# Institutional Review Board (IRB)

Delaware State University
Office of Sponsored Programs
Dr. Brian Friel, IRB Committee Chairperson

# What is the Institutional Review Board (IRB) Human Subjects Committee?

- The Institutional Review Board (IRB) is mandated by law for any institution engaging in research. The National Institute of Health (NIH) is one of the primary agencies responsible for monitoring and ensuring compliance in all research conducted at any institution.

# History

- Research conducted in Germany during World War II
- Nuremburg
- Generalizing effects on animals to the effect on humans
- Tuskegee Study-Public Health

# Composition of the Committee

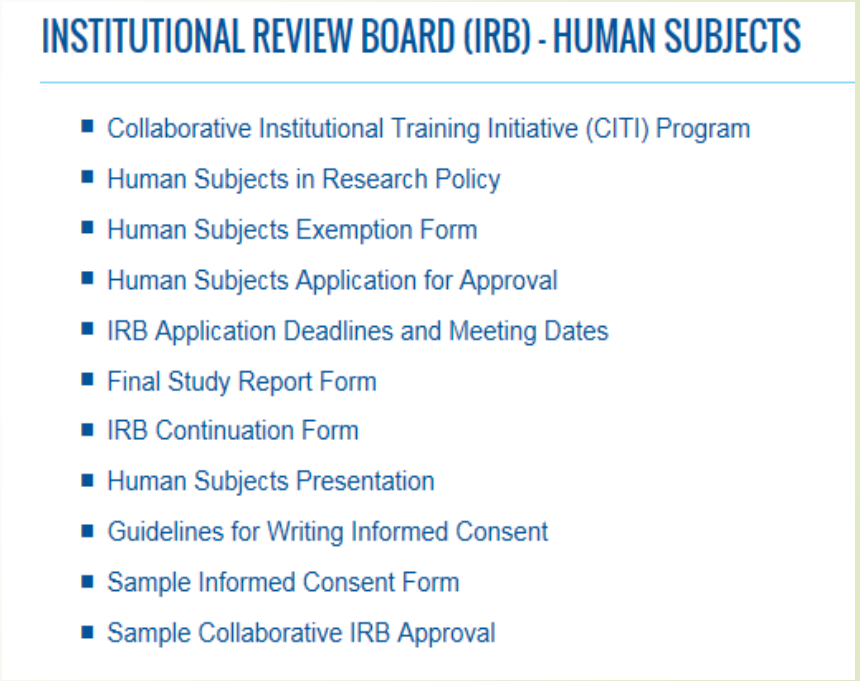
- Chairperson
- Community Member
- University Faculty
- Lay Person (non-affiliated)
- Practitioner

# Committee Responsibilities

- All research involving human subjects must be reviewed by the Institutional Review Board (IRB)-Human Subjects Protection Committee
- Committee follows various guidelines used in reviewing the research protocol to ensure that it is:
  - in compliance with federal and state regulations
  - in accordance with Delaware State University's institutional assurance compliance filed with the Office for Protection from Research Risks (OPRR)

# Where do I find the resources required to submit an application to the IRB?

- All forms and resources pertaining to the Institutional Review Board can be found on the Sponsored Programs site under the Forms Library.



# Exempt Application vs. IRB Application of Investigations Involving Human Subjects

- **Exempt Application-**The Code of Federal Regulations, Title 45 CFR Part 46, identifies several different categories of minimal risk research as being exempt from Federal Policy for the Protection of Human Research Subjects.
- The first page of the application lists 6 categories in which your project would qualify for an exemption.
- Processing of an exempt application takes 5 business days to process

- **Full Committee Review Application-** Any proposed research not qualifying for Exempt status or Expedited review requires a Full Review, in which a majority of IRB members review and vote on the proposal.
  - projects that place human subjects at more than minimal risk
  - involve sensitive topics or vulnerable populations such as prisoners, terminally ill patients, children, veterans, or cognitively impaired persons
- Processing of a “full” application takes 30 days.

Survey instruments

Informed Consent

Letter of approval from cooperating institutions

Copy of external support proposals

Responsible Conduct of Research Training certificate

When submitting either an Exempt Application or Full Committee Review Application, you want to ensure that you provide all supporting documents (listed above) that are relevant to your study.

Let us dive a little deeper into the required information required in a full IRB application

# Proposed Research Project

- A. Provide a brief summary of the proposed research (hypothesis and research design)

Example: This study is designed to assess students' perception of career choice and income. This research study will employ a survey design using graduating college seniors and graduating masters-level students

# B. Describe the source(s) of subjects and the selection criteria. Specifically, how did you obtain the potential subjects and how will you contact them?

Example: The subjects for this study will be drawn from the graduating senior class and the graduating masters level students at Delaware State University.

First, clearance and cooperation will be negotiated with University officials that the study will be able to access these graduating students during graduation rehearsal (normally the week before graduation). During this time and at the conclusion of the rehearsal, a request will be made for students (bachelors and masters) to stop at an established station that would have a supply of questionnaires. Each student responding to the request will be requested to complete the survey instrument. It is anticipated that 75 seniors and 50 graduate students will participate

# C. Informed Consent: Describe the consent process and attach all consent documents. Elements of informed consent are:

**1**. A clear statement that “the study involves research”

Example: We are requesting that you participate in this research study

**2.** All the research purposes are clearly stated

Example: There are three purposes that this study is designed to address:

- 1. to discern what are the career choices of graduates
- 2. to determine what are the perceived income levels associated with career choices, and
- 3. to assess the perceived relationship between career choices and income levels.

# Informed Consent continued

**3. The expected procedures to be followed**

Example: The procedures to be utilized in executing this survey is as follows.

When graduating students report to the research station, a research assistant will provide each student with the informed consent “Signature Sheet”.

Students will be asked to take two minutes to read and sign the sheet. After students have signed the sheet, they will be given the 2- page, 15 item survey instrument to complete.

# Informed Consent continued

**4. The duration of involvement by the subject**

Example: The instrument has been field tested and it is confirmed that the average student should complete the instrument within 10 to 15 minutes. Combined with the two minutes for reviewing the informed consent “signature sheet”, the total time to complete the survey process is estimated at a minimum of 12 minutes and a maximum of 17 minutes

**5. When procedures are experiential**

Example: Does not apply to this study

# Informed Consent continued

**6. Reasonable foreseeable discomfort and risk**

Example:

Considering that this study is based on student perception and there are no invasive procedures or information request, no discomforts or risks can be identified.

**7. If more than minimal risk, "In case of injury or severe adverse reaction…"**

a. is medical care available? by whom? Where?

b. is compensation available? How?

c. whom should the subject contact?

**Example:** This study has minimal risks attached to it relative to the participants. Therefore, issues such as medical care and compensation are not active concerns.

# Informed Consent continued

**8. Reasonable expected benefits to subject and others.**

**Example:** While the researcher can discern no direct benefits to the participating subjects, this study will be of benefit to others by enabling understanding of the extent to which student perceptions are consistent with reality. This clarification will then enable faculty to understand the extent to which their curricula are informing students relative to the work world. This kind of clarification can lead to meaningful changes in curricula to enable students to have a more informed view of the world of work.

# Informed Consent continued

**9. How and where will the data be published?**

**Example:**

This study and its data will be presented in a formal paper submitted to my research mentor and the director of the McNair Program.

**10. The alternatives to the research's diagnostic method or treatment**

**Example**: This item is not applicable to the study described in this document.

# Informed consent continued

**11. How confidentiality or anonymity will be maintained**

**Example**: First, student participants are asked to read and sign a separate signature sheet to address informed consent. These documents will be kept in my research mentor's office in a locked file until the data is analyzed and the report is generated. These forms will then be shredded under the supervision of the research mentor when the written report is accepted. There are no identification included in the survey instrument. So there will be no way of identifying responses with the respondents.

# Informed consent continued

**12. Who will answer questions about the research itself?**

**Example**: The lead researcher will be posted at the reporting station to provide answers to any questions that may be posed by participants. In addition, a number will be provided for participants to call should they have questions at some future date.

# Informed Consent

**13. Who will answer questions about the subjects rights?**

Participants should contact the Office of Sponsored Programs at 302-857-6810 regarding their rights.

# D. Procedures: Provide a step-by-step description of each procedure, including frequency, duration, and location of each procedure.

**Example:** The procedures are fairly simple. They consist of the following.

At the conclusion of graduation rehearsal, a request will be made for students (bachelors and masters) to stop at an established station that would have a supply of questionnaires. Each student responding to the request will be requested to complete the survey instrument. It is anticipated that 75 seniors and 50 graduate students will participate.

The procedures to be utilized in executing this survey is as follows.

When graduating students report to the research station, a research assistant will provide each student with the informed consent “Signature Sheet”. Students will be asked to take two minutes to read and sign the sheet. After students have signed the sheet, they will be given the 2-page, 15 item survey instrument to complete.

# E. How will confidentiality of the data be maintained?

**Example**: First, student participants are asked to read and sign a separate signature sheet to address informed consent. These documents will be kept in my research mentor's office in a locked file until the data is analyzed and the report is generated. These forms will then be shredded under the supervision of the research mentor when the written report is accepted. Identification is not included in the survey instrument. So there will be no way of identifying responses with the respondents.

# F. Describe all known and anticipated risks to the subject including side effects, risks of placebo, risks of normal treatment delay.

**Example**: This study has minimal risks attached to it relative to the participants.

# G. Describe the anticipated benefits to subjects, and the importance of the knowledge that may reasonably be expected to result.

**Example**: While the researcher can discern no direct benefit(s) to the participating subjects, this study will be of benefit to others by enabling understanding of the extent to which student perceptions are consistent with reality. This clarification will then enable faculty to understand the extent to which their curriculae are informing students relative to the work world. This kind of clarification can lead to meaningful changes in curriculae to enable students to have a more informed view of the world of work.

# Important things to remember

- Depending on the risk factors of your research will determine whether you will submit an IRB Exempt application or a full IRB Application.
- No matter which application you submit, remember to include all supporting documents
- The IRB committee meets once a month and all correspondence will be sent from the Office of Sponsored Programs
- Exemption applications normally take 5 business days to provide a decision.
- All resources related to Delaware State University's IRB Committee can be found on the Office of Sponsored Programs website.
- Any questions regarding the status of your application should be emailed to Chanel Haman in the Office of Sponsored Programs.

Questions?