

INSTRUCTIONS TO RESEARCHERS

INSTITUTIONAL REVIEW BOARD – HUMAN SUBJECTS

The Federal Requirement. As of 2001 Duquesne University maintains a relationship with federal research and funding agencies known as a “federal-wide assurance.” Duquesne assures all federal agencies that research conducted under its auspices complies with federal guidelines as spelled out generally in the Belmont Report and as specified in the “Common Rule” (formally, 45-Code of Federal Regulations-46) accepted in 1991. The Institutional Review Board is assigned the duty of overseeing that compliance. Its purpose is, first of all, to protect the rights of participants. Second it is to protect researchers by demonstrating that an independent institutional body has deemed the research ethical and in compliance with federal guidelines.

Duquesne’s Policy. Duquesne’s administrative policy (TAP #41), complies with that regulation. The preamble to TAP 41 states the following, derived from the Common Rule: “This policy is applicable to any research activity conducted at or sponsored by Duquesne University which involves human subjects, i.e. living individuals about whom an investigator (professional or student) conducting research obtains:

1. data through intervention or interaction with the individual, or,
2. identifiable private information.”

Duquesne also accepts the federal guidelines’ definition of research: “A systematic investigation (i.e., the gathering and analysis of information) designed to develop or contribute to generalizable knowledge.”

Types of Projects. Reviews are required for faculty research, whether it is federally funded or not, and whether it is a pilot study or a final study. This breadth of the requirement is part of the “assurance” that the university offers federal agencies. The board also reviews dissertation research, pilot research for dissertations, and in-class research. TAP #41 states: “The policy is applicable whether the research is undertaken on a large or small scale. Pilot projects, student dissertation projects, independent study projects, and course projects must follow this policy if they involve human subjects in research.” Some in-class data collections can be construed as class exercises rather than actual research, allowing the IRB process to be by-passed, but it is prudent to allow IRB representatives to make that judgment.

Interactions with Duquesne IRB Members. The IRB is composed of representatives from the University administration, faculty representatives from various schools and colleges, and members of the community outside the University. Members are listed on the Duquesne IRB web site. The entire Board meets to deliberate proposals that require full-board review. The Board meets every two months, and its schedule is shown on the IRB web site. Exempt and expedited studies can be reviewed at any time, irrespective of the Board meeting schedule. Exempt and expedited protocols must be signed by one IRB representative, the primary reviewer, prior to submission to the IRB Chair. The primary reviewer can be located by contacting your dean’s office or by contacting the IRB office at 412-396-6326. If more complete proposals, such as grant proposals or thesis proposals, exist, they should be made available upon request to the primary reviewer. For full board proposals, two IRB representatives review and sign the transmittal form.

Exempt Status. Exempt status does not mean that the IRB process is by-passed. You must apply for exempt status by submitting one copy of your proposal as described above. Once the status is approved, however, continuing review is not required as it is for expedited and full-review cases. The categories to which exempt status apply are shown in the Transmittal Form. Usually when exempt approval is sought, only one reviewer signs the transmittal form prior to submission to the IRB chair, however, if either the primary reviewer or chair wishes, they can pass the proposal to a second IRB representative for additional review. In addition to IRB representatives' signatures, the transmittal form must include the PI's original signature, and, in the case of students, the advisor's original signature.

Expedited Status. Expedited review is allowed when research involves minimal risk to subjects and does not involve vulnerable groups of people as subjects. Those vulnerable categories are shown in the next section. Minimal risk is defined as no greater risk than would be expected from everyday activities in people's lives. Risk is not confined to physical risk. For example, it might also be financial, social or psychological. In addition, risk applies to the storage and publication of data where loss of confidentiality could negatively affect subjects' lives. Usually when expedited review is sought, only one reviewer signs the transmittal form prior to submission to the IRB chair. If either the primary reviewer or chair wishes, they can pass the proposal to a second IRB representative for additional review. In addition to IRB representatives' signatures, the transmittal form must include the PI's original signature, and, in the case of students, the advisor's original signature.

Full Review Status. Full board review applies to research in which procedures involve greater than everyday risk or the participants are defined, as a group, as especially vulnerable. Duquesne's IRB includes the following categories for full review: subjects under the age of 18; subjects who are pregnant; frail elderly subjects; incarcerated subjects or persons on parole; mentally impaired subjects; procedures involving false or misleading information given to subjects; procedures involving information such that informed consent is in question; procedures requiring debriefing of subjects (usually related to the previous two categories); biomedical procedures; procedures that are not accepted ethical practice in the field; risky procedures or anticipated harmful effects (such as invasive procedures, research making subjects vulnerable to harassment, invasion of privacy, controversial information, or information creating legal vulnerability). Federal guidelines ask IRB members and chairs to use their own judgment on individual cases, above and beyond specified categories, to determine whether proposals require full-board review. In the case of full-board reviews, two IRB representatives must sign the original that is delivered to the IRB office either in hard copy or via electronic submission. The hard copy should be delivered to Marianne Volk at the Office of Research, Room 424 Rangos Building, and the electronic submission should be sent to volk@duq.edu. These are due by noon 7 working days prior to the IRB meeting. If more complete proposals, such as grant proposals or thesis proposals, exist, they should be made available to the IRB Chair upon request. Deadlines are shown on Duquesne's IRB web site. You may consult with the IRB Chair at any stage during the process for advice.

NIH On-line Training. All researchers, including Principal Investigators and Co-Investigators, need to complete the NIH on-line training for the protection of human subjects. If researchers are students, their advisors also complete the training. Certificates of training should be submitted as part of the IRB proposal. NIH training can be found on Duquesne's web site under "academics," then "office of research," then "compliance," then "human subjects."

Health Information Records as Data. If the research involves medical records or any other kind of health information, go to the IRB website for HIPAA instructions and forms. Relevant forms must be attached to this IRB proposal and will be reviewed by the university HIPAA officer.

Applications for Review. Packets should include the following items:

1. **A TRANSMITTAL FORM.** The transmittal form can be found at the IRB web site. The researcher provides the study title, then the names and contact information of researchers involved. First is the name of the principal investigator along with mailing address, email address, and phone numbers. Next are names and contact information of co-investigators. In cases of student research, the faculty advisor is listed as principal investigator, the student as co-investigator along with the student's mailing address, email address, and phone numbers. Then there are various questions, including the category of review that the researcher seeks. For each category (exempt, expedited, full-review) there is a checklist with items appropriate to the category. Sometimes only one item within a category is pertinent; other times, more than one.
2. **AN ABSTRACT.** The abstract length varies depending on the complexity of the research design and subject protections. Ordinarily a minimum length is approximately 3 single spaced typed pages. The abstract should begin with a general picture of the research—the research question, its purpose and significance. In that introduction the literature review should be truncated. Its purpose is to provide a framework for discussion of research methods. Methods should be described in concrete detail. Most method descriptions cover at least 5 areas: 1) subject recruitment; 2) data collection; 3) data storage; 4) data analysis; 5) presentation of results. Subject protections, including confidentiality, should be emphasized throughout discussion of methods. Duquesne's administrative policy #41 states the following: "the methods used for approaching subjects and securing their participation should be designed carefully to protect the privacy of the subjects and should be reasonable in terms of their condition or circumstances. No coercion, explicit or implicit, should be used to obtain or maintain cooperation."

The abstract should also explain the consent, permission, and assent forms. The rationale for specifics in the forms should be explained. The outline for this section of the abstract is the same as that for the forms themselves, shown in # 6 below.

3. **COPIES OF ALL DOCUMENTS RELATED TO RECRUITMENT AND DATA COLLECTION.**
4. **COPIES OF ALL INVESTIGATORS' NIH TRAINING CERTIFICATES** if researchers already certificates on file at the office of research, they may designate the protocols to which existing certificates were attached instead of providing another copy.
5. **CONSENT, PERMISSION, AND ASSENT FORMS.** The forms should be written in accessible language. The first page of each should be shown on Duquesne university letterhead. When the consent forms are approved, the IRB office will stamp them with an

approval date and a one-year expiration date. If researchers still need to utilize the forms after one year, they need to resubmit the forms for a new one-year approval. Consent may be given only by adults (18 years or older). Research studies with minors or cognitively impaired persons require both permission forms (parents/guardians) and assent forms (participants). Consent, permission, and assent forms should include the following:

a. **An overall description of the purpose and significance of the research.** If the title of the project is clear and obvious then the language of the title suffices; however, in many cases titles are too abstract or scientific, requiring a rewording in everyday language clearly explaining the purpose of the study. Also a short description of the role of participants should be made clear from the start, even though it will be detailed later in the consent form. How will they be providing data? How many participants will be involved?

b. **Information about the researcher and sponsoring institution.** Give your full name, affiliation, address, phone number and e-mail address. Make it easy for participants to get in touch with you. Do the same for the IRB chair whose name and contact information appear on the IRB web site. If the research is a student project forms should show both the faculty advisor as PI and the student as co-investigator, with full contact information for both individuals. At the end of the form potential subjects are given names and contact information for persons to who they can report problems. The names and contact information of the graduate student should be repeated there along with the IRB chair's name and contact information.

c. **A description of participants' involvement.** Concretely and in detail, what will they be asked to do, how much time will it take, and where will that involvement take place?

d. **Assurance of voluntary involvement.** Subjects need to be told that their participation is voluntary and that they can withdraw at any time. Many people mistakenly think that once they sign a consent form, they are obligated to complete a study. Withdrawal from a study does not require a signature. There should not be the slightest hurdle to withdrawal.

e. **Assurance that full confidentiality will be maintained.** Measures to ensure confidentiality should be described in detail. Confidentiality of participants needs to be protected, but so does confidentiality of anyone participants might identify or describe in the data. What kinds of identifying material will be collected? Once collected, how will it be deleted from data transcriptions? What will be done with original data recordings? Will they be destroyed? When? How will transformed data be shown in published form?

f. **Description of risks and benefits to participants.** Risks can be physical, especially in biomedical research, but they can be psychological as well. If there are any risks, describe protections and remedial actions that are in place.

g. **Signatures.** Once the study is underway, two consent forms should be signed by both the researcher and the participant, with each retaining a copy.

A sample consent form can be found on Duquesne's web site, but it is a mistake to take a standardized form and just plug in your own information. The sample form is meant as a guide, but ultimately your form should be your own creation, reflecting the particularities of your research study.

In addition to the sample, there are general instructions for constructing the consent form, also on Duquesne's IRB web site.

Approval and Expiration of Consent, Permission and Assent Forms. At the time of approval forms are stamped with an approval date and, ordinarily, a one-year expiration date. If the forms are in use after one year, they must be resubmitted and stamped with new approval and expiration dates.

Continuing Review. For expedited and full-review projects researchers complete and return a continuing review forms, sent to them by the Office of Research. Ordinarily continuing review is annual but it can be more frequent at the discretion of the IRB. Even in Exempt studies, for which there is not automatic continuing review, adverse events or unforeseen human subjects problems must be reported to the IRB prior to proceeding with further research activity. When a study is complete, the researcher should provide the IRB with a short (one page) summary of the research.

AMENDMENTS TO APPROVED STUDIES. If researchers wish to make changes of any kind to approved research procedures, they must contact the IRB Chair before doing so. If the Chair deems the changes to be significant, an amended proposal must be submitted and approved before they may be initiated. The Chair designates an IRB representative or representatives to review the amended protocol. The proposed amendment should include a transmittal form and all pertinent documents with explanations of how and why the approved procedures will be altered. Amended research procedures may not be instituted until the PI receives written approval from the IRB Chair.