

Excelsior College
Institutional Review Board Handbook
May 2019

Introduction

Excelsior College's Institutional Review Board (IRB) is charged with protecting the rights and welfare of individuals who participate in research as well as facilitating and promoting ethical research by faculty, students, and staff. Excelsior College complies with the federally mandated process to review research proposals that involve human participants.

This Excelsior College 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.

The IRB process pertains only to research involving human beings as participants. Excelsior College's IRB is required by the U.S. Department of Health & Human Services (DHHS), Office for Human Research Protections (OHRP) to review and approve all research conducted by any Excelsior College 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) Excelsior College's 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 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 College 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.

Excelsior College IRB: Membership

The members of the Excelsior College IRB 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 College's auspices. In addition, IRB membership ensures respect for its advice and counsel for safeguarding the rights and welfare of human research participants. The IRB shall possess 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.

Members of the IRB must hold a current NIH or other certification on the protection of human participants, participate in trainings facilitated by Excelsior College, review IRB applications as requested, and participate in committee meetings. IRB members are asked to take the online training course "Protecting Human Research Participants Online Training."

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 College’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 College 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) Journalistic activities (e.g., oral history, legal research)
- (2) Public health activities
- (3) Collection and analysis of information for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes
- (4) Authorized 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. He/she 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 College, 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

Excelsior College’s IRB may use the expedited review procedure to review the following:

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. 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 need be included in the proposal.

Review Procedures

Expedited Review

The review is carried out by three authorized designees of the IRB, including an IRB Co-Chair. The designees 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, he/she has 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. 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 her/his 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 consent only under the following circumstances:

- (1) Sufficient opportunity is provided to the prospective participant or her/his representative, to consider whether or not to participate;
- (2) The possibility of coercion or undue influence is minimized;
- (3) The information that is given to the prospective participant, or her/his representative, shall be in language understandable to the participant or representative; and
- (4) The participant, or her/his representative, cannot be made to waive or appear to waive any of her/his 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;
- (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 statement describing the extent to which confidentiality of records identifying the participant will be maintained;
- (5) 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; and
- (6) 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.

For research involving more than minimal risk, an explanation that the College 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 her/his legal rights).

When appropriate, one or more of the following elements of information shall also be provided to each research participant:

- (1) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant;

- (2) An identification of any procedures which are experimental;
- (3) A statement that the research may involve risks to the participant which are currently unforeseeable;
- (4) Anticipated circumstances under which the participation may be terminated without regard to the research participant's consent;
- (5) Any additional costs to the participant that may result from being part of the research;
- (6) The consequences of a participant's decision to withdraw from the research and procedures for orderly termination of participation by the participant;
- (7) 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
- (8) 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 her/his 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 of time following completion of the study.

Excelsior College's Institutional Review Board has designated a sample form that can be used as a guide in preparing the consent form that will actually be used in the research project or activity. 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 no more than minimal, provision may be made for oral or written presentation and consent. Under this procedure, the participant is 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 presentation must be approved by the IRB. A major 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.

In some cases, the IRB may approve a consent procedure which does not include, or which alters some or all of 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.

The criteria for approval by the IRB are the following:

The application is complete and all required supporting documentation is provided.

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 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 have successfully completed a training session that is conducted or approved by the Health and Human Services/NIH. The PI must submit a certificate of completion of training that is not over three years old.

Provost Override

As is indicated in this handbook IRB approval must be sought before any data collection can occur. There are times, however, when projects are conducted for program improvement/internal purposes and are exempt from IRB review yet after the study has concluded the PI wishes to use those findings in a conference presentation or publication. The Provost Override requires the PI to complete a project information form which provides an overview of the project, includes all materials sent to participants, and includes any participant complaints or other issues that arose during data collection. The Provost will review this form and make a determination whether the data were conducted without harm and if the PI can use the findings in a public setting. If so, the Provost completes the Provost Override Checklist and submits this via email to the IRB at irb@excelsior.edu. This process should not be viewed as an alternative to seeking IRB review

and approval prior to data collection and will be applied sparingly for projects under unique circumstances.

Survey Research

All surveys which are designed to be sent as a link or document through an e-mail invitation to Excelsior College employees, staff and/or 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 College. Once a research project has received IRB approval, the investigator must contact SIE to discuss scheduling the distribution of their survey instrument in accordance with Policy 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, informed consent letter signed by the PI

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

The attached survey has been approved by the Excelsior College Institutional Review Board for distribution to employees, staff and or students. Any participation on your part is completely voluntary. Surveys are distributed with the oversight of Analytics and Decision Support and contact is made via the information that has been provided in EC SIS. Excelsior College, as an institution of higher education, supports educational research by interacting with approved researchers and students to further the knowledge and understanding of online higher education.

Student Research: Supervisory Responsibilities

All student investigators must have a supervisor (e.g., faculty, staff) who is responsible for insuring that all procedures of the approval are complied with by the investigator. The supervisor must sign the proposal certifying that the project is under her/his supervision. In addition, supervisors must complete the online training once every four years 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 College faculty, employees, current students, staff, and administrators may be identified as the principal investigator (PI) on the IRB application. Regardless of an external investigator's role in the research, they cannot serve as the primary principal investigator on Excelsior College's IRB application. Individuals who separate from the College will no longer be eligible to submit an IRB application or receive IRB approval to continue data collection.

Multi-Institutional Collaborations and Agreements

Excelsior College research that has been approved by an IRB at another institution where the data collection will occur under the auspices of that institution does not require additional review by Excelsior's IRB. The principal investigator of such research is required to submit their IRB approval to Excelsior's IRB.

Researchers who are not affiliated with Excelsior College who wish to conduct research that takes place at Excelsior College or that would involve Excelsior's faculty, students, or staff should submit a copy of the application to and approval letter from their institution's IRB to Excelsior's IRB by email.

Protecting Privacy of Human Participants and Securing Data

Principal Investigators are responsible for protecting the privacy of the participants involved in his/her 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 College. Electronic data files saved on a portable storage device or laptop should be password protected, encrypted and transferred to a secured Excelsior College 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 College's IRB accepts applications via an online submission process. Applications are approved by the IRB, not any individual member. 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), 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. Any proposed changes (amendments) to the research must be approved prior to implementing the change.

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

Depending on the type/extent of the proposed changes, approval will remain in place 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 1/14/19, continuing review will no longer be required for most new studies that qualify for expedited review. The Excelsior College 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.

Terminations

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, noncompliance with federal (45 CFR §46.113) or state regulations, or has been associated with unexpected serious harm to individuals.