

INSTITUTIONAL REVIEW BOARD: ETHICS IN HUMAN SUBJECTS RESEARCH

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Why IRB Review Required?

- **1932-1972 The Tuskegee Syphilis Study** (involved documenting the natural history of syphilis in African-American males)
 - **Ethical concerns:** lack of informed consent, deception, withholding information, withholding available treatment, putting men and their families at risk, exploitation of a vulnerable group of subjects who would not benefit from participation
- **World War II (1939-1945):** NAZI scientists conduct research on Jewish prisoners; many experiments resulted in death
 - **Ethical concerns:** coercion to participate, subjects did not willingly volunteer, no informed consent, use of vulnerable population
- **1955 Willowbrook Hepatitis Study** (involved studying effects of hepatitis in mentally retarded children)
 - **Ethical concerns:** exploitation of a vulnerable group of subjects, withholding information about risks, coercion or undue pressure on parents to volunteer their children
- **1963 Milgram Study, aka Obedience to Authority** (involved determining response to authority in normal humans)
 - **Ethical concerns:** ethical issues based on deception, undue influence, and debriefing



Why We Care? It's the Law – Results of Unethical Research Practices

- 1949: Nuremberg Code—10 principles designed to protect human subjects
- 1963: NIH adopts laws governing IRB oversight at all institutions
- July 12, 1974: National Research Act (response to Tuskegee)
- 1979: *The Belmont Report* (Respect for Persons, Beneficence, Justice)
- 1981: Code of Federal Regulations Title 45, Part 46 aka *The Common Rule* adopted (following 1975 revision of Declaration of Helsinki)—baseline standard of ethics all academic institutions require of their PIs (regardless of funding)

SHSU IRB Mission & Goal

- The mission of the IRB is to protect the rights and welfare of research subjects
- Goal: to review all research involving Human Subjects with this mission in mind
- *The IRB conducts its review based on The Belmont Report Principles: Respect for Persons; Beneficence; Justice*



THE BELMONT REPORT



The Belmont Report Principle of Respect for Persons

- Respect for Persons requires that participants, to the degree they are capable, be given the opportunity to choose what and what will not happen to them
- **Significance for the IRB:** The application most associated with this Principle: Informed Consent process
 - To be complete, it must contain these 3 elements:
 1. Information
 2. Comprehension
 3. Voluntariness




Informed Consent: Information

► Items generally found in the consent form:

1. The research procedure
2. Purpose of the research
3. Foreseeable risks and Anticipated Benefits
4. Alternative procedures (when therapy is involved)
5. Statement offering subjects the opportunity to ask questions
6. Opt-out clause: Statement that subjects can withdraw from the research at any time without penalty; also, a statement that informs subjects that if they choose not to participate, this will not harm their relationship with SHSU
7. How subjects are selected
8. Person responsible for the research

► **NOTE:** Most of the above language is included in the consent and cover letter templates on the IRB website:

<http://www.shsu.edu/dept/office-of-research-and-sponsored-programs/about/resources.html>



Informed Consent: Comprehension

- Manner & context information is conveyed is just as important as the information itself:
 1. **Do not** present information in a disorganized fashion (use the template!)
 2. **Do not** present information in a rapid fashion – allow plenty of time for the subject to fully comprehend what's about to happen to them
 3. Ensure that the consent form is in language (e.g. layperson's language – no jargon) that is understandable to participants (e.g., learning-disabled participants)
 4. You have an obligation to ascertain that participants have comprehended the information
 5. The consent form should be free of grammatical and typographical errors



Informed Consent: Voluntariness

- An agreement to participate in research constitutes a valid consent only if **voluntarily** given
- This element requires conditions free of coercion and undue influence – the IRB has found the latter to be more common here at SHSU
- Undue Influence: occurs through an offer of an excessive, unwarranted, inappropriate or improper reward for participating in a research study
- Examples: over compensating with extra credit, money, etc.
- Unjustifiable pressures can occur when the researcher is in a position of authority over the participant (i.e., teacher-student, employer-employee)
- It is highly recommended by the IRB that if the latter is true, that someone other than the researcher should conduct the consent process; the researcher should never know if a participant decided not to participate

The Belmont Report Principle of Beneficence – Assessing Risk & Benefits of the Research to Subjects

- THERE IS RISK IN EVERY STUDY – telling the IRB that there are no risk to participants will not suffice
- Risks in Social, Behavioral and Educational research:
 1. Invasion of Privacy
 2. Breaches of Confidentiality
- **Significance for the IRB:** In the IRB application, you must list the potential risks to participants and outline your data security plan for protecting subjects' confidentiality **(covered in the Project Risk section of the IRB application)**
- **Common methods** of managing the above risks (include but not limited to):
 1. de-identify all data collected from participants
 2. if storing data electronically, store it in an encrypted, password-protected flashdrive or computer
 3. if storing hard copies of data, always store in a locked file drawer/cabinet in a locked office (i.e., see if your faculty advisor can assist in storing the data in their office)

The Belmont Report Principle of Justice

– Equitable Selection of Subjects

- This Principle prohibits the selection of subjects based on convenience
- **Significance for the IRB:** Subjects cannot be excluded based on sex, race, ethnic group, or religion
- If certain groups will be/must be excluded, you must list the population(s) that will be excluded and provide the reason(s) for the exclusion (**this is covered in the Recruitment section of the IRB application**)
- Also, in the Recruitment section, if you select any of the following methods, you will be required to provide a copy to the IRB for review:
 1. Recruiting by Mass Email, through the Internet, or through media ads
 2. Recruiting by Posted Notices/Recruiting Flyers/Letters to subjects
 3. Recruiting by Telephone (the IRB will want to review a script)
 4. Recruiting via the Psychology Research Participation venue (PerP)

Criteria for IRB Approval of Research


- Risks to subjects are minimized (i) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes; [BENEFICENCE]
- Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility. [BENEFICENCE]
- Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons. [JUSTICE]
- Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by 45 CFR 46.116. [RESPECT FOR PERSONS]
- Informed consent will be appropriately documented, in accordance with, and to the extent required by 45 CFR 46.117. [RESPECT FOR PERSONS]
- When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects. [BENEFICENCE]
- When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data. [BENEFICENCE]
- When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects. [JUSTICE]

Required Supporting Documentation (must be attached to the IRB Application)

- CITI Completion Report
- Institutional Permission
- Data collection Instrument (i.e., survey, interview, etc.)
- Recruiting documentation (i.e., email, posted notices, etc.)
- Informed Consent/Cover Letter*
- Parental Consent*
- Child Assent (age-appropriate language)*

* TEMPLATES CAN BE FOUND in the IRB Documents:

<http://www.shsu.edu/dept/office-of-research-and-sponsored-programs/about/resources.html>



Common Pitfalls in the IRB Application

Common Pitfalls Found in IRB Application

Institutional Approval Letter (Institutional Policy)

- Must list the PI as the person with approval
- Must be on school/company letterhead
- If SHSU IRB approval is needed prior to permission, then state that the PI has conditional approval in the letter
- Final Permission letter on letterhead is needed to begin

Common Pitfalls Found in IRB Application

Consent (Respect for Persons)—templates on website

- MUST contain the 8 elements of consent
- If requesting a waiver of consent = discuss
- If requesting participant deception = discuss
- Include the PI's contact information
- Include your faculty sponsor's contact information
- Include Sharla Miles' contact information: 936-294-4875; irb@shsu.edu
- Subject participation time should match the time stated in your IRB application
- Procedures outline should match your application (working appropriate to your target audience)
- Audio taping consent signature line (study, taping, use taping for education purposes)

Common Pitfalls Found in IRB Application

Recruiting Participants

- How recruited
- Equitable selection of subjects (Justice)
- Participants can opt out of questions, withdraw completely without penalty
- Participants can withdraw voluntarily without adversely affecting relationships

Common Pitfalls Found in IRB Application

Data/Records

- Who collects, who has access
- Where and how stored as well as by whom
- How long kept before the data/records are destroyed (law is 3 years)

Common Pitfalls Found in IRB Application

Assessment of Risks/Benefits (Beneficence)

- How do you plan to deal with them
- “Distress or Discomfort” (be forthcoming, not used as a qualifier for a “pass” (disapproval) by the IRB)

Title

- Clear title of the study (not misleading)

Cover letter (alternative consent—requires waiver)

- Clearly describes the purpose of the study and accurately discusses the types of questions on the instrument/interview; contains 8 elements of consent, but no signature line.



Contact for Questions?

PLEASE CONTACT SHARLA MILES IN ORSP AT
PHONE: 936-294-4875

EMAIL AT IRB@SHSU.EDU

LINKS:

[IRB: http://www.shsu.edu/dept/office-of-research-and-sponsored-programs/compliance/irb/index.html](http://www.shsu.edu/dept/office-of-research-and-sponsored-programs/compliance/irb/index.html)

CITI: <https://www.citiprogram.org/>

SHSU IRB Form System:

<https://samweb.shsu.edu/form01wp/>