

Excelsior University
Institutional Review Board Handbook
Last Updated November 6, 2023

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Introduction

This Excelsior University Institutional Review Board (IRB) handbook is designed to provide information about the IRB process, including the factors that must be considered in conducting research with human participants, the types of projects that are subject to IRB review, the types of reviews conducted by the IRB, and the documentation required for each type of IRB review.

PURPOSE: Excelsior University's Institutional Review Board ensures that when research is conducted within the institution, the rights and welfare of the human research participants are adequately protected. The IRB possesses the professional competence necessary to ascertain the acceptability of proposals in terms of institutional commitment and regulations, applicable law, standards of professional conduct and practice, and compliance with the Belmont Report.

Excelsior University complies with the federally mandated process to review research proposals that involve human participants.

MISSION: Excelsior University's Institutional Research Board complies with U.S. Department of Health & Human Services (DHHS), Office for Human Research Protections (OHRP) requirements to review and approve all research conducted by any Excelsior University constituent or affiliate that involves humans as research participants. In keeping with the Code of Federal Regulations (45 CFR Part 46, also known as the Common Rule), the IRB aims to protect the rights and welfare of these participants. The IRB has the authority to approve, require revisions, or disapprove all research activities that fall within its jurisdiction as specified by DHHS.

All research at Excelsior University must be approved by the IRB prior to initiating any activities associated with the research. In accordance with state and federal regulations and professional standards of ethical conduct, it is the responsibility of the University to reasonably ensure that, in research conducted under its auspices, the rights and welfare of human participants are adequately protected. The primary responsibility for protecting human participants, however, rests with each who initiates, directs and/or engages in research.

VISION: The IRB facilitates and promotes academic work by providing oversight that enables the university to be a place of scholarship and excellence.

Excelsior University: Membership

The IRB consists of seven (7) members of the Excelsior University who are appointed to a three-year term by the provost. There are two co-chairs of the IRB. In addition to other requirements of state and federal regulations, the membership of the IRB shall be composed of individuals who are qualified through experience and research expertise to assure complete and adequate review of activities commonly conducted under the University's auspices. The IRB shall possess a diversity of membership including race, gender, and cultural backgrounds—sensitive to such issues as community attitudes—to promote respect for its advice and counsel for safeguarding the rights and welfare of human research participants. Members shall also have the professional competence necessary to ascertain the acceptability of proposals in terms of institutional commitment and regulations, applicable law, and standards of professional conduct and practice.

The membership includes at least one external member; one member with a PhD one with a terminal degree in physical or biological science; and one member who holds a non-scientific degree (i.e., lawyer, clergy, etc.).

Members of the IRB must hold a current certification on the protection of human participants (e.g., CITI, NIH, PHRP, HHS), participate in related trainings facilitated by Excelsior University, review IRB applications as requested, and participate in council meetings. For IRB members and others in the Excelsior University community without existing or certification, the institution requires completing the five free lessons in this Human Research Protection Foundational Training from the U.S. Department of Health and Human Services (HHS): <https://www.hhs.gov/ohrp/education-and-outreach/human-research-protection-training/human-research-protection-foundational-training/index.html>

The IRB may also invite individuals with competence in specific areas to assist in review of a project(s) that requires expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

Definition of Research With Human Participants

The Office for Human Research Protections (OHRP) has defined research in the following manner: “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.” Activities which meet this definition constitute research for purposes of Excelsior University’s policy, whether they are conducted or supported under a program which is considered research for other purposes. The determination regarding whether a given activity should be considered human participants research will be made by the IRB. Certain categories of research involving little or no risk to participants do not need to be reviewed and approved by the full IRB and are eligible for less intensive review procedures. The IRB shall develop and promulgate appropriate categories of research and determine the review procedures for each category. The IRB shall apply additional criteria during the review of research involving Excelsior University prospective and enrolled students, faculty, staff or alumni.

Each researcher should make the initial determination regarding the appropriate category of review, although the IRB may require review under another category. The researcher can always request a higher level of review than that required.

Activities Not Deemed to Be Research

The following activities are deemed not to be research:

- (1) Scholarly and journalistic activities (e.g., oral history, legal research, historical scholarship)
- (2) Public health surveillance activities

- (3) Collection and analysis of information by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes
- (4) Authorized operational activities in support of intelligence, homeland security, defense, or other national security missions.
- (5) Research on elected or appointed public officials or candidates for public office

The initial determination as to whether a research project should be considered human participants research should be made by the investigator. They should consult the IRB Chairs for advice on this question. Final authority for making this determination rests with the IRB.

In general, research which involves data gathered solely for internal use (e.g., program evaluation or institutional research) would not need to be reviewed. If, however, the results of this research will be disseminated to audiences external to the University, then the research must receive prior approval. If no dissemination is planned at the time the data are gathered, but the possibility of future dissemination exists, the PI is advised to submit the project for approval prior to initiating the research.

A “human participant” (the term “subject” was formerly used) is 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 Review Categories

There are four types of IRB reviews: Exempt, Exempt Limited, Expedited, and Full, all of which require submission of an application. While the researcher is encouraged to identify the level of requested review, the IRB makes the final determination of review category. A brief description of each review type is given below.

Exempt Status

Human participants research activities subject to the IRB may be granted exempt status. This status signifies that the research activity is not monitored by the IRB codes of professional conduct.

Exempt Limited

A limited IRB review is a type of expedited review process required in the Revised Common Rule (January 2019). Its purpose is to ensure confidentiality protections are in place with exempt research that involves the collection or use of sensitive, identifiable data.

Expedited

Following are some examples of the types of projects that Excelsior University’s IRB may use the expedited procedure to review:

Anonymous mail surveys on innocuous topics,
Anonymous, noninteractive, nonparticipating observation of public behavior,
Secondary analysis of existing data,
Educational research involving no interaction with students, e.g., passive observance of regular advising activity or test-taking activity,
Research involving the use of educational records if information taken from these sources is provided to the researcher in such a manner that participants cannot be identified,
Research on individual or group behavior of adults where there is no psychological intervention, or physiological intervention or deception,
Interviews and surveys on non-sensitive topics where confidentiality is assured.

Full

Research that does not qualify for exempt or expedited levels of review must undergo a full IRB review. Examples of research activities that may require a full review include:

Research which might put participants at risk,
Research involving psychological or physiological intervention,
Noncurricular, interactive research in schools, test sites, hospitals,
Research involving deception,
Interviews or surveys on sensitive topics,
Research on persons who are under age 18, are in prison, or have mental and/or emotional disabilities,
Research conducted outside the United States, regardless of the procedures involved.

The IRB has developed a unified Human Participants Research Review Form which is used in submitting proposals in both project categories. The form is designed so that only the information required for the appropriate project category needs to be included in the proposal. The form can be accessed via web: <https://forms.office.com/r/nWfzvmSBwP>

Review Procedures

Expedited Review

The review may be carried out by an IRB Co-Chair or by one or more experienced reviewers designated by a Co-Chair from among members of the IRB. The IRB Co-Chair or designee(s) may approve the project, request additional information or submit the proposal to the IRB for full review and approval. The investigator is notified in advance of this review. If the investigator questions any determination made under expedited review, they have the option of requesting a full review by the IRB, which will make the final determination.

Full Review

The review is generally conducted at the next convened meeting of the IRB. The IRB meets on an as-needed basis but at least once annually. Investigators are welcome to attend the meeting and answer questions or provide additional information regarding their projects.

Informed Consent

Informed consent means the knowing consent of an individual, or their legally authorized representative, who can exercise free power of choice without undue inducement or any form of force, fraud, deceit, duress or other form of constraint or coercion. An investigator shall seek informed consent as follows:

- (1) Sufficient opportunity is provided to the prospective participant or their representative, to consider whether to participate and the possibility of coercion or undue influence is minimized;
- (2) The information that is given to the prospective participant, or their representative, shall be in language understandable to the participant or representative;
- (3) Key information is given to the participant or their representative in sufficient detail which would enable a reasonable person to make an informed decision about whether to participate and provides an opportunity to discuss the information; and
- (4) The participant, or their representative cannot be made to waive or appear to waive any of their legal rights, or release or appear to release the investigator, the sponsor, the institution or its agents from liability for negligence.

The federal regulations detail the following basic elements of information necessary to such consent:

- (1) A statement that the study involves research, an explanation of the purpose of the research and the expected duration of the participant's participation and a description

of the procedures to be followed and identification of any procedures that are experimental;

- (2) A description of any foreseeable risks or discomforts to the participant;
- (3) A description of any benefits to the participant or to others which may be reasonably expected from the research;
- (4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant;
- (5) A statement describing the extent to which confidentiality of records identifying the participant will be maintained;
- (6) An explanation of whom to contact for answers to pertinent questions about the research and research participants' rights and whom to contact in the event of a research related injury;
- (7) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which that individual is otherwise entitled, and the participant may discontinue participation at any time; and
- (8) A statement about any research involving the collection of identifiable private information or identifiable biospecimens.

For research involving more than minimal risk, an explanation that the University does not have a formal plan or program to provide medical treatment or compensation for any injury which occurs as a result of the individual's participation (the participant should also be informed that this does not waive any of their legal rights).

When appropriate, other elements of information shall also be provided to each research participant, for example:

- (1) A statement that the research may involve risks to the participant which are currently unforeseeable;
- (2) Anticipated circumstances under which the participation may be terminated without regard to the research participant's consent;
- (3) Any additional costs to the participant that may result from being part of the research;
- (4) The consequences of a participant's decision to withdraw from the research and procedures for orderly termination of participation by the participant;

- (5) A statement that significant new findings developed during the research which may relate to the participant's willingness to participate will be provided to the participant; and
- (6) The approximate number of participants involved in the study.

In projects where participants are determined to be at risk, the actual procedure utilized in obtaining "legally effective informed consent" must be fully documented. This is accomplished by using a written consent form embodying the elements of information required for the project. The consent form must be read by or to the participant or their legally authorized representative and signed by the person giving consent. A copy of the consent form should be given to the person signing the form and the signed form must be maintained in the investigator's files for an indefinite period following completion of the study.

Excelsior University's Institutional Review Board has designated a sample form that can be used as a guide in preparing the consent form that will be used in the research project. Please note that the final form that the PI administers must first be approved by the IRB before it can be legally administered.

In rare cases, where these procedures will surely invalidate important objectives of the project, IRB approval of modified procedures may be sought.

In projects where risk to participants has been determined to be minimal, the participants shall be informed of those basic elements of consent which are applicable to low-risk procedures and no signed document is necessary on the part of the participant. However, a sample copy of the research statement to be presented to participants must be approved by the IRB. An exception to this policy occurs when research involves persons under the age of 18 as research participants, in which case, written consent from a parent or a guardian is required.

According to 45 CFR §46.116(e-f), in specific instances, the IRB may approve a consent procedure which does not include, or which alters some or all the elements of informed consent or may entirely waive the requirement to obtain informed consent.

Conditions of Approval

Approval of a project by the IRB applies only to the procedures submitted in the proposal. The investigator must secure prior approval from the IRB for any changes in the procedures that will affect the use of research participants. The investigator must also report to the IRB any problems that arise in connection with the use of research participants.

Approval for projects is valid for one year only. Investigators must request a continuation for the approval yearly if the activity lasts more than one year. Only two continuations will be granted for a given project.

In addition, the Dean (or designee) or appropriate Vice President (or designee) needs to approve the use of human participants under their purview/authority.

The criteria for approval by the IRB are the following:

The application is complete, and all required supporting documentation is provided^{i*}.

Recent training certification for every investigator is submitted.

Potential risks to participants are identified.

Appropriate steps are identified to protect the privacy and confidentiality of research participants.

Brief description of the research study.

Description of informed consent.

The determination regarding whether a given activity should be considered human participants research will be made by the IRB or its designee. The principal investigator (PI) and Co-PIs listed on an IRB application must hold a current certification on the protection of human participants (e.g., CITI, NIH, PHRP, HHS). The PI must submit a certificate of completion of training that is not over three years old. As mentioned earlier in the handbook, the institution requires people without a certificate complete the five free lessons in this Human Research Protection Foundational Training from the U.S. Department of Health and Human Services (HHS): <https://www.hhs.gov/ohrp/education-and-outreach/human-research-protection-training/human-research-protection-foundational-training/index.html>

Survey Research

All surveys which are designed to be sent as a link or document through an e-mail invitation to Excelsior University employees, staff, alumni, and/or current students must be distributed by Analytics and Decision Support (ADS). No e-mail addresses of these individuals will be shared with the researchers by the University. Once a research project has received IRB approval, the investigator must contact ADS to discuss scheduling the distribution of their survey instrument in accordance with the Excelsior University Policy on Survey Administration (CMC-002). This email to ADS should be sent to surveyresearch@excelsior.edu with:

- (1) a copy of the IRB approval letter
- (2) a copy of the survey or a link to the survey site
- (3) a detailed description of the intended audience, for example “please distribute this survey all ADN Nursing students”
- (4) the anticipated time range
- (5) The invitation to participate, and informed consent letter signed by the PI

Researchers must familiarize themselves with the Excelsior University Policy on Survey Administration (CMC-002). In addition, all surveys approved to be distributed to Excelsior University employees, staff, and/or students, must include the following paragraph in the invitation to participate/informed consent letter:

As part of its mission, Excelsior University supports educational research. The attached survey has been approved by the Excelsior University Institutional Review Board (IRB) for distribution to potential participants (i.e., faculty, staff and/or students). Any participation on your part is completely voluntary.

Student Research: Supervisory Responsibilities

All student investigators must have a supervisor (e.g., faculty, staff) who is named as a co-investigator on the proposal and responsible for ensuring that all procedures of the approval are complied with by the investigator. The supervisor must sign the proposal certifying that the project is under their supervision. In addition, supervisors must hold a current certification on the protection of human participants (e.g., CITI, NIH, PHRP, HHS) and provide a copy of their certificate of completion to the IRB.

The IRB expects supervisors to monitor the student's progress with the research, assist the student in notifying the IRB of changes needed to the research study, and facilitate a renewal request if the student's research exceeds one year from the approval date.

Principal Investigators of Research

Only Excelsior University faculty, employees, current students, alumni, staff, and administrators or other individuals directly affiliated with the University may be identified as the principal investigator (PI) on the IRB application.

Multi-Institutional Collaborations and Agreements

Multi-institutional proposals are those that involve more than one institution. When multi-institutional research is conducted, each participating institution is responsible for safeguarding the rights and welfare of their own human participants. To seek approval for a multi-institutional research proposal, unless otherwise required by law, for research conducted in the U.S. by U.S. institutions approval is given by the IRB of the institution where the researcher is primarily affiliated, and the research proposal is initiated.

Therefore, generally Excelsior University research that has been approved by an IRB at another U.S. institution where the data collection will occur under the auspices of that institution in the U.S. does not require additional review by Excelsior's IRB. The principal investigator of such research is required to submit their primary institution's IRB approval to Excelsior's IRB by email for exempt review.

There are exceptions where more than one IRB approval is mandated: (1) as required by law (including tribal law) or (2) when a federal agency determines that approval by more than one IRB is proper for the context.

Barring any legal/agency requirements, for research conducted outside the U.S. and/or by a non-U.S. entity, an institution participating in a cooperative project may enter a joint IRB arrangement, rely on the review of another IRB, or make similar arrangements for avoiding duplication of effort.

Protecting Privacy of Human Participants and Securing Data

Principal Investigators are responsible for protecting the privacy of the participants involved in their research. The PI must determine whether the project can guarantee anonymity (no identifying information is available to the PIs and cannot be linked to the participants based on their responses) or if confidentiality is all that can be expected.

- (1) Personal identifiable information should be removed from the data records.
- (2) Signed Informed Consent forms should be kept in a separate location from the data records.
- (3) Any document or recorded data (audio/video/digital images) that can identify the research participant should be kept separate from the informed consent document.
- (4) During the informed consent process, explicit permission should be obtained from a participant if you plan to publish or publicly present any information or image(s) that can be directly connected with a participant.

The IRB will need documentation of permission for e-mail contact information or other personally identifiable information to be released for the purposes of recruitment of research participants; this should be included with the IRB application. Proposed involvement of vulnerable populations may require special consideration and a full review by the IRB.

Principal Investigators have a responsibility to ensure the security of the data collected throughout the project, including consideration of the methods used to collect and store the data.

The IRB recommends that hard copies of research materials (e.g., informed consent sheets, surveys, transcripts of interviews) be kept in a locked cabinet in a secure office at Excelsior University. Electronic data files saved on a portable storage device or laptop should be password protected, encrypted and transferred to a secured Excelsior University server or drive as quickly as possible and then deleted from the portable storage device.

All records relating to the research approved by the IRB should be kept for at least three years after completion of the research. In addition, all records shall be accessible for inspection and duplication by the IRB.

Submitting an Application to the IRB

Excelsior University's IRB accepts applications via an online submission process via webform: <https://forms.office.com/r/nWfzvmSBwP>

Applications are approved by the IRB, individual members should not be contacted directly. The anticipated timeframe for review and approval is influenced by the type of review that is needed, e.g., expedited, full.

The approval process will be delayed if the application is not clearly written, not thorough, or incomplete (missing attachments^{ii*}), resulting in the need for revision and resubmission of the application. Researchers must plan on a minimum of one week for every resubmission.

Resubmissions

If revisions are required prior to approval, a detailed description that outlines the necessary changes will be sent to the PI and the faculty supervisor (if applicable).

The review process may be significantly delayed if the requested revisions are not made and/or if the application remains incomplete.

Revisions after approval should be brought to the attention of the IRB Chairperson(s). Any proposed changes (amendments) to the research must be approved prior to implementing the change. The expiration date will not change unless it is explicitly one of the proposed modifications to the research plan.

Examples of modifications that require the submission of a revised approved application include but are not limited to changes in or additions to participant recruitment strategies, data collection strategies, timelines, and/or storage of participant information.

Depending on the type/extent of the proposed changes, approval will remain in place, an additional letter of approval will be sent, or the PI will be required to submit a revised IRB application that incorporates the changes.

Renewals

Prior to implementation of the revised Common Rule, IRB approval for the data collection phase of an expedited or full-review project was granted for one year. After January 21, 2019, continuing review will no longer be required for most new studies that qualify for expedited review. The Excelsior University IRB will make the determination of whether continuing review is necessary.

Renewal for ongoing data collection beyond the end date should be requested at least one month before the IRB approval will expire by using the “Continuing Renewal” application.

Certification of the PI, all Co-PIs, and supervisor (when applicable) should be current through the renewal end-date.

Concluding a Research Study

The PI is required to notify the IRB Chairperson(s) when the research study has ended. If the research is concluded prior to the end of the approval, the end date shall be included in the notification. Lastly, the notification shall include a brief summary (no more than 3-4 paragraphs)

of the research findings. If notice has not been sent by the PI prior to the approval end date the IRB will send a notification letter that their approval has ended and will request this information.

Terminations

Pursuant to 45 CFR §46.113, the IRB has the authority to terminate or suspend their approval of research if the research is not conducted in accordance with the process specified in the approved application, is noncompliant with federal or state regulations or has been associated with unexpected serious harm to individuals. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, appropriate institutional officials, and the federal department or agency head, if applicable.

ⁱ Supporting documentation:

- * Human Subjects Protection Training Certification
- * informed consent form(s)
- * Primary Institution IRB review if Excelsior is not primary research site
- * Study instruments/protocols

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