Cambridge College

Institutional Review Board

Handbook for Researchers

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Cambridge College

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I. Statement of Policy

Cambridge College is committed to the guiding principles stated in the Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, also known as the Belmont Report. The Belmont Report lays out ethical principles to which research in an academic institution must adhere in order to ensure the rights of subjects and the academic freedoms and responsibilities of researchers. As such, Cambridge College has filed a Federal-Wide Assurance for the Protection of Human Subjects with the U.S. Department of Health and Human Services (DHHS).

The three basic ethical principles cited in the Federal Guidelines are:

1. **Respect for Persons**

    a. Individuals should be treated as autonomous agents who are capable of deliberation and acting according to those deliberations. Those with diminished autonomy should be entitled to protections from harmful activities and even possible exclusion from some activities. The level of protection should depend on a carefully crafted risk/benefit analysis

2. **Beneficence**

    a. Research should "do no harm" and maximize the possible benefits while minimizing the possible harms.

3. **Justice**

    a. According to the Belmont Report, there are five conceptions to the fair distribution of burdens and benefits associated with research: (1) to each person an equal share, (2) to each person according to individual need, (3) to each person according to individual effort, (4) to each person according to societal contribution, and (5) to each person according to merit. Researchers should carefully analyze their selection process and research design to adequately address the principles of justice in their study.

II. The Cambridge College Institutional Review Board (IRB)

The Institutional Review Board (IRB) is charged with reviewing and approving all research involving human participants conducted by members of the Cambridge College community. The Board is composed of scientists and non-scientists, members of the Cambridge College community, and non-affiliated individuals. Moreover, the membership of the IRB reflects the multiplicity of Cambridge College's gender, ethnic, and disciplinary composition. Cambridge College's IRB's registration is IRB00007234. Cambridge College's FWA registration is FWA00010125

III. Investigator Responsibilities

The responsibilities of investigators include:

- The **ethical conduct of their research**; the conduct of participating faculty, students, and staff; and the conduct of research participants
- The review of research involving human subjects by the Institutional Review Board **prior to the start of the research project**.
- Seeking approval for making changes to the research protocol.
- Reporting to the IRB any problems or adverse events related to the research project.
- **Retaining copies of IRB approval documents**.
- **Retaining copies of signed consent forms for three years** after the completion of the research.

IV. Research Subject to Review

Cambridge College asserts that all research endeavors involving human participants conducted by members of the Cambridge College community should be conducted in accordance with the ethical principles outlined above and in the Belmont Report, however, not all research must necessarily be reviewed by the IRB.

IRB review is optional for activities that are not intended for publication, are not considered original in the field of study, or are intended for use only at, and by,

Cambridge College employees or students. For example, institutional research, such as interviews with employees, does not require review from the IRB. A researcher can choose to have their research or educational activity reviewed by the IRB in order to offer them institutional protection.

The types of research that do require IRB review are as follows:

1. Research that involves human participants

    a. Reviewable research can include interviews, observation and psychological or medical studies.

    b. Review is dependent upon the design of the study and the level of risk posed to participants.

2. Research that uses data from previous research projects where the investigator is able to identify the participants.

    a. Research that is in aggregate form or masks participants does not require review.

3. Research conducted at other institutions

4. International Research

5. Student Research

    a. Research that goes beyond the mere fulfillment of course requirements (i.e. an ILP involving human participants) requires submission by the investigator(s) to the IRB. An advisor or instructor is required to approve the student's IRB application.
    b. If the research is part of a course requirement, the faculty member is ultimately responsible for the investigator, the participants, and the research outcomes. This may require IRB submission by the faculty member prior to the initiation of research.

V. IRB Review Criteria

The IRB will consider four primary criteria when reviewing research proposals.

1. Risks & Benefits
2. Participant Selection

3. Privacy and Confidentiality
4. Consent

1. Assessment of Risks and Benefits

Risk is defined as the possibility that harm may occur. There are levels of risk, such as "high risk" or "low risk", related to the probability and severity of possible harm. Benefit is defined as something of positive value related to health or welfare. The risks and benefits of research can affect the psychological, legal, social, and economic status of individuals, families, communities, and society at large. Based on the ethical principles of the Belmont Report, research should always strive to have a favorable outcome when balancing risks and benefits.

Although there are no clear-cut quantitative means by which to weigh the risks and benefits of a study, there are several principles that can be used to assess the justifiability of research:

1. Inhumane treatment of subjects is never morally justified.
2. Every effort to reduce or eliminate risks should be explored in the research design.
3. If vulnerable subject populations are involved in the research, then it is necessary to closely examine the appropriateness of using the population and the specific risks and benefits intended for such persons.
4. Benefits and risks are clearly documented and illustrated in proposal materials and materials being given to potential subjects.

2. Participant Selection

Researchers should follow the ethical guidelines based on respect for persons, beneficence, and justice outlined above when selecting subjects for research. In particular, researchers should be cognizant of justice and fairness at both the individual and social level. Researchers should not offer benefits to only some subjects and should not select only certain individuals or groups for high risk research. Explanations of procedures and selection criteria are a necessity for any proposal to the IRB, including reasons why certain groups (gender, ethnic, or socio-economic) are being included or excluded. Moreover, special attention should be paid to the inclusion of high-risk groups such as children or prisoners.

3. Privacy and Confidentiality

Information about subjects must be carefully collected, stored, and monitored. Whenever confidential information is collected by researchers, all such information must remain confidential. Every effort should be made to protect participant information stored on computers and on paper. Privacy and Confidentiality issues are lessened if publicly available data cannot be traced to individuals, and IRB review may not be needed.

Observations of Public Behavior are of particular interest to the IRB. If research is conducted in a way that participants can be identified at a later date, they face potential risks to their personal, social, and economic well-being. The IRB must determine whether the benefits outweigh the risks of involving unconsenting participants.

4. Consent of Participants

Individuals must be given, to the degree that they are capable, the opportunity to choose whether to participate in research and a clear explanation of the consequences. This principle is fulfilled when proper channels of informed consent are in place and an informed consent form is completed by the participant. According to the Belmont Report, **informed consent is the compilation of information, comprehension, and voluntariness.**

- **Information**
    - Subjects should be given sufficient information to make an informed choice. Such materials typically include a number of the following: (a) the research procedure, (b) the purpose of the research, (c) the subject's purpose, (d) the anticipated risks and benefits, (e) how confidentiality will be maintained, (f) description of any compensatory conditions of participation, (g) informing the subject that they may withdraw at any time from the research, (h) researcher and IRB contact information, (i) contact information for mental or medical health services (if applicable).
- **Comprehension**
    - The researcher is responsible for providing clear information and making sure subjects understand the materials. Special provisions may need to be made when comprehension is ambiguous or severely limited, as in the case of children or mentally disabled individuals. In some cases a third party may be consulted on behalf of a participant who can act in the person's best interest.

- The reading level and language of the information materials should be appropriate for the subject population. Clear headings and structure also aid in successfully conveying information to participants.

- **Voluntariness**

  - Informed Consent is only valid if consent is voluntarily given and free of coercion or undue influence.

  - Coercion occurs when an overt threat of harm is intentionally presented by one person to another in order to obtain compliance. Undue influence occurs when an offer of excessive or improper reward is provided in order to obtain compliance.

VI. Procedure for Securing Approval

- The investigator is responsible for determining whether the project requires IRB review and submitting a complete application for approval.

- Research must be approved by the IRB prior to its initiation, including recruitment, in order to fully protect participants.

- **Research is reviewed on one of three levels.** Only the IRB can determine the level of review of a proposal according to IRB interpretation of college and federal guidelines:

1. *Screening for exemption from full IRB review***:**

- Researchers must file an application requesting that a project be classified as exempt; **this cannot be determined by the researcher.**

- Exempt research vetted through the IRB retains the same level of protection for the researcher(s) and participants as expedited and full reviewed proposals.

- If a proposal does not qualify for exempt status, it will be considered for expedited or full review.

- **Research exempt from full review includes:**

  - **Routine Instructional Research**

  - Research on instructional strategies conducted in educational settings that involves normal educational practices (e.g. research on the effectiveness of a particular assessment technique or curricula)
- Anonymous surveys (typically the omission of names or other personal identifiers, such as social security or student ID numbers)
- Public behavior research (on adults) as long as the information obtained cannot be linked to particular individuals or disclosure of information does not place participants at risk of criminal or civil liability.
- Survey and Public Behavior Research on Public Officials as long as the participants are elected or appointed officials or federal statutes require the confidentiality of the participant or the participant's information.
- Research on existing data and specimens if the data is publicly available or participants cannot be identified by the information.
- NOTE: Observational or survey research involving sensitive aspects of participants' behavior or illegal activities are not exempt. Examples include substance abuse, sexual activity, sexual abuse, criminal behavior, or detailed health history.

2. Expedited IRB review

Research that qualifies for expedited review must involve one of the following activities that are federally approved for expedited review and involve no more than minimal risk to participants.

 Activities approved in the federal regulations include:

- Collection of small amounts of blood from healthy adults
- Collection of biological specimens (e.g. hair) through noninvasive means
- Research on existing data or specimens (some research is exempt)
- Collection of data from voice, video, digital or image recordings
- Research on individual or group characteristics or behaviors (some research is exempt)
- Research involving surveys, interviews, or focus groups (some research is exempt)
- Continuing review of non-exempt research previously approved by the IRB, where no new participants will be enrolled, and where minimal risk is involved.

- It is the researcher's responsibility to indicate in their IRB proposal how the research fits into one of these categories in order to qualify for expedited review.

- The submitted proposal is forwarded to the appropriate committee member who can approve, deny, ask for revisions, or forward it to the larger committee for full review.

3. Full IRB review

- Full review is required for all research involving more than minimal risk to participants.

- Examples of research requiring full review include:

    - Any research that poses more than minimal risk to participants.

    - Any survey or interview that is likely to be stressful for the participant:

        - Survey research involving sensitive questions or information about AIDS, as per federal regulations that identify AIDS suffers as a vulnerable population.

    - Case-Control Studies (e.g. exposure to a particular drug) in most cases that involve the researcher reviewing medical records and interviewing subjects.

VIII. Additional Resources

Additional information about IRB proposals, research procedures, and federal guidelines can be obtained through several sources:

- The U.S. Department of Health and Human Services website:
    - http://www.hhs.gov/ohrp/

- A copy of the Belmont Report:
    - http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm

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