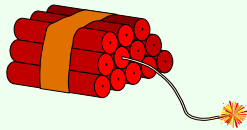


Institutional Review Boards and Grant Applications

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Hot Topics from the IRB World

- Grant Applications and Human Subject Protection
- IRB Approval of Grants
- NIH Just in Time Procedures
- HIPAA



Are Human Subjects Involved?

- **HUMAN SUBJECT**
Is there an intervention or an interaction with a living person that would not be occurring or would be occurring in some other fashion, but for this research?

Intervention

- **Intervention** includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

Interaction

- **Interaction** includes communication or interpersonal contact between investigator and subject.

Examples of when to say YES

- Prospective collection of specimens
- Use of existing specimens that were collected either for research or for clinical reasons that are identifiable or you have access to a code which identifies the donor (e.g. discarded specimens from clinical labs, pathology or the operating room)
- Use of data from medical records for non-clinical or non-Quality Improvement (QI) reasons
- A review of your own patient's data in order to publish a paper
- Calling patients for follow-up information for purposes of a publication

Examples of when to say NO

- ⊗ Specimens came from a cadaver
- ⊗ A single Case Report
- ⊗ Material/ data satisfies both of the following conditions:
 - 1. The material/data, in its entirety, was collected for purposes other than this project (e.g. the material was collected solely for clinical purposes, or for unrelated research purposes, with no “extra” material collected for use in this project).
 - 2. The material/ data is given to the researcher without any identifiers* (e.g., no codes or links of any sort may be maintained, either by the researcher or the person releasing the material/ data)

NIH Grant Applications and Human Subject Protection

Section E: Human Subjects

- Affecting Scores



Information to Include

- Protection of Human Subjects
- Inclusion of Women
- Inclusion of Minorities
- Inclusion of Children
- Data and Safety Monitoring Plan



Protection of Human Subjects

- Responsibilities of Principal Investigator
(See UVA Investigators Agreement)
- Reviewed by an IRB compliant with 45CFR46/21CFR50/ ICH/HIPAA
- All subjects will sign an informed consent compliant with 45CFR46/21CFR50/ICH/HIPAA

Protection of Human Subjects (Continued)

- Inclusion/Exclusion Criteria that will protect an inappropriate subject from participating
- How will you protect confidentiality (Very important in tissue banking/genetic testing protocols)
- Recruitment
- Obtaining Consent
- Verification of Assurance- FWA

Women/ Minorities/Children

- Women , minorities and children must be included in all NIH biomedical and behavioral research involving human subjects in clinical research.
- Make sure you have valid reasons for why they will not be included in the protocols affiliated with this grant, even if the protocol has been deemed exempt.

Clinical Research

- NIH defines human clinical research as: (1) Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual.

Clinical Research- cont

- Patient-oriented research includes:
 - 1.(a) mechanisms of human disease,
 - (b) therapeutic interventions,
 - (c) clinical trials,
 - (d) development of new technologies.
- 2. Epidemiologic and behavioral studies.
- 3. Outcomes research and health services research.

Clinical Trial

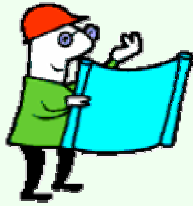
- a clinical trial is a prospective biomedical or behavioral research study of human subjects that is designed to answer specific questions about biomedical or behavioral interventions (drugs, treatments, devices, or new ways of using known drugs, treatments, or devices).

Clinical Trial (cont)

- Clinical trials are used to determine whether new biomedical or behavioral interventions are safe, efficacious and effective.

Data and Safety Monitoring Plan

- Adverse Event Reporting
- Safety Monitoring
- Safety Data to be Collected



Adverse Event Reporting

- How will adverse events be collected?
- Definition of what is an adverse event for your protocol
- What information will be recorded about the adverse event?
- Reporting requirements to IRB/sponsor.

Safety Monitoring

- Designate who is responsible for overall safety monitoring. (PI/DSMB)
- How often will review of Adverse Events be done?
- How will this review be done?
- How will results of review be shared?

Safety Data to be Collected

- List labs/tests that will be done to protect subject
- Example: If an investigational drug is being given that is excreted in the kidneys - what tests/labs will be done to monitor kidney function. How often will they be done? Who will monitor results?

Data and Safety Monitoring Boards

- Required by most NIH Institutes for Phase III trials
- FDA Guidance on DSMB due out in early 2003- have not yet seen it.
- IRB can determine if a DSMB is required.

DSMB(Board) or DSMC(Committee)

- Include member names with their affiliation/experience
- Frequency of meetings
- Frequency of reports

IRB Approval of Grant Applications

- May 1999, All research at Duke suspended!
- Item # 12 in Closure letter stated:
"HHS regulations at 45CFR46.103(f) require that an institution with an approved assurance shall certify that "each application" or proposal for research covered by the assurance has been reviewed and approved by the IRB ."



NIH Just in Time Procedures

- Institutions with Federal Wide Assurances (FWA"S) must treat all grants/ protocols the same regardless of funding source.
- Many sponsors also follow NIH "Just in Time" procedures.
- NOTE: Need only IRB Grant approval, not protocol approval to get funds.
- UVA FWA #- 00006183- Expires 12-23-06

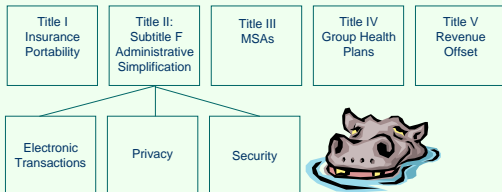
Human Subject Research Protection Training

- On June 5, 2000, the NIH announced that effective October 1, 2000 all KEY PERSONNEL listed on a grant must have completed training in the protection of human subjects in research.

Key Personnel

- Individuals who contribute to the scientific development or execution of the project in a substantive way, whether or not salaries are requested.
- UVA Definition- Anyone who has access to subjects or identifiable data

What is "HIPAA"? The Health Insurance Portability and Accountability Act of 1996



Three Categories of Persons DIRECTLY Subject to the Privacy Rule (AKA "Covered Entities")

- **Health care providers** who electronically transmit health information in a HIPAA-covered transaction
 - » Includes researchers who provide treatment to research subjects
 - » Includes researchers who access individually identifiable health information
- **Health plans** (does not include worker's compensation, disability, sickness funds, liability coverage)
- **Health care clearinghouses** (entities that translate nonstandard data elements into standard data elements)

Persons INDIRECTLY Subject to the Privacy Rule (AKA "Business Associates")

Any person/entity who on behalf of a Covered Entity:

- Creates, uses or discloses PHI to perform or assist with a function or activity
- Uses PHI to perform identified services



Data Elements That Make Health Information Identifiable Under HIPAA

- Name
- Address, including city, county and zip code
- Dates, including birth date, admission date, discharge date and date of death
- Telephone and fax numbers
- Electronic mail addresses
- Social security numbers
- Medical record numbers
- Health plan beneficiary number
- Account number
- Certificate/license number
- Vehicle or other device serial number
- Web URL
- Internet Protocol address
- Finger or voice prints
- Photographic images
- Any other unique identifying number, characteristic or code

Data Elements not allowed with a Limited Data Set

- Name
- Postal address information, other than town or city, state and zip code.
- Telephone numbers
- Fax numbers
- Electronic mail addresses
- Social security numbers
- Medical record numbers
- Health plan beneficiary number
- Account number
- Certificate/license number
- Vehicle or other device serial number
- Web URL
- Internet Protocol address
- Finger or voice prints
- Photographic images

Difference Between De-identified and Limited Data Set

- Limited Data Sets allow the use of address information greater than street address- ie city, state, zip code
- Limited Data Sets allow use of a code derived from info regarding the subject (e.g. initials, maiden name, last 4 digits of SS#
- Limited Data Sets allow use of full dates

Six Ways to Access to PHI for Research Purposes

- Use De-Identified PHI
- Access Limited Data Set pursuant to Data Use Agreement
- Get Authorization from subjects
- Obtain Privacy Board Waiver of Authorization
- Review only PHI that is "minimally necessary" to prepare a protocol or to study information of deceased individuals
- Conduct internal QA/QI study for health care ops

How Can You Avoid HIPAA?

Move
to Kazakhstan!



The END

