**FAQs - Submission of IRB Application:**

1. Do all research investigators that are involved in the research study need to complete CITI Training?

Yes. The Principal Investigator and all research investigators must be listed in the proposal for the research. This includes student investigators. Certificates indicating completion of the CITI training module(s) appropriate to the researchers’ role must be included with the proposal.

2. Do I need to include a description of all data collection procedures in the research study in the IRB application?

Yes. All procedures in which the volunteer subject participates during the research must be described in detail. Procedures to minimize risk must be defined. (Example: “Blood will be collected by finger puncture.” is not adequate. “A two-drop sample of blood will be collected from a finger puncture using aseptic technique and employing only disposable single-use safety lancets.” is better because it defines the precautions used to prevent infection and cross-contamination. New or non-standard methods or procedures must be described in detail and accompanied by sufficient reference material to allow the IRB to make an informed determination as to the level of risk.

3. Do I need to include copies of all the data collection instruments in the IRB application?

Yes. Studies which collect data by surveys, interviews, focus groups, etc. must include the specific questions to be asked in the proposal. If a survey is to be used, a copy of the survey which includes all questions to be asked must accompany the proposal. If data must be collected by face-to-face interview, the proposal must include an interview flow sheet which contains the specific questions to be asked, the order in which they are asked, and the boundaries within which the responses are acceptable. This is necessary to prevent unstructured responses from a participant from including information which is deemed sensitive or places the respondent at social, psychological, or employment risk. Example: If the interviewer will ask about the level of job satisfaction of the respondent, there must be a limitation which indicates that the interviewer will not allow the respondent to make specific comments regarding an assessment of a superior’s performance or treatment of the respondent. Allowing this would expose the respondent to unacceptable risk to employment status were the supervisor to learn of the response. The same concerns and limitations are associated with data collection by focus group, but even more of concern because of the presence of others in the response setting.

The distinction between anonymity and confidentiality must be recognized. The use of a survey which can be distributed and collected anonymously carries a lower risk than a face-to-face interview. Data which is collected in such a way that the responses cannot be connected to the respondent always carries a much lower risk than data in which confidentiality may be breached, however well-intentioned the researcher is in collecting it.

4. Can you please provide guidance on data collection procedures that minimize risk to human subjects?

Only the data necessary to the question stated in the proposed research should be collected. There is a distinction between distractor questions and data mining. While distractor questions might be necessary for the research, “Shotgunning” or “data mining” by asking anything the researcher thinks might eventually be relevant is not appropriate, and typically results in longer delays than necessary in the approval process. Example: In a study asking about the perception of the public about the use of dashboard cameras by police, a distractor question regarding their comfort with surveillance cameras in businesses would be appropriate. Although a question about the income level of the respondent might be interesting, it is not central to the question posed in the research and asks for private information of the respondent.

5. Can you provide guidance on how to conduct the consent process?

The method of inviting volunteer participants in the proposed research must be clearly indicated. The language used here is critical. Researchers invite voluntary participation. They do not “select subjects.” The method of inviting participation must be free of either real or perceived coercion. Examples: It is not appropriate for an instructor to hand around a sign-up sheet which the instructor collects. Students may (correctly or incorrectly) infer that the instructor will view them more favorably if they agree to participate. It is not appropriate for a supervisor in a work setting to indicate that s/he would appreciate the participation of subordinates in a study. It is appropriate for an instructor to allow an investigator to present a brief invitation to participate in research and make a voice mail or phone contact available for interested students to pursue. It is appropriate for printed surveys to be left in a staff room for interested participants to pick up and return anonymously. It is not appropriate for courses to require participation as subjects in research unless other means of earning the same credit (for a similar time commitment) are made available to the student.

6. When the Informed Consent template is required for my research study, can I modify it and only use a summary of the consent template content?

When the research study requires use of the Consent Form, the complete Informed Consent Form must be used in the research. This must be the complete Informed Consent document and not merely a summary of its content.

* If the research cannot reasonably be conducted without a waiver of the normal informed consent process, a statement giving clear reasons why a waiver of informed consent is required. A description of how the researchers will assure assent to participation by the volunteer must accompany the request for waiver of informed consent.
* Participation by minors in research requires permission of one or both parents as well as assent of the minor (if competent to give it.) DeSales University students who have not reached their 18th birthday may not participate as volunteer research subjects unless parental/guardian permission is obtained. Personal communication with the parent(s) by the Principal Investigator is required to obtain permission.

7. Do I need to include a statement about how the research data is stored?

Yes. The proposal must contain a statement of how the individual data records will be stored for the duration of the study. Data records which can be identified with the individual volunteer or respondent must be stored securely under lock and key. If the records contain medical data, they must be stored consistent with current standards.

8. Can you provide guidance on destroyed research data at the conclusion of the research study?

The proposal must contain a statement of how the individual data records will be destroyed at the conclusion of the study. Data records which can be identified with the individual volunteer or respondent must be destroyed by a process which renders them irretrievable. Paper records should be destroyed by shredding or burning. Electronic records should be destroyed by a file-shredder program or similar process which exceeds the simple erasure of the file name from the directory.