

**DUQUESNE UNIVERSITY INSTITUTIONAL REVIEW BOARD
PROTOCOL FOR PROTECTION OF
HUMAN SUBJECTS IN RESEARCH**

IRB SUBMISSION INSTRUCTIONS

I. For all categories of review, provide 2 packets to your primary reviewer according to the following instructions. You can find the names of your college/school/division IRB representatives by looking at Duquesne's IRB web site or by inquiring at 412-396-6326. If review is for exempt or expedited approval, they can be submitted at any time. If it is full-board review, it must be submitted in accordance with the deadlines shown at web site.

1. Complete this transmittal form in duplicate by answering all questions in type or in print, providing your original signature at the end of both. If this is a student research project, also obtain two signatures of your faculty advisor before submitting to the primary reviewer.
2. Attach an abstract (approximately 3 pages) of the study that includes the following information: statement of the research question, purpose and significance of the study, research design and procedures, instruments, sample selection and size, recruitment of subjects, informed consent procedures, collection of data, and method of data analysis. Emphasize issues relating to interactions with subjects and subjects' rights.
3. Attach a copy of any announcements or instructions relating to subject solicitation, such as announcements publicly posted or instructions to professionals who will be asked to contact potential subjects based on particular criteria.
4. Attach a copy of research instruments (e.g. questionnaire, survey, semi-structured interview guide.)
5. Attach a copy of all consent forms and assent forms.
6. Attach copy of NIH training certificate (see Duquesne University Research web site for link to training.)
7. Attach relevant HIPAA forms if utilizing health information records.

For exempt review, one school reviewer signs both copies, and both of these will be submitted to the Office of Research. In the case of expedited review, two reviewers sign both copies, and both of these will be submitted to the Office of Research. In the case of full-board review, in addition to two copies with original signatures, 24 copies of the packet are submitted to the IRB chair (424 Rangos Building) after making revisions in accordance with initial reviewers' requests. Researchers also can request preliminary feedback from the IRB chair by delivering a copy of the packet to 424 Rangos Building by *12 noon 10 working days before the full-board meeting*. The final *24 copies are due at 424 Rangos Building 7 working days prior to IRB meetings by 12 noon*. The due dates are listed on the Duquesne web site under IRB calendar.

If a full research proposal, such as a grant proposal or dissertation proposal, exists, a copy should be made available to the primary reviewer upon request in expedited cases. In full-board cases, 1 copy of the full proposal should be supplied to the IRB chair when the 24 copies of the proposal packet are delivered so that board members can refer to it if the need arises.

Date of Submission:	_____
Protocol Number:	_____
Review Category:	<input type="checkbox"/> Exempt
	<input type="checkbox"/> Expedited
	<input type="checkbox"/> Full Board Review

DUQUESNE UNIVERSITY INSTITUTIONAL REVIEW BOARD
PROTOCOL FOR PROTECTION OF HUMAN SUBJECTS IN RESEARCH
TRANSMITTAL FORM

Title of Study: _____

Name of Investigator: _____

School/Department: _____

Address of Investigator: _____
(address to which
correspondence should
be mailed) _____

Phone: _____ E-mail: _____

Names of Co-Investigators: _____

Name of Faculty Advisor: (if applicable) _____

Phone: _____ E-mail: _____

Intended sponsor/funding agency: _____

Date of submission: _____

If you have submitted this protocol to another IRB, give the following information:

Name of institution: _____

Date Submitted: _____

Approval status: (Check one.)

- Approved (attach copy of letter)
- Pending (date of expected review) _____
- Disapproved (attach copy of letter)

Will subjects receive money, course credit or gifts in exchange for their participation?

yes (specify)

no

Does your research involve the use of data from health information records?

yes If yes, include relevant HIPAA forms

no

Category of Review Requested: (Check one.)

Exempt

Expedited

Full (studies that do not meet criteria for Exempt or Expedited must be reviewed by the full IRB at one of the regularly scheduled meetings)

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If seeking **Exemption** complete this section by checking the number of all that apply.

1.  Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special educational instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
2.  Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

3.  Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b) (2) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
4.  Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
5.  Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.
6.  Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

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If seeking ***Expedited*** Review complete this section by checking the number of all that apply.

1.  Clinical studies of drugs and medical devices only when the drugs or devices have been approved for marketing and are used as prescribed.
2.  Collection of blood samples by finger stick or venipuncture from non-pregnant healthy adults in amounts less than 550 ml in an eight-week period and no more than twice per week.
3.  Prospective collection of biological specimens by non-invasive means (e.g. hair and nail clippings, extracted teeth, excreta and external secretions, uncannulated saliva, placenta removed at delivery, amniotic fluid obtained at rupture of membrane prior to or during delivery, dental plaque and calculus, mucosal and skin cells collected by swab and sputum collected after saline mist nebulization.)
4.  Collection of data through non-invasive procedures routinely employed in clinical settings, excluding x-rays or microwaves (e.g. physical sensors that do not shock or invade the subject's privacy, weighing or testing sensory acuity, magnetic resonance imaging, EEG, EKG, moderate exercise or strength testing with healthy non-pregnant subjects.)

5.  Research involving data, documents, records or specimens collected for non-research purposes, such as medical records.
6.  Collection of data from audio or visual recordings.
7.  Research on individual or group characteristics when considering the subject's own behavior (including perception, cognition, motivation, identity, language, communication, socio-cultural beliefs, practices or behavior) or research employing survey, interview, oral history, focus group or program evaluation measures for purposes of research.

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 If seeking **Full** Review, check the categories that apply to your subjects or methods.

1. subjects under the age of 18
2. pregnant women subjects
3. frail elderly subjects
4. incarcerated subjects or persons under a correctional sentence (parolees)
5. mentally impaired subjects
6. false or misleading information to subjects
7. withholding information such that subjects' consent is in question
8. procedures for debriefing subjects (specify)
9. biomedical procedures (If checked, answer the following)
 - (a) are provisions for medical care necessary?

yes (give details)

no

(b) has a qualified MD participated in planning the study?

yes (attach letter)

no

(c) will the study involve drugs, chemical agents, recombinant DNA, genetic research, ionizing radiation, non-ionizing radiation, microwaves, lasers, high-intensity sound, stem cells

yes (specify and describe)

no

10. procedures that are novel or not accepted practice (if this category applies, explain in the abstract and consent forms how provisions are made to correct, treat or manage unexpected adverse effects)

11. risky procedures or harmful effects, including discomfort, risk of injury, invasive procedures, vulnerability to harassment, invasion of privacy, controversial information, or information creating legal vulnerability (if this category applies, explain in the abstract and consent forms how harmful effects will be addressed and how benefits outweigh risks)

12. other conditions that might affect IRB approval (specify)

Signatures:

Investigator:

_____ **Date:** _____
Typed or Printed Name

_____ **Date:** _____
Signature

Co-Investigator (if applicable):

_____ **Date:** _____
Typed or Printed Name

_____ **Date:** _____
Signature

Co-Investigator (if applicable):

_____ **Date:** _____
Typed or Printed Name

_____ **Date:** _____
Signature

Faculty advisor (if applicable):

_____ **Date:** _____
Typed or Printed Name

_____ **Date:** _____
Signature

IRB representative (one if Exempt, two if Expedited or Full review):

1. _____ **Date:** _____
Typed or Printed Name

_____ **Date:** _____
Signature

2. _____ **Date:** _____
Typed or Printed Name

_____ **Date:** _____
Signature

***Complete this form in duplicate, obtain two sets of original signatures,
and include all attachments prior to delivering both originals to the
IRB Office (424 Rangos Building).***

PROTOCOL SUMMARY

For Duquesne University Institutional Review Board review, the following items should be discussed in the abstract (approximately three pages).

1. Statement of the research question
2. Purpose and significance of the study
3. Research design and procedures
4. Instruments
5. Sample selection and size
6. Recruitment of subjects
7. Informed consent procedures
8. Collection of data and method of data analysis
9. Emphasize issues relating to interactions with subjects and subjects' rights