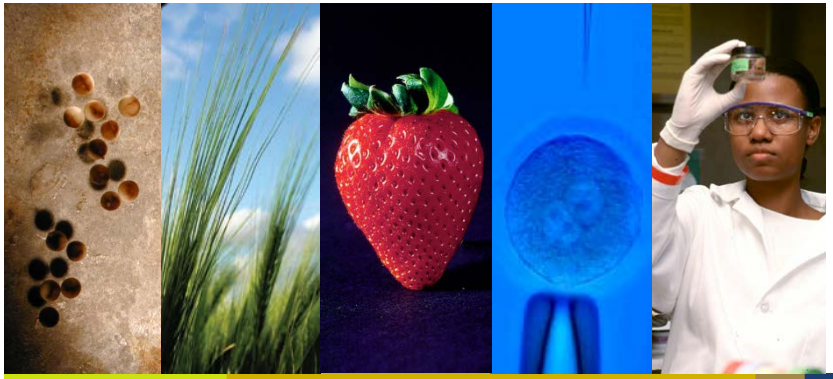

UC DAVIS OFFICE OF RESEARCH

AAHRPP Preparation
UC Davis Human Research
Part III – Investigator Manual

Cindy Gates
IRB Administration

UCDAVIS
OFFICE OF RESEARCH

What is the purpose of the "INVESTIGATOR MANUAL?

The manual is designed to guide the reader through policies and procedures related to the conduct of Human Research that are specific to this organization. This document discusses the mechanics of working with the IRB and Human Research Protection Program and is not meant to be a repeat of required training.

Who is eligible to be a PI?

1. Faculty members with paid appointments > 50% or more of full time
2. Students who have a qualified faculty sponsor/advisor who oversees, guides, and signs off on the research. The Faculty Advisor is required to be listed as part of the research personnel (staff) of the study and to complete applicable training requirements.

What training must PIs And their staff have before They can conduct human subject research?

- Minimal Risk:

  CITI or

  NIH online course

- > Than Minimal Risk:

  CITI

- Clinical Trial

  CITI + GCP

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What are the different categories of review a submission may fall under?

- Not human subject research
- Research that is exempt
- Review through an expedited procedure
- Review by a convened committee

What decisions may the Committee make when conducting a review?

- Approve
- Modification required to secure approval
- Deferred
- Tabled
- Disapprove

If the research is not subject to FDA jurisdiction, how long must an investigator maintain research records?

- Three years after the study is completed
- If children are included – at least 7 years after the youngest child reaches age 18
- If research involves in vitro or pregnant women – at least 25 years
- If sponsored – review the CTA, contact the sponsor, or ask the Office of Sponsored Programs

If the research is subject to FDA, how long must the PI maintain research records?

- The retention requirements outlined in the Clinical Trial Agreement (CTA) or
- Two years following the date a marketing application is approved for the drug/device for the indication for which it is being investigated; or, if no application is to be filed or if the application is not approved for such indication, for 2 years after the investigation is discontinued and the FDA is notified

How long must IRB records by maintained?

Three years after the research is completed

What if a PI needs need to use an unapproved drug, biologic or device and there is no time for IRB review?

- Contact IRB Chair to discuss
- If no time to discuss, check HRP 322 – Emergency Use Worksheet for criteria
- If there is time, prepare and use HRP 506 Emergency Use Template Consent Form
- Submit a report to the IRB within five business days
- Submit an IRB application (protocol) within 30 days

Emergency use: What is the difference between the requirements for unapproved drugs and devices?

FDA defines emergency use of an unapproved drug or biologic as “research.” The individual getting the drug is a “subject” and informed consent is required.

FDA regulations do not consider emergency use of an unapproved device as “research” and the individual getting the device is not a “subject.” However, FDA guidance recommends following rules similar to the emergency use of an unapproved drug or biologic

How does DHHS look at the data obtained through emergency research?

Individuals getting an unapproved drug, biologic, or device without prior IRB review cannot be considered a “subject” as defined by DHHS and their results cannot be included in prospective “research” as that term is defined by DHHS and their results cannot be included in prospective research as defined by DHHS.

At UC Davis - What other internal reviews are routinely required besides IRB review?

- Institutional Biosafety Committee (IBC)
- Conflict of Interest Committee (COIC)
- Radiation Use Committee (RUC)
- Stem Cell Research Oversight Committee (SCROC)
- Cancer Center Scientific Review Committee (CCSRC)

What information must a PI report within 5 days?

- Information that indicates a new or increased risk, or a new safety issue
- Harm experienced by a subject that is unexpected and probably related to the research procedures.

***Additional required reports will be covered when we discuss the forms and checklists*

Thank you – Don’t miss Part IV of this continuing series!