Champlain College Institutional Review Board Policies and Procedures

Champlain College Institutional Review Board

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Contents

Rationale

The Champlain College Institutional Review Board (IRB) will protect the safety, health, dignity and privacy of human subjects participating in research conducted by Champlain faculty, staff, and students. The IRB will provide a structured review, aligning the college with the norms of acceptable practices and the requirements for research involving human subjects (as defined herein, see Definitions) established by the federal government (see 45 CFR 46 and 21 CFR 56) which conform to ethical standards for a particular research activity or method.

Institutional Authority

Institutional authority shall be invested in the Champlain College IRB with the approval of the Board of Trustees.

In accordance with federal regulations (see 45 CFR 46.109) Champlain College's IRB will have the exclusive authority to:

- Approve, require modifications in (to secure approval), or disapprove of all research activities involving human subjects conducted at Champlain College.
- Suspend or rescind approval of research involving human subjects not conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects.

Officials of the institution may not approve a research proposal if Champlain College's IRB has disapproved it (see 45 CFR 46.112).

The Champlain College IRB is the author of these policies and procedures, and shall make changes only by consensus at official meetings of that body. Changes to policies that govern the institutional authority, scope of authority, principles, responsibilities, membership, procedures, and reporting activities must be approved in accordance with the procedures of the Faculty Handbook.

Scope of Authority

Anyone formally affiliated with Champlain College who engages in research involving human subjects, either on- or off-campus, must apply for IRB approval. Researchers not affiliated with Champlain College but who want to conduct research with human subjects under the auspices of Champlain College must apply for IRB approval. Anyone using unpublished institutional data from human subjects collected at Champlain College for research purposes, as defined herein, must have IRB approval.

It is the responsibility of faculty overseeing instructional activity that may involve human subjects to abide by professional and legal standards of conduct, including Champlain College's Principles for Ethical Research Involving Human Subjects (see below). Instructors should seek, or require students to seek, IRB approval for course assignments in which students are required to engage in substantial independent research with human subjects.

Principles for Ethical Research Involving Human Subjects

Champlain College affirms that all policies and guidelines related to research involving human subjects will be aligned with the following principles. Champlain College is committed to protecting the safety, health, dignity and privacy of individuals and groups participating in research conducted either at Champlain College or by any employee or student doing research in their capacity as an employee or student of Champlain College. All researchers at Champlain College are responsible for ensuring that all research practices involving human subjects satisfy the following requirements:

- *Risks are minimized:* All research methods are safe and involve no undue risk to the life, health, or well-being of the research subjects.
- *Benefits outweigh risks:* The benefits of the research clearly outweigh the anticipated risks of that research.
- *Privacy is respected:* The research will avoid unnecessary invasions of privacy and maintain, when appropriate, confidentiality.
- *Autonomy is respected:* Active participation in the research is voluntary, and a process is in place to obtain and, when appropriate, document informed consent from all subjects. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as, but not limited to, children, students, prisoners, and mentally disabled persons, additional safeguards have been included to protect the rights and welfare of these subjects.
- *Data is monitored closely:* When appropriate, information gained from the research will be used for the stated research purpose, and adequate provisions to monitor the data will be made to ensure the safety of subjects.
- *Equity is sought:* When selecting subjects for research, the distribution of burdens and benefits is equitable considering the methodology, purpose, and setting of the research.

Responsibilities

The responsibilities of the Institutional Review Board are to:

1. provide integrated oversight of ethical and regulatory issues in human subjects research conducted at Champlain College;

2. develop common tools and resources including standardized application forms, consent form templates, operating procedures, and a database for managing and tracking protocols; and
3. provide additional resources to improve services and functioning such as compliance and monitoring as well as training and education.

Membership

Champlain College's Institutional Review Board will consist of a minimum of seven voting members including:

- one member from the Division of Business,
- one member from the Division of Education and Human Studies,
- one member from the Division of Communication and Creative Media,
- one member from the Division of Information Technology and Sciences,
- one member from the Core Division

The composition of this committee must include:

- at least one member from Graduate studies,
- at least one member whose expertise lies in a scientific area,
- at least one member whose expertise lies outside of the sciences,
- a representative from the public without active ties to the College or to an organization sponsoring research, and
- an administrator (ex officio).

One voting faculty member, nominated by the President of the Senate and approved by the Provost, will serve as Chair of the IRB for a three-year term. Faculty members of the IRB will be appointed by the Faculty Senate Executive Committee, also for three-year terms (with initial appointments being staggered.) The administrator will be appointed by the Provost of the College. The representative from the public will be invited to serve by the Provost of the College on a yearly basis, although this member may serve for as many consecutive terms as he or she is invited and willing.

In addition to the members of the IRB, the IRB Chair may, at his or her discretion, enroll one additional member, either from within Champlain College or from outside, on a temporary basis to review a particular research proposal. This member will have expertise in the research methods and/or discipline of the research project in question. This member may offer support but will not vote.

Every effort will be made by the Provost, the Faculty Senate Executive Committee and the Chair of the IRB to ensure that the membership of the IRB adheres to federal regulations (See 45 CFR 46.107). Every effort will be made by the Provost, the Faculty Senate Executive Committee and the Chair of the IRB to ensure the continuity of the IRB by staggering terms of service if necessary. Members will, at a minimum, complete the NIH Office of Extramural Research Web-based training course "Protecting Human Research Participants." A record of certification must be on file before a member may participate in the review of research.

Finally, an IRB member will recuse himself or herself from the review of a particular research proposal if a conflict of interest occurs.

Procedures

All research proposals involving human subjects must be submitted for IRB review. The IRB Chair will determine the level of review necessary for a project. The IRB will review and respond to all research proposals in a timely manner so as to cause no undue delays in the conduct of the research project.

Proposals will fall into one of three categories, as determined by the IRB Chair: Full Review, Expedited Review or Exempt.

- **Level 1 (Exempt):** Research involving human subjects that poses very little or no foreseeable risk to the health or welfare of the research subjects, as described in 45 CFR 46.101 (b), is generally *exempt* from an expedited or full-board review. Proposals will be deemed *exempt* by the Board Chair, with a report made to the full Board.
- **Level 2 (Expedited Review)**: Research involving human subjects that poses minimal foreseeable risk (see Appendix: Definitions) to the health or welfare of the research subjects can be *expedited* by the IRB Chair. Projects eligible for *expedited* review will be voted on by three Board members chosen by the IRB Chair. Outcomes of a Level 2 review are accept, return for revision/clarification, or move to Level 3 review.
- **Level 3 (Full Review):** Research involving human subjects that poses more than minimal foreseeable risk, is funded by federal grants, involves deception, or involves subjects from a group awarded special protections (see Appendix: Definitions) requires a *full*-board review. Projects requiring *full* review will be voted on by a quorum of the full Board. A majority of the members must be present to constitute a quorum. The Board will usually approve, disapprove, or return for revision/clarification proposals by consensus, but if consensus cannot be reached, then the Board will decide in favor of the majority opinion. If the committee is split, then the administrator will vote.

A review from the IRB, regardless of level of review, will result in one of three outcomes: approval of the proposal, disapproval of the proposal, or return to the investigator for revision/clarification.

- **Approval:** If a research proposal is approved by the IRB, an IRB Certificate of Approval (CoA) will be supplied to the investigator, and the CoA will be filed with the Board, as well as the appropriate authorities of Champlain College (the Provost). The principal investigator is free to proceed with the research under the auspices of Champlain College and its Institutional Review Board. The IRB will determine the length of the approval period.
- **Disapproval:** If a research proposal is disapproved, the principal investigator will be notified in writing. The notification will include a statement of the reasons for the Board's decision. The notification will be filed with the Board, as well as the appropriate authorities of Champlain College. The disapproved research cannot proceed under the auspices of Champlain College or its Institutional Review Board. A research proposal can only be disapproved by a quorum of the full Institutional Review Board.
- **Return for revision/clarification:** A research proposal may be returned to the principal investigator for revision and/or clarification. The Board will explain the reasons for the proposal's return in writing, along with requested changes or portions of the proposal that need further explanation. The return letter will be filed with the Board, as well as the appropriate authorities of Champlain College. The investigator may submit the revised proposal for full Board review.

Any proposed post-acceptance changes to a research design or its implementation must be reported to the IRB. Major changes in research design constitute a new research proposal and necessitate a new review submission and review process. Minor changes in research design can be approved by the Board as an amendment to the original proposal. The IRB Chair will determine whether changes made to a research design must be re-submitted as a new proposal or approved as an amendment.

Renewals and Extensions: The IRB will determine the period of time between the initial approval and the subsequent renewal date. Most protocols will be approved for continuing review on an annual basis in accordance with federal regulations (see 45 CFR 46.109). The term of approval will be provided on the Certificate of Approval. Protocols must be renewed with the IRB by the date stipulated on the Certificate of Approval.

Appeals: If an investigator disagrees with an IRB decision to disapprove a research proposal, the researcher may appeal the decision by re-submitting the same application form to the IRB with 1) a letter of appeal stating the arguments for approval, and 2) any additional information in support of the appeal. Applications submitted for appeal will be considered by the full board at

the next scheduled meeting date. If the proposal is not approved during this meeting, the research cannot be conducted under the auspices of Champlain College.

Reporting Activities

Following federal regulations (see 45 CFR 46.115), Champlain College will keep a record of all applications for approval of research involving human subjects, including all submitted research documents. Further, records will be kept that identifies the IRB members (including the Chair) who performed the review, the Chair's notes, email correspondence between the researcher and the IRB, and the approval, disapproval, and clarification/revision notices. These documents represent the complete records kept by Champlain College of any IRB submission. Records will be kept for seven years after the conclusion of research.

The IRB will conduct an annual review its records to maintain compliance with federal regulations (see 45 CFR 46.115).

Researchers are responsible for maintaining all data and documentation gathered during research including signed consent forms resulting from the research. Sponsors of student research (teachers or advisors) will arrange for the storage of these documents. These records must also be kept for a minimum of three years.

Appendix: Definitions

Anonymity: Anonymity implies that the data, by virtue of the method of collection, can never reasonably be connected with the human subject(s).

Anonymous surveys do not require written consent, though explanations of the research protocol that are standard on a written consent form should be included at the beginning of the survey. Consent to participate is implied when a subject completes and returns the survey. An example would be a mailed questionnaire with directions for subjects not to sign their names, where no code is used, where responses to questions will not reveal identities, and where the subject group is sufficiently large to avoid inadvertent identification.

Assent: Assent is a legal minor's affirmative agreement to participate in research after an adequate explanation has been provided. The absence of a minor's objection does not constitute assent. (See 45 CFR 46.402)

Certification of Approval: If a funding or sponsoring agency of research requires that research proposals involving human subjects are appropriately reviewed and sanctioned by an institutional review board, it shall be the responsibility of the researcher to obtain and have completed all appropriate documents. (See 45 CFR 46.102)

Coercion: Participants, including students who are taking part in classroom experiments or faculty research, must not be induced to participate by means or in circumstances that might affect their ability to decide freely.

Researchers must inform participants that they are free to withdraw from active participation in the research at any time. Subjects who indicate a desire to withdraw will be allowed to do so promptly and without penalty or loss of benefits to which any subject is otherwise entitled. At the minimum, this condition must be clearly stated as part of the informed consent statement.

In a classroom setting, course credit need not be offered to students for their participation. However, when course credit is offered for participating in research, some other mechanism to earn that credit must also be made available to those students who choose not to participate as human subjects. Rewards for participating should be in line with the burden imposed by participating, to avoid presenting an undue influence on a person’s ability to freely choose to participate (or not).

Confidentiality: Where the identity of subjects is known or knowable by name, by specific data, or by appearance, it is usually necessary to make provisions for confidentiality. Data should be stored securely, accessible only to the investigator and his or her authorized staff or representatives. No identifying information, including personal and sensitive information, may be released except with the express permission of the subject.

Where confidentiality in reports of results or in reports of specific incidents of interest to the scholarly community cannot be assured, this information must be included in the consent form. In those instances where unique information is received but was not anticipated at the time of consent, later consent for the release of identifying information must be obtained. Changes in informed consent or confidentiality must be reported to the IRB (see Procedures).

In some circumstances, it may be necessary to break confidentiality. If this is foreseen, the study subjects should be informed of this possibility on the consent form.

Deception: Deception occurs whenever information about an activity is deliberately withheld from subjects. A dilemma may arise in some research when fully informed consent may itself have injurious effects on the subject, or it may invalidate the experiment.

The act of concealing information is related to the requirement for informed consent. Research involving deception compromises a participant's ability to give 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 deception.
- The potential value of the research outweighs any potential risks to the participant.
- The participants are informed of the nature of the research as soon as possible.
- The research involves no more than minimal risk.

Human Subject: Human subject (see 45 CFR 46.102) means 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.

Intervention or interaction includes both physical procedures by which data are gathered (including observational studies) and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject.

Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record).

Incompetent: In the context of the human subjects review process, an individual who is unqualified to give or is incapable of giving informed consent is considered to be incompetent. An incompetent may be a minor, an adult who has been declared legally incompetent, or an adult whose competency may be questioned because of an illness or an unusual circumstance.

Informed Consent: The ethical and professional codes governing the use of human subjects in research (see 45 CFR 46.116 and 45 CFR 46.117) provide that no research involving human subjects should be undertaken without the informed and voluntary consent of the human subject, or the consent of his or her authorized representative if the subject lacks the capacity to consent.

When a subject's consent is obtained, it must be "informed" consent (i.e., the knowing consent of an individual or his or her legally authorized representative, so situated as to be able to exercise free power of choice without the presence of excessive inducement or any element of force, fraud, duress, or other form of restraint or coercion).

Further, consent should be a reasoned judgment to participate in an activity in full recognition of what will, or could, happen. In most cases, the investigator must discuss with the subject, in language that can be readily understood, all matters pertinent to the decision to participate.

Finally, a researcher must disclose to a subject, upon request, the source of support for the research.

For guidelines on informed consent, see the HHS Office of Human Research Protections website: http://www.hhs.gov/ohrp/policy/consentckls.html.

International Research: Human research conducted outside the United States should conform to the same ethical and regulatory standards to which research conducted in the United States is held, and should conform to applicable local laws and norms of the host country. The Office for Human Research Protections publishes *The International Compilation of Human Research Standards*, a listing of over 1,000 laws, regulations, and guidelines on human subjects protections in over 100 countries and from several international organizations (available here: http://www.hhs.gov/ohrp/international/index.html). International human research should be conducted in accordance with Champlain College's Principles for Ethical Research involving Human Subjects, including those concerning informed consent and participation of vulnerable populations.

Institutional Review Board: Institutional Review Board (IRB) is the term used for a committee or group which has been formally designated by an institution to review and approve research involving human subjects.

Legally Authorized Representative: Legally authorized representative (see 45 CFR 46.102) means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

Personal and Sensitive: Examples of personal and sensitive information are: some demographic data; questionnaires, inventories, and scales which elicit subjective responses; opinions on

sensitive issues or about other individuals or groups; and records, such as medical, academic, photographic, audio tapes, and videotapes.

Privacy: Individuals have the right to privacy, which is the right of individuals to decide for themselves how much they will share with others their thoughts, their feelings, and the facts of their personal lives.

Research: Research (see 45 CFR 46.102) means a systematic investigation, including development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes.

For the purposes of this policy, the following are not considered "research" and thus do not fall under the purview of the IRB:

- Work that deals entirely with secondary sources (public data sets are considered such secondary sources)
- Activities in which human subjects perform exclusively for instructional purposes (though the intent or effort to publish data from such activities—at any time—converts these activities to research involving human subjects)
- Data gathering for the purposes of fundraising by the external affairs offices; market research for the purposes of admissions recruiting; recruiting efforts for faculty or staff; statistical data collected for the management of institutional affairs; and attitudinal research of alumni, students, or parents for the purposes of institutional affairs
- Journalism

Risk: Risk is the potential for physical, psychological, social or financial harm.

Human subjects may be exposed to different types of risks that are inherent in various research procedures. Risk is most obvious in medical and behavioral science research projects involving procedures which may induce a potentially harmful altered physical, mental or social state or condition. Some examples are: the requirement of strenuous physical exercise or the subjection to deceit, public embarrassment, or humiliation.

A wide range of medical, social, and behavioral projects may be proposed that carry no immediate physical, psychological or social risk for the subject(s) (e.g., those involving the use of personality inventories, interviews, questionnaires, observations, photographs, tapes, records, and stored data). However, some of these procedures may involve varying degrees of discomfort, harassment or invasion of privacy, or constitute a threat to the subject's dignity, all of which could constitute more than minimal risk.

Research that poses little or no foreseeable risk will result in **Level 1** review (see Procedures). For more detailed description of risk levels see the federal regulations (45 CFR 46.101).

Research that poses minimal foreseeable risk will result in **Level 2** review (see Procedures). Minimal risk (see 45 CFR 46.102) means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Research that foreseeably could pose more than minimal risk for subjects requires **Level 3** review.

Vulnerable Populations: Potentially vulnerable populations include pregnant women (45 CFR 46.202), children (see 45 CFR 46.402), prisoners (see 45 CFR 46.303), the mentally ill, the physically ill, the developmentally disabled and the physically disabled.

For guidelines on potentially vulnerable populations, see the HHS Office of Human Research Protections website: http://www.hhs.gov/ohrp/policy/consentckls.html.