study staff 120 days prior to expiration.
  - A closure letter will be generated if the study expires
  - If the approval period lapses, all research activity must stop, unless the IRB approves a request to continue follow-up for safety purposes
  - Federal regulations make no provision for any grace period extending the conduct of research beyond the expiration date of IRB approval

EXPEDITED CONTINUING REVIEW (RENEWAL)

- A revised version of the Common Rule went into effect on January 21, 2019, which eliminated the **Continuing Review for research reviewed under <u>Expedited Procedures</u>.**
  - Decrease burn of IRB review for investigators
  - Implementation at BCM occurred in November 2020 for new studies and January 2021 for existing qualifying protocols
- The following types of studies no longer need to go through annual Continuing Review.
  - Studies whose initial application was reviewed by the Expedited Review process and continue to meet expedited criteria.
  - Research that has progressed to the point that it involves only one or both of the following, which are part of the IRB-approved study:
  - Data analysis (including analysis of identifiable private information or identifiable biospecimens), and/or
  - Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.
  - Instead, the Principal Investigator will only need to complete an administrative "check-in" for these studies at 5-year intervals.

Baylor College of Medicine

RESEARCH

EXPEDITED CONTINUING REVIEW (RENEWAL) CONT'D

- Are there exceptions?
  - Yes. This does not apply to studies that are:
    - Food and Drug Administration (FDA) regulated
    - Funded by the Federal Department of Justice

- How will this change affect my IRB-approved study?
  - New Studies
  - All new studies approved through Expedited procedures **on or after November 23, 2020** will not require continuing review in the future.

- Existing Studies
  - Studies approved **before November 23, 2020** that met expedited approval criteria when approved, will be converted to 5 year "check in" at the time of their next scheduled continuing review.

Baylor College of Medicine

RESEARCH

EXPEDITED CONTINUING REVIEW (RENEWAL) CONT'D

- At the time of continuing review, the PI will be required to make the following modifications:
  - Respond to the new biospecimen questions in the BRAIN protocol summary **Section K** and **J1** as applicable
  - Respond to the new question in **Section J1a** on research among members of a distinct cultural group or community in which signing forms is not the norm (if applicable)
  - If your protocol has a consent form, you will be required to include these new sections and elements for consent:
    - Complete section **Qa1**- Concise and focused presentation
    - Respond to questions regarding identifiable information, biospecimens and clinically relevant results in **Section Qc**
    - Respond question regarding cell lines in Section **Qk**

You will receive a notification **120 days before your renewal is due**; you might wish to begin work promptly on the consent form changes to avoid submitting the renewal too close to the deadline.

Baylor College of Medicine

RESEARCH

EXPEDITED CONTINUING REVIEW (RENEWAL) CONT'D

Things to Note:

- These changes ONLY apply to studies approved through Expedited Review procedures. Studies approved by the fully convened board still require annual continuing review.
- Even for expedited studies not requiring continuing review:
  - ALL changes to study procedures or informed consent documents must be still submitted to the IRB as an amendment for review and approval prior to implementation unless the change is necessary for the safety of subjects.
  - Reconsenting of subjects will not be required for these changes.
  - You must inform the IRB of unanticipated problems involving risks to subjects or others (UPIRSO) encountered during the study or of any new and significant information that may impact the research.
  - Principal Investigators must comply with the **5 year check-in** when required.

Baylor College of Medicine

RESEARCH

WHAT INFORMATION IS REQUIRED?

Study progress during the last approval period:

- ✓Detail the number of subjects enrolled
- ✓Summarize monitor findings
- ✓Attach any DSMB reports to section S
- ✓Report the current phase of the study in the Protocol Status section.
- ✓Include any new information
- ✓Summarize the progress of the study in the General Summary section.
- ✓Detail any increased risks during the last approval period that can or has modified the Risk/Benefit Ratio.

CONTINUING REVIEW, CONTINUED

- An amendment can be incorporated into the renewal & reviewed as part of the submission.

  HOWEVER…

- Briefly outline changes in the "new information" or “general summary” section of the renewal form.

  HOWEVER…

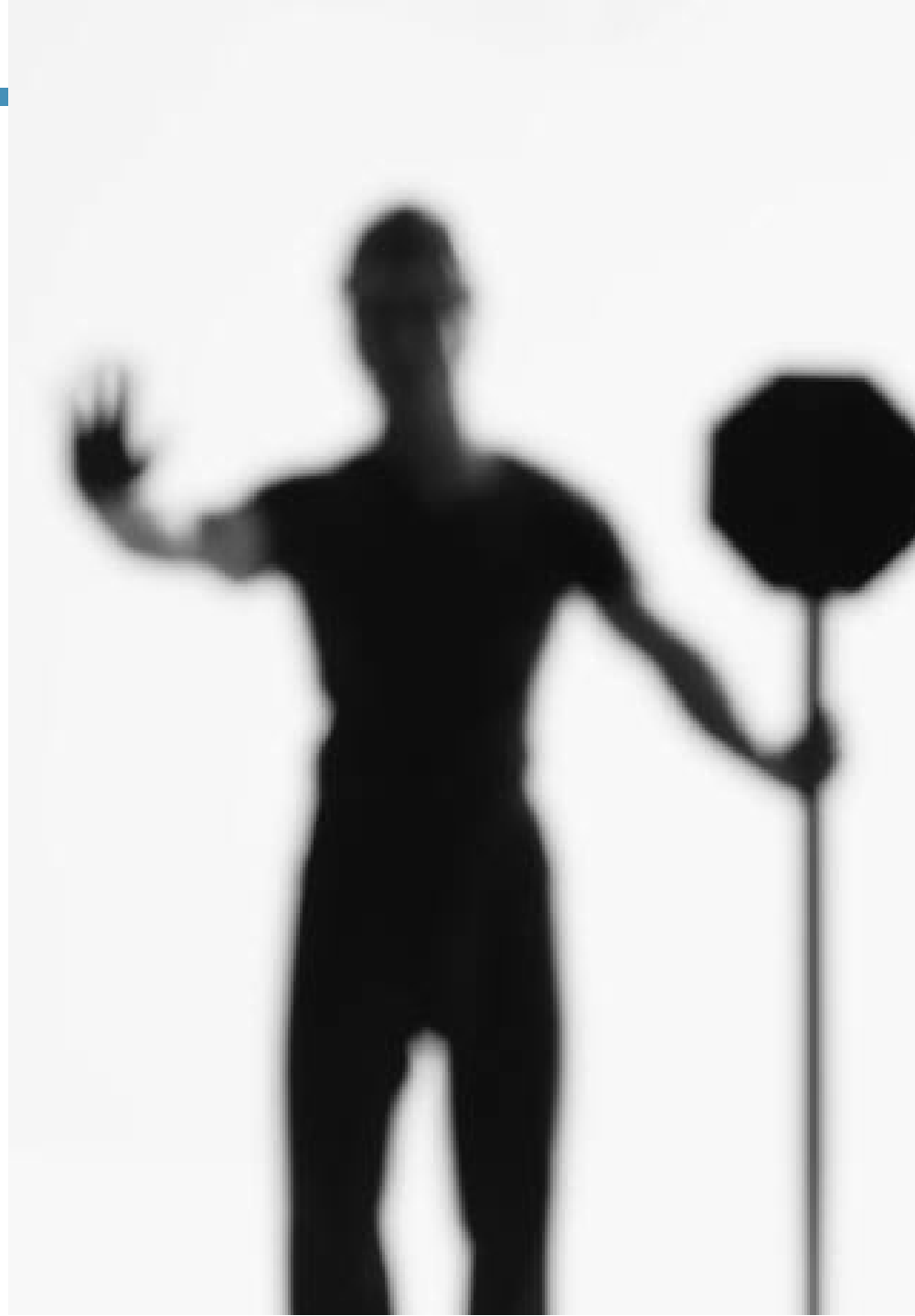
Baylor College of Medicine

RESEARCH

IF A PROTOCOL EXPIRES OR LAPSES…

All research activities must

stop.



Baylor College of Medicine

RESEARCH

IF A PROTOCOL EXPIRES OR LAPSES PRIOR TO CREATING A RENEWAL…

- Reinstate the protocol by creating a new submission:

  -In the title of the protocol, indicate (FORMERLY H-XXXX)

- In the background section of the protocol summary:
  - Include the previous IRB protocol number
  - Explain he purpose for the reinstatement

- Provide renewal information on the Renewal Information Template [.doc] as an attachment in section S.

Baylor College of Medicine

RESEARCH

TYPES OF IRB SUBMISSIONS

- New 
- Amendment 
- Renewal 
- Events and Problems
- Request for closure

Baylor College of Medicine

RESEARCH

UNANTICIPATED PROBLEMS INVOLVING RISKS TO SUBJECTS/OTHERS (UPIRSO

Stay tuned! There is a section coming up…

PROTOCOL DEVIATIONS

UPIRSO

OR

Renewal

Deviation is defined in the

BCM Human Research Protections manual

Baylor College of Medicine

RESEARCH

TYPES OF IRB SUBMISSIONS

- New 
- Amendment 
- Renewal 
- Events and Problems 
- Request for closure

Baylor College of Medicine

RESEARCH

CLOSURES

- The IRB must be notified promptly, via BRAIN, when a research study has been completed, closed, or is inactive.
- Protocols should only be closed if all subject intervention/interaction have been completed.
- All queries should be complete
- BRAIN will present you with a text box for summary

WHAT INFORMATION SHOULD I PROVIDE TO THE IRB?

- Number of subjects (charts, records or specimens) studied.
- Report any results.
- If no research subjects, indicate no subjects.

Baylor College of Medicine

RESEARCH

QUESTION

What do you do with deviations that do not meet criteria for prompt reporting?

- Ignore them – they don't matter
- Report to the IRB at renewal
- Email them all to the IRB and file the email in your binder

Baylor College of Medicine

RESEARCH

Unit 6: Event Reporting Required of Investigators

WHAT ARE UNANTICIPATED PROBLEMS?

- Fed regs require prompt reporting of any unanticipated problems involving risks to subjects or others (UPRISO) – although the phrase is not defined in either HHS or FDA regs.

➢ **OHRP provides the following criteria for meeting the definition of a UPIRSO:**

1. **Unexpected** in nature, severity or frequency given the procedures in the protocol-related documents and consent form(s) and the characteristics of the study population

2. **Related** or possibly related to participation in the research

3. Places subjects or others at a **greater risk** of harm (physical, psychological, economic, social) than what was previously known or recognized

➢ If the event, in the opinion of the PI meets all the above-mentioned criteria, then the PI is required to report to the IRB within **5-business days.**

WHAT ARE UNANTICIPATED PROBLEMS?

- OHRP: events meeting these three criteria will likely result in substantive changes

- FDA: requiring a significant, and usually safety-related, change in the protocol such as revising inclusion/exclusion criteria or including a new monitoring requirement, informed consent, or investigator's brochure).

WHAT ARE SOME SUBSTANTIVE CHANGES THAT MAY BE REQUIRED?

- Changes initiated by the PI without IRB approval in order to eliminate hazards to subjects
- Modification of inclusion/exclusion criteria
- Implementation of additional monitoring procedures
- Suspension of enrollment of new subjects
- Modification of consent form with newly recognized risks

WHAT ARE ADVERSE EVENTS?

- Non-VA research: An undesirable and unintended, although not necessarily unexpected, result arising during the course of a research protocol

- VA research: Any untoward physical or psychological occurrence in a human subject participating in research.

UPIRSO: COMPONENT #1: DETERMINING WHETHER THE EVENT IS UNANTICIPATED

- The nature, severity, or frequency is not consistent with:
  - Protocol documents (including Investigator's Brochure)
  - IRB approved consent form
- Other relevant sources of info (such as product labeling and package inserts)
- The expected natural progression of any underlying disease, disorder or condition of the subject(s) experiencing the event

WHAT DOES THE FDA SAY?

- In general, an AE observed during the conduct of a study should be considered an UPIRSO, and reported to the IRB, only if it were:

- Unexpected, serious, and would have implications for the conduct of the study

- An individual AE occurrence ordinarily does not meet these criteria because its implications for the study cannot be understood.

https://www.fda.gov/media/72267/download

Baylor College of Medicine

RESEARCH

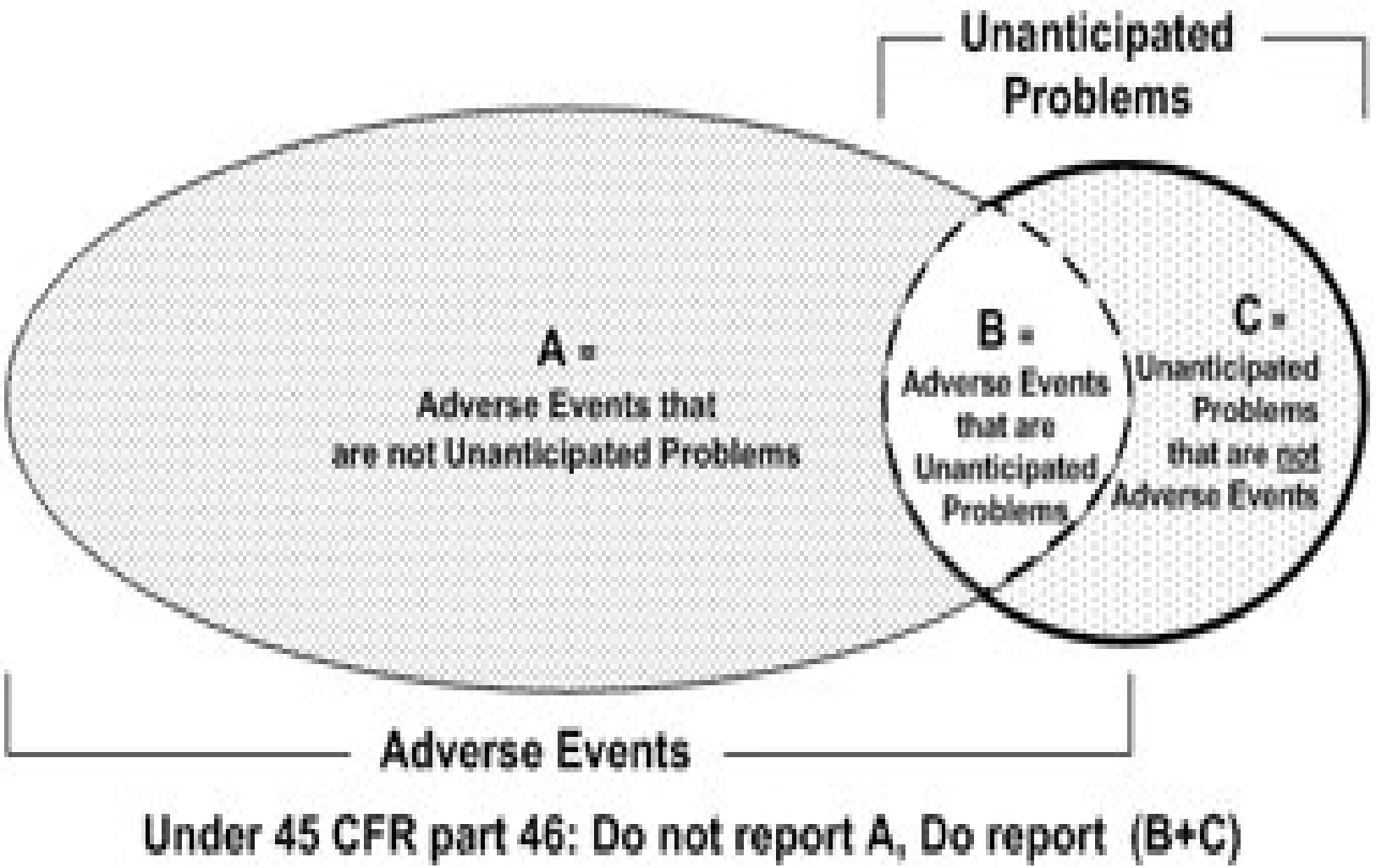
UPIRSO: COMPONENT #2: DETERMINING WHETHER THE EVENT IS RELATED OR POSSIBLY RELATED TO PARTICIPATION IN THE RESEARCH

- Adverse events at least partially caused by the procedures involved in the research

- How does OHRP define possibly related to research?
  - There is a reasonable possibility that the adverse event may have been caused by the procedures involved in the research

UPIRSO: COMPONENT #3: DETERMINING WHETHER THE EVENT SUGGESTS THAT THE RESEARCH PLACES SUBJECTS OR OTHERS AT A GREATER RISK OF HARM THAN WAS PREVIOUSLY KNOWN OR RECOGNIZED

- death
- life threatening
- Inpatient hospitalization or prolongation of existing hospitalization
- Persistent or significant disability/incapacity
- Congenital anomaly/birth defect
- May jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition
- Suggests that the research places one or more participants or others at a greater risk of harm (including physical, psychological, economic, or social harm). Unanticipated problems include other incidents, experiences, and outcomes that are not adverse events



Under 45 CFR part 46: Do not report A, Do report (B+C)

Baylor College of Medicine

RESEARCH

QUESTION

Scenario: A subject participates in a myeloma study. The subject then develops neutropenia and sepsis. Then the subject subsequently develops multi-organ failure and dies. Neutropenia and risk of life-threatening infections is a known complication of the regimens being tested in this clinical trial and these risks are described in the IRB-approved protocol and informed consent document.

The PI determines:

- The subject's infection and death are directly related to the research interventions.
- A review of data on all subjects enrolled so far reveals that the incidence of severe neutropenia, infection, and death are within the expected frequency.

- Question: Is this event an unanticipated problem needing to go to the IRB within 5 days?

EXAMPLE OF UNANTICIPATED PROBLEMS INVOLVING RISKS TO SUBJECTS OR OTHERS THAT WOULD *NOT* BE CONSIDERED ADVERSE EVENTS

- An investigator conducting behavioral research collects individually identifiable sensitive information about illicit drug use and other illegal behaviors by surveying college students. The data are stored on a laptop computer without encryption, and the laptop computer is stolen from the investigator's car on the way home from work.

- ADVERSE EVENT? No, not an untoward or unfavorable medical occurrence in a human subject

- UPIRSO? Yes, because the incident was (a) unexpected (i.e., the investigators did not anticipate the theft); (b) related to participation in the research; and (c) placed the subjects at a greater risk of psychological and social harm from the breach in confidentiality of the study data than was previously known or recognized.

Baylor College of Medicine

RESEARCH

SUBMITTING THE EVENT REPORT TO THE IRB

WHAT TO INCLUDE IN YOUR REPORT TO THE IRB

- Detailed description of the event
- Explanation of the basis for determining that the event represents an unanticipated problem involving risks to subjects or others
- Description of the changes to the protocol or consent form that have been taken or will be proposed

Baylor College of Medicine

RESEARCH

WHAT TO INCLUDE IN YOUR REPORT TO THE IRB

- DSMB findings regarding the event
- The number of subjects currently enrolled
- The number of subjects to whom the drug has been given
- Any steps taken by the PI to eliminate apparent hazard to subjects, including providing subjects with new risk information

Baylor College of Medicine

RESEARCH

BCM REQUIRED EVENT REPORTING

OTHER EVENTS THAT ARE REQUIRED TO BE REPORTED PER BCM POLICIES

- Changes made to the research protocol without prior IRB review to eliminate apparent immediate harm to a research participant(s)
- Any event that requires prompt reporting according to the research protocol or plan or the sponsor
- Any accidental or unintentional change to the IRB-approved research protocol or plan that involved risks or has the potential to recur.
- Any publication in the literature, safety monitoring report, interim result, or other finding that indicates an unexpected change to the risks or potential benefits of the research

OTHER EVENTS THAT ARE REQUIRED TO BE REPORTED PER BCM POLICIES

- Any complaint of a participant that indicates unanticipated risk or that cannot be resolved by the research team
- Protocol violation (meaning an accidental or unintentional change to the IRB approved protocol) that placed one or more participants at increased risk, or has the potential to occur again
- Any instance of non-compliance including PI self reports
- Any suspension or termination of research approval

Baylor College of Medicine

RESEARCH

OTHER EVENTS THAT ARE REQUIRED TO BE REPORTED PER BCM POLICIES

- Unanticipated adverse device effect or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.)

- Unauthorized disclosure of Protected Health Information (PHI) or breach of electronic security (these events should concurrently be reported to the BCM Privacy Officer and IT Security)

SPECIAL REPORTING REQUIREMENTS

- Research relying on an external IRB

- VA regulated research

For more information: BCM HRP manual, Page 152

http://www.va.gov/vhapublications/publications.cfm?pub=2 (1058.01 handbook)

http://www.va.gov/ORO/Docs/Guidance/1058_01_Decision_Chart_Rsch_Death_SAE_Problem_09_14_2015.pdf

Baylor College of Medicine

RESEARCH

Baylor College of Medicine

RESEARCH

HOW ARE THE EVENTS REVIEWED BY THE IRB?

IRB REVIEW OF EVENTS

- An experienced IRB member will review event reports submitted by investigators to determine whether the event is an UPIRSO:
- Was unanticipated/unexpected/unforeseen,
- Places a person or others at increased risk of harm than was previously known or recognized, and
- Was related to or possibly related to the research procedures.

Baylor College of Medicine

RESEARCH

IRB REVIEW OF EVENTS

- The reviewer(s) determine(s) that the event does not meet the UPIRSO criteria no further action is taken.

- If the experienced IRB member and IRB Chair/designee believe that the event(s) report may meet the UPIRSO criteria, the event is reviewed under the primary reviewer system (see Primary and Team Reviewers, Research Materials). The IRB will determine whether each event is an UPIRSO.

- OHRP Guidance

  http://www.hhs.gov/ohrp/policy/advevntguid.html

- FDA Guidance
  https://www.fda.gov/media/72267/download

- VA Regulated Research sources of information
  - VHA handbook 1200.05
  - VHA handbook 1058.01
  - BCM Human Research Protections Manual

Baylor College of Medicine

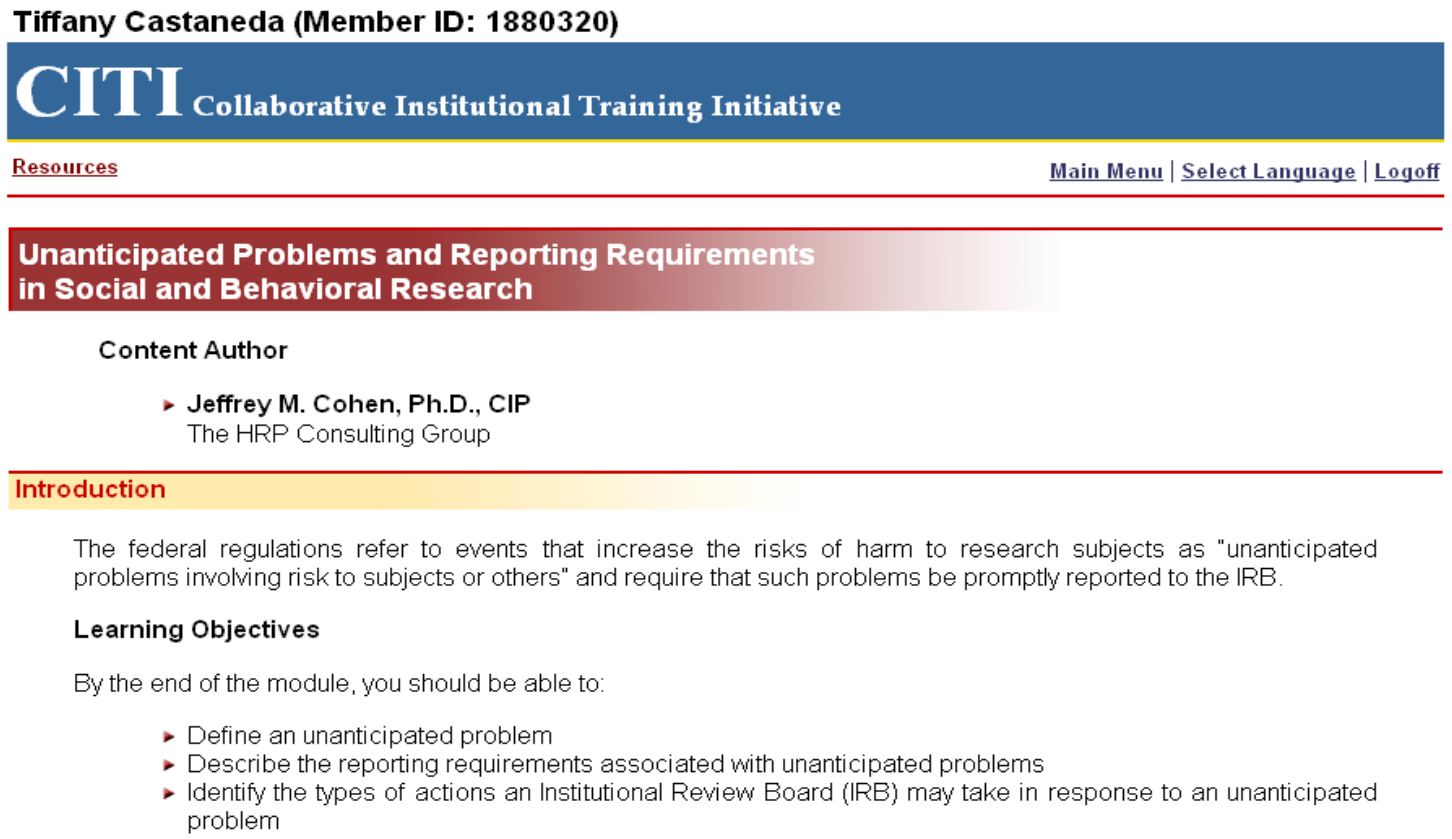
RESEARCH

Baylor College of Medicine

RESEARCH

CITI Training Online

"Unanticipated Problems and Reporting Requirements in Social and Behavioral Research"



Tiffany Castaneda (Member ID: 1880320)

CITI Collaborative Institutional Training Initiative

Resources

Main Menu | Select Language | Logoff

Unanticipated Problems and Reporting Requirements in Social and Behavioral Research

Content Author

- **Jeffrey M. Cohen, Ph.D., CIP**
  The HRP Consulting Group

Introduction

The federal regulations refer to events that increase the risks of harm to research subjects as "unanticipated problems involving risk to subjects or others" and require that such problems be promptly reported to the IRB.

Learning Objectives

By the end of the module, you should be able to:

- Define an unanticipated problem
- Describe the reporting requirements associated with unanticipated problems
- Identify the types of actions an Institutional Review Board (IRB) may take in response to an unanticipated problem

Baylor College of Medicine

RESEARCH

UNIT 7: THE WORLD OF RELIANCE

DEFINITIONS

- **Reliance Agreement**: A reliance agreement (also called an IRB Authorization Agreement) is a document signed by two or more institutions engaged in human subjects research that permit one or more institutions to cede review to another IRB. The signed agreement permits a single IRB to review human subject research activities for more than one site
- **Single IRB Review**: a legal arrangement that allows one IRB to review the research on behalf of other engaged institutions.
- **IRB of Record**: the IRB that reviews and makes required regulatory determinations (Reviewing IRB)
- **Relying Institution**: institution that cedes IRB responsibilities to the IRB of Record

RELIANCE AGREEMENTS – WHAT ARE THE BENEFITS?

- Streamlines the review process for multi-site research
- Faster processing times means more competitive enrollment
- Makes BCM more competitive in bringing sponsored research to our Institution

CURRENT RELIANCE MANDATES

- As of February 1, 2017: All BCM industry sponsored drug/device/biologic studies are required to be reviewed by a commercial IRB

- Beginning January 25, 2018, all NIH-funded multi-site studies involving non-exempt human subjects research are required to utilize a single IRB-of-Record (sIRB) for the review of human subject protections

- Beginning January 20, 2020, the new common rule regulations at 45 CFR Part 46.114 require that any institution located in the United States that is engaged in cooperative research must rely upon approval by a single IRB for that portion of the research that is conducted in the United States.

COMMERCIAL IRBS

- Advarra IRB
- Biomedical Research Alliance of New York (BRANY IRB)
- Western IRB

Baylor College of Medicine

RESEARCH

IRB RELIANCE PLATFORMS – SINGLE IRB REVIEW

Smart IRB

Smart IRB is funded by the National Center for Advancing Translational Sciences (NCATS) and is intended to serve as a roadmap for institutions to implement The National Institutes of Health (NIH) Policy on the Use of a Single Institutional Review Board for Multi-Site Research. The list of institutions signed on is continually updated. 842 institutions as of February 2021.

- To be used when BCM is serving as the IRB of Record

IRB Reliance Exchange (IREx)

IREx is a tool used to facilitate the single IRB review process that is distinct from, but can be used with, the SMART IRB agreement. IREx can also be used to support other reliance agreements. The list of institutions signed on is continually updated. 370 institutions as of February 2021.

Baylor College of Medicine

RESEARCH

Baylor College of Medicine

RESEARCH

ARE THERE STILL FEES?

YES!

- A big bulk of the burden is with the post approval monitoring and everything that happens after IRB approval. The BCM fees cover:
  - Administrative costs
  - Costs of maintaining compliance for reliance protocols.
    - In a reliance situation, BCM is still primarily responsible for safeguarding the rights and welfare of each research participant (in fact, our accrediting body AAHRPP requires that our reliance agreements which we enter into to specifically state that BCM is primarily responsible for this).
  - Compliance monitoring
    - BCM is also still responsible for compliance monitoring (many times done on behalf of the IRB of record as the commercial IRBs are located in Seattle, NY, etc.) and compliance regarding conflict of interest (since BCM investigators must still abide by BCM's conflict of interest policy).
  - Education
    - BCM would also still be responsible for the education and continuing education of researchers and research staff.

REMINDER: RELIANCE WEBSITE

- The Reliance website is updated as new agreements are signed
  - Forms and consent boilerplate page
  - Submission Process page
    - Contains updated list of signed agreements
    - Also contains boiler plate language for consents (Commercial IRB)
  - HRP Manual link: https://intouch.bcm.edu/documents/preview/4046/Human-Research-Protections-Manual
    - BCM's SOP for Designating an External IRB link – pg 26
    - Cooperative Research – pages 27 - 29
    - Single IRB – pg 30 - 31
  - Note: The VA has an agreement with WIRB and Advarra. For additional information please email VAHOUprojectsubmissions@va.gov.

Baylor College of Medicine

RESEARCH

Baylor College of Medicine

RESEARCH

RELIANCE WEBSITE

RELIANCE WEBSITE

- Graphic Communications/Document Center
- Media Relations
- Web Management

Compliance and Audit Services

- Audit Services
- Corporate Compliance Program
- Code Of Conduct
- Integrity Hotline and Web Portal
- Coding and Documentation
- HIPAA Compliance Program
- Privacy and Security
- Government Investigations
- Baylor Excluded Parties

Philanthropy and Alumni Relations

- Giving
- Payroll Deduction (BCM log-in required)

Environmental Safety

- Biological Safety
- Chemical Safety
- Safety Compliance & Training
- Emergency & Disaster Response
- Occupational Safety
- Radiation Safety

- Accounting
- BCM Wellness Center
- Budgets
- Fast Card
- Food Services
- General Services
- Grants & Contracts
- Mail Services
- Parking & Commuter Services
- Receiving/Shipping
- Shuttle Services
- SRM/MarketPlace
- Supply Chain Management
- Travel Services

General Counse

- Security
- Risk Management
- Clery Crime Log

Human Resources

- Benefits
- BCM BeWell Program
- Compensation
- Employment
- Employee Relations
- International Services

Clinical Operations

- Patient Business Services
- Patient Experience
- Epic Solutions

Office of Research

- VIICTR
- BRAIN
- Institutional Animal Care and Use Committee
- Institutional Biosafety Committee
- Institutional Review Board for Human Subject Research
- Institute for Clinical and Translational Research
- Reliance on External IRBs
- Committee on Scientific Integrity
- Research Conflict of Interest Committee
- Research Compliance
- Intramural Funding and Awards
- Sponsored Programs
- Research Resources
- Baylor Licensing Group
- Center for Comparative Medicine
- MEDVAMC - BCM Dual Appointments of Investigators
- VA Research and Development

Baylor College of Medicine

RESEARCH

Reliance on External IRBs

Baylor College of Medicine may consider relying on an external institutional review board for review and approval of human research, if such reliance benefits BCM, its affiliated institutions/hospitals, its investigators or research participants. Possible external IRBs include those of other institutions and organizations, and independent commercial IRBs.

The decision for BCM to rely on an external IRB is made on a case-by-case basis by the Director of Research Oversight and the Institutional Official. It is BCM's preference that an external IRB on which BCM relies be accredited by the Association for the Accreditation of Human Research Protection Programs (AAHRPP). BCM may rely upon an IRB that is not AAHRPP-accredited and in that case will require that the institution must have undergone or have initiated an assessment of the quality of its human research protection program ("HRPP"). Such assessment must have occurred or have been initiated within the past (5) years prior to the institution joining the Agreement. The assessment may be accomplished by accreditation through an external organization, or through OHRP's Quality Assessment Program, or other equivalent approach.

Examples of when such reliance may be considered include:

- Multi-site research in which a BCM faculty member or employee is involved as a collaborator in a research protocol approved by a non-BCM IRB.
- Phase I, II, III or IV multi-site, industry-initiated, industry-sponsored research.
- Federally-sponsored cooperative research studies.

Questions? Contact Us
Direct any questions to reliance@bcm.edu or call 713-798-6970.

Forms and Consent Boilerplate Language

Submission Process

IRB Reliance Platforms

Submission Process for the UT System Master Reciprocity Agreement

Human Research Protections Manual

Institutional Designation of an IRB

BCM Procedure on Reliance on External IRBs

VA Reliance on External IRBs

« Navigation

- Research Home
- Calendar
- News
- Training
- BRAIN
- Human Subject Research
- Animal Research
- Laboratory Research and Services
- Research Funding
- Financial Conflict of Interest in Research
- Research Compliance Services
- Office of Clinical Research
- Institute for Clinical and Translational Research
- Institutional Dual Use Research of Concern Committee
- Trade Control

Contact Us
Documents & Forms
Policies & Procedures

What are the general steps for requesting reliance for a particular study?

#1: Check the Reliance Website to make sure:

- Make sure your study meets the criteria for using the external IRB

#2: Complete a reliance request form (provide link) and provide the following via e-mail to reliance@bcm.edu:

- The human protocol draft in BRAIN (ESP1)
- The proposal number for the funding for the study (ESP2)

QUESTIONS?

Possible situations:

1. You have an upcoming NIH-funded multi-site project with *X* many institutions participating
2. You have a currently funded NIH-funded multi-site project with *X* many institutions participating and your competing renewal is coming up
3. An institution you are working with has asked you for a reliance agreement (sometimes they are called institutional authorization agreements)
4. Your PI has asked you if we have a reliance agreement with X institution

https://bcm.app.box.com/s/b5wewh9hfg3he0za1ycvm87ri34xbav9

Call or email reliance@bcm.edu

Baylor College of Medicine

RESEARCH

THANK YOU! QUESTIONS?