Institutional Review Board

Policy and Bylaws

I. Introduction

Institutional Review Boards evaluate and approve research proposals to ensure that human and/or animal research participants are protected in accordance with federal regulation and institution-specific research ethics and principles.

CCS students often involve human and/or animal participants in their research through the use of surveys, interviews, focus groups, and observational studies. This policy offers a formal process to screen these studies, ensuring that human and/or animal research subjects are protected and that risks are assessed and mitigated.

The College is accredited by the Higher Learning Commission (HLC), which asserts that a criterion for accreditation is that "The institution provides effective oversight and support services to ensure the integrity of research and scholarly practice conducted by its faculty, staff, and students." The policy and procedures of the College's Institutional Review Board respond to this criterion.

There is also pedagogical value in developing an Institutional Review Board (IRB). In-depth research is a high-impact educational practice that falls within the framework of several of the College's Institutional Learning Outcomes. Learning about the history and rationale for IRBs and following the process for research proposal approval will provide students with a more comprehensive understanding of research ethics and the responsibility they have when impacting the lives of other human beings and/or animals.

Having a properly composed IRB will also allow the institution to register for Federal-Wide Assurance (FWA). If the opportunity arises for federally funded research, FWA registration is required.

II. Policy Statement and Definitions

In accordance with federal regulation, all research projects involving human and/or animal subjects must be reviewed by the College's Institutional Review Board (IRB). Approval for a project must be granted by the IRB before the research project may begin. The IRB cannot provide approval for research projects that are underway or have concluded.

For the purpose of this policy, research is defined as systematic investigation that develops or contributes to generalizable knowledge that is intended to be applicable and shared beyond the populations or situations being studied. Activities such as the collection of quantitative or qualitative

data; use of surveys, testing, interviews, or focus groups; and/or observation of individual or group behavior qualify as systematic investigation.

Funded or unfunded research conducted by or directed by CCS employees in connection with their institutional responsibilities; research that makes substantial use of CCS property, personnel, equipment or facilities; and/or research that involves the use of the institution's non-public information to identify subjects are all included in this definition.

Quality assurance activities internal to the institution, service or course evaluations, course or program assessment, and classroom exercises performed solely to fulfill requirements are typically not considered generalizable and therefore do not need IRB approval.

Human and/or animal subjects are living individuals being studied through the use of intervention or interaction, or identifiable private information. Intervention and interaction can take the form of any physical manipulations of the subject or their environment (e.g. use of devices, cognitive tasks) or communication/interpersonal contact between the researcher and subject, to include anonymous surveys. Identifiable private information includes behavior that takes place when an individual can reasonably expect that they are not being observed or recorded, or information provided for specific purposes and not intended for public posting.

III. Statement of Research Ethics and Principles

College for Creative Studies affirms that all individuals, particularly those performing as human and/or animal research subjects, should be treated with dignity, respect, and with due regard for their welfare. The following principles should guide all research on human and/or animal subjects.

1. Research that exposes human (including self) and/or animal subjects to unreasonable harm will not be conducted. Unreasonable harm is defined as causing mental or physical trauma or injury, and/or financial, reputational, professional, or legal damage.
2. Researchers will explain the research objectives, process, and potential risks to human and/or the owners of animal subjects prior to their agreement to participate.
3. Researchers will not use individuals as human and/or animal subjects unless they are satisfied that they, or those legally responsible for their well-being, are capable of understanding the consequences of their participation and have given informed consent.
4. The privacy and confidentiality of human and/or the owners of animal subjects will be respected.
5. Research subjects will be selected fairly. The appropriateness of involving vulnerable populations must be demonstrated.
6. Investigators will not deceive or withhold pertinent information related to their participation from human and/or the owners of animal subjects.
7. At any time, human subjects and/or animal subjects are free to withdraw, without prejudice, from active participation in the research.
8. All student research will be faculty or staff supervised, with faculty ensuring that the student is qualified to adequately safeguard the well-being of human and/or animal subjects.
9. All research is governed by the CCS Intellectual Property Rights policy.
10. Faculty will not require students to participate in their own research projects, nor may they induce students through "extra credit" to participate.

IV. Institutional Review Board Remit

1. Determine whether an activity constitutes human and/or animal subject research.
2. Review and offer approval or refusal of research proposals prior to the commencement of research.
3. Require that human and/or the owners of animal subjects be given information that complies with the appropriate laws, regulations, standards, and College policies as part of informed consent. The Board may require additional information dissemination to participants at any point during or after the research is conducted.
4. Require documentation of informed consent from the researcher(s).
5. Notify the researcher(s) and institution in writing of IRB decisions.
6. Conduct continuing review of approved research at intervals appropriate to the degree of risk.
7. Suspend or terminate approval of research that is not conducted in accordance with the IRB policy or is causing harm to participants.
8. The IRB is a board, not a committee. Hence, the IRB renders decisions, not recommendations. Executive leadership has the right to disapprove a study that the IRB has approved, but not approve a study the IRB has disapproved.

V. Bylaws

A. The Board

i. **Membership and Appointment:** The College for Creative Studies Institutional Review Board (IRB) will be comprised of three (3) members selected by the three deans. One (1) of the members will be faculty from a studio major department, including Foundation, one (1) will be a faculty member from the Liberal Arts or Art Education Department, and one (1) will be a staff member. The graduate and undergraduate representative will serve as Chairs of the Board. The Director of Academic Research will serve as ex-officio Secretary . Every effort will be made to ensure that the Board has diverse representation. The IRB may invite individuals with specific expertise to assist in the review of projects; however, they may not vote. The Board service commitment is three years including summers. Membership is staggered and determined by appointment.

ii. **Duties:**

- Attend Board meetings
- Review, evaluate, and vote (as applicable) on all assigned proposals within the time frame specified by the Board
- Complete required IRB member training for human/animal studies research

B. The Chairs

i. **Appointment:** The appointed graduate and undergraduate representative serve as Chairs and are voting members.

ii. **Duties:**

- Chair all IRB meetings

- Complete IRB Chair training
- Work with the Secretary to develop a timeline for IRB proposal consideration and continuing review, and delegate research as needed
- Suspend research not in compliance with guidelines or having adverse effects
- Designate a consultant with specific expertise to assist in the review of a proposal
- Work with the Secretary to assure records compliance and archive IRB records in the Academic Affairs Office
- Manage the IRB budget related to training, event, and consultant costs
- Organize and participate in educational activities related to the IRB (i.e. training/preparation sessions for students and faculty)
- Remain informed on federal and state guidelines related to IRB research and communicate that information to IRB members and the campus community
- Act as liaison between federal and state agencies and researchers regarding human and/or animal subjects research as needed
- Manage IRB registration with federal agencies should the need arise

C. The Secretary

i. **Appointment:** The Director of Academic Research serves as Secretary and ex-officio.

ii. **Duties:**

- Works with the IRB Chairs to assure records compliance
- Takes minutes at all IRB meetings
- Collects documentation
- Works with the IRB Chairs to archive IRB records in the Academic Affairs office
- Communicates with Board members, consultants, Principal Researchers, and Faculty Advisors regarding Board processes and decisions
- Works with the Chairs to develop a timeline for IRB proposal consideration and continuing review, and delegate research as needed
- Facilitates training and onboarding of new Board members
- Consults with IRB applicants as necessary
- Supports/facilitates educational activities related to the IRB (i.e. training/preparation sessions for students and faculty)

D. Alternates

i. **Appointment:** A list of external alternate members are selected by the Board based on area of expertise.

ii. **Duties:**

- Alternate members review, evaluate, and vote (as applicable) on assigned proposals when a voting member of the IRB brings forth a proposal or a conflict of interest necessitates external involvement

E. Meetings and Voting

i. **Meetings:** The Board will meet as needed throughout the academic year. Meeting necessity will be determined by the IRB Chairs and Secretary based on submitted documentation and continuing review needs. Meetings may be held with a quorum, although all members must vote on each full proposal. Expedited proposals do not require a meeting.

ii. **Voting:** Decisions are made with a majority vote. Three members, appointed by the Chairs, will vote on each expedited proposal. Chairs will give final approval. Members may be recused if they have a conflict of interest with the project under discussion.

iii. **Chairs' Action**

In cases requiring time sensitive scrutiny, proposals may be reviewed and approved by both Chairs (or one Chair and an IRB member), who in turn must inform the full IRB Committee of their decision.

F. Changes to Guidelines, Remit, and/or Bylaws

- Changes mandated by the federal government or other regulatory agency or accreditor will be made effective immediately upon passage.
- Changes to the College's IRB bylaws and process will be reviewed and voted upon by the Board, then forwarded to the Academic Division Deans (ADDs) for final approval.
- Prior to final approval, the Board Secretary will inform the College community of the proposed changes and a ten (10) day period for comment will initiate, after which a decision will be rendered. Notice of the change will be given to the Principal Researcher and Faculty Advisor (as applicable) for any research underway.

G. Collaborations with Other Institutions

Collaboration agreements with other institutions will be developed by Academic Affairs and other offices within the College as appropriate and be provided to the Board as part of the Proposal packet when applicable.

H. Record Keeping

Records will be kept in hard copy and/or digital form for at least three years after research completion by Academic Affairs. These records include:

- IRB minutes, meeting notes, and relevant communications
- IRB procedures and blank forms
- Lists of IRB members by year
- Evidence of training completion
- Completed and signed *IRB Exemption Checklists*
- *Institutional Review Board Proposals* with all attachments
- *Institutional Review Board Proposal Evaluation and Decision* forms
- *Adverse Consequences/Unintended Effects* forms
- Institutional collaboration agreements

I. Registration for Federal Funding

Human subjects research conducted or supported by any U.S. federal department or agency that has adopted the Common Rule (including, but not limited to, Department of Education, Department of Veterans Affairs, Environmental Protection Agency, etc.) requires registration for Federal-wide Assurance (FWA). CCS's IRB is not currently registered with FWA. However, if the opportunity arose for federally funded collaborative research with an institution that does have FWA, the study could be approved through that institution's IRB. If the opportunity arises for the College to participate in federally funded research with a department or agency that has adopted the Common Rule, the College's legal team should review the materials found on the Office for Human Research Protections and the Health and Human Services websites.

VI. Procedures

Member Selection

The initial three-year term will consist of suitably qualified and experienced candidates appointed by the academic Deans. Future Board members will be appointed by the academic Deans in consultation with the Faculty Executive Committee and serve for three-year terms on a staggered schedule. Selected candidates are appointed prior to each academic year. Faculty IRB membership counts for College Service in the same manner as Tier I Committee membership.

If a Board member wishes to propose research to the IRB or a conflict of interest presents, an alternate member will be asked to participate in the proceedings and vote on the proposal.

Training

IRB members, faculty advisors, and researcher training is available through the College's institutional membership with Citi Training. Training module selections are determined by participant role and automated through Citi.

Training for researchers and faculty advisors needs to take place prior to proposal submission. Training for IRB members must take place within the first month of their membership on the Board.

Meetings

The IRB Chairs and Secretary will meet during the summer to schedule the initial meeting for the next academic year. The Secretary will manage the meeting calendar, adding and removing meetings as needed.

Proposal Submittal

Typically, proposals should be submitted by the first Friday of each month. Proposals are submitted to the IRB Secretary who works with the Chairs to schedule IRB meetings and develop review timelines, which are communicated to the Principal Researcher. In certain circumstances, an immediate Chairs' review may be requested; however, follow up may be required.

Faculty Advisors are required for student Principal Researchers at both the graduate and undergraduate levels.

Principal Researchers will typically submit full proposals, requiring review and voting by the full IRB. Expedited proposals are less prevalent and are for research that involves no more than minimal

risk (defined as the anticipated probability of harm being no greater than that ordinarily encountered in everyday life) to participants OR is being reviewed strictly for minor changes to previously approved proposals. Proposals seeking exempt status will fall into one of the following six, federally defined categories to qualify.

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects: and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
3. Research involving the use of education tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (2) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) Federal statue(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources 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.
5. Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: i) Public benefit or service programs; ii) procedures for obtaining benefits or services under those programs; iii) possible changes in or alternatives to those programs or procedures; or iv) possible changes in methods or levels of payment for benefits or services under those programs.
6. Taste and food quality evaluation and consumer acceptance studies, i) if wholesome foods without additives are consumed or ii) if a good is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant 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.

<u>Proposal/Documentation Consideration</u>
When possible, the Board is sent proposals and documentation under consideration one week in advance of each meeting by the Secretary. Board members are expected to be prepared to discuss the content of all documentation when they arrive at the meeting.

The Board reviews and approves proposals using the *Institutional Review Board Evaluation and Decision* form. If the proposed study is in an area of study unfamiliar to IRB members, a consultant with specific expertise may be called upon to lend insight. The Chairs make the decision to hire consultants. The Principal Researcher and Faculty Advisor (as applicable) may be invited by the Secretary to attend

the IRB meeting in which their proposal will be voted upon so that they may answer questions from the Board.

Voting

All members must vote on each full proposal, though meetings may be held with a quorum. Voting may take place in absentia. Decisions are made with a majority vote. Three members, appointed by the Chairs, will vote on each expedited proposal, though the Chairs will ultimately sign the approval form. Decisions on expedited proposals are made with a majority vote. Members may be recused if they have a conflict of interest with the study under discussion and an alternate member may be selected.

The Board's decisions are communicated by the Secretary to the Principal Researcher, Faculty Advisor, and other appropriate parties via the *Institutional Review Board Evaluation and Decision* form in a timely manner.

Continuing Oversight

For studies lasting more than one year, Principal Researchers must submit a *Continuing Review* form at the start of each subsequent year summarizing intermediary results and clarifying future activities. If the intent of future activities differs from those approved in the initial proposal, the Principal Researcher may be asked to submit a new proposal; the depth of the changes will determine if the new proposal will be for a full or expedited review.

Adverse Consequences/Unintended Effects

If adverse consequences or unintended effects occur during the course of a study, the Principal Researcher must submit an *Adverse Consequences/Unintended Effects* form immediately (within 24 hours of occurrence) to the IRB Secretary and halt the study. The IRB Chairs will determine what, if any, action should be taken and respond to the Principle Researcher using the same form. The Principal Researcher may only resume the study with IRB approval.

Principal Researcher/Faculty Advisor Record Retention Policy

The Principal Researcher and Faculty Advisor (as applicable) are responsible for the maintenance and security of all participant records (to include signed *Informed Consent* forms) for three years following the end date of the study. In the case of student research studies, the Faculty Advisor manages this responsibility. These hard copy or digital files must be kept on the College's campus or on College technology, with corresponding copies provided to the Secretary.

VII. Forms and Checklists

- *IRB Exemption Checklist*
- *IRB Proposal*
- *IRB Proposal Evaluation and Decision* form
- *Informed Consent* form
- *Adverse Consequences/Unintended Effects* form
- *Continuing Review* form