COLLEGE OF DuPAGE
Office of Research & Analytics

Guidelines for Human Subject Research

A. College of DuPage Institutional Review Board Overview

The College of DuPage Institutional Review Board (IRB) is a local, unregistered IRB. Its primary purpose is to ensure that research conducted at the College protects the welfare of human participants. Although the IRB is modeled after a formal IRB registered with the U.S. Department of Health and Human Services, the College of DuPage IRB is not registered. As a result, research that has been approved by the IRB is not eligible for federal funding through the Department of Health and Human Services programs. Also, some research publications require approval from a formal registered IRB. If you believe that your research might require approval of a formal registered IRB, please contact the IRB Coordinator to discuss options.

Otherwise, if you are planning to conduct research using human participants at College of DuPage, you are required to have College of DuPage IRB approval before proceeding.

B. General Human Subject Research Guidelines

The purpose of these guidelines is to assist those planning to conduct research involving human participants with the process of submitting a proposal for review to the College’s IRB.

C. Definitions (Taken from the code of federal regulations, Title 45, Part 46, Subpart A)

**Research** means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this guideline, whether or not they are conducted or supported under a program which is considered research for other purposes.

**Human subject** means a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual or identifiable private information.

**IRB approval** means the determination of the IRB that the research has been reviewed and may be conducted at the institution within the constraints set forth by the IRB and by other institutional and federal requirements.

**Minimal risk** means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

- Vulnerable populations include children, prisoners, pregnant women, or people with intellectual disability.
- People with intellectual disability are not officially considered a vulnerable population in the current code of federal regulations as there is no subpart devoted to this group. They are included here as their inclusion appears to be consistent with the spirit of the regulations. Be sure to refer to the current code of federal regulations for information concerning vulnerable populations.
D. Composition of the IRB

The IRB will have a minimum of six members that include the Vice President of Planning and Institutional Effectiveness, the Vice President of Academic Affairs, the Director of Research and Analytics, one representative from Student Affairs and two representatives from the full-time faculty. The IRB will be co-chaired by the Vice President of Planning and Institutional Effectiveness and a faculty member. The Director of Research and Analytics will serve as the IRB Coordinator. Additional ad hoc members may be added as deemed necessary by the co-chairs.

E. Role of the IRB

The College’s IRB has the responsibility to review human subject research proposals to ensure that the rights and welfare of human subjects used in research studies by College personnel, students, or researchers are protected. Specifically the IRB will evaluate and determine if:

- Risks have been considered and minimized.
- The potential for benefit has been identified and maximized.
- All human subjects only volunteer to participate in research after being provided with informed consent (unless waived).
- Research is being planned in an ethical manner and in compliance with established ethical principles and applications as outlined in the Belmont Report.

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<thead>
<tr>
<th>Ethical Principles and Applications as Outlined in the Belmont Report</th>
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<tr>
<td><strong>Ethical Principles for Research</strong></td>
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<tr>
<td><strong>Respect for Persons</strong></td>
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<tr>
<td>• Individuals should be treated as autonomous agents.</td>
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<td>• Persons with diminished autonomy are entitled to protection.</td>
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<td><strong>Beneficence</strong></td>
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<tr>
<td>• Human participants should not be harmed.</td>
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<td>• Research should maximize possible benefits and minimize possible risks.</td>
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<td><strong>Justice</strong></td>
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<td>• The benefits and risks of research must be distributed fairly.</td>
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F. Outcomes of IRB Review

Once a proposed research project has been reviewed by the IRB there are four possible outcomes:

- **Approval**: No further action is required from the investigator prior to initiating the study.
- **Approved if Designated Changes are Made**: The investigator may initiate the study after requested changes are made, and the IRB receives these revisions and notifies the investigator that he or she may proceed.
- **Revise and Resubmit**: More extensive changes are required before the study may begin. Additional information must be submitted to the IRB prior to approval.
- **Denied**: The proposed research, because of the level of risk involved, cannot be initiated.

In addition to IRB review, in some cases approval from the appropriate Senior Management Team member may be required.

G. Long-Term Research

Research approved by the IRB that is ongoing must be re-reviewed on an annual basis by the IRB.

H. Categories for IRB Review

There are three types of reviews that the IRB conducts, depending on the particular characteristics of individual projects:

- **Exempt from IRB Review**
  The research project does not require review and approval by the full IRB. The exempt decision is made by the IRB co-chairs using the federally-approved Categories of Exemption (see section I. Exempt from IRB Review Protocol).

  If participants can be identified and linked to their responses or observations of them, the research is not Exempt and must be submitted as Expedited or Full Review research.

- **Expedited Review**
  Review of a research project conducted by the co-chairs of the IRB or by one or more individuals designated by the co-chairs. Research can be approved through this process, or referred to the IRB for full review.

  Research that does not qualify as Exempt may still be subject to Expedited review if all of the following apply:
  
  - The research has been previously approved by an IRB with at most minor changes that do not increase risk to participants.
  - The research involves only normal educational practices in established or commonly accepted educational settings or
    The research involves only behavior of normal adults (18 years of age or older) where there is no psychological intervention or deception.
  - The research involves no more than minimal risk (the amount of risk an individual would expect to encounter in an ordinary day).
  - Identification of participation would not put them at risk of criminal or civil liability, or social or economic damage.
Full IRB Review
Research that cannot be submitted as Exempt or Expedited review must be submitted for full IRB review.

I. Exempt from IRB Review Protocol

Research activities involving human subjects in the following categories may be exempt from review by COD’s IRB.

The principal investigator/project director is authorized to make the first determination of eligibility for exemption; however, the College bears the responsibility for concurring in that determination based on notice provided by the principal investigator to the IRB.

The following exemptions do not apply when (a) deception of subjects may be an element of the research; (b) subjects are under the age of eighteen; (c) the activity may expose the subject to discomfort or harassment beyond levels encountered in daily life; or (d) fetuses, pregnant women, human in vitro fertilization, children, or individuals involuntarily confined or detained in penal institutions are subjects of the activity.

Except for the above exclusions, the federally-approved Categories of Exemption are:

1. Research conducted in established or commonly accepted educational settings involving normal educational practices, such as: (a) research on regular and special education instructional strategies; (b) 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: (a) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (b) any disclosure of the human subjects’ responses outside the research 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, or achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under Category 2 if: (a) the human subjects are elected or appointed public officials, or candidates for public office, or (b) 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: (a) public benefit or service programs; (b) procedures for obtaining benefits or services under those programs; (c) possible changes in or alternatives to those programs or procedures; or (d) 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: (a) if wholesome foods without additives are consumed, or (b) if a food is consumed that contains a food ingredient or 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 U.S. Food and Drug Administration or approved by the U.S. Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.
Exempting an activity from review does not absolve the investigator(s) of the activity from ensuring that the welfare of subjects in the activity is protected and that methods used and information provided to gain subject consent are appropriate to the activity.

Questions about whether a research activity may be exempt from human subjects review can be directed to the IRB Coordinator.

J. External Research Requests

In the event a researcher from another institution of higher education wishes to conduct human subject research at COD, he/she should first secure IRB approval from their institution’s IRB. This approval in addition to all supporting documentation should be presented to the COD Office of Research and Analytics.

K. Approval Process

The researcher files the appropriate Review Form and other required documentation (see item J above) with the Office of Research and Analytics. After receiving the completed request from the researcher, the IRB Coordinator will verify the following items:

- A Review Form and other required documentation has been completed.
- The appropriate signatures have been obtained by the researcher.
- The proposed research is compatible with COD’s mission and is education-related. The research should deal with the teaching and learning environment or with the College's operations.
- The proposal meets the requirements of Protection of Human Subjects (45 CFR 46).

General Principles:

Names of individuals will not be used in the study unless the individuals grant permission in writing. The name of the College will be used only if authorized by a member of the Senior Management Team.

Research considered exempt and/or research that must be expedited will be immediately evaluated by the IRB co-chairs or designee. Other research will be reviewed by the full IRB for approval.

Ordinarily the requestor will be contacted concerning the status of the request within ten working days of receipt of the proposal. If possible, approval or denial of the request will be made at that time. If a delay is necessary, an appropriate timeline will be negotiated with the requestor.

If a research request is denied, the notification will include the reason(s) for the denial. A revised proposal, or sections thereof, may be submitted for reconsideration.

Under certain circumstances, the IRB will submit the request to the appropriate Senior Management Team member for review and guidance.

L. Associated Forms

- Human Participant Review Form
- Exempt Protocol Summary Form
- Student Consent to Participate in Research and Waiver of FERPA Rights Form

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