Institutional Review Board: Revised Policy and Procedures Elmhurst College

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Institutional Review Board Policy and Procedures
Elmhurst College

A. Purpose and objectives

1. An Institutional Review Board (IRB) has been established to evaluate potential risks to human subjects involved in research conducted at Elmhurst College. The board's function shall also be to conduct initial and continuing review of research projects involving humans according to guidelines specified in external sources governing research, such as those in the Federal Register, as well as guidelines developed by the Board specific to the College (see below).

2. Elmhurst College desires to comply with federal regulations regarding the protection of human subjects used in research projects conducted at the College. Compliance with the regulations of the Department of Health and Human Services is required for research funded directly by HHS[1] and some other federal funding agencies. These regulations, and others such as the Belmont Report[2] have served as a model for general protection of human subjects and the development of the specific guidelines elaborated below.

3. The IRB will develop specific procedures and policies for evaluating research conducted at the College and ensure that researchers comply with these standards. The IRB will further catalog and track the research being conducted.

B. Membership of the IRB

The IRB will consist of at least five persons of diverse backgrounds (race, gender, culture, professional interest, and sensitivity to protection of vulnerable subjects) appointed by the President of the College. At least one of these members will represent a nonscientific professional area and at least one member will not be affiliated with the college. Any member who has a conflict of interest in a particular research project shall be excluded from the decision-making in that instance. Alternate members may be selected as needed.

C. General ethical guidelines for research conducted at Elmhurst College

The following are general principles that the IRB expects all research conducted at the College to follow. In evaluation of research proposals, the IRB will consider the following issues in

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[1] . Protection of Human Subjects. Code of Federal Regulations--45 CFR 446, revised June 18, 1991, effective August 19,1991. Department of Health and Human Services National Institute of Health Office for Protection from Research Risks.

[2] The Belmont Report: Ethical principles for the Protection of Human Subjects of Research. The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, April 18, 1979.

Determination of the appropriateness of a study.

1. Participants' rights and welfare are adequately protected before, during, and after their participation.
2. Participants are not exposed to unreasonable risks to their general health or well-being. 3. Participants are not coerced and freely agree to participate in the research.
4. Participants are provided reasonable informed consent about the research and any potential risks and/or harms. In the case of deception, participants are provided as much information as possible to make their determination on whether to participate.
5. Participants are free to withdraw at any point during the experiment without penalty.
6. Participants' responses and/or data are kept anonymous or confidential.
7. Participants are debriefed after the research, particularly in the case of deception.

D. Types of risk

There are two types of research risk; "minimal" and "at-risk". Listed below are criteria that specify each of these types of risk. For all research the investigator determines the level of risk and the IRB reviews that determination. In cases where additional information or clarification is needed, the IRB may contact the investigator.

1) Minimal risk

A research project involves minimal risk if;

1. The participant experiences no pain or physical danger.
2. The participant experiences no emotional arousal or psychological stress beyond the levels normally expected in daily life.
3. The research neither induces nor attempts to induce long-term significant change in the participants' behavior, attitude, or personality.
4. Any deception about the nature of the research is minor and, had the full purpose of the study been revealed, there is a reasonable degree of likelihood that the participant would have consented to participate.

Example of such research might include observational studies, memory or perceptual experiments, or questionnaire research.

2) At risk

While the IRB realizes that most research at the College will likely be of minimal risk, research may occasionally be performed that does not meet the above criteria. There may also be a question about whether this research meets the general ethical guidelines listed above. This research would be considered at-risk. An example of such research might be an experiment that administers IQ tests and provides bogus negative feedback about performance to assess emotional responding to threat. Such a project would not only involve significant deception, but also place an emotional burden on a participant greater than that experienced in daily life. In the case of at-risk research, the IRB will determine whether the above general guidelines are met and

conduct a risk-benefit analysis. This analysis weighs any potential risk to participants with the potential benefits to the researcher's field or to society in general. In the case where the benefits outweigh the risks and basic ethical issues are addressed and properly managed, the IRB may allow such a project to be completed. The researcher would have to demonstrate clearly the potential benefits of such research and stipulate how they would manage any risk to participants. Additionally, the IRB may take extra steps to ensure that at-risk research is being conducted in accordance with the initial proposal and that it continues to meet ethical standards.

E. Exempt from formal IRB review

Some research at the college, typically that of an administrative nature, does not raise the same risk-related issues as other research and is exempt from formal IRB review. Examples of such research include;

1. The use and analysis of anonymous/confidential records for the administrative purposes of Departments or the College.

2. The use and analysis of anonymous/confidential surveys to assess college or department related activity (e.g., advising, student satisfaction surveys).

3. The use and analysis of anonymous/confidential assessment tools to evaluate class-related activities.

4. Student research with human participants conducted as part of a class or independent study that entails minimal risk (see below). When these projects are considered at-risk, they must go through IRB review and be approved.

F. Student research

Because research at the College is done by students as part of a class or independent study, ethical guidelines for student research deserves special mention. First, the IRB expects student research to follow the same general guidelines and procedures as other research. The IRB also expects that the supervising faculty member be responsible for the ethical review and analysis of minimal risks projects using the guidelines established above. In the case of at risk research or whether there is a question of the level of risk, the IRB will evaluate the project. In the case of all student research, the IRB requires faculty to provide a list of projects so that these can be tracked and recorded.

G. Special Populations

1) Minors/Children

Permission to conduct research with children and minors (those under 18 years age) requires special considerations of ethical issues, as well as their level of understanding. In such cases, informed consent must be obtained from the parent or appropriate legal guardian, as well as assent from the child. These forms are provided in Appendix D.

2) Potentially Vulnerable Populations

Special care must be taken to ensure that ethical guidelines are followed when working with potentially vulnerable populations and that they are not coerced. For instance, in the case of prisoners, the informed consent form must make it clear that their participation in research will have no effect on their treatment or potential parole. In the case of mentally disabled/handicapped individuals, a legal guardian or patient advocate must give informed consent and the individual must also provide assent. Although only two categories are mentioned here, the researcher has special responsibility to ensure ethical guidelines are followed when potential participants have circumstances that might affect their ability to voluntarily give informed consent.

H. Procedures

1. Upon receipt of completed materials, the chair of the IRB (hereafter referred to as the Chair) will distribute materials to all members of the IRB.

2. A majority of the IRB will meet to discuss and deliberate on each new submission. A majority vote will make one of the following decisions;

a. approve the project as presented.
b. approve the project with minor changes and/or revisions.
c. defer on voting on the project pending significant changes or alterations in the project.
d. disapprove the project.

In all cases, the Chair will inform the investigator in writing about the decision of the Board. The Federalwide Assurance Institutional Signatory Official and/or Human Protections Administrator will also be notified in writing of all Board decisions. In case of a., the project may begin as soon as the investigator receives this notification. In the case of b, the investigator must submit the necessary minor changes/revisions to the Chair. If these changes adequately address the IRB's feedback, the project may begin once written notification is sent to the investigator. In the case of c., when the Chair receives the significant revision, another meeting of the full IRB will be called and a new review of the project will take place. The investigator also has the option of meeting with the IRB to further discuss and/or clarify the project. In the case of d., the investigator may revise the project to address the ethical issues raised by the IRB. The investigator also has the option of appealing the decision and may meet with the IRB to discuss and/or clarify the project.

In all IRB meetings, any member who has a conflict of interest on a project will recuse him or herself from deliberations on that project. If this is the Chair, he or she will appoint a designee as Acting Chair.

3. Minutes will be taken at all IRB meetings and kept for at least a 3 year period. Other records, including proposals, committee action, and correspondences to investigators will also be kept for a period of at least three years.

4. In the case of project revisions during the course of the project, the investigator will detail the proposed changes and modifications in writing and submit them to the Chair. All changes and modifications may not be initiated without IRB review and approval, except when necessary to eliminate apparent immediate hazards to the subjects. In the case of significant changes, the Board will re-review the project at a convened meeting. In the case of minor changes, the Chair will re-review the project.

5. Upon completion of projects, the investigator will notify the Chair in writing to indicate that the project is completed.

6. Approved research is subject to continuing IRB review at least yearly, or more frequently if specified by the IRB [45 CFR 46.109(e)]. This review must take place before the approval expiration date; any lapse in approval will result in suspension of subject recruitment, enrollment, data collection, and, if the research is sponsored by any division of the U.S. Department of Health and Human Services, notification to the funding Agency. The approval date and the termination (expiration) date are clearly noted on all IRB communications sent to the investigator and must be strictly adhered to. Investigators should include in their project planning sufficient time for development and review of renewal submissions. Renewal applications should be sent in writing to the Chair and this application consists of a general description of the status of the project (e.g., the number of subjects enrolled, number of subjects who withdrew prematurely and reason(s) for their withdrawal, etc.). The Chair will review the renewal application, and, if necessary, convene the Board to review the renewal application.

7. The IRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to research participants. Any suspension or termination of approval must include a written report describing the reasons for the IRB's action. A copy of this written report must be promptly delivered to the principal investigator, appropriate institutional officials, and as appropriate the sponsor and/or Department of Health and Human Services or Agency head.

8. All members of the Elmhurst College community involved in human subjects research are expected to comply with the highest standards of ethical and professional conduct in accordance with federal and state regulations and institutional and IRB policies governing the conduct of research involving human subjects.

Non-compliance is defined as failure to comply with any of the regulations and policies described in this document. Non-compliance may be minor or sporadic or it may be serious or continuing.

Minor or sporadic non-compliance is defined as failure to comply with IRB policies, which (in the judgment of either the IRB Chair or the convened IRB) are administrative in nature. Examples of minor or sporadic non-compliance include turning in a report of an unanticipated problem a day late or failure to date a consent form.

Serious non-compliance is defined as failure to follow any of the regulations and policies

described in this document, which (in the judgment of either the IRB Chair or the convened IRB) increases risks to participants, decreases potential benefits, or compromises the integrity of the human research protection program. Research conducted without prior IRB approval is considered serious noncompliance.

Continuing non-compliance is defined as a pattern of non-compliance which (in the judgment of the IRB Chair or convened IRB) suggests the likelihood that instances of non-compliance will continue without intervention. Continuing non-compliance also includes failure to respond to a request to resolve an episode of non-compliance.

9. Unanticipated problems involving risks to research participants or others and serious or continuing noncompliance with regulations or the requirements or determinations of the IRB must be promptly reported to the Chair and the Human Protections Administrator and/or Federalwide Assurance Institutional Signatory Official. Furthermore, such events will be reported to the Federal Office for Human Research Protections and any sponsoring department or agency head.

Appendix A

Institutional Review Board Proposal
Elmhurst College

On a separate sheet of paper, please type your responses to the following items. Attach questionnaires, tests, consent forms, and other supporting documentation.

1 **. Project Title** (Please type or print):

Principal Investigator(s)

Department _____ Phone _____ E-mail

Project Start Date: _____ End Date:
A. Is this project EXTRAMURALLY FUNDED? Yes No
Funding Source:_____

B. Is this project INTERNALLY FUNDED? Yes No
Funding Source: _____

2. **Type of proposal**: Original Proposal Revised Proposal

3. **Determination of risk**: Minimal Risk At-Risk

4. **Purpose of the Project**: Briefly describe the main purpose and objectives of your research.

5. **Participants:** Describe the participants you will be using, including the following; age, sex, approximate number, inclusion/exclusion criteria (if any), and recruitment method.

6. **Compensation**: Indicate how participants are to be compensated for their participation (e.g., money, course credit) and how much they will be compensated.

7. **Procedure and Duration:** Explain the procedures of the study in sufficient detail to allow the IRB to fully understand what is expected of the subject. Also indicate the approximate amount of time required of each subject. Include interview questions, surveys, questionnaires, or other data gathering instruments that will be used.

8. **Deception:** Indicate whether or not deception is involved. Specify the nature and extent of the deception. Had the full purpose of the research been revealed at the outset, is there a reasonable degree of likelihood that the participant would have given consent to participate? If not, describe why this deception is necessary and, if applicable, why the benefits of this research outweigh such deception.

9. **Risks** Describe, in detail, any risks to the participants' physical and/or psychological well-being that might reasonably be expected to occur. If there are no known risks that are likely to occur, clearly state that.

10. **Risk Management:** If participants are at risk, describe steps to minimize risk. For instance, if procedures could be emotionally distressing, describe arrangements for support services and/or assistance. (e.g., psychological counseling).

11. **Benefits**: Indicate anticipated benefit(s) to the subject, society, and/or science.

12. **Safeguarding Subject's Identity:** Indicate how the confidentiality and privacy of the participants' responses will be safeguarded. What precautions will be taken to safeguard identifiable records or individuals?

13. **Informed consent**: Specific provisions for informed consent must be specified, and a copy of the informed consent form you intend to use must be attached. See Appendix A for details and sample

14. **Debriefing**: Briefly describe how you will debrief participants, particularly in the case of deception.

15. **Off campus research (if applicable)**: If the research is conducted off campus, indicate where the research will be conducted and whether research has been reviewed by another sites' research review board. If so, please attach supporting documentation.

16. **Research on children or minors (if applicable):** If your research involves children or minors, you must have an informed consent form completed by their parents and an assent form completed by the child (see Appendix D).

I have read the policy and procedures of Elmhurst College's IRB and agree to abide by it. I also agree to report any significant and relevant changes in the procedures and instruments to the Board for additional review.

Principal Investigator and Date Faculty Advisor (if necessary) and date

Appendix B

Necessary Components for Informed Consent Forms

The following information needs to be included in informed consent forms. All informed consent forms should be in clear, non-technical language that is appropriate to the participant. An informed consent form must be completed by each participant; for minors, an informed consent must be signed by the legal representative and the minor must also complete an assent form. The informed consent or assent forms must be kept for a period of three years following completion of data collection.

1. The title of the research and the researchers. An invitation to contact these researchers should the participant have any questions should be made.
2. The purposes and/or objectives of the research.
3. A brief explanation of the experimental procedures and their likely duration for each participant.
4. Any reasonable foreseeable risks to the participant. In the case of "at-risk" research, a brief description of how these risks will be managed and what provisions have been taken to ensure this should be included.
5. Any reasonable benefit to the participant or others that might be expected to occur with participation.
6. How participants' confidentiality and/or anonymity will be ensured.
7. A clear statement that participation is voluntary and can withdraw at any time without penalty.
8. Whom to contact with further questions and/or complaints about participation in the study. This should be the Chair of the IRB.
9. A signed and dated statement indicating the above have been explained and that they agree to participate.

Appendix C

Example of Informed Consent Form for Adults

This example is provided to assist investigators in preparation of informed consent forms. This format does not necessarily need to be precisely followed, as long as the information below is included.

1 . Project Title
Patient and Professional Relationships

2. Introduction of Researcher(s)
I am Professor Mary Smith of the Department of Sociology at Elmhurst College. Should you have any questions about this project at any time, feel free to contact me (us) at Name, Department of Sociology, Elmhurst College, 190 Prospect Ave. Elmhurst, IL 60126, (630) 617-xxxx.

3. Purpose of Research
My colleague, Joseph Hernandez and I are conducting a study of how medical professionals relate to patients. We would appreciate your participation in this study, as it will assist us in making recommendations for improving the teaching of health professionals and the way they treat you.

4. Explanation of Procedures
You will be completing a questionnaire that takes approximately 15 minutes to complete. Our study will run for three months and there will be 100 people filling out the questionnaire.

5. Risks and Benefits
We do not anticipate any foreseeable risks or discomfort other than the inconvenience to you in completing the questionnaire. Although this study may not directly benefit you, it potentially will benefit our understanding of the doctor-patient relationship.

6. Safeguards of Data
We will use no code numbers to identify you. Data will be published in aggregate form and may be presented at professional meetings or in professional journals. Data will be kept in a locked file in the investigator's office. The data will be destroyed at the conclusion of the study.

7. Freedom to withdraw from the study
Your participation is completely voluntary. If you choose to withdraw from the study, the information gathered at that point will be destroyed and you will not be penalized (i.e., you will still receive course credit).

8. **Third Party Referral**
If you have any complaints about your treatment as a participant in this study, please call or write to the chair of the Institutional Review Board: Dr. _____, Institutional Review Board, Elmhurst College, 190 Prospect Avenue, Elmhurst, IL 60126, (630) 617-*extension*. Although Dr. _____ will ask your name, all complaints are kept in confidence.

9. **Closing**

I have received an explanation of the study and agree to participate. I understand that my participation in this study is strictly voluntary.

Name Date

This research project has been approved by the Elmhurst College Institutional Review Board.

Appendix D

Example of Assent Form for Child/Minor

I, _____ , understand that my parents (Mom and Dad) have given permission (said it's okay) for me to take part in a project about memory formation being done by Dr. Smith. I am taking part because I want to. I have been told that I can stop at any time I want to and nothing will happen to me if I want to stop.

Signature of participant and date