

Institutional Review Board (IRB)

Office of Sponsored Programs
St. Cloud State University



Agenda

- What is IRB?
- IRB at SCSU
 - Project Examples
 - Types of Reviews
- How IRB affects you and your projects?
- IRB Application Process
 - IRB Application
 - Consent Forms
- Student Research Funds
- Student Research Colloquium
- Questions & Discussion



What is IRB?

- An Institutional Review Board (IRB), according to federal law, must evaluate the potential physical or psychological risk of research involving human subjects.
- All proposed human research must be reviewed and approved by an IRB before experimentation begins.
- This includes any surveys or questionnaires to be used in a project.



Why?

- The IRB protects any and all research programs/projects that involve the use of Human Subjects.



IRB Governing Body

- US Department of Health and Human Services (HHS)
 - Office for Human Research Protections (OHRP)
 - <http://www.hhs.gov/ohrp/>
 - Human Subject Protection began in 1947
 - In 1978, the “Ethical Principles and Guidelines for the Protection of Human Subjects of Research,” also known as the [Belmont Report](#) was published.
 - Belmont Report identifies three fundamental ethical principles for all human subjects research
 - respect for persons,
 - beneficence, and
 - justice.
 - In the late 1970s and early 1980s, HHS revised and expanded its regulations that are now codified at 45 CFR part 46, subparts A through D.
 - The statutory authority for the HHS regulations derives from 5 U.S.C. 301; 42 U.S.C. 300v-1 (b); and 42 U.S.C. 289.



IRB at SCSU

- Faculty, staff, and some graduate student research-or any other efforts to add to the fund of human knowledge-must be approved by St. Cloud State University's Institutional Review Board (IRB).
- <http://www.stcloudstate.edu/osp/irb/default.asp>



Activities include anything that:

- intervenes in people's lives, observations of human behavior, or use data obtained directly or indirectly from living individuals, and
- involve the name, employees, or facilities of the University.



Some examples include:

- Surveys, Focus Groups & Interviews
- Voice, video, digital or image recording
- Noninvasive Procedures
 - Moderate exercise,
- Blood sample collection
- Biological specimen collection
 - Hair, nails, saliva



Types of IRB Review

- Full Review
 - Research involves more than minimal risk.
 - The full IRB reviews the application during a regularly scheduled meeting.
- Expedited Review
 - Research falls within one or more of the common categories of Expedited Review and involves **no more** than minimal risk.
 - Approval usually 5 to 10 day after submission
- Exempt Review
 - Research falls within one or more of the common categories of Exempt Review and involves **no more** than minimal risk.
 - Approval usually within 7 days of submission



No IRB Approval?

- Researchers may not begin recruiting or contacting potential subjects.
- It is an academic offense to conduct unapproved research.



Student Projects & IRB

- Student projects or assignments (undergraduate/graduate/thesis) are require faculty sponsor IRB review.
- Faculty Sponsors:
 - evaluate students' proposed projects to determine whether the projects require IRB review, AND
 - provide supervision and guidance to students during the execution of all projects involving human subjects-- regardless of whether the projects require IRB review.



Application Process

- Complete IRB Training
 - <http://www.stcloudstate.edu/osp/irb/IRBTraining.asp>
- Complete and Submit IRB Application
 - <http://www.stcloudstate.edu/osp/irb/irbapplication.asp>
- Provide answers to any follow-up questions



IRB Application

- Includes:
 - Project Management
 - Researchers
 - Sponsors
 - External Funding
 - Grants
 - Contracts
 - Certifications Statement
 - Type of Review
 - Common Categories to choose from



IRB Application (con't)

- Includes:
 - Project Description
 - Subject Populations
 - Age
 - Vulnerable populations
 - Subject Identification & Recruitment
 - Finding potential participants
 - Written Documentation of Cooperation/Permission
 - Compensation for Participation



IRB Application (con't)

- Includes:
 - Methods & Procedures
 - Equipment Use
 - How will data be collected, recorded and stored?
 - Will there be data identifiers?
 - When will data be destroyed?
 - Risks & Benefits
 - More than Minimal Risk?
 - Precautions taken?
 - Consent Process



Informed Consent

- Informed Consent begins when you approach potential subjects and continues throughout your research:
 - Present information that enables individuals to knowledgeably and voluntarily decide whether or not to participate as a research subject,
 - Document consent with a written form signed by the subject, and
 - Respond to any questions/concerns during the research and communicating any new findings that may affect the subject's willingness to continue participating.



Informed Consent Form

- Invitation
 - Background Info & Purpose
 - Procedures
 - Risks
 - Benefits
 - Confidentiality
 - Research Results
 - Additional Recourses
 - Contact Info
 - Voluntary Participation/Withdrawal
 - Signatures



Implied Consent

- When using an **anonymous** survey or questionnaire to collect data, you may fulfill requirements by providing subjects with a cover page or letter that explains the following items:
 - **purposes** of the research and **expected duration** of the subject's participation
 - whom to **contact for answers** to questions about the research and how to contact them
 - where/how overall **research results** will be made available
 - anonymity of the results; the subject cannot be identified
 - implied consent: "returning the questionnaire indicates your voluntary consent to participate"
 - **participation is voluntary**, refusing to participate or discontinuing participation will involve **no penalty** or loss of benefits to which the subject is otherwise entitled



Parental Informed Consent

- When research involves individuals under the age of eighteen, parents or guardians consent is required.
 - Informed consent from one parent/guardian is sufficient for research that involves minimal risk or may directly benefit the child/minor, and
 - Signed documentation from children/minors who are capable of deciding whether or not to participate in your research.



IRB Approvals

- Full & Expedited Projects
 - Continuing/Final Review required yearly
 - If no annual review, data collection must be discontinued until annual review completed.
- Exempt Projects
 - Researchers CANNOT deem their projects exempt, the IRB must
 - No expiration of approval unless study changes are made



IRB Summary

- The IRB protects all human subjects participating in research.
- The IRB ensures the integrity of research involving human subjects.



Student Research Funds

- Support for academic research and creative activity by SCSU undergrad and grads students
 - Faculty sponsor required
 - Up to \$1,500 award
 - Recipients must present at Student Research Colloquium in Spring
 - Next Deadline is February 2, 2009
 - <http://www.stcloudstate.edu/src/researchfund.asp>



Student Research Colloquium

- Opportunity for students to present their research and scholarly & artistic activities
 - Formats
 - Oral presentation of a paper
 - Poster display
 - Performances and creative works
 - April 21, 2009
 - 12th Annual Event
 - Deadlines
 - Intent to Present 2/15/09
 - Competition Opt-In 3/6/09
 - <http://www.stcloudstate.edu/src/>



Questions and Discussion

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