RESEARCH INVESTIGATOR WORKSHOP – DAY 2

MANAGING HUMAN SUBJECTS RESEARCH AT BAYLOR COLLEGE OF MEDICINE

Provided by:

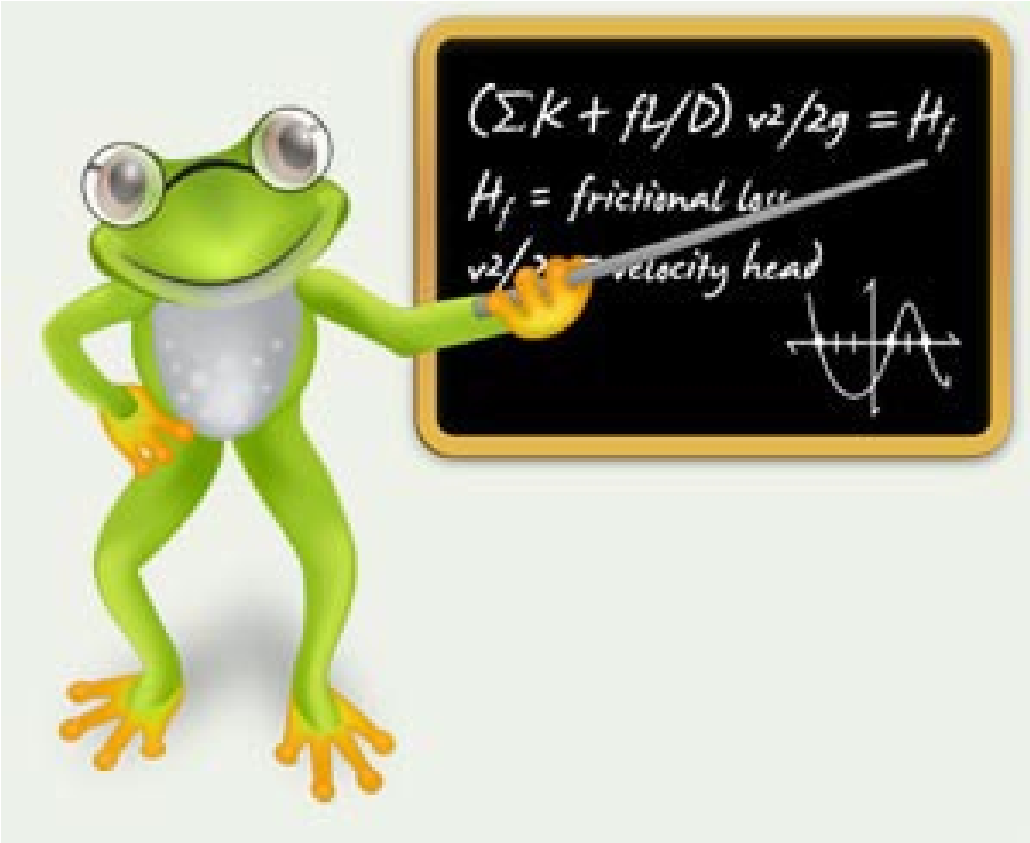
1. Research Compliance Services
https://intouch.bcm.edu/sites/research/SitePageModern/4129/reporting-research-compliance-concerns

AND

2. Institutional Review Board:
Research - Institutional Review Board for Human Subject Research (bcm.edu)

Baylor College of Medicine

WELCOME!!



POLL: WHO IS IN OUR AUDIENCE?

What is your role in research?

- PI
- Coordinator (Research/Regulatory)
- Other

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 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 for documentation of research and study monitoring
- Provide training and address requirements for ClinicalTrials.gov registration
- Discuss Investigator Initiated Trials and Expanded Access
- Discuss the importance of Good Clinical Practice

UNIT I: DOCUMENTATION AND STUDY MONITORING

REGULATORY REQUIREMENTS FOR STUDY RECORDS

- How long must study records be kept?
  - OHRP: 3 years after the study is complete
  - FDA: 2 years after the latter of the following dates:
    - The date on which the study is terminated, OR
    - The date the records are no longer needed for purposes of supporting a pre-market approval application or a notice of completion of a project development protocol
  - VA: 6 years after the study is complete
- Note: It is important to determine from the study sponsor how long they want to records of each study kept. The retention requirement may be longer than the minimum required by the FDA.
- Also, make sure that storage fees will be covered by the sponsor!

"RECORDS" INCLUDES ALL DOCUMENTS RELATED TO THE STUDY, SUCH AS:

- Research protocols
- Grant Applications
- Investigator Brochures
- All correspondence with the IRB
- Original data (source documentation such as lab tests)
- Case report forms, (FDA requires these to be signed and dated by the PI, attesting to the authenticity and accuracy of the data)
- Signed consent/assent documents
- Test article subject dispensing records
- Telephone contact logs

MONITORING

- Data and Safety Monitoring
- Sponsor/Contract Research Organization/Funding Agency
- Federal agencies
- Institutional Review Board

DATA AND SAFETY MONITORING

- For the IRB to approve research, the research plan must make adequate provision for monitoring the data collected to ensure the safety of subjects. 45 CFR 46.111(a)(6)

- This plan should be included in the IRB protocol submission

SPONSOR/CONTRACT RESEARCH ORGANIZATION/FUNDING AGENCY

- A sponsor shall select a monitor qualified by training and experience to monitor the progress of the investigation. (21 CFR 312.53(4)(d); 21 CFR 812.43 (d))

- The sponsor should ensure that the trials are adequately monitored.

- The sponsor should determined the appropriate extent and nature of monitoring. The determination of the extent and nature of monitoring should be based on considerations, such as the objective, purpose, design, complexity, blinding, size, and endpoints of the trial. (ICH GCP E6 5.18.3)

FEDERAL AGENCIES

- Examples: FDA, OHRP, VA
- Federal agencies may inspect research it oversees by monitoring (for-cause or not-for-cause):
  - Investigators
  - Sponsors/CROs
  - IRBs
  - Nonclinical Laboratories

- Based on findings, administrative/corrective actions may be required. Significant findings by a federal agency may result in significant actions, up to and including suspension of research, disqualification of investigators, and Institutional ramifications.
- Outcomes should be reported to the IRB and all entities required by the sponsor.

RESEARCH COMPLIANCE

- In accordance with 45 CFR 46.103, the BCM IRBs have the responsibility and authority to oversee the use of human subjects in research that is under their jurisdiction.

- BCM is required by law to report any instances of serious and/or continuing noncompliance

TYPES OF IRB ASSESSMENTS

- Routine Monitoring
- For-Cause Assessment
- PI-Initiated Requests for review

IRB COMPLIANCE DEFINITIONS

Non-compliance: conducting research involving human subjects in a manner that violates federal regulations or institutional policies governing such research

**Serious non-compliance: violations that have or pose greater than minimal risk of harm or discomfort to research participants or others involved in the research

**Continuing non-compliance: A pattern of non-compliance that has the potential to compromise human research protections.

** - reportable to federal agencies and sponsors

RESEARCH COMPLIANCE STEPS

- Initiation – IRB Administrator selects protocols to be monitored from varying risk levels and complexities
- Notice of Assessment
- Preliminary Review
- Research Intermediary Conducts Assessment (interviews, review of research records, etc.)
- Research Intermediary Drafts Report
- Draft Report sent to PI
- Final report/corrective actions communicated to PI by RCS
- Final report presented to IRB
- RCS follow-up
- Appeal opportunity
- Communication with authorities

ROUTINE MONITORING COMMON FINDINGS

- Informed consent forms:
  - forms reviewed were without signatures or dates as required
- Documentation of Qualifications/Training
- Over-enrollment
- Protocol not conducted as approved

FOR-CAUSE MONITORING

- Noncompliance reports can come from a number of different sources, including:
  - Investigators - Research Personnel
  - Oversight committees - IRB staff members
  - Subjects/family - Institutional personnel
  - The media -The public
  - Anonymous sources

- <u>Reporting a Concern:</u>

  Verbal or written reports may be made to either of the following:

  - IRB administrator – Amara Azobu
  - Research Compliance Services (RCS)

    researchcomplianceservices@bcm.edu

Baylor College of Medicine prohibits retaliation against any employee for reporting or pursuing grievances.

PI-INITIATED REQUEST FOR REVIEW

A PI can also initiate an assessment of his/her own research

- If a compliance concern comes up during the course of the study
- This may be recommended by IRB staff in certain circumstances

PRIVACY OVERVIEW

What is PHI?

- Individually identifiable health information (IIHI)

  AND

- Transmitted or maintained in any form or medium (i.e., verbal, paper or electronic)

What is IIHI?

- Information that relates to past, present or future physical or mental health or condition; healthcare; or payment for healthcare

  AND

- Identifies an individual or can reasonably can be used to identify

  AND

- Created or received by a covered entity (healthcare provider, health plan, or clearinghouse)

PROTECTED HEALTH INFORMATION (PHI)

- Name
- All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes,
- All elements of dates (except year) for dates directly related to an individual
- Telephone numbers
- Fax numbers
- Electronic mail addresses
- Vehicle identifiers and serial numbers, including license plate numbers
- Social security numbers
- Medical record numbers
- Health plan beneficiary numbers
- Account numbers
- Certificate/license numbers
- Full face photographic images and any comparable images
- **Any other unique identifying number, characteristic, or code and the covered entity has no reasonable basis to believe it can be used to identify an individual.**

DE-IDENTIFIED PHI

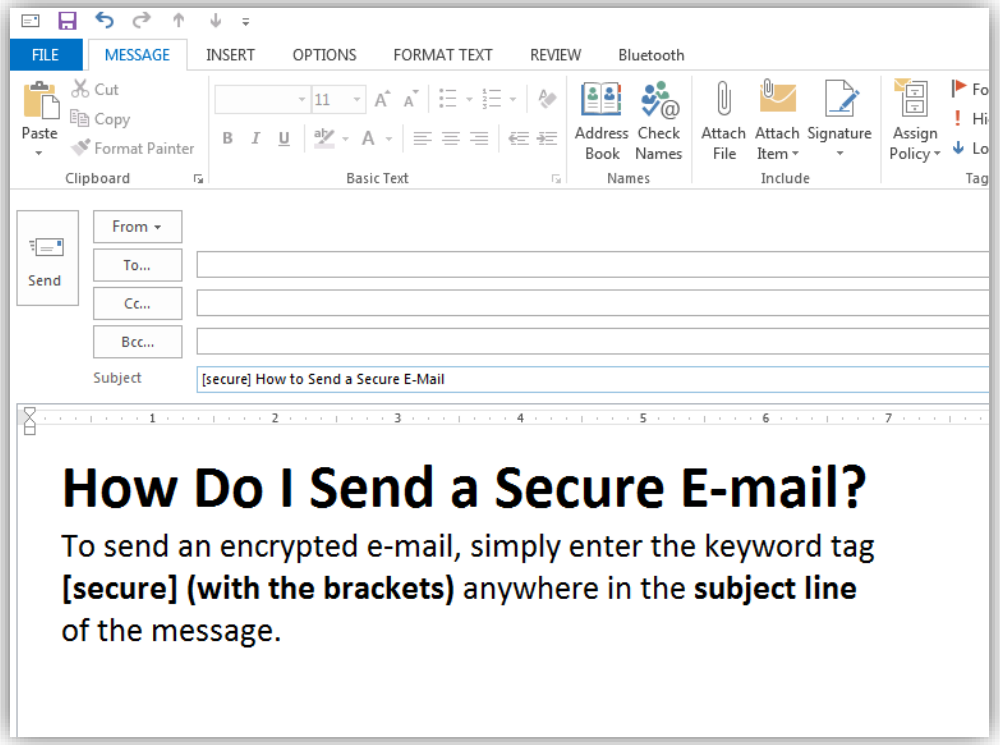
- Information that cannot be used to identify an individual is not protected.
- How to de-identify information:
  - Hire an expert to determine that information to be used or disclosed contains no identifying information.
  - Remove all specified identifying information.

ENCRYPTED MESSAGING (E-MAILS)

All members of the BCM Community are responsible for the protection of confidential information through the following security requirements:

Do use BCM encrypted secure messaging (e-mail) and websites to guard against unauthorized access to confidential information being transmitted. Google, DropBox, and other public internet sites may not be secure or encrypted.

DO NOT use non-BCM or non-affiliate institution e-mail or websites for BCM business, particularly for **collecting or maintaining confidential information.**



REPORTING VIOLATIONS

- **HIPAA Privacy Compliance**
  - privacycompliance@bcm.edu
- **HIPAA Privacy Incident Report Form**: BCM Intranet <Admin Offices <Compliance and Audit <HIPAA Compliance Program <Forms
- **Integrity Hotline**
  - Call 855-764-729 (toll free); OR
  - Submit a report online at: BCM Intranet < Admin Offices <Compliance and Audit <Integrity Hotline

UNIT 2: FDA REGULATED ACTIVITY

FDA REGULATIONS

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

FDA regulations are published in title 21 of the CFR. The following FDA human subject research regulations apply to the IRB and to University and Affiliate researchers conducting clinical trials, and research involving investigational drugs and devices:

- 21 CFR 50 Protection of Human Subjects (i.e. The Common Rule)
  21 CFR 56 Institutional Review Boards
  21 CFR 312 Investigational New Drug Application (IND)
  21 CFR 812 Investigational Device Exemptions (IDE)

OHRP VS. FDA

- The requirements of the FDA regulations differ from DHHS/Common Rule regulations as follows:
- Contain no Assurance requirement
- Define *human subject* and *clinical investigation* (*research*) differently
- Require specific determinations for the IRB review of device studies
- Have different conditions for exemption and waiver of IRB review and Informed Consent requirements
- Include specific requirements for reporting adverse events that are not found in the Common Rule or DHHS regulations
- Do not include specific additional protections for pregnant women, fetuses, and human neonates (Subpart B) and prisoners (Subpart C)

WHAT IS A SPONSOR?

A *sponsor*:

- Is usually a pharmaceutical, biotech, or medical device company
- Can be an individual or group of individuals
- Can be the investigator, called the sponsor-investigator when the individual investigator is also the initiator of the clinical investigation

SPONSOR RESPONSIBILITIES

The sponsor of a clinical investigation:

- Initiates and holds the IND or IDE for a clinical investigation
- Maintains the Biologics License, when applicable

May or may not actually conduct the investigation

INVESTIGATIONAL NEW DRUGS

- It is a requirement of the College that a decision be made regarding the applicability of IND requirements. This decision regarding the applicability of the IND requirements as well as the validity of the IND is to be made by the IRB.
- Drug – Any substance that is used to elicit a pharmacologic or physiologic response whether it is for treatment or diagnostic purposes.
- Biologic - A virus, serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or other similar product used to prevent, treat or cure disease or injury

WHEN IS AN IND REQUIRED?

An IND application is not necessary if ALL of the following seven drug criteria are met:

- The drug is lawfully marketed in the U.S.
- It is not intended to be reported to the FDA in support of a new indication for use or to support any other significant change in labeling of the drug; and
- It is not intended to support a significant change in the advertising of the product; and
- It does not involve a route of administration or dosage level, used in a subject population, or other factor that significantly increase the risks (or decreases the acceptability of the risks) associated with the use of the drug product; and
- It is conducted in compliance with the requirements for IRB review and informed consent 21 CFR, parts 56 & 50; and
- It is conducted in compliance with the requirements concerning the promotion and sale of drugs 21 CFR 312.7; and
- It does not intend to invoke 21 CFR 50.24 (Emergency Use)

Note: The Principal Investigator attests to these criteria being true. The IRB determines whether these criteria have indeed been met. The IRB reviews and approves the plan for storage, control and dispensing of the investigational drug.

IRB REVIEW OF DEVICE STUDIES

Study Type	Description
Significant Risk (SR) Device	A SR device study: • Presents a potential for serious risk to the health, safety, or welfare of a subject • Is one of the following: – Intended as an implant – Used in supporting or sustaining human life – Of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise prevents impairment of human health. • Requires: – Full IRB review – Full Board approval for all devices with an IDE number Reason: The FDA considers studies of all SR devices to present more than minimal risk.
Non-Significant Risk (NSR) Device	• A device study that does not meet the definition of a SR study • Some investigations involving Non-Significant Risk devices are considered to have approved applications for IDEs under the abbreviated requirements 21 CFR 812.2(b)

IRB REVIEW OF DEVICES

- The IRB may also request additional information if necessary from the sponsor or investigator or ask the FDA to provide a risk assessment.
- A device study that is deemed to involve a NSR may begin immediately since it would not require the submission of an application to the FDA. These clinical investigations involving Non-Significant Risk devices are considered to have approved applications for IDEs under the abbreviated requirements 21 CFR 812.2(b).

OFF LABEL USE OF APPROVED DRUGS OR DEVICES

When off-label use of a marketed product …	Then …
Is solely intended as the practice of medicine	Neither are required: • The IRB review • The submission of an IND or IDE
Is part of a systematic investigation designed to develop or contribute to generalizable knowledge	The IRB review is required.
Is intended to support a change in labeling	Both are required: • The IRB review • The submission of an IND or IDE

EMERGENCY USE OF UNAPPROVED DRUG OR DEVICE

- An exemption under FDA regulations at 21 CFR 56.104(c) permits the emergency use of an investigational drug, device, or biologic on a one-time basis per institution without IRB review and approval. This exemption allows for one emergency use of a test article without prospective IRB review. FDA regulations require that any subsequent use of the investigational product at the institution have prospective IRB review and approval.
- ***Note 1*:** The FDA acknowledges, however, that it would be inappropriate to deny emergency treatment to a second individual if the only obstacle is that the IRB has not had sufficient time to convene a meeting to review the issue.
- ***Note 2***: REPORT TO IRB WITHIN **5 DAYS**

EMERGENCY USE OF UNAPPROVED DRUG OR DEVICE

Even in an emergency use situation without IRB review and approval, the investigator is required to obtain informed consent from the subject or the subject's legally authorized representative.

The only exception is if both the investigator and a physician that is not otherwise participating in the clinical investigation (the treatment and medical care of the subject with the test article) certify in writing that ALL of the following conditions have been met for the emergency use of the test article without informed consent:

- The subject is confronted by a life-threatening situation necessitating the use of the test article, and,
- Informed consent cannot be obtained because of an inability to communicate with or obtain legally effective consent from the subject, and,
- Time is not sufficient to obtain consent from the subject's legally authorized representative, and,
- No alternative method of approved or generally recognized therapy is available that provides an equal or greater likelihood of saving the subject's life.

OTHER AREAS OF INTEREST

- Planned Emergency Research With Exception from Informed Consent:

https://www.fda.gov/downloads/regulatoryinformation/guidances/ucm249673.pdf

- Humanitarian Use Devices:

https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm110203.pdf

UNIT 3: EXPANDED ACCESS
(COMPASSIONATE USE)

DEFINITION AND TYPES

- Expanded access, sometimes called "compassionate use," is the use outside of a clinical trial of an investigational medical product (i.e., one that has not been approved by FDA)
- Types
  - Expanded Access to Investigational Medical Devices
  - Expanded Access to Investigational Drugs and Biologics
    - Expanded access for individual patients, including for emergency use
    - Expanded access for intermediate-size patient populations; and
    - Expanded access for widespread use.

REQUIREMENTS FOR ALL EXPANDED ACCESS USES

A patient may seek individual patient expanded access to investigational products for the diagnosis, monitoring, or treatment of a serious disease or condition if the following conditions are met.

- The patient and a licensed physician are both willing to participate.
- The patient's physician determines that there is no comparable or satisfactory therapy available to diagnose, monitor, or treat the patient's disease or condition.
- That the probable risk to the person from the investigational product is not greater than the probable risk from the disease or condition.
- FDA determines that there is sufficient evidence of the safety and effectiveness of the investigational product to support its use;

REQUIREMENTS FOR ALL EXPANDED ACCESS USES (CONT'D)

- FDA determines that providing the investigational product will not interfere with the initiation, conduct, or completion of clinical investigations to support marketing approval;

- The sponsor or the clinical investigator (or the patient's physician in the case of a single patient expanded access request) submits a clinical protocol that is consistent with FDA's statute and applicable regulations for INDs or investigational device exemption applications (IDEs), describing the use of the investigational product; and

- The patient is unable to obtain the investigational drug under another IND or to participate in a clinical trial.

IRB REQUIREMENTS

- Expanded Access Use
  - BRAIN Submission
  - IRB Review and approval prior to use
- Emergency Use
  - Within 5 working days, submit
    - Short background of the patient and his/her condition
    - Description of the emergency and the use of the investigational drug, device, or biologic
    - Statement confirming that EACH one of the required four conditions for the emergency use were met
    - Statement confirming that EACH one of the required four conditions for emergency use without informed consent were met (if consent was not obtained prior to the emergency use)
    - Statement that no new use of the investigational drug, device, or biologic will occur without prior IRB review and approval

UNIT 4: INVESTIGATOR-INITIATED TRIALS

- An individual who both conceives, initiates, designs and conducts a clinical trial and under whose immediate direction the study drug is administered.

  21 CFR 312.3

- Investigator submits and holds FDA Investigational New Drug Application

- Must comply with requirements of both investigator and sponsor – plans, designs, conducts, monitors, manages data, prepared reports, oversees regulatory & ethical issues, publishes manuscript

SPONSOR-INVESTIGATOR RESPONSIBILITIES

- Held to the same standards and regulations as industry sponsored trails.
- Potential challenge for safety & data quality.
- Carry greater risk and liability.

SPONSOR-INVESTIGATOR RESPONSIBILITIES

Responsibilities may include:

- Protocol development
- Submit IND/IDE application & required documents to FDA
- Register the trial on Clinicaltrials.gov per ICMJE publication requirements
- Select qualified investigators, sites and monitors
- Provide all information needed to conduct investigation
- Ensure that study sites get appropriate IRB approval
- Develop Case Report Forms and data collection tools
- Provide investigational drug or device

SPONSOR-INVESTIGATOR RESPONSIBILITIES

- Monitor and ensure study conducted according to protocol and good clinical practice
- Ensure compliance with regulations
- Provide study supplies and/or investigational product
- Inform FDA and PIs regarding adverse events and safety reporting

SPONSOR-INVESTIGATOR RESPONSIBILITIES

- Monitor data for safety and efficacy - Data Safety Monitoring Plan (DSMP)
- Perform data analysis and report findings
- Final reports
- disposition of study article – assure return or
- destruction of any unused investigational drug

*Refer to handout

GUIDANCE

- https://www.fda.gov/downloads/Drugs/Guidances/UCM446695.pdf
- BCM HRP manual Sponsor and Investigator Reporting
- https://www.c3isolutions.com/blog/fdas-may-2015-draft-guidance-for-investigator-initiated-trials-studies/?rf=c3ihc.

CONTACT INFO

1. Clinical Trial Agreements – Monica Gri – Monica.Gri@bcm.edu

2. Qualifying Clinical Trial (QCT) – Jose Rodriguez – Jose.Rodriguez3@bcm.edu

3. Clinical Trial Budgets – Crystal Diaz-Trejo – Crystal.Diaz-Trejo@bcm.edu

UNIT 5: GOOD CLINICAL PRACTICE

WHAT IS IT?

In 1996, the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) developed "Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance" (ICH GCP guidance (E6)). This document provides a unified standard for the European Union (EU), Japan, and the United States to comply with the regulatory authorities in these countries.

BCM complies with ICH GCP guidance (E6) only to the extent that it is compatible with FDA and DHHS regulations **OR** when required by contract with the sponsor. GCP standards contained in the ICH document are not regulatory requirements in the United States.

SEE:

- http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R2__Step_4.pdf

HELPFUL CHECKLIST

- http://www.hopkinsmedicine.org/institutional_review_board/about/compliance_monitoring/researchers_tool_kit/sample_gcp_checklist.doc

Unit 6: ClinicalTrials.gov

OBJECTIVES

- What is the Purpose of Registering a study on ClinicalTrials.gov?
- What studies should be registered?
- Why is maintaining the protocol record Important to you and Baylor College of Medicine?

ClinicalTrials.gov

A service of the U.S. National Institutes of Health

ClinicalTrials.gov is a registry and results database of publicly and privately supported clinical studies of human participants conducted around the world. Learn more about clinical studies and about this site, including relevant history, policies, and laws.

Find Studies | About Clinical Studies | Submit Studies | Resources | About This Site

ClinicalTrials.gov currently lists 200,201 studies with locations in all 50 States and in 190 countries.

Text Size

Search for Studies

Example: "Heart attack" AND "Los Angeles"

Search

Advanced Search | See Studies by Topic

See Studies on a Map

Search Help

- How to search
- How to find results of studies
- How to read a study record

Locations of Recruiting Studies

Total N = 36,658 studies
(Data as of October 09, 2015)

- See more trends, charts, and maps

For Patients and Families

- How to find studies
- See studies by topic
- Learn about clinical studies
- Learn more...

For Researchers

- How to submit studies
- Download content for analysis
- About the results database
- Learn more...

For Study Record Managers

- Why register?
- How to register your study
- FDAAA 801 requirements
- Learn more...

Learn More

- Tutorials for using ClinicalTrials.gov
- Glossary of common site terms
- For the Press
- Using our RSS Feeds

HOME | RSS FEEDS | SITE MAP | TERMS AND CONDITIONS | DISCLAIMER | CONTACT NLM HELP DESK

PURPOSES OF THE REGISTRY

Registry Purpose	Group That Benefits
Fulfill Ethical obligations to participants and the research community	Patients, the general public, the research community
Provide information to potential participants and referring clinicians	Patients, clinicians
Reduce Publication bias	Users of the medical literature
Help editors and others understand the context of study results	Journal editors, users of the medical literature
Promote more efficient allocation of research funds	Granting agencies, the research community
Help institutional review boards (IRBs) determine the appropriateness of a research study	IRBs, ethicists

WHY REGISTER?

- The 2007 Food and Drug Administration Amendments Act (FDAAA) – Section 801
  - ACT Checklist: https://prsinfo.clinicaltrials.gov/ACT_Checklist.pdf
- The International Committee of Medical Journal Editors (ICMJE)
- When BCM personnel serve as Sponsor in a clinical trial this will apply
- Required for NIH proposals
- Communication about non-compliance goes to BCM

CONSEQUENCES OF NOT MAINTAINING THE STUDY RECORD

- Financial penalties for failure to comply with the act
- Can reach up to $12,462K per day for ongoing non-compliance

RESPONSIBLE PARTY AND RECORD OWNER

- The *Responsible Party*/Record Owner*± - has data entry privileges and the primary responsibility of maintaining the study record.

- Release the record - Once an update has been completed, the Responsible Party must log onto the website and "Release" the record in order to be reviewed by the system (and ultimately seen by the public). The record must be reviewed and released after each update.

- Updates are required at specific study time points and follow the life of the study

RESPONSIBLE PARTY *(CONTINUED)*

Responsible Parties should update their records within 30 days of a change to any of the following:

- *Recruitment status** and *Overall Recruitment status** data elements
- Completion Date (see *Primary Completion Date** data element).
- Other changes or updates to the record must be made at least every 12 months. The *Record Verification Date* should be updated at least every 12 months for studies that are not yet completed, even if there were no changes to the record.
- See *How to Edit Your Study Record* for details on updating study information

SUGGESTIONS FOR MANAGING STUDIES ON CLINICALTRIALS.GOV

- **List-** Maintain a list of all protocols (and Principal Investigators) that you manage.
- **Delegate** - Assign an individual to review the website periodically; notify the Responsible Party when action is required
- **Regulatory binder and reminders**
  - create a tab in regulatory binder/ add process to existing study checklist
  - use Outlook to set update reminders
  - update the website at the time the IRB Annual Renewal is due in BRAIN

COMMON PROBLEMS

Responsible Party/Record Owner is no longer with BCM and the current staff is unaware that updates are due on the study record

- Annual Review information in BRAIN indicates that subjects were enrolled
- *Qualifying Clinical Trials* where results are required per *FDAAA 801**
- Current staff at BCM have no knowledge of the study (or study documentation); and are unable to update the record
- Records are not annually verified by Responsible Party

PROBLEMS REPORT

Problems Report

- BCM OOR receives a report of record entries that require action

- Data entry errors
- Study status changes
- Annual review/Record updates
- Results

RESOLVING ITEMS ON THE PROBLEMS REPORT

- Active protocols missing required information will be reviewed by the Institutional Review Board (IRB) Office
- Emails will be sent to the Responsible Party/Record owner for immediate updating (within 2 weeks)
- Closed protocols missing required information will be reviewed by Research Compliance Services (RCS)
- RCS will work with Department Administration (or other study contact) so the department can resolve the problem record

COMMUNICATION

- IRB office emails the Responsible Party regarding item on the problem report

- Responsible Party makes the update, reviews for errors and "releases the record"

> Good Afternoon (***Responsible Party***),
>
> ClinicalTrials.gov notifies BCM when there are problems with study records. Please log into the ClinicalTrials.gov website and locate your study **H-XXXX**. Please review the record for accuracy and then select the option of "release record."
>
> Thanks for your prompt attention to this matter.

CLINICALTRIALS.GOV RESOURCES

- The Office of Clinical Research Provides "Assurance" Services:
  - Set-up of new user accounts/additions to access list
  - Provide oversight for accuracy of registrations
  - Reminders to both responsible party and record owner for updating records and reporting
- Guidance and education
  - https://clinicaltrials.gov/ct2/manage-recs/present#OnlinePresentations
  - https://clinicaltrials.gov/ct2/manage-recs/present#GuidedTuts
  - https://clinicaltrials.gov/ct2/manage-recs/present#ResultsWorkshopSlides
  - ClinicalTrials.gov Resources Website: https://ocr.research.bcm.edu/CTGov/ClinicalTrialsdotGov.html
  - CITI Program: Protocol Registration and Results Summary Disclosure
  - Tailored Guidance: OCR_Regulatory@bcm.edu
  - Monthly Q & A sessions (prs list serv)

HELPFUL LINKS

Register a trial: https://clinicaltrials.gov/

U.S. Public Law 110-85 (Sep 2007) http://www.gpo.gov/fdsys/pkg/PLAW-110publ85/pdf/PLAW-110publ85.pdf

FDA Amendments Act of 2007 (Sep 2007) http://www.gpo.gov/fdsys/pkg/PLAW-110publ85/pdf/PLAW-110publ85.pdf

NIH Guidance on New Law (Nov 2007) http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-014.html

FDAAA 801 Requirements: https://clinicaltrials.gov/ct2/manage-recs/fdaaa

ICMJE registration policy http://www.icmje.org/recommendations/browse/publishing-and-editorial-issues/clinical-trial-registration.html

Grants.gov http://www.grants.gov/web/grants/learn-grants.html

THANK YOU! QUESTIONS?