School of the Art Institute of Chicago
Institutional Review Board
Policy and Procedures

I. Introduction

The School of the Art Institute of Chicago ("SAIC") Institutional Review Board ("IRB") is an official committee of SAIC. The IRB protects human subjects who are participating in research conducted by the faculty, staff, students, and other professionals affiliated with SAIC. Beyond protecting human subjects, the IRB acts to ensure that SAIC stakeholders as artists, designers and scholars conduct research that is ethical and socially responsible.

Every institution that has community members who perform research involving human subjects is required by law to have an Institutional Review Board. The processes used by the IRB are in accordance with the Code of Federal Regulations for the Protection of Human Subjects (45 CFR 46) issued by the Department of Health and Human Services ("DHHS"). The IRB functions to assess research methods, to promote fully informed and voluntary participation by potential subjects, and to maximize the safety of subjects once they become consenting participants in a project.

Those performing research projects at or on behalf of SAIC ("Investigators") are responsible for understanding this policy and how it applies to their research projects.

II. Scope of the IRB Policy and Procedures

All research undertaken by SAIC stakeholders in which human subjects participate is subject to review under this Policy. For the IRB Policy and Procedures to be applicable, the project must be "research" on a "human subject" as these terms are defined in the Code of Federal Regulations and as these terms apply in practice to a higher education institution committed to the study of art and design.

- "Research" is a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge applicable beyond a single individual or case. This research may be scholarly, draw from and engage art and design practice, or be hybrid in form (i.e., combine scholarly ways of knowing and art and design practice). It may lead to the creation of new knowledge that advances emergent ways of thinking, understanding, and conducting research. The following activities are deemed not to be research as specified in 45 CFR 46.102 (I) (1): "Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected." Examples of research activities at SAIC constituting research consistent with the federal definition can be found here.

- "Human subject" means a living individual about whom an Investigator (whether professional or student) conducting research obtains (a) data through interventions or interaction with the individual, or (b) identifiable private information.

If an Investigator's project does not meet *both* of these definitions, it is not subject to IRB review and no application needs to be submitted to the IRB for review.

III. IRB Authority, Structure, and Composition

A. Authority of the IRB

When a research project application is submitted, the SAIC IRB may:

1. Determine whether the IRB regulations are applicable to the proposed research project;

2. Determine whether the project is exempt from further review, is subject to expedited review, or requires full IRB review;

3. Ask persons submitting an application to make revisions to the documents, procedures, and/or other materials related to the application; or

4. Reject a submitted application entirely. In this case, the Investigator may not conduct the proposed research project.

Investigators may not proceed with their research until given final approval by the IRB.

B. IRB Composition

The IRB consists of no fewer than five (5) Members including the Chair. In addition, two (2) Alternates should be designated in the event that a Member may not be able to serve. Members and Alternates must have the background necessary to evaluate human subjects research and its institutional, legal, scientific, and social implications. To achieve this within the context of an art and design school like SAIC, the IRB:

1. Must be broadly representative so as to nurture and advance an ethical research environment in which different expertise, perspectives, and backgrounds can be heard, valued, and utilized. reflect the interests of stakeholders engaged in art and design practice, scholarship, and where some curricular programs prepare students for careers requiring licensure;

2. Should be attentive to the unique concerns and needs of curricular programs that prepare students for careers requiring licensure;

3. Must have one (1) outside member not affiliated with SAIC who, by virtue of their non-SAIC commitments, provides an additional means to protect participants as well as offer additional perspective on ethical and socially responsible research.

4. Must have a membership with a majority of the members coming from the SAIC Faculty; and

5. Must have a Chair who is an SAIC Faculty Member.

IRB Members and Alternates are appointed for three-year terms and appointments should reflect a sense of the importance of continuity.

IRB Members including the Chair, Alternates, and the Outside Member are appointed by the Dean of Faculty, Chair of Faculty Senate, and Chair of the Faculty, who after consulting with one another, act in concert as conduits of shared governance. In the event of a vacancy on the IRB, the Dean of Faculty, Chair of Faculty Senate, and Chair of the Faculty consult and act in concert to fill any vacancy.

The IRB Chair shall not serve more than two consecutive terms.

The IRB Chair receives one course release per academic year. IRB Members who are tenured or tenure-track faculty receive institutional service credit that counts towards their contractual service obligations. Members who are Adjunct Faculty receive compensation consistent with compensation received by Adjunct Colleagues providing service to SAIC other than teaching. The Outside Member may receive compensation set by the Dean of Faculty.

The IRB Chair reports to the Dean of Faculty and Senior Vice President for Academic Affairs.

C. IRB Committee Meetings and Time Frame for Review

The IRB meets as needed to conduct full reviews of proposed research, to consider revising policies or procedures, and to conduct any other business that the Chair deems to require a meeting of the entire IRB.

A quorum for meetings of the entire IRB exists when two-thirds (2/3) of IRB Members are present and any action at such meetings requires a majority vote.

Minutes must be submitted by the Chair to the IRB for approval.

When an applicant anticipates a full review will be required for project approval, the applicant should submit their application before the end of the 10th day of fall and spring semester (i.e., the end of the Add/Drop Period). This allows the Chair adequate time to determine the type of review and to, if necessary, convene the IRB for a full review meeting.

The time frame for reviews are as follows: four-to-six (4-6) weeks for a full review; three (3) weeks for an expedited review; and two (2) weeks for an exempt review. The Investigator should understand that incomplete, ambiguous, confusing, or careless applications may result in additional review time, follow-up questions and proposed modifications, and/or non-approval of a project.

The IRB Chair may request additional information from the Investigator by telephone, email or in writing.

The IRB Chair will notify the Investigator of the results of the review process in writing.

IV. IRB Review Pathways

A. Introduction

Federal regulations delineate three review pathways for human subjects research:

1. Research reviewed using exempt review procedures;

2. Research reviewed using expedited review procedures; and

3. Research using full IRB review procedures.

Investigators are encouraged to use the Human Subject Regulations Decision Charts provided by the U.S. Department of Health and Human Services and/or contact the IRB Chair to help determine which review pathway is appropriate. The review pathway will ultimately be determined by the IRB Chair. The IRB Chair may grant final approval for research reviewed using exempt and expedited review procedures. But research requiring full IRB review may only be approved after the full IRB has convened and made a determination.

For projects requiring use of the expedited review or full IRB review pathways because there is more than minimal risk, the IRB must use set criteria when determining whether a project may be approved. These criteria may be accessed here.

B. Exempt Review Pathway

Many of the research projects involving human subjects at SAIC will be reviewed using the exempt review pathway which, with IRB approval of the Research Proposal Application, will exempt the research project from further IRB review. It must be noted that even research deemed to be exempt from further IRB review requires the Investigator to submit a Research Proposal Application. Provisions detailing exempt research including exemption categories and what exempt research receives limited IRB review may be accessed here.

If an Investigator believes that the planned research falls into one of the exempt categories, they may so indicate on the Research Proposal Application.

C. Expedited Review Pathway

Non-exempt research that otherwise involves no more than minimal risk to human subjects may be reviewed in an expedited manner. An explanation of expedited review procedures may be accessed .

For purposes of determining the appropriate review pathway, the IRB will find "minimal risk" where "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."

If an Investigator believes that the planned research meets the guidelines for the expedited review pathway, they may so indicate on the Research Proposal Application.

The IRB Chair may also approve modifications to ongoing projects involving no more than minimal risk. (See Section VII.B., below).

D. Full Review Pathway

All projects not reviewed using the exempt or expedited pathways will need to be approved by the full IRB.

E. Reporting Results

The IRB Chair must provide the IRB with a written report on Research Proposal Applications reviewed using the exempt and expedited pathways. Reports should be given at the end of each Fall semester and each Spring semester.

V. Informed Consent

A. Introduction

Projects that require expedited review or full IRB review have higher levels of risk that vary from project to project. Because there are higher levels of risk involved, in most cases the law requires that informed consent be obtained from the participants.

Investigators are responsible for retaining all informed consent and assent documents signed by human subjects or the subjects' legally authorized representative. These documents shall be maintained by the investigator for a minimum of three (3) years after completion of the research project.

B. Requirements of Informed Consent

Investigators shall ensure that no human subject will be involved in their research project prior to obtaining informed consent from the subject or the subject's legally authorized representative. This responsibility may not be delegated to personnel who are not listed as Investigators on the application approved by the IRB. Informed consent must be obtained under circumstances that offer the subject or the subject's legally authorized representative sufficient opportunity to consider whether the subject should or should not participate. The informed consent must not include exculpatory language through which the subject or the subject's legally authorized representative is made to waive or appear to waive any of the subject's legal rights or releases, or appears to release the Investigator, the funding sponsor, the institution or its agents from liability for negligence.

Informed consent must be obtained in language understandable to the subject and/or the subject's legally authorized representative. The Investigator should use language that the average person of the age of the proposed human subject is likely to understand. Technical and scientific terms should be adequately explained or common terms substituted. In cases where the study population includes non-English speaking people, the IRB will require that the informed consent document be written in each subject population's language and that an independently qualified translator be available during the consent process for those subject population that do not understand English. If any member of the research population is illiterate, then the investigator is responsible for having the informed consent document explained to the subject in the subject's native language by an individual fluent in that subject's native language.

C. Basic Elements of Informed Consent

The regulations require that the following basic information be provided to subjects asked to participate in a research project:

1. A statement that the project involves research;

2. An explanation of the purposes and duration of the subject's participation;

3. A description of the procedures to be followed;

4. Identification of any procedures that are experimental;

5. A description of any reasonably foreseeable risks or discomforts to the subject;

6. A description of the expected benefits to the subject or others that may reasonably be expected from the research;

7. A disclosure of appropriate alternative procedures or courses of treatment available (if applicable);

8. A statement describing plans for maintaining confidentiality of subject information;

9. A statement regarding any compensation that will be provided to study participants;

10. An explanation of who to contact with questions about the research or the subject's rights, or in case of a research-related injury to the subject;

11. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled;

12. A statement that a copy of the consent form will be given to the subject;

13. The date that the consent form was approved by the IRB; and

14. A statement explaining the procedure for subjects to be provided the results of the research project, if appropriate.

D. **Additional Elements of Informed Consent**

For certain research projects, the following additional elements of informed consent may be appropriate:

1. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant), which are currently unforeseeable;

2. Anticipated circumstances under which the subject's participation may be terminated by the Investigator without regard to the subject's consent;

3. Any additional costs to the subject that may result from participation in the research;

4. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

5. A statement that significant new findings developed during the course of the research, which may be related to the subject's willingness to continue participation, will be provided to the subject; and

6. The approximate number of subjects involved in the project.

In certain situations, the regulations allow the IRB to approve an informed consent procedure which does not include, or which alters, some or all of the elements of informed consent when the research could not practicably be carried out without the waiver or alteration. Investigators should contact the IRB Chair for more information if they believe that their research cannot practicably be carried out without a waiver or alteration to some or all of the elements of informed consent.

The IRB will make available a template that Investigators may use to develop a written consent form appropriate for their proposed study. This template may allow for a type of informed consent called "broad consent" that would permit the Investigator to engage in research use of identifiable data without the requirement to obtain additional consent for the future storage, maintenance, or research uses, so long as the future activities are within the scope of the broad consent.

E. **Documentation of Informed Consent**

Informed consent shall be documented by the use of a written consent form approved by the IRB, and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.

1. **In Writing:** The consent form may be a written consent that embodies the elements of informed consent listed above. This form may be read to the subject or the subject's legally authorized representative. In any event, the Investigator should give either the subject or the representative adequate opportunity to read it before it is signed.

2. **Orally:** The consent form may be a short form written consent document, stating that the elements of informed consent have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.

3. **Waiver of Requirement for Signed Informed Consent Form:** An IRB may waive the requirement for the Investigator to obtain a signed consent form for some or all subjects, if it finds either:

a. That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

b. That the research presents no more than minimal risk of harm to subjects, and involves no procedures, for which written consent is normally required outside of the research context.

In cases in which the documentation requirement is waived, the IRB may require the Investigator to provide subjects with a written statement regarding the research.

F. **Assent of Minors & Consent of Parent(s)/Guardian(s)**

For research involving minors under the age of 18 and in lieu of obtaining informed consent as described above, the Investigator must obtain each minor subject's assent and also consent from each minor subject's parent(s)/guardian(s).

1. **Assent of Minors:** Assent is defined as a minor's affirmative agreement to participate in a research project. Assent is not granted by a minor's passive acquiescence to a project's procedures. When a research project involves minors as research subjects, the regulations require that the Investigator obtain and document the minors' assent (where the minors are capable of providing assent) prior to initiating the research project. The assent document for minors should be more simplified than an informed consent document, and the document should be age-appropriate (i.e., the substance of the document will be different for minors 7-8 years old in comparison to an assent document for minors who are 15-17 years old).

2. **Consent of Parent(s)/Guardian(s)**: Investigators are responsible for obtaining parental consent from the parents or guardians of each minor subject enrolled in a research project. The parental consent form must be approved by the IRB. When creating a parental consent document, Investigators should consider the basic elements of informed consent described above.

   The IRB may find that consent of one parent or guardian is sufficient. The IRB may also waive the parental consent requirement for projects that include no invasive procedures and present no more than minimal risk to the minor subjects. The IRB may also waive the parental consent requirement when such consent is not a reasonable requirement to protect the subjects (for example, neglected or abused children). However, an adequate mechanism to protect the minors as research subjects must be in place and properly documented.

II. Ethics Training

All IRB Members, excluding Alternates, must complete CITI training and provide documentation indicating that training was completed. All applications submitted to the IRB must include documentation indicating that Investigators and Co-Investigators successfully completed CITI training. CITI training may be initiated here. Alternate IRB Members may complete DHHS training

which may be accessed here or training deemed appropriate by the Chair. Contact the SAIC IRB at [insert email address] for more information about training.

III. Administrative Matters

A. Filing an Application

Applications and supplementary materials should be filed with the SAIC IRB at [**insert email address**] by uploading a separate PDF for each document submitted.

B. Request for Changes to Ongoing Projects

An **Institutional Review Board Change to Proposed Research Form** should be completed and filed with the IRB if Investigators wish to make changes to the protocol or informed consent documents which were previously approved by the IRB. Requests for changes may be subject to the expedited review process if the changes involve no more than minimal risk. Otherwise, changes will be subject to full IRB review.

C. Request for Continuing Review of Ongoing Projects

An **Institutional Review Board Continuing Review of Ongoing Projects Form** should be completed and filed with the IRB in the following situations:

1. If a project is expected to last longer than one (1) year in duration. The IRB is required to review ongoing projects at least once per year even if no changes are being requested. The Form should be filed one (1) month prior to the anniversary date of the project (and every year thereafter for multi-year projects). Failure to promptly file these documents may result in the IRB not being able to properly review the project prior to the end of the year. This will cause the project to be suspended (until the IRB can review and approve it) or terminated.

2. If Investigators anticipate that their projects will last longer than originally expected (even if less than one year). The IRB will need to provide further approval for projects that will last longer in duration than contemplated in the original application. The Form should be filed with the IRB as soon as reasonably possible after it is determined that the project will last longer than originally expected, but no less than one (1) month prior to the original completion date. Failure to promptly file these documents may result in the IRB not being able to properly review the project prior to the end of the original completion date. This will cause the project to be suspended (until the IRB can review and approve it) or terminated.

D. Completion or Cancellation of a Research Project

For administrative purposes, all Investigators must file an **IRB Project Closure Form** with the IRB upon completion or cancellation of their research projects.

E. Faculty's Role in Projects with Student Investigators

When students are conducting research as a part of their academic curriculum that involves the IRB Policy and Procedures, the sponsoring faculty members have the following obligations:

1. Sponsoring faculty members are required to educate students on the IRB Policy and Procedures.

4. Sponsoring faculty members are required to help and guide students in completing their IRB applications.

5. Sponsoring faculty members must sign off on the completed application prior to a student application being submitted to the IRB. By signing off on the application, faculty members are acknowledging that they have educated students about the IRB Policy and Procedures, have guided them through the application process, and have read students' completed application and deemed it acceptable prior to submission to the IRB.

6. IRB regulations do not differentiate between students and more experienced Investigators. Therefore, student applications will be reviewed with the same scrutiny as other applications. Student applications that are lacking may result in additional review time and a student not being able to complete a project within an academic semester.

II. Additional Information and Questions

Certain types of research projects subject to the IRB Policy and Procedures may have additional requirements and considerations. Some examples include international research, research involving prisoners or minors, and research with survey procedures that use electronic surveys. Questions about these types of research projects or methods should be directed to the IRB Chair. Other questions related to the IRB may also be directed to the IRB Chair.

III. Brief Summary of the IRB Policy and Procedures

1. Investigators should fill out the Research Proposal Application with complete information and required materials. Investigators should include proof of ethics training for themselves and any Co-Investigators.

2. Investigators should submit a completed application to the IRB and allow for sufficient time for review as described in Section VII.B., above. Sponsoring faculty members should sign off on the applications for student Investigators prior to submission.

3. When requesting changes and/or continuing review, Investigators should file a **Request for Changes Form** or a **Request for Continuing Review Form** with the IRB.

4. When Investigators complete or cancel their research projects, they should file an **IRB Project Closure Form** with the IRB.

5. For research subject to expedited review or full IRB review, Investigators should keep all signed Informed Consent documents (if applicable) for a minimum of three (3) years after completion of their projects.

IV. Applicable Regulations and Questions

The Office for Human Research Protections ("OHRP") website is a valuable source of information relating to the IRB. Other regulations and guidelines related to the IRB are:

- 45 CFR 46 – Protection of Human Subjects
- Family Educational Rights and Privacy Act (FERPA)
- Health Insurance Portability and Accountability Act (HIPAA)
- Protection of Pupil Rights Amendment (PPRA)
- Guidance on Broad Consent (SACHRP)
- Belmont Report – On July 12, 1974, the National Research Act (Pub. L. 93-348) was signed into law, creating the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. One of the charges to the Commission was to identify the basic ethical principles that should underlie the conduct of biomedical and behavioral research involving human subjects. Another charge was to develop guidelines, which should be followed to assure that such research is conducted in accordance with those principles. In carrying out the above, the Commission was directed to consider: (i) the boundaries between biomedical and behavioral research and the accepted and routine practice of medicine, (ii) the role of assessment of risk-benefit criteria in the determination of the appropriateness of research involving human subject, (iii) appropriate guidelines for selection of human subjects for participation in such research, and (iv) the nature and definition of informed consent in various research setting. For a more complete version of the Belmont Report, follow the link above.