NIH Revisions to Human Subject Research

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What's new at NIH?

- Certificates of Confidentiality
- Single IRB Review
- NIH funded "Clinical Trials"
  - Good Clinical Practice
  - ClinicalTrials.gov
  - Definition of "Clinical Trial"

NIH Funded Research

Certificates of Confidentiality

Almost all NIH funded human subject research is covered by a Certificate of Confidentiality.

NIH Funded Research

Certificates of Confidentiality

Policy:

- Applies to all research that started or was ongoing on or after 12/13//2016
- Funded wholly or in part by the NIH by a grant, cooperative agreement, contract, other transaction award, or
- Conducted by the NIH Intramural Research Program

NIH Funded Research
Certificates of Confidentiality

Policy

- Applies to human subject research that collects or creates **sensitive** identifiable information

- **"Sensitive"** = Information about an individual that is gathered or used during the course of biomedical, behavioral, clinical, or other research

- **"Identifiable"** = An individual is identified; or there is at least a very small risk that some combination of the information and other available data sources could be used to deduce the identity of an individual.

NIH Funded Research

Certificates of Confidentiality

Investigator responsibilities for studies with Certificates of Confidentiality

Investigators shall:

- Establish and maintain effective SOPs that provide reasonable assurances that the award is managed in compliance with the CoC's terms and conditions
- Ensure that any investigator or institution not funded by NIH who receives a copy of identifiable, sensitive information protected by a CoC, understand they are also subject to the requirements of the CoC
- Ensure that all sub-recipients that identifiable, sensitive information protected by a CoC understand they are also subject to the terms of the CoC.
- Include template language in the consent document describing the CoC.

NIH Funded Research

Certificates of Confidentiality – What you need to do:

- Develop required SOPs
- Ensure all recipients of identifiable information form the study understand their requirements and are committed to comply with the COC provisions
- Ensure all consent documents for NIH-funded studies have the required template language

NIH Funded Research
Certificates of Confidentiality

Investigator responsibilities for studies with Certificates of Confidentiality

Investigators shall not:

- Disclose or provide, in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding, the individual's name or any information, document, or biospecimen that contains identifiable, sensitive information about the individual if it was created or obtained for the research, unless the individual consents to the disclosure; or
- Disclose or provide to any other person not connected with the research the name of the individual or any information, document, or biospecimen [illegible] identifiable, sensitive information about the [illegible] created or obtained for the research.

What if regulatory auditors come to inspect the study?

NIH Funded Research

Single IRB Mandate

NIH Funded Research
Single-IRB

Policy

NIH funded non-exempt, human subject research involving more than one domestic site where each site will conduct the same protocol involving human subjects must use only one IRB to approve and oversee the study. UC Davis IRB will serve as a sIRB.

- Note: NIH Career development (K), research training (T), and fellowship (F) awards are not subject to the NIH single IRB policy.

NIH Funded Research
Single-IRB

Options

- Use an IRB at a participating site may serve as the Lead IRB
- Use an Independent IRB
- Use the IRB required in the Funding Opportunity Announcement (NCI IRB)

NIH Funded Research
Single-IRB

What are the exceptions to the NIH sIRB policy?

- sIRB is prohibited by federal, tribal or state law, regulation or policy
- International sites
- Sites funded by the grant but are not conducting the same protocol

NIH Funded Research
Single-IRB

What does this new requirement mean?

- Lead IRB must obtain “reliance agreements” from all relying sites
- Lead IRB will establish processes for submissions and reporting
- Lead IRB will establish fee schedule
- PI must comply with the reviewing IRB’s requirements with respect to submissions and reporting

NIH Funded Research
Single-IRB Process at UC Davis

UC Davis Procedures

1. Questionnaire #1

We determine whether the research qualifies for sIRB

2. Questionnaire # 2 or 3

You provide us with additional information needed to move forward with the process.

IRB Administration

The Institutional Review Board (IRB) Administration is committed to following the federal regulations to protect the rights and welfare of human subjects involved in research conducted under the auspices of the University of California, Davis.

Quick Links for Researchers

- Does My Project Need IRB Review
- How to Submit to the IRB
- Go to IRBNet.org
- Forms and Templates
- Policies, Procedures and Regulations
- Education, Training, CITI
- Multisite Reliance Agreements
- MORE...

Quick Links for Participants

- Things You Should Know
- Your Rights as a Research Subject
- Research at the UC Davis Health System

- Windows Photo Viewer

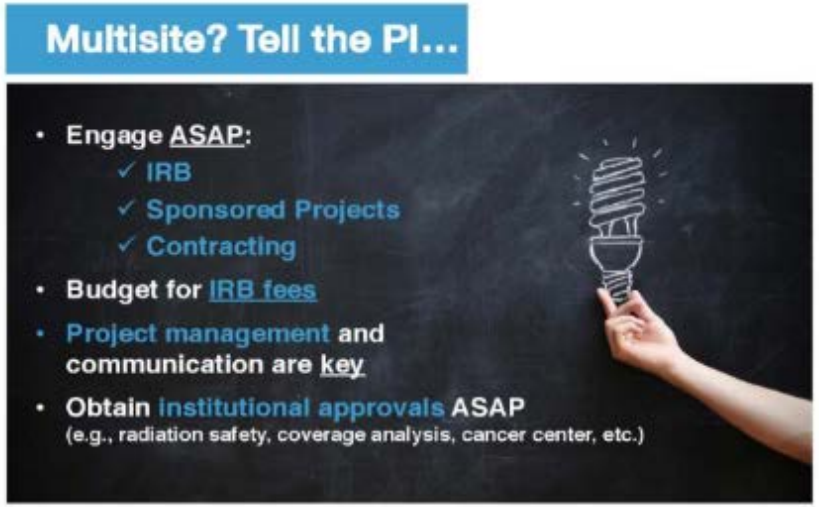
In This Section

- IRB Administration
  - For Researchers
    - Does My Project Need Review by the IRB
    - Researcher Roles and Responsibilities
    - For Student and/or Medical Resident Researchers
    - Faculty Advisor Responsibilities
    - Informed Consent Process
    - Recruiting Study Participants
    - How to Submit to the IRB
    - IRB Forms
    - IRB Actions and Correspondence
    - IRBNet
    - Conflicts of Interest
    - Ancillary Reviews
    - About the Committees
    - Reporting to the IRB – What You Need to Know
    - Emergency Use of an Unapproved Drug, Biologic or Device
    - FDA Research
    - Federally Funded Research
    - HIPAA Guidance
    - FERPA
    - Single IRB and Reliances
    - IRB Fees
  - For Research Participants

Single IRB and Reliances

Sites and personnel who are not part of UC Davis are not covered by UC Davis' IRB review unless certain agreements are in place. If your project or study involves collaboration with any sites and/or personnel outside of UC Davis, you will need to work with the UC Davis IRB and the other individual/institution to ensure that all reliance issues are addressed. UC Davis IRB may opt to serve as the IRB of Record for collaborating research sites (or single investigators) or rely on another IRB for certain studies. Only certain NIH-supported or funded research requires a single IRB. Please contact the UC Davis IRB Reliance Team for assistance.

If you are interested in establishing an IRB agreement, click here to complete a questionnaire that will provide the UC Davis IRB information about your research project and proposed arrangements for IRB review. The IRB will review the information provided and contact you with next steps.



+ Reliance Agreements

+ NIH Supported or Funded Research

NIH Funded Research
Single-IRB

What does this new requirement mean?

- PI need to work with UC Davis IRB Administration whether or not we are reviewing or relying.
- NIH applications/proposals must include a plan describing the use of a single IRB - including the identification of the IRB, if possible.
- Budget should include the IRB review cost.
- Sites should agree to the single IRB arrangement prior to the submission of an application or proposal .

Generally, NIH requests certification of IRB approval as part of the Just-in-Time process

NIH “Clinical Trials”

NIH Funded "Clinical Trials"

Good Clinical Practice

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

NIH Funded "Clinical Trials"

Good Clinical Practice

- "Investigator" = The individual responsible for the conduct of the clinical trial at a trial site
- "Staff" = Individuals who are delegated by the investigator to:
  - Coordinate study conduct
  - Recruit and enroll subjects
  - Obtain consent from subjects
  - Collect and record data from subjects
  - Manage study data
  - Report study events per protocol, regulations and IRB requirements

NIH Funded "Clinical Trials"

Good Clinical Practice

- GCP training may be achieved through:
  - CITI GCP for Drugs
  - CITI GCP for Devices
  - CITI GCP for Behavioral Research

NIH Funded "Clinical Trials"
ClinicalTrials.Gov

Policy

To promote broad and responsible dissemination of information from NIH-funded clinical trials through ClinicalTrials.gov. The policy establishes the expectation that all investigators conducting clinical trials funded in whole or in part by the NIH will ensure that these trials are registered at ClinicalTrials.gov, and that results information of these trials is submitted to ClinicalTrials.gov.

...we believe that the work should not be seen as a burden, but, rather, an inherent part of an investigator's commitment to the advancement of science

NIH Funded "Clinical Trials"
ClinicalTrials.Gov

Applicability

This policy applies to all NIH-funded clinical trials regardless of study phase, type of intervention, or whether they are subject to the regulation. For example, NIH-funded phase 1 clinical trials of an FDA-regulated product are covered by this policy as are clinical trials studying interventions not regulated by the FDA, such as behavioral interventions.

All NIH-funded clinical trials will be expected to register and submit results information to ClinicalTrials.gov.

NIH Funded "Clinical Trials"

What is a clinical trial?

A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

NIH Funded "Clinical Trials"
What is a clinical trial?

What is an intervention?

- An intervention is defined as a manipulation of the subject or subject's environment for the purpose of modifying one or more health-related biomedical or behavioral processes and/or endpoints. Examples include:
  - drugs/small molecules/compounds;
  - biologics;
  - devices;
  - procedures (e.g., surgical techniques);
  - delivery systems (e.g., telemedicine, face-to-face interviews);
  - strategies to change health-related behavior (e.g., diet, cognitive therapy, exercise, development of new habits);
  - treatment strategies; prevention strategies; and, diagnostic strategies.

NIH Funded "Clinical Trials"
What is a clinical trial?

Four questions to ask

- Does the study involve human participants?
- Are the participants prospectively assigned to an intervention?
- Is the study designed to evaluate the effect of the intervention on the participants?
- Is the effect being evaluated a health-related biomedical or behavioral outcome?

- If the answers are all "yes," the study is a clinical trial.
- If any answers are "no," the study is not a clinical trial

NIH Funded "Clinical Trials"

What is a clinical trial?

Are these studies "Clinical Trials?"

- The study involves the recruitment of research participants with condition X to receive investigational compound A. It is designed to assess the pharmacokinetic properties of compound A.
- The study involves the recruitment of research participants with disease X to test an investigational in vitro diagnostic device (IVD). It is designed to evaluate the ability of the device to measure the level of an antibody in blood.
- The study involves the recruitment of research participants with disease X to be evaluated with an investigational in vitro diagnostic device (IVD). The study is designed to evaluate how knowledge of certain antibody levels impacts clinical management of disease.
- The study involves the recruitment of healthcare providers to assess the extent to which being provided with genomic sequence information about their patients informs their treatment of those patients towards improved outcomes.