NIAID NEW INVESTIGATOR WORKSHOP

HUMAN SUBJECTS BASICS

Clare K. Schmitt, Ph.D.
Program Officer, Enteric Diseases
Division of Microbiology and Infectious Diseases
NIAID

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GOAL

Familiarize you with NIH human subjects definitions & requirements

HUMAN SUBJECT

Legally-defined term indicating living persons from whom an investigator obtains specimens or data through direct interaction or intervention or through identifiable, private information.

DOES YOUR PROJECT INVOLVE HS?

- Are the specimens/data:
  - Obtained from living individuals?
  - Human cell lines obtained from a commercial provider?
  - Unidentifiable & obtained from a commercial provider?
  - Unidentifiable & obtained from a provider that is prohibited from releasing identifiers by established regulations or policies?
- Were (will) the specimens/data (be) collected specifically for the proposed research through an interaction or intervention with living individuals?
- Can the *recipient* link the specimens/data directly to identifiable living individuals?
- Can the *provider* link the specimens/data, directly or indirectly, to identifiable living individuals?

Collaborators?

BOTTOM LINE

If you receive or have access to existing individually-identifiable private information or identifiable specimens from living individuals:

you <u>are</u> conducting human subjects research.

Research that Involves Human Subjects = Clinical Research

- **Clinical Research**
  - Human subjects term indicating research conducted on human subjects or on material of human origin identifiable with the source person. Policy covers large and small-scale, exploratory, and observational studies.

- **Clinical Trial**
  - Human subjects term indicating a prospective study of human subjects designed to answer questions about biomedical or behavioral interventions, e.g., drugs, treatments, devices, or new ways of using known treatments to determine whether they are safe and effective.

TYPES of CLINICAL RESEARCH

- Patient-oriented research involves human subjects or materials from human subjects and can include:
  - Studies of mechanisms of human disease
  - Collection of samples from humans
  - Clinical trials (e.g., therapeutic interventions, vaccines)
  - Development of new technology
- Epidemiological and behavioral studies examine the factors that affect health and health-related decisions.
- Outcomes and health services research seek to identify the most effective and most efficient interventions, treatments, and services.

CLINICAL RESEARCH EXAMPLES

- Non-interventional Studies
  - Collection of blood or stool samples
  - Collection of intestinal tissue samples
- Interventional = Trial
  - Phase 1 study of a vaccine or drug
  - Administration of pathogenic bacteria ("challenge model")
  - Allergen provocation

CLINICAL TRIALS

- NIAID no longer supports clinical trials (interventional studies) via R01 mechanism

- R34/U01 Mechanism

CLINICAL RESEARCH DOCUMENTATION

- PI submits to Program Official <u>Prior to Award</u>:
  - IRB/IEC name and OHRP registration #
  - Federal-wide assurance (FWA) number
  - IRB/IEC protocol approval letter
  - IRB/IEC approved protocol & consent forms
  - IRB review of applications for DHHS support to ensure that protocol is consistent with grant
  - Targeted/Planned Enrollment Table (if not included with grant application)
  - Documentation of training in human subjects protection

Package submitted to IRB/IEC

Congratulations!

NIH GRANT AWARD

CAN YOU START YOUR STUDY?

- READ your Notice of Grant Award (NGA)
- NIAID Clinical Terms of Award & Guidance:
  - http://www.niaid.nih.gov/ncn/pdf/clinterm.pdf
  - http://www.niaid.nih.gov/ncn/pdf/clintermguidance.pdf
- Restriction of Funds for Clinical Research?
- Contact Program Official if questions.

CAN YOU START YOUR STUDY?

- **Minimal/Low Risk Study**
  - **Usually does not require review and approval of clinical research study protocol by NIAID if already approved by IRB, but…**
- **Greater than Minimal Risk Study or Trial**
  - **Usually does require working with program staff to develop, review, & approve the protocol, form SMC/DSMB, etc.**

CLINICAL RESEARCH DOCUMENTATION

- PI submits to Program Official <u>annually</u>:
  - IRB/IEC name, OHRP registration #, and site FWA.
  - IRB/IEC continuing review and approval letter
  - IRB/IEC approved protocol & consent form
  - Documents related to protocol amendments, suspensions, or termination.
  - Training in human subjects protection for any new study staff
  - Inclusion Enrollment Report Table (eSNAP)
  - Clinical Trial: additional submission requirements

Package submitted to IRB/IEC

HS INVOLVEMENT: POPULATION DATA

- Inclusion data on human subject Inclusion Enrollment by gender, race, ethnicity
- PI responsibility to report with annual Progress Report
  - PI enters data directly into electronic Streamlined Non-competing Award Process (eSNAP; annual progress report) through eRA Commons (http://era.nih.gov/Docs/eSNAP_UG_August2003.pdf, page 31; *PREFERRED method*)
  - PI includes table in science portion of progress report

EXCEPTIONS to POP TRACKING

- **Exceptions to POP data tracking:**
  - **Most training and career mechanisms (T/F/K)**
  - **Other exceptions:**
    - **"SS" Small Sample Size (< 10 subjects *over entire study period*)**
    - **"DR" Duplication of Reporting**
    - **"PR" Parent Records**
    - **"SA" Secondary Analysis**
    - **"ET" Early Stage of Tech Development**
    - **"NC" Not Clinical Research**
    - **Samples collected for use as research reagents: discuss with Program official.**

Exceptions to tracking requirements require action on part of Program official.

SUMMARY of PI RESPONSIBILITIES

- Adhere to Clinical Terms of Award
- Comply with human subjects regulations
- Submit HS-related docs prior to award
- Submit HS-related docs annually
- Contact Program Officer/Director with questions, concerns

RESOURCES

- **NIAID Human Subjects, Clinical Research site: http://www.niaid.nih.gov/ncn/clinical/default_human.htm#app**
- **Research Involving Private Information or Biological Specimens Decision Tree http://grants.nih.gov/grants/policy/hs/PrivateInfoOrBioSpecimensDecisionChart.pdf**
- **HS FAQs: http://grants.nih.gov/grants/policy/hs/faqs_specimens.htm**
- **DHHS Office for Human Research Protections (OHRP): http://www.dhhs.gov/ohrp/**