IRB Overview:
Research and Paperwork

Miles McFann
IRB Administration
Outreach, Training, and Education
Objectives

• IRB Responsibilities
  • Knowledge of the Ethical Principles
  • Definitions of human subject research
• Submitting to the IRB
  • Know the forms
  • IRBNet
• Post-Approval Responsibilities
  • Investigator Responsibilities
  • Reportable New Information
• Helpful Tips
Institutional Review Board (IRB)

• Approve/modify/disapprove research protocols involving human subjects

• Protect rights and welfare of human subjects

• Apply federal, state, and institutional regulations, policies, and laws
What is Research?

Research as defined by Department of Health and Human Services:

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

45 CFR 46.102(d)
What is a Human Subject?

• A living individual about whom an investigator (professional or student) conducting research obtains:
  ❖ data through intervention or interaction with the individual,
  or
  ❖ identifiable private information.

45 CFR 46.102(f)
Ethical Principles – Belmont Report

**Respect for Persons**
- Informed Consent
  - Obtain and document
  - Voluntariness/no coercion
  - Protect privacy

**Beneficence**
- Risks/Benefits
  - Procedures w/least risk
  - Risks reasonable in relation to benefits
  - Maintain confidentiality

**Justice**
- Enrollment
  - Select participants equitably
  - Avoid exploitation of vulnerable populations
The Common Rule

45 CFR 46 (Public Welfare)
Review Types

- Not Human Subject Research (NHSR)
  - Exempt
  - Expedited
  - Convened Meeting
Submitting to the IRB
IRB Submission Documents

Application Forms

- Initial Review Application (IRBNet) (January 1st, 2016)
- Continuing Review Progress Report (HRP-212)
- Modification (HRP-213)
- Reportable New Information Form (HRP-214)
- Research Personnel List (HRP-215)
- Administrative Approvals (HRP-226)
- Sponsor Fee Form
IRB Submission Documents

**Templates**

- Online Initial Review Application
- Protocol (HRP-503)*
  - Standard
  - Retrospective/Prospective Data/Record/Specimen Review
  - Surveys/Questionnaires/Interviews/Focus Groups
- Consent Form (HRP-502)
IRB Submission Documents

Subject Facing Documents
- Evaluation Instruments and Surveys
- Advertisements (printed, audio, and video)
- Recruitment Material and Scripts
- Etc.....

Additional Documents
- Form 1572
- Sponsor Protocol
- Investigator’s Brochure
- Federal Grant
- Ancillary Committee Review
Initial Submission

- **IRBNet**
  - Upload, access and review documents anywhere
  - Electronic Signatures
  - Repository for all your IRB documents
  - Meets federal regulations for security

- **Online Initial Review Application**
  - Smart Form
  - Protocol*

- **HRP-226 Administrative Approval**

- **Supporting Documentation***

- **Review times**
  - Expedited/Exempt 2 to 3 weeks
  - Committee Review 30 to 35 days
Record/Data Research Submissions:

Retrospective Chart Review:
(data **existing** at time of **initial** IRB submission)
- Online Initial Review Application
- Abbreviated HRP-503 Record/Data Review
- HRP-226 Administrative Approvals

Prospective Chart Review
(data **not existing** at time of IRB submission)
- Online Initial Review Application
- Abbreviated HRP-503 Record/Data Review
- HRP-226 Administrative Approvals
- Consent Form (HRP-502)
- Advertisements (if applicable)
Common Research Submissions:

**Specimen Collection**
- Online Initial Application Form
- HRP-226 Administrative Approvals
- Abbreviated HRP-503 Record/Specimen Review
- Consent Form (HRP-502)
- Surveys and/or Questionnaires (if applicable)
- Advertisements (if applicable)
Common Research Submissions:

**Drug Clinical Trial**
- Online Initial Application Form
- HRP-226 Administrative Approvals
- Sponsor Protocol
- Consent Form (HRP-502)
- Form 1572
- Investigator’s Brochure
- Sponsor Fee Form (if applicable)
- Surveys and/or Questionnaires (if applicable)
- Advertisements (if applicable)
- Conflict of Interest (if applicable)
Yeah, it’s approved!
Anything else?
Post – Approval Responsibilities

- Protect human subjects.
- Ensure all personnel comply with protocol requirements and determinations of IRB.
- Avoid undue influence in enrolling subjects.
- Ensure that informed consent is adequate and understandable to subjects.
- Report new information as stated within HRP-214, Reportable New Information Form.
- Submit changes in research to IRB for approval prior to implementation, Modification Form (HRP-213).
Post – Approval Responsibilities

**Modifications**

- Modification HRP-213
- Supporting Documentation
- Clean and Marked copies
- Initial Review Application
- Submit via IRBNet
Post – Approval Responsibilities

**Continuing Review**

- All protocols have an expiration date*
- Submit renewal 45 days prior to expiration date (admin due date)
- Continuing Review Progress Report (HRP-212)
- Modifications (HRP-213) can be submitted with renewal
- *Closure of the study follows this same process*
Post – Approval Responsibilities

**Reportable New Information (HRP-214)**

- Serious Adverse Events
- New Risk
- Increased Risk
- Non-compliance with regulations
- Breach of confidentiality
- Incarceration of subject
- Failure to follow protocol
✓ Don’t enroll prisoners. State of California does not allow biomedical research to be conducted on prisoners.

✓ De-identified doesn’t mean anything regulatory. Your data is one of the following three descriptions:

  ▪ **Identifiable**: the data will be directly labeled/recorded with the personal identifying information when acquired.
  ▪ **Coded**: the research personnel can link the research to personal identifying information when acquired.
  ▪ **Anonymous**: not be labeled with any personal identifying information, nor with a code that this research team can link to personal identifying information.

✓ **Be consistent with the information amongst the documents** (e.g. enrollment numbers, procedures being done, inclusion/exclusion criteria)
✓ Address all the IRB analysts concerns and revisions request in a timely manner.

✓ **Utilize and follow the Protocol and Consent Form Template instructions when creating your application and forms.**

✓ Attach all relevant documentation. If it is listed by the Online Application Review Form and applicable to your research, submit it.

✓ Have your research staff complete their human subject research certification (CITI and GCP training) prior to submission.

✓ Follow all UCDHS regulations.
research.ucdavis.edu/irbadmin

- Human Research Protection Program
- Investigator Manual
- IRBNet Instructions
- Standard Operating Procedures
- Policies and Procedures
- Worksheets *(IRB Admin Use Only)*
- Checklists *(IRB Admin Use Only)*
Questions?
Thank You

Miles McFann, CIP
mtmcfann@ucdavis.edu