Institutional Review Board / Institutional Animal Care and Use Committee

Policy and Procedures - 2023 Revision

Elmhurst University

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A. Purpose and Objectives

The Institutional Review Board (IRB) / Institutional Animal Care and Use Committee (IACUC) has been established to evaluate potential risks to human or animal subjects involved in research conducted at Elmhurst University. The board's function shall also be to conduct initial and continuing review of research projects involving humans or animals 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 University (see below).

Elmhurst University desires to comply with federal regulations regarding the protection of human or animal subjects used in research projects conducted at the University. Compliance with the regulations of the U.S. Department of Health and Human Services (HHS) is required for research funded directly by HHS and some other federal funding agencies. These regulations, and others such as the Belmont Report, serve as a model for general protection of human subjects and the development of the specific guidelines elaborated below.

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

1. IRB – The IRB protects the rights and welfare of human research subjects recruited to participate in research activities conducted at or sponsored by the University. The IRB evaluates potential risks to human subjects through initial and continuing review of research projects, and has the authority to approve, require modifications in, to disapprove all research activities that fall within its jurisdiction as specified by both the federal regulations (45 CFR Part 46) and local 108 institutional policy. The Office of the Vice President for Academic Affairs (VPAA/Dean), in consultation with the IRB/IACUC Chair, will assure that federal compliance and documentation are maintained. Members will complete and maintain current online training throughout their terms.

2. IACUC – The primary role of the IACUC is to ensure the humane care and use of animals in research. The IACUC is responsible for ensuring compliance with the regulations of the Public Health Service by reviewing research projects that involve animals, maintaining and enacting procedures for evaluating the institution's animal care and use, maintaining and enacting an adequate veterinary care program, maintaining and enacting an occupational health and safety program, maintaining and enacting a program for housing and management of animals, and overseeing and inspecting facilities for housing and support of animals as required by law. The Office of the Vice President for Academic Affairs (VPAA/Dean), in consultation with the IRB/IACUC Chair, will assure that federal compliance and documentation are maintained. Members will complete and maintain current online training throughout their terms.

B. Membership of the IRB/IACUC

1. Membership of the Institutional Review Board/Institutional Animal Care and Use Committee (IRB/IACUC) is comprised of the following persons:
    a. At least five persons of diverse backgrounds (race, gender, culture, professional interest, and sensitivity to protection of vulnerable subjects) appointed by the Faculty Council and approved by the President of the University.
    b. At least one member whose primary concerns are in scientific areas with experience in human subjects research; one experienced in research involving animals; and at least one member whose primary concerns are in nonscientific areas.
    c. At least one member who is not otherwise affiliated with the University and who is not part of the immediate family of a person who is affiliated with the University, and who is not a laboratory animal user or former user.
    d. At least one member who is a Doctor of Veterinary Medicine - to be called upon on as needed basis if the research proposed involves animals.
    e. Three alternate members who meet the criteria stated will be appointed by the Faculty Council and approved by the President to be called as needed.

2. Terms of membership:
    a. Terms will be for four years.
    b. Faculty may be re-appointed.
    c. An individual who meets the requirements of more than one of these categories may fulfill more than one requirement, but the committee must consist of at least five members.

3. Chair Roles & Responsibilities

    The IRB/IACUC chair is selected by the committee. The chair is responsible for:

    - Receiving/reviewing all IRB/IACUC proposals and other requests
    - Maintaining a record of all proposals, exemption requests and classroom-based research being conducted by university faculty, students, and staff with a log of assigned proposal numbers
    - Maintaining, updating, and creating policies, procedures, and forms necessary for IRB/IACUC business
    - Setting meeting dates/times/locations and providing agenda items
    - Communicating committee decisions with PIs and following up with those who need to make modifications before approval can be granted
    - Working with other entities on campus, such as the Center for Scholarship and Teaching (CST) or Faculty Development Committee (FDC), to ensure that research that receives grant funding is approved by IRB/IACUC as needed

- Working with other institutions when a reliance agreement or other collaborative agreement is required

4. Committee Roles & Responsibilities

   Faculty are appointed as either committee members or alternates. Regular committee members have the following responsibilities:

   - Participation in monthly meetings either in-person or online
   - Provide feedback on full IRB/IACUC proposals that come before the committee, with particular focus on participant safety, confidentiality, and informed consent
   - Provide feedback and guidance on updated/new policies, procedures, and forms
   - Regular members and alternates are included on all committee communication and have access to all IRB/IACUC documents, currently provided in Microsoft Teams.

   Alternates are not required to attend meetings or provide feedback unless specifically called upon to do so due to conflict of interest or other unavailability of regular committee members.

   All IRB/IACUC members will complete appropriate CITI training as indicated in Appendix I.2.

5. Member/Chair Training

   All members will complete IRB & IACUC member training provided by CITI. These modules are valid for 3 years, and members will renew their certifications as needed to maintain current training throughout their membership term. See Appendix I.2 for current required modules for members.

   In addition, the IRB/IACUC chair will complete additional CITI training as specified in Appendix I.3.

6. Federalwide Assurance

   The VPAA/Dean of the Faculty serves as the Federalwide Assurance (FWA) institutional signatory official. FWAs must be renewed every five years. The VPAA or Associate Dean manages this process.

   Elmhurst University's registration numbers are:

   - Federalwide Assurance Number: FWA00025094
   - IRB Organization Information: IORG0004187
   - Elmhurst College IRB #1: IRB00004966

C. General Ethical Guidelines for Research Conducted at Elmhurst University

1. All members of the Elmhurst University community involved in human or animal 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/IACUC policies governing the conduct of research involving human or animal subjects.

   The IRB/IACUC follows the regulations and guidelines listed below:

   a. Human Subjects Research
      - U.S. Department of Health and Human Services – Code of Federal Regulations, Title 45, Public Welfare, Part 46, Protection of Human Subjects
      - The Belmont Report
      - The Nuremberg Code
      - The World Medical Association Declaration of Helsinki

   b. Animal Subjects Research
      - Animal Welfare Regulations and Rules of Practice - U.S. Department of Agriculture, Animal and Plant Health Inspection Service - Code of Federal Regulations, Title 9, Chapter 1, Subchapter A, Animal Welfare, Parts 1, 2, 3 & 4
      - U.S. Department of Agriculture Animal Welfare Act (AWA)
      - National Institutes of Health Office of Laboratory Welfare, Public Health Service, PHS Policy on Humane Care and Use of Laboratory Animals
      - U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training

2. The following are general principles that the IRB expects all human subjects research conducted at the University to follow. In evaluation of research proposals, the IRB will consider the following issues in determination of the appropriateness of a study.

   a. Participants' rights and welfare are adequately protected before, during, and after their participation.
   b. Participants are not exposed to unreasonable risks to their general health or well-being.
   c. Participants are not coerced and freely agree to participate in the research.
   d. 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.
   e. Participants are free to withdraw at any point during the experiment without penalty.
   f. Participants' responses and/or data are kept anonymous or confidential.

g. Participants are debriefed after the research, particularly in the case of deception.
h. Participants who are minors or are members of other vulnerable populations will have a parent/guardian provide consent and they will assent to participate.
i. Appendix J includes references and further information about recruiting participants in accordance with the guiding principles of the Belmont report, especially in the era of anonymous/online participant recruiting.

3. Informed Consent is required with every proposal provided to the IRB/IACUC. The purpose of informed consent is to document that participants not only give their permission to participate, but that they understand what they are giving permission for.

4. 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.

    a. Minor or sporadic non-compliance is defined as failure to comply with IRB/IACUC policies, which (in the judgment of either the IRB/IACUC Chair or the convened IRB/IACUC) are administrative. 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.

    b. 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/IACUC Chair or the convened IRB/IACUC) increases risks to participants, decreases potential benefits, or compromises the integrity of the human research protection program. Research conducted without prior IRB/IACUC approval is considered serious noncompliance. This includes instances where a project has been approved by the IRB/IACUC, but modifications have been made to the protocols and assessments without IRB/IACUC approval.

    c. Continuing non-compliance is defined as a pattern of non-compliance which (in the judgment of the IRB/IACUC Chair or convened IRB/IACUC) 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.

D. Types of Risk to Human or Animal Subjects

There are two types of research risk with human subjects: "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/IACUC reviews that determination. In cases where additional information or clarification is needed, the IRB/IACUC may contact the investigator.

1. Minimal Risk (Human Subjects)

   A research project involves minimal risk if:

   a. The participant experiences no pain or physical danger.
   b. The participant experiences no emotional arousal or psychological stress beyond the levels normally expected in daily life.
   c. The research neither induces nor attempts to induce significant long-term change in the participants' behavior, attitude, or personality.
   d. 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.

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

2. At Risk (Human Subjects)

   While the IRB/IACUC realizes that most research at the University 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/IACUC 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 participants, 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 responsibly managed, the IRB/IACUC 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. Also, the IRB/IACUC may take extra steps to ensure that at-risk research is conducted in accordance with the initial proposal and that it continues to meet ethical standards.

3. Exempt from Formal IRB/IACUC Review

   Some research at the University, typically that of an administrative nature, does not raise the same risk-related issues as other research and is exempt from formal IRB review. Exempt studies are generally not required to obtain written informed consent, do not need to be reviewed annually, and are not required to submit modifications prior to implementation, unless they potentially affect the exempt status of the study. Those who believe their research is exempt from IRB/IACUC review should submit the Checklist for Determining Exempt Research Status (Appendix E) to irb@elmhurst.edu.

   Examples of such research include:

   a. The use and analysis of anonymous/confidential records for the administrative purposes of Departments or the University.
   b. The use and analysis of anonymous/confidential surveys to assess college or department related activity (e.g., advising, student satisfaction surveys).
   c. The use and analysis of anonymous/confidential assessment tools to evaluate class-related activities.
   d. Student research with human participants conducted as part of a class or independent study that entails minimal risk (see Section F below). When these projects are considered at-risk, they must go through IRB/IACUC review and be approved.

4. Risk in Animal Research

   All research on animals must undergo IACUC review. Those submitting IACUC proposals must assess the potential pain and distress of the animals involved, categorized by the USDA Pain and Distress categories listed below. Any category E animals must be thoroughly explained.

   - Category B: No pain or distress. Animals kept for breeding or holding in a colony.
   - Category C: No more than momentary or slight pain or distress, no use of anesthetics.
   - Category D: Pain or distress relieved with anesthetics, analgesics and/or tranquilizer drugs or other methods for relieving pain or distress.
   - Category E: Pain or distress or potential pain or distress that is not relieved with anesthetics, analgesics and/or tranquilizer drugs or other methods for relieving pain or distress.

E. Student Research

1. Course-Based Research Projects

   Course-based projects that involve research with human participants are not subject to IRB oversight because these are not typically designed to contribute to generalizable knowledge or lead to broad dissemination, which is the federal regulatory definition of research. Therefore, CITI training modules are not required, but these can be a useful teaching tool. Modules from the standard Social Sciences or Health Sciences training sets may be used with students, or other modules deemed appropriate (see Appendix I.1).

   Instructors using course-based projects that involve research with human participants must complete appropriate CITI training, since they will serve as a proxy for the IRB/IACUC - —students complete paperwork related to their research proposal and use standard informed consent and debriefing processes. The goal of the research process in these courses is to provide students with research experience, rather than answer a particular issue in the field. The scope of topics used in these courses is limited to ones with no potential for harm to participants.

   Consultation and recordkeeping of all research activities involving human participants are still essential ethical safeguards. To avoid creating an unmanageable IRB/IACUC caseload and unnecessary delays for projects that must be carried out within semester courses, faculty supervising course-based research projects should submit the Course-Based Research Checklist (Appendix D) to irb@elmhurst.edu as early in the semester as possible.

2. Independent Research Projects

   All independent student research projects must be submitted as an exemption request or a proposal to the IRB/IACUC before data collection. IRB/IACUC approval/exemption will be emailed to the student investigator(s), their faculty mentor(s), and the department chair.

   In addition, all research involving animal subjects, even course-based projects, must undergo IACUC review, and all students must be trained in the appropriate CITI (Collaborative Institutional Training Initiative) training modules (see Appendix I.1).

F. Special Populations

1. Minors/Children

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

2. Other Vulnerable Populations

Particular 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 individuals with intellectual or cognitive disabilities, 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. CITI training modules on working with vulnerable populations are strongly recommended for projects considering these populations.

G. Outside Researchers

1. Outside Researchers Using Elmhurst University Subjects

An outside researcher (not affiliated with Elmhurst University) wishing to conduct research at Elmhurst University or with Elmhurst University students, faculty and/or staff, must complete the following:

- Receive IRB approval/exemption from the external institution
- Submit to the Elmhurst University IRB the full packet of materials submitted to the external institution IRB including:
    - Letter of IRB approval/exemption for the project;
    - The IRB protocol application;
    - Consent form or information sheet;
    - Recruitment flyer or ad;
    - Instruments or measures to be used; and
    - Any additional supporting documentation.

The IRB/IACUC Chair will review the request and issue indicating the compliance and IRB concerns have been met. The IRB/IACUC reserves the right to have requests for permission to recruit on campus go to the full board for review and approval, should the Chair decide that the nature of the study requires the independent scrutiny of the IRB/IACUC to protect its students and employees.

If the research involves recruiting a specific set of students (i.e., Psychology majors, Nursing faculty, female lacrosse athletes), outside researchers must also contact the appropriate department and/or Student Affairs for permission to recruit those students.

The external researcher will communicate that they have already contacted the Elmhurst University IRB/IACUC and have met all compliance concerns.

2. Collaborative Research Across Institutions

When Elmhurst researchers are working collaboratively with investigators from other institutions, there are several options for IRB involvement:

A. Separate/Multiple IRB Reviews
B. “Single IRB” Review
C. One IRB Reviews

A. Separate/Multiple IRBs Review

In some cases, it is most efficient for researchers from each participating institution to obtain IRB approval from their own institution's IRB, covering any regulated human participant activities that will occur at their site. This will almost always be the case when research is eligible for exemption from IRB review.

B. "Single IRB" Review

A Single IRB ("sIRB) is the IRB of record, selected on a study-by-study basis, which provides the ethical review and related administrative coordination for all sites participating in a multi-site study and assumes responsibility for all human participant research compliance.

Under the revised (2018) Common Rule, federally funded multi-institution studies--with very few exceptions--are required to use an sIRB for review and approval of cooperative studies conducted in the United States. This applies to all cooperative research applications and contract proposals submitted on or after January 20, 2020.

For NIH (National Institutes of Health) studies, a version of the sIRB requirement has been in effect since January 2018. For applications submitted on or after January 25, 2018, NIH-funded multi-site studies involving non-exempt research must use an sIRB, when the same protocol is used at multiple domestic study sites.

The Elmhurst IRB is currently not equipped to serve as the sIRB, but will comply with the requirements for a participating IRB when another institution serves as the IRB of record. Researchers should speak with the Elmhurst IRB Chair prior to submitting a proposal to NIH or any other federal agency for a multi-site project so that a suitable partner can be identified to act as the sIRB.

C. One IRB Reviews

In some situations, to avoid duplicative reviews and increase efficiencies, the Elmhurst IRB will consider acting as the IRB of record or ceding IRB review to another institution's IRB. The reviewing IRB is usually chosen from among participating institutions. The IRB at each participating site will need to formally cede their IRB review to the reviewing IRB using a fully executed authorization agreement, also called a reliance agreement.

3. Reliance Agreements

A sample reliance agreement with Elmhurst acting as the IRB of record may be found in Appendix H.

H. Procedures

1. PI Training – CITI Modules

The IRB/IACUC recommends the following set of modules in CITI training for Principal Investigators (both faculty and students), depending on their research focus. The full list of modules for each focus may be found in Appendix I.1. Certification is for three years and requires a passing score of 80.

Modules selected by Elmhurst University IRB/IACUC

- Health Sciences (HSR): Basic Course
- Social Sciences (HSR): Basic Course

CITI Standard Modules

- Humanities Responsible Conduct of Research: RCR
- Physical Science Responsible Conduct of Research: RCR
- Social & Behavioral Research: Basic Course
- Social and Behavioral Responsible Conduct of Research: RCR

2. Submission Procedures

Principal investigator(s) and/or their faculty mentor(s) submit their proposal (Appendix A for IRB proposals, Appendix C for IACUC proposals), or the exemption checklist (Appendix E), the course-related project checklist (Appendix D) or a request for interinstitutional collaboration to the IRB/IACUC chair at irb@elmhurst.edu. IRB proposals should include informed consent/assent documentation, in multiple languages or reading levels as appropriate for the study participants (Appendix B).

An informed consent document should include the following:

- title and general description of the study,
- estimate of the amount of the participants time to complete the study,

- instruments and tasks generally described to the participant,
- statement that they can withdraw at any time without penalty,
- statement that the Principal Investigator will protect the identity of the participants
- assurance that all data and material from the study will be held confidential and locked in a file cabinet or secured electronically,
- information about debriefing from the study (if applicable),
- contact person for IRB should the participant have questions or concerns,
- participant signature/acknowledgement; minor/vulnerable population assent

If changes within the study are made (e.g., personal contact by appointments are changed to password work protected Zoom meetings), an updated informed consent must be provided, reviewed, and signed.

3. Review Procedures

Upon receipt of completed materials, the IRB/IACUC Chair (hereafter called the Chair) will distribute materials requiring full committee review to all members of the IRB/IACUC via Microsoft Teams or another electronic method. Each proposal, exemption request, reliance agreement request, and course review checklist will be logged with a unique number consisting of the fiscal year and sequential three-digit number corresponding to date of submission, for example, FY23-021 is the 21st submission to the IRB/IACUC of the 2023 fiscal year.

The Chair (or their designee) will evaluate all exemption checklists and provide PIs with exemption letters that include the logged proposal numbers. The Chair (or their designee) will also determine whether proposals should be reviewed through an expedited process by the Chair (or their designee) or require full consideration by the Board.

In general, research may qualify for expedited review if it is judged to involve only minimal risk, does not include intentional deception, and includes appropriate informed consent procedures. Common proposals reviewed and approved as expedited include the following:

- Studies involving the collection of identifiable information in surveys, interviews, or focus groups, and sensitive information that is also identifiable.
- Study involving the analysis of voice recordings.
- Study involving collection of hair or saliva samples.

The full list of categories of research that may be reviewed as expedited can be found in 45 CFR 46.110.

All expedited studies must adhere to the requirements for informed consent. All modifications must be approved by the IRB/IACUC prior to their implementation unless they are necessary for the immediate safety of subjects.

For proposals requiring full review, a majority of the IRB/IACUC will meet to discuss and deliberate on each new submission at their monthly meeting, currently held the second Tuesday of the month during the academic year. This meeting may be in person, online via Microsoft Teams or another conferencing software, or a hybrid meeting. 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 of the project.

In all cases, the Chair will inform the investigator via email regarding the Board's decision.

4. Actions After Review
    a. Approved projects may begin as soon as the investigator receives IRB/IACUC notification.
    b. Projects needing minor changes/revisions require, the investigator must submit the necessary minor changes/revisions to the Chair. If these changes adequately address the IRB/IACUC's feedback, the project may begin once written notification is sent to the investigator.
    c. For major revisions, when the Chair receives the significant revision, another meeting of the full IRB/IACUC will be called and a new review of the project will take place. The investigator also can meet with the IRB/IACUC to further discuss and/or clarify the project.
    d. If a project is disapproved, the investigator may revise the project to address the ethical issues raised by the IRB/IACUC. The investigator can also appeal the decision and may meet with the IRB/IACUC to discuss and/or clarify the project.

The IRB/IACUC has the authority to suspend or terminate approval of research not conducted in accordance with the IRB/IACUC's requirements or 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/IACUC'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.

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.

5. Amendments to Approved Projects

   In the case of project revisions during the project, the investigator will detail the proposed changes and modifications in writing and submit them to the Chair (see Appendix F for format). All changes and modifications may not be initiated without IRB/IACUC review and approval, except when necessary to eliminate apparent immediate hazards to the subjects.

   Minor modifications to previously approved projects include those that do not alter the risk-benefit assessment for the research. Examples include changes in the investigators, minor wording, or formatting changes in the consent form(s), recruiting materials, interviews, or questionnaires; minor changes in compensation, time of participation, or subject recruitment; or the use of a new site that is not materially different from a previously approved site.

   Major modifications include significant protocol changes that would cause subjects to engage in activities not previously approved; or that involve an increased level of risk to the physical, emotional, or psychological well-being of participants (including the loss of confidentiality); or that involve a decreased benefit; or that otherwise result in alteration of the risk-benefit assessment for the research. For example, adding a new subject population, changing inclusion or exclusion criteria, changing the informed consent process, and changing procedures affecting subject confidentiality all constitute potentially major modifications.

   In case of significant modifications, the Board will re-review the project at a convened meeting. In the event of minor modifications, the Chair will re-review the project.

6. Renewal/Continuing Projects

   Approved research is subject to continuing IRB/IACUC 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/IACUC 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 Chairirb@elmhurst.edu. A sample renewal application may be found in Appendix G 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. Pending review, the investigators will be notified of the committee's decision by the Chair.

7. Completed Projects

   Upon completion of projects, the investigator will notify the Chair via irb@elmhurst.edu in writing to indicate that the project is completed.

8. Conflicts of Interest

   In all IRB/IACUC meetings, any member who has a conflict of interest on a project will recuse themselves from deliberations on that project. If this is the Chair, they will appoint a designee as Acting Chair. Members with a conflict of interest may not participate in proposal review except to provide information requested by the committee and must recuse themselves from deliberations pertaining to the review. The following circumstances may indicate a conflict of interest if the IRB/IACUC member:

   - has current or anticipated financial interest, remuneration, and/or other types of personal gain;
   - is, or a member of their immediate family, or anyone with whom they have a close relationship, is listed as the investigator on the study, or as a member of the research team;
   - is an academic sponsor of the Principal Investigator, or a situation in which any investigator must report to or is under the professional supervision of the IRB/IACUC member;
   - has an interest that they believes conflicts with their ability to review a project objectively;
   - is in direct competition with the investigator for limited resources, funding, sponsorship;
   - is considered a personal or professional adversary of the investigators.

9. Recordkeeping Procedures

   Minutes will be taken at all IRB/IACUC meetings and kept for at least a three-year period. Other records, including proposals, committee action, and correspondences to investigators will also be kept for at least three years. The Federalwide Assurance Institutional Signatory Official and/or Human Protections Administrator will have access to all Board decisions.

I. Works Consulted or Cited

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