Institutional Review Board

Protecting Human Subjects in Research

Presented by:
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Purpose of the Institutional Review Board

- The IRB serves to protect the rights and welfare of human subjects recruited to participate in research activities involving students, faculty, and staff at UIS
- Ensure implementation of the Belmont Report: Created by the National Commission for the Projection of Human Subjects of Biomedical and Behavioral Research (30 Sept. 1978)

Revised Policy and Procedures

- Federalwide Assurance (FWA) – Annual renewal verifying that the institution is in compliance with the US Dept. of Health and Human Services (HHS) Office for Human Research Protections (OHRP)
- IRB application process: More user friendly by going digital
  - New procedure details will be released via campus wide email
  - Instructions located on Grants & Contracts Webpage (www.uis.edu/grants)

Ethical Principles: Belmont Report

- Respect for persons – recognition of personal dignity and autonomy
- Beneficence – obligation to protect persons by maximizing anticipated benefits and minimizing possible risks of harm
- Justice – benefits and burdens of research must be distributed fairly

Required Training

- CITI (Collaborative Institutional Training Initiative)
  - Completed training is valid for 3 years
  - Research will not be approved until ALL investigators as well as Responsible Research Supervisors (RRS) are confirmed
  - The Social and Behavioral Research Basic Course Gradebook includes:
    - Signing The Integrity Assurance Statement
    - Six required modules for certification:
      - Belmont Report and CITI Course Introduction
      - History and Ethical Principles – SBR
      - Defining Research with Human Subjects – SBR
      - Assessing Risk in Social Behavioral Sciences – SBR
      - Informed Consent – SBR
      - Privacy and Confidentiality – SBR
  - The minimum passing score per module is 80.

Additional CITI training

- Specialty modules may be applicable to your research
- Other modules include research with:
  - Prisoners
  - Children
  - Public Elementary and Secondary Schools
  - International Research
  - Internet Research

Locate CITI Training

- UIS and UIUC have a collaborative agreement for all UIS investigators to access the CITI training modules through the UIUC registration.
- Step by step instructions on registration and accessing courses are located on the UIS IRB website

http://www.uis.edu/grants/irb/requiredtrainingforhumansubjectsresearchinvestigators/

What is Human Subjects Research?

- OHRP defines RESEARCH: as a systematic investigation designed to develop or contribute to generalizable knowledge
- Non-generalizable knowledge: *Does not necessarily exclude you from IRB application*
  - Biographies
  - oral histories that are designed solely to create a record of specific historical events *New procedures for IRB application on website
  - service or course evaluations, unless they can be generalized to other individuals
  - services or concepts where it is not the intention to share the results beyond any agency supporting the research
  - classroom exercises solely to fulfill course requirements or to train students in the use of particular methods or devices
  - quality assurance activities designed to continuously improve the quality or performance of a department or program where it is not the intention to share the results beyond the institutional community
- HUMAN SUBJECTS: living individual(s) from whom an investigator conducting research obtains data through intervention or interaction with the individual

What level of privacy is involved?

- Anonymous: no identifying markers to link the research to any particular individual
- Confidential: the identity of the participant will be known to the researcher, but will not be released with the outcomes of the study
  - Must be protected throughout the research project – during data collection, after the data is collected, in storage, when reporting
  - Applies to all identifiers related to a person

Risk – Benefit Analysis

- Two Sources of Potential Risk
  - Harm resulting from participation in the research
    - e.g. acute emotional reactions to certain questions, physical stress, reaction to medication, etc.
  - Harm resulting from breach of confidentiality
    - e.g. recruitment practices, sample size, data collection practices, storage/management of identifying information & data, reporting, presenting, & publishing, etc.

Internet Based Research

- Primary source of risk is confidentiality
  - Anonymity of data collected on the Internet is difficult to achieve
  - Webservers automatically store personal information about visitors to a website
  - Data transmitted via email cannot be anonymous without using external processes
    - Must use an "anonymizer"
    - Typically a 3rd party site that strips off the sender's email address before data is stored

Breach of Confidentiality/Anonymity

- Two potential sources of breach of confidentiality using electronic data
  - Inadvertent disclosure
  - Hacking
- Usage of computers & Internet to obtain, store, analyze, & communicate data increases inadvertent disclosure of data
  - e.g. Stolen or lost computers, thumb drives, etc.

Protecting Your Research Data

- Reasonable security steps
  - These do not guarantee absolute security
    - Controlled access privileges
    - Firewalls
    - Encryption
    - Limited Internet access on computer
    - Physical restrictions to computer (locked room, etc.)
    - No electronic transmittal of data
    - No uncontrolled duplication of data (sharing or storage)

Disclosure

- Expectations for Disclosure:
  - Document security procedures must be explained in the protocol and full disclosure must be made clear in Consent Document(s)
  - Complete a risk analysis to determine level of security required
  - Level of security should relate to the level of sensitivity of the data and potential external interest in the data

Benefits

- Consent requires an explanation of benefits that can be reasonably expected
  - For the subject or others
  - Should not be overstated or coercive – factual
  - If there is no known benefit

Recruitment

- Methods for recruitment should be well defined in IRB application
- Appropriate location & timing of recruitment
- Individual(s) performing recruitment appropriate (trained, impartial, knowledgeable)
- Recruitment materials must appropriate & approved
- Acceptable method for screening subjects before recruitment
- Avoid family and friends!

Recruitment Materials

- Flyers, posters, etc.
  - Must present sufficient information
    - accurate & balanced; containing elements necessary for subject to make an informed decision about participation
- Basic requirements
  - Straightforward & honest approach
  - The type of research should be specified
  - Ages for eligibility must be included
  - Purpose clearly stated
  - Benefits included
  - Contact person's name & information included
  - Institution identified

Inducement

- Use with caution!
  - You may raise question of undue influence
  - Belmont principle of respect for persons requires participation to be completely voluntary
- Models of inducement:
  - Reimbursement
  - Wage payment
  - Lotteries
  - Class credit

What is informed consent?

- Informed Consent: a person's voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in research

- Assent: agreement by an individual not competent to give legally valid informed consent to participate in research

Protected Classes of Subjects

- Special consideration to protect the welfare of vulnerable subjects, including:
  - Children
  - Prisoners
  - Fetuses and pregnant women
  - Individuals with questionable capacity to consent
  - Terminally ill or comatose patients
  - Students/employees

General Requirements of informed consent

- Must give the subject opportunity to consider participation, and minimize possible coercion or undue influence
  - Must give subject adequate time to ask questions
  - Use of incentives – must be balanced with the situation
    - Gift cards, money, extra credit in a course, etc.
    - Must include odds of winning if not given to everyone
    - Must be applied equally to all subjects
    - Must include explanation should incentive by removed or reduced based upon participation, etc.

General Requirements, cont.

- Exculpatory language is prohibited
  - Can't waive or appear to waive subjects legal rights
  - Can't release or appear to release investigator, sponsor, institution or its agents from liability for negligence
    - Be careful with how things are phrased in the consent document!
    - If you have questions:
      - Sample consent documents located on website : http://www.uis.edu/grants/irb/samples/
      - Contact the IRB office:
        - 217.206.7409
        - ORA@uis.edu

Required Elements of Informed Consent

1. Statement that study is research; information about purposes, duration, procedures

2. Reasonable foreseeable risks and discomforts
    1. Risk of breach of confidentiality is always present
    2. Loss or theft of computer or data storage device
    3. Exposure of data with identifiers during the researcher's review
    4. Problem with encryption if data is transmitted electronically

Required Elements of Informed Consent, cont.

3. Reasonable expected benefit to subject or others

4. Alternatives to research participation which might be advantageous to the subject
    1. Alternate sites or method of participation
    2. Medical research – alternative treatment options

Required Elements of Informed Consent, cont.

5. Provision for Confidentiality
    1. Description of how identifying information will be kept confidential (consider everything from signed informed consent to forms used and data collection)
    2. Electronic submission (use of encryption, acronyms, separate transmission of data from identifiers, etc.)
    3. Internet is not a secure medium (use of secure survey sites, etc.)

Required Elements of Informed Consent, cont.

5. Provision for Confidentiality, cont.
    4. Explain how data is transmitted
    5. Explain how data is maintained (will data be shared electronically among researchers, etc.)
    6. Do NOT absolutely guarantee confidentiality
    7. If aggregated anonymized data will be made publically available, consider if the subjects could be re-identified (small sample size, specificity of things including level of degree, age, gender, length of employment, etc.)

Required Elements of Informed Consent, cont.

6. Information on compensation for injuries/medical treatment (unless identified as minimal risk)
7. Voluntary participation; no penalty or loss of benefit for refusal or withdrawal; the right to answer only questions with which they are comfortable
8. Contact person for information on research, injury, subjects rights (Consider if local contact is advisable – such as need for a local mental health clinic, etc.)

***Note:** There should be one paragraph describing who to contact for information on research and a second paragraph describing who to contact concerning subjects rights

The Additional Elements of Informed Consent

1. Statement that there may be unforeseeable risks
2. Circumstances under which investigator could terminate subjects participation
3. Additional costs to the subject
4. Consequences of subjects withdrawal from research; procedures for termination
5. Statement that subjects will be told of new findings which might affect willingness to continue to participate
6. Approximate # of subjects in the study

Elements of Informed Consent cont.

- Passive consent or "opt out" procedure requires a waiver of informed consent or elements of the informed consent
  - This is more problematic for internet research

- Informed consent documents must be "date stamped"
  - Date stamped consent must be used for all research using consent
  - If conducting online research and date stamped consent can't be uploaded, then consent document must include a statement that contains the expiration date of the consent document

Submission Requirements

- Required components for IRB Application
  - Protocol (UIS application) – Located on the website: http://www.uis.edu/grants/irb/protocol/ (With appropriate signatures!)
  - Consent document(s): Templates, checklists and samples all available on the UIS IRB website: www.uis.edu/grants/irb
  - CITI Training verification for ALL PIs/Research Team members/Responsible Research Supervisors
  - Copy of any questionnaires/surveys/interview questions to be used
  - Letter of authorization for off-site locations (if necessary)

Review Procedure

- Intake
  - Receive, log, and assign protocol number
  - Check for completeness
  - Date stamp receipt
- Initial Review
  - Complete "Research Description Checklist"
  - Read protocol, methodology, and consent
  - Identify potential level of approval (exempt, expedited, full board)
  - Identify issues, errors, and omissions

Review Procedure, cont.

- Follow-up with PI
  - Notify of protocol # assignment
  - Ask questions for clarification of protocol and procedures
  - Make/Request changes to consent, if needed
  - Wait for PI response

- Finish Initial Review
  - Verify protocol is complete
  - Prepare letter of approval for exempt/expedited review and date stamp consent form
  - Present protocol, all materials, Research Description Checklist, letter of approval and consent to the Human Subjects Review Officer for final revisions and approval

Levels of Review: Exempt

- Six specific categories of research that meet exempt status (see list at www.uis.edu/grants/irb/protocol)
- The Human Subjects Review Officer reviews and applies exemption status
- Status does not remove requirement for informed consent

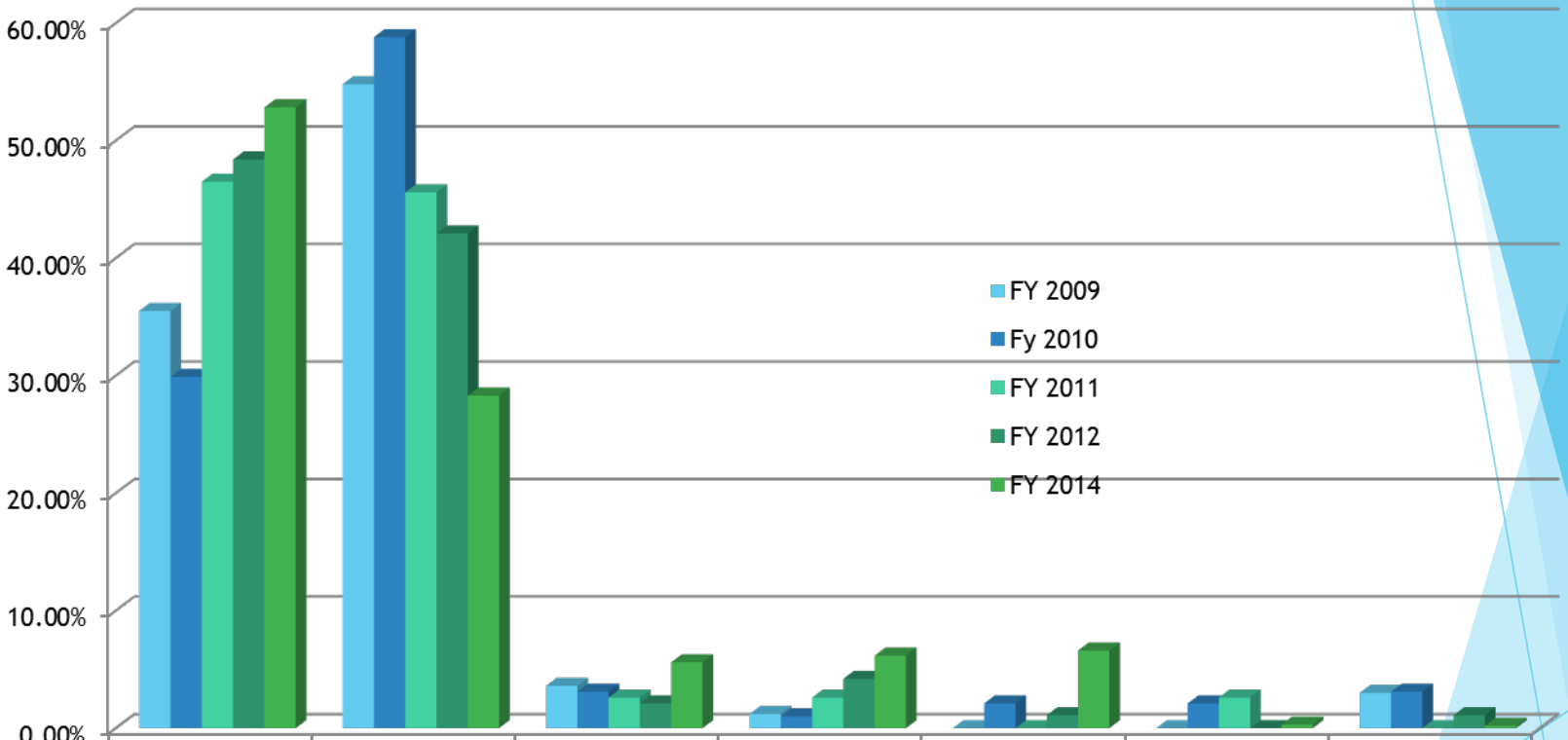
Levels of Review: Expedited

- Can be carried out by the IRB chairperson or experienced reviewers
- Human Subjects Review Office approves the review
- Expedited reviews are minimal risk to the subject and includes the same criteria as full committee reviews and continuing review is required at least annually
- Nine specific categories in the regulations (see list at www.uis.edu/grants/irb/protocol)

Levels of Review: Full-Committee IRB Review

- Required for research that has more than minimal risk
- Concerns issues with confidentiality
- Potential conflicts of interest
- Complex and controversial issues
- Protected subjects and vulnerable population

Submission Trends



	Exempt	Expedited	Full Board	Continuation	waiver	Withdrwn	External
FY 2009	35.50%	54.80%	3.60%	1.20%	0	0	3.00%
Fy 2010	29.90%	58.80%	3.10%	1.00%	2.10%	2.10%	3.10%
FY 2011	46.50%	45.60%	2.60%	2.60%	0.00%	2.60%	0
FY 2012	48.40%	42.10%	2.10%	4.20%	1.10%	0	1.10%
FY 2014	52.83%	28.30%	5.60%	6.17%	6.60%	0.30%	0.20%

Additional Resources on the UIS Grants & Contracts, IRB Website

- Forms: http://www.uis.edu/grants/irb/formstemplatesandchecklists/
  - Consent Outline
  - Continuation Request
  - Debriefing
  - HIPAA
  - English as a Second language
  - Adverse Events
  - Unanticipated Problem Report
  - DCFS Mandated Reporter

Contacts

Staff to the UIS IRB:

Kathleen Furr: Asst. Director of Research Administration

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Jim Klein: Human Subjects Review Officer

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Website: www.uis.edu/grants/

- Contains the current IRB policy
- Forms
- Sample consent documents

- **Federal Regulations:** www.hhs.gov/ohrp/