**Centre College**

**Policy on the Protection of Human Subjects**

**I. Purpose**

The purpose of this policy is to establish guidelines for the protection of [human subjects](#humansubject) participating in [original research](#originalresearch) conducted by faculty, staff, or students of Centre College or by other researchers who are conducting studies on Centre’s campus. This policy is intended to ensure that human research subjects are aware of their rights and protections.

[Human subject research](#humansubjectresearch) involves the systematic collection of personal or private data from living human beings. Any scholarly discipline may involve human subject research. Sociological, anthropological, and psychological studies often involve human subjects; biological studies sometimes involve human subjects. Increasingly, research in the humanities involves human subjects.

Centre College applies a single, comprehensive standard to [original research](#originalresearch) involving human subjects. All faculty, staff, and students are urged to evaluate their research agendas in light of this policy, even if the use of human subjects is not common in their disciplines.

Research activities involving human subjects conducted at Centre College are guided by the ethical principles of “The Belmont Report: Ethical Principles” and the guidelines set forth by the Department of Health and Human Services policy on the Protection of Human Subjects (45 CFR 46). Although Centre’s policies regarding the protection of human subjects are influenced by the guidelines of numerous federal regulatory agencies, the College’s Institutional Review Board (IRB) is ultimately responsible for creating and overseeing policies specific to Centre College.

**II. Definitions**

**Anonymous data:** Data that, by virtue of the method of its collection, can never reasonably be connected with the person providing the data.

**Coercion:** An overt or implicit threat to withhold a benefit or to cause harm that is intentionally presented in order to obtain compliance.

**Confidential data:** Anonymous or non-anonymous data that a human subject gives an investigator with the understanding or assumption that the human subject’s privacy will be honored. Divulging the source of non-anonymous data to an outside party or failing to ensure that no outside parties will be able to connect data with their source normally constitutes a violation of confidentiality. Centre’s IRB presumes that all data collected from human subjects are considered confidential, unless subjects have explicitly waived their presumption of confidentiality in writing.

**Deception:** The intentional use of misleading or untruthful information; withholding information from a participant.

**Exempt Study:** A study that has been reviewed and approved by the IRB and has been determined to be free from further IRB supervision. Researchers conducting exempt studies may make minor changes to their protocols without additional review, assuming that the level or risk does not increase and that the study has not produced any negative unanticipated reactions.

**Human subject:** Any living person about whom a researcher obtains personal or [private information](#privateinformation) or data through [interaction](#interaction) with the individual. Experts sharing facts or professional opinions in the area of their expertise are not considered human subjects for the purposes of this policy.

**Human subject research:** Systematic collection of personal or private data from living human beings.

**Informed consent:** Informed consent is based on the principle of respect for the rights of others to make informed decisions concerning their participation. Informed consent provides research participants with sufficient knowledge about the purpose of the research, their involvement in the study, and the potential risks and benefits. Based on this knowledge, participants can then make an informed decision as to whether or not they want to participate in the research project. Investigators are required to secure informed consent of the participant or the participant's legally authorized representative.

**Interaction:** Observation of or contact or communication with a human subject, manipulation of the human subject, or manipulation of the human subject’s environment.

**Intervention:** Includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes.

**IRB:** Institutional Review Board. Centre College’s IRB is responsible for the ethical oversight of all research involving human subjects conducted by College faculty, students, or staff, as well as research conducted on Centre’s campus by outside investigators.

**Minimal risk**: Some potential for harm exists, but the probability and magnitude of harm are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

**No-risk:** A no-risk study is reasonably unlikely to have a negative impact on the research participant’s physical, mental, emotional, legal, economic, or social well-being, both in terms of participation itself and potential data breaches.

**Non-anonymous data:** Data that, by virtue of how it is collected or the nature of the information, can be connected (no matter how tenuously) to the person providing the data. Examples include surveys the researcher collects directly from subjects or collected surveys in which the researcher may recognize the handwriting of subjects and could therefore match data with a specific respondent.

**OHRP:** Officefor Human Research Protections. OHRP is part of the U.S. Department of Health and Human Services. OHRP provides clarification and guidance, develops educational programs and materials, maintains regulatory oversight, and provides advice on ethical and regulatory issues in biomedical and behavioral research.

**Original research:** Systematic investigation, including pilot projects and feasibility studies, designed to expand generalizable knowledge or understanding, including collecting and analyzing data from questionnaires, observing subjects, manipulating experimental conditions, sampling, experimenting, etc. Research using human subjects, even if conducted to verify existing hypotheses, theses, theories, or ideas, is considered original research. Student research projects, even if conducted as part of the institutional curriculum, are considered original research and require review by the IRB.

Though the following **are not** considered original research, it is strongly recommended that researchers submit these types of study for review so that they can receive documentation clearly stating that the IRB does not intent to supervise the study.

* + - Research that uses only secondary sources (e.g., public data sets)
    - Activities in which human subjects perform exclusively for instructional purposes, such as in-class demonstrations and lab exercises (The intent or effort to publish data from such activities converts these activities into original research involving human subjects. Researchers intending to publish human subject research ***must*** obtain IRB approval ***before*** collecting data.)
    - Data gathered for the purposes of fundraising by the development office, market research for admission recruiting purposes, recruiting efforts for faculty or staff, statistical data collected for the management of institutional affairs, and attitudinal research of alumni, students, or parents
    - Journalism
    - Information collected for entertainment purposes
    - Oral histories

**Principal investigator (PI):** The lead researcher. The PI can be a faculty or staff member, a student, or another professional.

**Private information:** Information that can be identified with a human subject and is obtained in a context in which an individual can reasonably expect that no observation or recording is taking place, or information that has been recorded for specific purposes which the individual can reasonably expect will not be made public (e.g., medical records).

**Protocol:** A detailed plan of the study to be conducted.

**Register a study/Registration:** Principal investigators conducting no-risk studies have the option of registering their study with the IRB and proceeding without formal IRB approval.

**Risk:** Potential for physical, psychological, social, legal, or financial harm.

**Unreasonable harm:** Any physical, psychological, social, legal, or financial damage or injury that can be avoided without sacrificing the goals of the research. Unreasonable harm also includes any damage or injury so extensive that it cannot be justified by any contribution the research might make to human understanding.

**III. General Principles**

**Principal investigators should NOT collect any data from** [**human subjects**](#humansubject) **until they have registered the study with the Institutional Review Board (IRB) or received written notice of approval from the IRB.**

All researchers conducting [original research](#originalresearch) are responsible for protecting their subjects from the [risk](#risk) of [unreasonable harm](#unreasonableharm). In assessing risk, the principal investigator should follow the guidelines of the relevant professional organization(s) and, where appropriate, the guidelines of governmental funding and regulatory agencies. A principal investigator (or his/her advisor, if applicable), should contact the IRB chair for assistance in determining risk.

At a minimum, research activities at the College should conform to the following standards:

**1.** **Protection of Human Participants**: All researchers involved in a human subjects study, even if they will not directly work with the human subjects, must complete a training session on the ethical treatment of human subjects. Centre’s IRB recommends “Protecting Human Research Participants,” offered by the National Institutes of Health. The course should take no more than two hours to complete and is available free online at <http://phrp.nihtraining.com/users/login.php>.

**2.** [**Informed consent**](#informedconsent)**:** Prior to participation, the principal investigator must explain to the subject the objectives of the research, the procedures to be followed, and the associated [risks](#risk) and benefits. Investigators may not use individuals as subjects unless the subjects or their legal guardian(s) freely provide consent to participating in the study and fully understand the consequences. Principal investigators must obtain consent from the test subject *and* his or her legal guardian(s) if the subject is less than 18 years of age. In accordance with guidelines in the Family Educational Rights and Privacy Act, college students who are under the age of 18 have autonomy to decide if they wish to participate in research studies.

* **Consent Documentation**: Evidence of informed consent can be gathered in several ways. Subjects may signal their agreement to participate by signing a consent form. In the case of electronic surveys, participants may indicate their agreement by marking a check box or radio button in response to a statement such as “I have read the consent form and willingly agree to participate.” [Examples of consent forms](https://www.centre.edu/academics/academic-affairs-office/institutional-review-board/irb-documents-and-forms/) can be found on Centre College’s IRB website
* **Waivers of Signed Consent**: The requirement for written or electronic consent may be waived by the IRB if the research involves [no risk](#nonanonymousdata), [minimal risk](#minimalrisk), or if the consent form will be the only evidence linking the subject to the research, and the primary risk of harm is to the subject’s privacy. Verbal consent is commonly obtained for telephone-based research. The waiver of signed consent form is available on Centre’s [IRB website](https://www.centre.edu/academics/academic-affairs-office/institutional-review-board/irb-documents-and-forms/).
* **Information Scripts or Sheets**: Even when the need for signed consent is waived, the human subject must be informed of the purpose of the study, any risks and benefits, and his or her rights in relation to the study. This information can be given verbally and/or the individual can be given an information sheet about the study to read. In these situations, the collection of data from the individual serves as evidence that he/she agreed to participate.
* [**Anonymous Data**](#anonymousdata): Data that is collected anonymously does not require written consent, though the standard information found on a consent form or information sheet should be presented. Consent to participate is implied when a subject completes and returns the survey. Anonymous data can be obtained by using questionnaires that are returned by mail (in envelopes with no return address or other identifying markers), by ballot box, by the collection of surveys that are returned to the researcher as a group, or internet surveys using software that renders it virtually impossible to connect answers with respondents.

**3.** [**Deception**](#deception)**:** Research involving deception compromises a subject’s ability to give true informed consent. The IRB will consider requests to waive some of the requirements for informed consent for research that intentionally involves deception, but only if all of the following criteria are met:

* + The research cannot be done without the deception.
  + The potential value of the research outweighs any potential risks to the subject.
  + The subject is informed of the true nature of the research as soon as possible.
  + The research involves no more than minimal risk.

**4. Waivers of Informed Consent:** Studies that meet certain criteria may qualify for a [waiver of informed consent](https://www.centre.edu/academics/academic-affairs-office/institutional-review-board/irb-documents-and-forms/). Waivers are often requested when gathering informed consent from the participants would potentially bias or otherwise adversely affect the study results. Examples of such studies may include observations or ethnographies. However, a waiver of gathering informed consent does not imply that a researcher can hide his or her intent to conduct research. The participants should be made aware of the study and their role in it if at all possible.

The IRB may or may not grant a waiver of informed consent request depending on the potential risks that are involved for the subjects. Waivers maybe be requested for an entire study or particular parts of a study. The researcher must justify how his/her study meets ALL of the following conditions.

* + - 1. The study involves no risk or only minimal risk.

1. The rights and welfare of participants are not adversely affected.
2. The research could not practicably be carried out without the waiver.
3. Whenever possible the subject will be provided with additional pertinent information following their participation in the study.

According to federal guidelines, even if a waiver of informed consent is obtained, the researcher must still offer the subject an opportunity to record their research participation. For example, if a study is approved to use oral consent, the researcher should have a written consent form made available in case the subject chooses to leave documentation of his/her participation with the researcher.

**5. Confidentiality:** Investigators must respect the privacy of their subjects. Investigators must protect confidential information and advise subjects in advance of any limits on their ability to ensure that the information will remain confidential.

If the data gathered by a student researcher is not anonymous, the IRB requires that the data be turned over to the research advisor at the end of the research period. The advisor then becomes responsible for properly storing the data for three years. The data can be destroyed three years from the ending date of the project. If a student plans to continue the research or use the data in future projects, he or she may request permission from the IRB to retain the data. Permission is contingent on the student’s agreement to protect the confidentiality of the data.

**6.** [**Coercion**](#coercion)**:** Subjects, including students who are participating in classroom experiments or faculty scholarship, may not be induced to participate by means or in circumstances that might affect their ability to decide freely. When course credit is offered for participating in research, some other mechanism to earn that credit must be made available to students who choose not to participate as human subjects. Alternative mechanisms for earning credits and the rewards for participating in research should be in line with the burden imposed by participating in the research to avoid presenting an undue influence on a person’s ability to freely choose to participate (or not).

Researchers must inform subjects that they are free to withdraw from the research at any time. Subjects who indicate a desire to withdraw must be allowed to do so promptly and without penalty or loss of benefits to which they are otherwise entitled. This condition must be clearly stated as part of the informed consent statement.

**7. Disclosure:** Upon request, an investigator must disclose the source of financial support for the research to a subject.

**IV. Persons Who Must Register their Study or Submit a** [**Protocol**](#protocol) **to Centre College’s IRB**

* Anyone formally affiliated with Centre College (faculty, staff, students) who engages in scholarly research involving human subjects, either on or off campus
  + See section VI regarding students who are conducting research as part of a course, class project, or John C. Young project.
* Researchers who are not affiliated with Centre College but who want to conduct human subject research on Centre’s campus.
  + Researchers conducting studies on Centre’s campus who have received IRB approval from another organization must submit their research protocol and IRB approval documentation to Centre’s IRB for consideration.

Note that studies must be [registered](#protocol) or receive IRB approval **before** data collection begins. IRB approval **CANNOT** be retroactively applied to studies that have previously occurred or that are in progress.

**V. IRB Review Categories**

**ALL researchers using human subjects must inform the IRB of their studies.** Depending on the level of potential risk involved, researchers may be required to submit a full application, or may have the choice of submitting a shortened application form or simply [registering](#risk) their project with the IRB. Researchers may schedule a call with a member of the IRB to discuss their studies prior to submitting their research proposals to the IRB.

**Level I** research presents [no foreseeable risk](#risk) to human subjects.

**Level II** research involves [minimal risk](#minimalrisk) to human subjects.

**Level III** research falls into at least one of the following categories:

• Presents more than minimal risk

• Is funded by a federal award

• Involves [deception](#deception)

• Involves subjects from a group awarded special protections, e.g., fetuses, persons under 18 years of age, those with uncertain citizenship status, prisoners, or those with diminished cognitive capacity. Research involving any group that has been awarded special protections cannot be considered for exempt status.

Examples of Level I, no-risk studies:

* Research conducted in established or commonly accepted educational settings involving normal educational practices, such as research on regular and special education instructional strategies or research on the effectiveness of instructional techniques, curricula, or classroom management methods.
* Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior. *However, such research is considered to carry some risk if the human subjects can be identified directly or through identifiers. Some risk also exists when the disclosure of the responses outside of the research context could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subject’s financial standing, employability, or reputation.*
* Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior of elected or appointed public officials or candidates for public office.
* Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens that are publicly available, or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
* Research and demonstration projects which are designed to study, evaluate, or otherwise examine public benefit or service programs; such as
  + procedures for obtaining benefits or services under those programs,
  + possible changes in or alternatives to those programs or procedures, or
  + possible changes in methods or levels of payment for benefits or services under those programs.
* Taste and food quality evaluation and consumer acceptance studies in cases where wholesome foods without additives are consumed.
  + Studies do not require IRB oversight if a food is consumed that contains a food ingredient at or below the level found to be safe for that particular use,
  + Studies do not require IRB oversight if the use of an agricultural chemical or environmental contaminant is at or below the level found to be safe by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

**VI. Preparing an Application to Centre College’s IRB**

Researchers are responsible for understanding the procedures for submitting a proposal to the IRB. When preparing an application, researchers should keep in mind that the members of the IRB are not experts in the research being reviewed. Adequate lay-language explanations should be provided to allow the members of the IRB to understand the objectives, the methods, the research implications, and the conditions and [risks](#risk) to which human subjects will be exposed.

**No student should conduct** [**human subject research**](#humansubjectresearch) **without the expressed support of a faculty or staff research advisor.**

***Special note on research conducted as part of a course or class project***

*IRB approval must be obtained for all research involving human subjects in courses that consist substantially of independent student research projects (e.g., PSY/BNS 350/351, directed study 400) or those that focus on research method instruction (e.g., PSY 205, PSY/BNS 210, ANT/SOC 305, MAT130, POL 205 and summer research assistantships). Acquiring IRB approval prior to data collection preserves the researcher’s ability to publish or present the data at a later time. A member of the IRB can give a class presentation and/or offer a decision tree that will help faculty members and/or students determine the level of potential risk in the proposed study.*

***Special note on John C. Young projects***

*Applicants to the John C. Young program and their advisors should note that projects involving human subjects must be reviewed by the Institutional Review Board (IRB) before the projects can be reviewed by the John C. Young Committee. The student researcher should contact a member of the IRB early in the project’s development. The IRB member will help the student determine whether or not the project needs to simply be registered, or a formal IRB review. The IRB will work with the student to preserve the integrity of the project while protecting human subjects.*

***Special note on research that has received IRB approval from another institution***

*Off-campus researchers must notify the Centre College IRB of their intent to initiate a study of Centre’s population. Researchers should access the IRB application survey and select “Review of a study that has received IRB approval from another institution.” The researcher will then follow the directions and upload the protocol and approval documentation from the other institution. Research cannot begin on Centre’s campus until Centre’s IRB issues a formal approval document.*

**A study’s registration or IRB application must be submitted online via the IRB application survey.** [Centre College’s IRB website](https://www.centre.edu/academics/academic-affairs-office/institutional-review-board/irb-documents-and-forms/) includes an IRB Application Survey Preview which contains all the questions asked in the application portal.

Key components of an IRB application are detailed below.

1. **Abstract**

The abstract should address the specific aims and hypotheses of the investigation, including a definition of the problem, the contribution the research is expected to make, and the importance of the hypothesis to be tested. The abstract should also state the relation of the proposed research to previous scientific investigations in the field, including relevant laboratory and animal studies. Clear justification for the participation of human subjects in the research must be given.

If specific hypotheses are not being tested, then information the researcher hopes to gain should be discussed. Researchers proposing a pilot or exploratory investigation should describe ways in which the information obtained from human subjects will be used in future studies.

**2. Personnel**

Identify all personnel who will participate in or assist in conducting the research. Identify each individual by name, role (faculty/staff advisor, student researcher, consultant, etc.), and his/her NIH Protecting Human Research Participants training number or other human subject protection training certification. Briefly outline each individual's qualifications (such as trained in using EEG equipment or leading a focus group) as related to the project. If specific skills are required to complete the research, investigators should include proof of licenses, accreditation, and/or background information that verifies the researcher is qualified to perform the procedures indicated.

1. **Methodology**

The application must contain a detailed description of all procedures to be performed on human subjects for the purposes of research. Proposals should indicate the type of [interactions](#interaction) and [interventions](#intervention) with subjects and the means of observation or interview to be used. Scripts used to provide instruction to the test subjects need to be presented, as well as any questionnaires, surveys, or other instrument used in the study. Standard psychological tests should be listed by name and described. If applicable, sample items, questions, or stimuli should be included.

Devices or activities that are not customarily encountered by subjects in their daily living or the unusual application of familiar devices or activities must be described in detail.

Any procedures involving electrical devices, radioisotopes, or drugs must be described in detail.

The “when” and “where” of the research must be described. The researcher should provide an expected start and end date for the data collection as well as for the overall research project. A tentative time schedule for the various procedures—or flow-chart where appropriate—should be provided showing how long each aspect of the study will take, the frequency and timing of ancillary procedures, the nature and duration of human discomfort, and the precise location in which the study is to be conducted. Frequency, duration, and location of interviews or observations should be indicated.

If applicable, the investigator must detail specific reasons for using deception and the plans to debrief the research subject following the study. If debriefing the subject will somehow invalidate the research objectives or the data, the researcher must detail those circumstances and justify the withholding of information.

1. **Participants**

The researcher should verify access to his/her research population and describe its characteristics and size. Effects of small sample size and the preservation of anonymity and confidentiality must be addressed.

Justification must be provided for the study of groups that are members of a population whose capability to provide [informed consent](#informedconsent) is absent or limited. Such populations include fetuses, persons under 18 years of age, persons with uncertain citizenship status, prisoners, persons with diminished cognitive capacity, and those who are confined to institutions (whether by voluntary or involuntary commitment). A pregnant or potentially pregnant woman's ability to provide consent is limited to activities where

* the risk to the fetus is minimal, or
* the purpose is to meet the health needs of the mother, and the fetus will be placed at risk only to the minimum extent necessary. (See 45 CFR 46 subparts B, C, or D.)

1. **Potential Risks and Benefits**

The researcher is required to discuss any possible [risks](#risk) to the human subject. Damaging effects may be physical, psychological, legal, economic, or social. Some research involves neither risks nor discomfort, but rather violations of expectations. Such violations, if any, should be specified. The researcher is then required to address how the risks will be managed and minimized. In addition, the research should assess the effectiveness of the proposed safeguards. The researcher must present the significance of the new knowledge that is being sought and an evaluation of the benefits to individuals and/or society with respect to the risks involved in the study.

1. **Confidentiality and Anonymity**

The researcher must describe how the identity of participants and their confidential information will be protected, including but not limited to

* the separation of [signed consent](#informedconsent) documents from the data (such as a completed survey) and from the research results.
* the use of numerical or symbolic codes to index and organize the data, as opposed to personal identifiers such as initials or first names.
* the protection of subjects’ confidentiality in publications and presentations.
* the disposal of research materials and informed consent documents.

Anonymity is desirable but not required. If participants’ anonymity is not to be maintained, the researcher must describe specifically why participants will not remain anonymous. Research subjects must be informed when their identity will not be kept confidential and be given the choice of whether or not to participate in the research.

1. **Data Protection**

Researchers must consider how they will protect the collected data. In addition to the steps suggested above that address confidentiality and anonymity, additional steps can be taken to ensure the security of the data set, such as storing hard-copy data in locked filing offices in locked offices or storying electronic data in password protected spreadsheets on password protected computers. Data can also be stored on a secure server. Explain the data protection measures you will take that are appropriate to your study.

1. **Other**

The IRB relies on the expertise of the researchers to provide insight about any peripheral benefits or potentially harmful effects of the research. Based on the researcher’s past experience and knowledge, identify any extraordinary moral, legal, or ethical concerns (either beneficial or harmful) that may be linked to this research.

**VII. Submitting an Application to the IRB**

To submit an application for review, fill out the [IRB Application Survey](https://centre.co1.qualtrics.com/jfe/form/SV_2moEk9ajmWVWVhz) (<https://centre.co1.qualtrics.com/jfe/form/SV_2moEk9ajmWVWVhz>). A printer-friendly version of the application is available on Centre College’s IRB website. Researchers are encouraged to compose their answers in a word processing document and then cut and paste their responses into the application survey.

The survey system allows for a person to begin an application, leave the site, and then return at a later time; however, there are limitations on this feature. The feature only works if the applicant returns to the survey on the same computer, using the same web browser, and if the applicant has not cleared the “cookies” from his or her computer since they last logged into the survey system. Partially completed surveys are saved for one week from the time they were last saved.

Before submitting an application, have the following documents saved in PDF format.

* Informed consent document or Information Script/Sheet
* If applicable, a Waiver of Signed Consent or Waiver of Informed Consent Request Form

And if applicable,

* Research instruments such as surveys, questionnaires, interview scripts, manipulation protocols, debriefing forms, advertisements/flyers, etc.
* Evidence of an authorization agreement from cooperating institutions (if any)
* Non-disclosure or other agreements with owners of restricted data sets
* Investigator licenses, skills training certificates, etc.
* If the study involves persons less than 18 years of age in a classroom setting, a signed letter from the school’s principal and the classroom teacher providing their consent for students to participate in the study.
* An International or non-Western Cultures Research Form should be submitted when the study seeks information from people who may not share the same cultural understandings of the researcher or the approving IRB. Through this form, the IRB seeks to ensure that the researchers have considered the cultural norms of their research populations and the benefits and risks that may exist for both researchers and subjects.

All documents must be submitted in English. If the research is being conducted in a language other than English, the surveys, scripts, and other materials used to interact with the test subjects must be submitted in the original foreign language accompanied by English translations.

**VIII. Review Procedures**

When a proposal is submitted through the online application survey, it is received by a designated IRB member. That person then assigns the application to a Lead Reviewer. The Lead Reviewer will conduct an initial review, determine the level of review that is needed, and shepherd the PI through any revisions that are necessary to make the study eligible for IRB approval. If desired, the Lead Reviewer may request a “second” reviewer to aid in the revision of the submitted materials. The reviewer(s) will alert the chair when they believe the application is ready for formal review (if required) or approval. The IRB chair will then review the documents and/or add the proposal to the agenda items for the next scheduled meeting of the IRB. The IRB will meet during the academic year for training purposes and to review protocols that require the review of the full IRB. Reviews may also be conducted via email.

**The IRB requires a complete application and relevant supporting documents no later than thirty (30) days prior to the intended start date of the research**. Though some reviews may be conducted quickly, researchers who submit applications less than 30 days prior to the intended start dates accept the risk that their projects may not start on time. Note that most applications require revision before they can be approved. The PI should keep a copy of the submission receipt that is automatically generated by the application system.

**Level I** applications are usually reviewed by one member of the IRB.

**Level II** applications are usually reviewed by two members of the IRB.

**Level III** research requires evaluation by a quorum (fifty percent plus one) of the IRB.

The IRB generally acts by consensus; if consensus cannot be reached, the board decides in favor of the majority opinion. If the IRB is evenly split, the vice president for academic affairs will vote.

Members of the IRB must recuse themselves from reviewing applications on which they are the principal investigator or advisor.

Researchers granted approval from the IRB will receive an approval letter and a stamped and signed consent form to be used in their research. An approval letter will indicate that the PI should promptly report to the IRB any changes to the project’s protocol or personnel, unanticipated problems, or adverse effects that the PI encounters in the process of completing the research.

Researchers whose applications are not approved will be provided with a list of the concerns cited by the IRB. Most researchers will be invited to revise and resubmit their applications for a new review.

**IX. Reporting of Unanticipated Problems, Serious or Continuing Non-Compliance, and Suspensions or Terminations of IRB Approval**

Investigators must immediately report to the IRB any adverse effects, events, serious non-compliance, or unanticipated problems involving risks to subjects or others. The IRB chair must report such events to the vice president for academic affairs, who may be obligated to contact the sponsors of the research and/or the [OHRP](#OHRP). The IRB chair and the vice president for academic affairs have authority to take one or more of the following actions:

* Suspend the study pending further investigation
* Terminate IRB approval and require the study to be closed (with appropriate protections for avoiding harm to enrolled participants)
* Require further training for the investigator as a condition of review for future research

**X. Renewals**

IRB approval is given in one-year increments unless the project has acceptable but significant enough risk that the Board elects to extend approval for only a six-month period. If the project continues beyond the approval period, the principal investigator must submit a status report on the project to date and a renewal request. Renewals may be submitted using the IRB online application survey located at <https://centre.co1.qualtrics.com/jfe/form/SV_2moEk9ajmWVWVhz>.

Renewal applications must be submitted with the following information and documents:

* The number of human subjects who participated in and withdrew from the study
* A summary of adverse events and any unanticipated problems involving risks to subjects or others; include the number and any reason given for the withdrawal of subjects from the research or complaints about the research since the last review
* A summary of any relevant amendments or modifications to the research since the last review
* Any other relevant information, especially information about risks associated with the research
* A copy of the current informed consent document and any newly proposed consent document

**XI. Revisions to Approved Protocols**

All changes to an existing approved protocol, including changes to the study-related procedures, personnel, or duration of the study, must FIRST be approved by the IRB unless said changes are necessary to avoid undue harm or increased risk to the participants. Changes made in response to adverse effects or events must be reported to the IRB immediately. Revisions may be submitted using the [IRB online application survey](https://centre.co1.qualtrics.com/jfe/form/SV_2moEk9ajmWVWVhz) at <https://centre.co1.qualtrics.com/jfe/form/SV_2moEk9ajmWVWVhz>.

Revisions eligible for expedited IRB review (Levels I and II)

* Changes in protocols for studies that have had no adverse effects or events reported and that will not result in a change in the level of risk to participants
* Changes in personnel or duration of the study that will not result in a change in the level of risk to participants

Revisions requiring full IRB review (Level III)

* Changes in protocols, personnel, or duration for studies that have had adverse effects or events reported
* Changes in protocols, personnel, or duration that may result in increased risk for the participants
* Changes in protocols that involve vulnerable populations (e.g., fetuses, persons under 18 years of age, prisoners, or those with diminished cognitive abilities)

**XII. End-of-Term Summaries and Closing Reports**

At the end of each long term, researchers will submit a brief summary report to the IRB. The [end-of-term summary](https://centre.co1.qualtrics.com/SE/?SID=SV_ePWh76UZDsyvUYB) is available <https://centre.co1.qualtrics.com/SE/?SID=SV_ePWh76UZDsyvUYB>. The form asks the

* Number of participants who have completed the study
* Number of participants who withdrew from the study
* Number of adverse effects or events that occurred and explanations of how those effects were managed
* Any revisions that were made to the study
* Status of the research, either complete or continuing. If the study is to be continued, the researcher should include the anticipated completion date and indicate whether an IRB renewal is requested.

**XIII. Appeals**

The Institutional Review Board will deny a research application if it believes the risks outweigh the benefits of the research. If the investigator disagrees with the IRB's decision, the researcher may make an appeal. The researcher should submit the following materials via email to [irb@centre.edu](mailto:irb@centre.edu):

* the same application that was denied,
* a letter of appeal presenting the researcher's arguments for approval, and
* any other pertinent information in support of the appeal.

Applications submitted for appeal are considered by the entire board. The decision of the IRB is delivered in writing and via email to the investigator. If the appeal application is not approved, the research cannot be conducted.

If a researcher questions the conduct of the IRB or feels that his/her appeal was unfairly reviewed, he/she may make an appeal directly to the vice president for academic affairs.

**XIV. Composition of the IRB**

The Institutional Review Board (IRB) is a standing committee with a minimum of five members. IRB members shall be appointed by the vice president for academic affairs and serve for three year terms. The IRB must include

* The vice president for academic affairs as the signatory official (*ex officio*, non-voting member except in the case of ties)
* A representative from the public without active ties to the college or organization sponsoring the research (45 CFR 46.107 b)
  + Note: College employees, students, and alumni of the college are not eligible to fulfill this position. Spouses, parents, immediate family members or offspring of employees, students, or alumni of the college should decline to serve as members of the Board if they feel they will be biased by their relationship to such individuals. In cases where the community member without active ties to the college may have a conflict of interest, that person will be temporarily replaced by another eligible community member.
* A member whose primary concerns are in non-scientific areas (45 CFR 46.107 c)
* A member qualified to address the validity of scientific experimental designs (45 CFR 46.107 c)
* Additional members as necessary to provide a balanced representation of disciplines that conduct research with human subjects (45 CFR 46.107 b)

The IRB is responsible for protecting people and for safeguarding the institution from unnecessary harm, thus the chair (who gives final approval on all applications) should be an experienced reviewer. Whenever possible, the chair of the IRB will be selected from among those members of the Board who have already served a three-year term. This continuity will aid the IRB in being consistent in its decisions and processes.

The IRB may invite individuals with competence in special areas to assist in the review of applications which require expertise beyond or in addition to that available on the IRB. These individuals may not vote on applications (45 CFR 46.107 f).

The IRB will strive to be sensitive to the composition and concerns of the community, in both its makeup and its decisions. Membership shall be made up of a balanced representation of gender and include members from a variety of professions and academic disciplines (45 CFR 46.107 b).

No IRB member may participate in the initial or continuing review of any project in which the member has a conflict of interest except to provide information requested by the IRB (45 CFR 46.107 e).

IRB members must meet the following minimum training requirements before reviewing research protocols:

* Read the Belmont Report
* Read the Centre College Policy on Protection of Human Subjects
* Read the Common Rule and B, C, and D of the U.S. Department of Health and Human Services (HHS) regulations 45 CFR part 46
* Complete the NIH’s “Protecting Human Research Participants” training (available at <http://phrp.nihtraining.com/users/login.php>). Completion certificates must be submitted to the IRB chair.
* Complete the required modules of CITI’s Human Subjects Research-IRB Social-Behavioral-Educational Focus training program. Board members will also complete three additional modules: Gender and Sexuality Diversity in Human Subject Research, Consent in the 21st Century, and Consent and Subject Recruitment Challenges: Remuneration. Completion certificates must be submitted to the IRB chair. CITI training must be renewed every three years (assuming the college covers the cost).

Issues regarding misconduct by researchers or IRB members will be reviewed and addressed by the vice president for academic affairs.

**XV. IRB Record Retention**

The college keeps records of all applications to the IRB. The files includes the decision letter, all email correspondence between the applicant and the IRB, and the end-of-term summary or closing report. Records are kept for three years from the conclusion of the research, after which time the IRB may continue to properly secure the review material or destroy the documents.

The researcher is responsible for keeping all data and documentation gathered during the research, including signed consent forms and any publications resulting from the research, in a secure manner for a period of three years after the end of the research. After that time, researchers may continue to properly secure the data or destroy the data. In the case of student research, the student’s research advisor may arrange for this documentation to be stored. If a student plans to continue the research or use the data in future projects, he or she may request permission from the IRB to retain the data.

The IRB reviews a list of all projects initiated or completed at the college at least once a year to ensure that projects are closed out properly and that any ill-effects of research are reported.