Research with Human Subjects: Human Subjects Committee Approval

SUNY Oswego
Human Subjects Committee
2012

Last Revised 10/28/2011

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Our Purpose

- Overview researchers' responsibilities and procedures when conducting research with human subjects.

Our Mission

- Protect all subjects- especially students and vulnerable populations.
  - e.g., children, pregnant females, prisoners, impaired individuals.

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What is Research?

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

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Are You Doing Research?

Collecting information…

- Interview
- Survey
- Document Records
- Case Studies
- Observation

to be shared with others

- Conferences
- Journals
- Books
- Publications

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Common Purposes of Research

- Description
- Prediction
- Improvement
- Explanation
- Theory Testing

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Not Research: Education Examples:

- Data that is collected as part of the instructor's class for the purpose of evaluating students' performance in the class
- Data that is collected as part of the instructor's class for the purpose of assessing the instructor's performance
- Data that is collected as part of the instructor's class for the purpose of an internal assessment of the (school's or department's) program
- Data that is collected as part of a cooperating teacher's class for the purpose of assessing a student teacher

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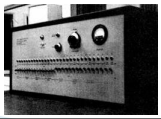
Brief History

- **Tuskeegee Syphillis Study** (1932-1972)

- **WWII Concentration Camp Studies** (1933-1945)

- **Milgram Studies** of obedience and authority (1963)



Responses to this History

Principle	Application
Respect for persons Individuals treated as autonomous agents. Persons with diminished autonomy are entitled to protection.	**Informed Consent:** Opportunity for subjects to choose what shall/ shall not happen to them. The consent process must include three elements: 1) information, 2) comprehension, and 3) voluntariness.
Beneficence Subjects should not be harmed; Research maximizes benefits & minimizes harms.	**Assessment of risks and benefits** The nature and scope of risks and benefits must be assessed in a systematic manner
Justice The benefits and risks of research must be distributed fairly.	**Selection of subjects** There must be fair procedures and outcomes in the selection of research subjects

Institutional Review Board (IRB)

- Faculty, staff, & students of SUNY Oswego are obligated to comply with Federal Department of Health and Human Services regulations for the protection of human participants in research (it's the law!)

  ☑ Human Subjects Committee
  ☑ Institutional Care and Use of Animals

- Human Subjects Committee
  - Outside set of eyes to verify that your study doesn't raise ethical issues.
  - Address ethical issues that may come up by offering helpful suggestions.

Human Subjects Committee

Does Your Study Involve Human Subjects?

- lab experiments
- field studies
- observations
- interviews
- questionnaires
- etc.

Yes

Submit to Human Subjects Committee (HSC) for approval

Exempt Review | **Expedited Review** | **Full Committee Review**

One More Time: Who submits their study for approval to the HSC?

- **All** research studies that include human subjects must be approved by the HSC
- ***Data cannot be collected until approval has been received in writing from the HSC***
- Turnaround is fast- typically within a few days
- Visit the HSC website for specific details

http://www.oswego.edu/hsc

National Institute of Health (NIH) Mandatory Training!

National Institute of Health (NIH) Training!

- US federal government requires us to provide training and education in the protection of human participants in research. All investigators and research personnel involved with human participants should be trained.
- Free and takes about three hours online.
- A copy of the training certification must be included in any submission.

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Practice Version of HSC Submittal

- Students ***must*** work with their faculty sponsor in learning how to use this transmittal form by using the practice version
  - PRACTICE Online Human Subjects Transmittal Form
- When a student researcher completes this form and clicks on the submit button, a copy is sent electronically to the student and to his/her faculty sponsor.
- The faculty sponsor then coaches the student as needed and ensures all necessary attachments are provided. The student researcher then submits online using the "real" online transmittal form.

http://www.cs.oswego.edu/~dab/IRB/PracticeHSTForm.html

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Human Subjects Transmittal Form

YES	NO	
		1. The attached application involves scientific investigation using human subjects and I have completed the mandatory training within the past two years
		2. The attached application uses human subjects below the age of 18. If yes, this must be discussed in the protocol and parental informed consent or consent of the subject's legally authorized representative must be obtained in addition to the informed consent of the minor.
		3. The attached application involves experimental biomedical procedures, or use of drugs or toxic substances.
		4. The attached application involves the administration of questionnaires, inventories or personality tests.
		5. It is affirmed that the investigation will adhere to the policies and Procedures of the State University of New York for the study of human subjects.
		6. Additions to or changes in procedures involving human subjects that occur after review of the application will be brought to the attention of the review committee as will anticipated problems involving risks to subjects or others.

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Human Subjects Transmittal Form

- A. Brief description of the research (e.g., purpose, hypotheses). 125 words maximum
- B. A description of the benefits of the research to the human subjects, if any, and of the benefits to human or scientific knowledge. 125 words maximum
- C. Description of subjects, indicating especially whether any are minors or otherwise members of vulnerable populations (e.g., subjects under the age of 18, pregnant females, prisoners). 150 words maximum

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Human Subjects Transmittal Form

- D. Description of how the subjects will be used (e.g., how they are selected, what they will do - such as complete questionnaires or participate in a simulated task). 90 words
- E. Description of the risks and discomforts, if any, to subjects. 75 words
- F. Does the proposed research involve deception, e.g., through provision of misinformation, withholding information, etc.? 90 words.
  - **If it does involve deception, explain why and how/when you will debrief your subjects.**

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Human Subjects Transmittal Form

- G. Upload your NIH Certificate, the Informed Consent Form, followed by any surveys, questionnaires or other material that involves the subject. Please upload only Word, .rtf, or .pdf files. **This includes a consent form!**

Before submitting this form, please review your entries to ensure that you have:

- ☑ entered your name and official Oswego email address
- ☑ entered your faculty sponsor's name
- ☑ correctly chosen yes/no for the six submission questions
- ☑ entered text into each of the boxes A through F
- ☑ uploaded a copy of your **NIH certificate**
- ☑ uploaded the subject's Informed Consent form
- ☑ uploaded an Informed Consent form for parents if the subject is a child **or a member of a vulnerable population!**
- ☑ uploaded any surveys or other instruments the subjects will complete

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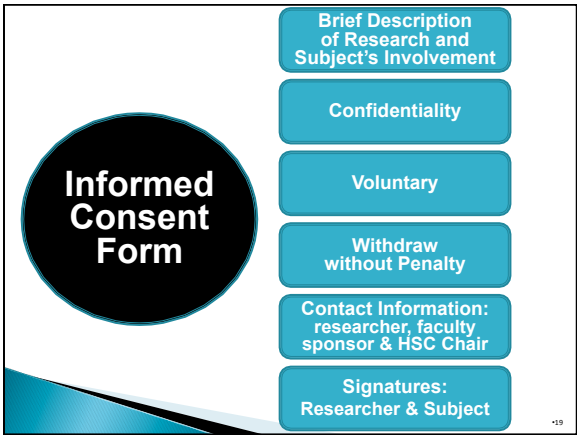
Informed Consent Form
Brief Description of Research and Subject's Involvement
Confidentiality
Voluntary
Withdraw without Penalty
Contact Information: researcher, faculty sponsor & HSC Chair
Signatures: Researcher & Subject
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