SAIC School of the Art Institute of Chicago

INSTITUTIONAL REVIEW BOARD FORM 1:
RESEARCH PROPOSAL APPLICATION

This proposal must be completed if you are seeking Institutional Review Board (IRB) approval for your research project involving human participants. The United States Department of Health and Human Services (HHS) defines research as:

> *Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.* (http://www.hhs.gov/ohrp/policy/cdebiol.html)

As the Primary Investigator, you will use this form, the School of the Art Institute of Chicago's (SAIC*) IRB Form 1: Research Proposal Application* (RPA), to detail the protocol you plan to follow during your research project. The IRB will review your application to verify its adherence to the ethical criteria established by HHS, and will determine which of three categories your project falls under:

Exempt Review
If your project contains very minimal risk to the human participant *and* comports with the narrowly defined exemptions found in the *Code of Federal Regulations*, then your project will be awarded an *exempt review*. Examples of exempt projects would include surveys in which data cannot be tied back to individual participants and research projects interpreting already published and publically available data. Although an "exempt" review is, in effect, neither approving nor rejecting your proposal, full proposals must be made before the IRB can make a determination of exemption.

Expedited Review
An *expedited review* can, as the name implies, take place relatively quickly, even on an *ad hoc* basis at times; however, it is only available for proposals in which there is no more than minimal risk to human participants. In an expedited review, the chair and at least one other IRB member, appointed by the chair, must review and accept the proposal. While expedited reviews anticipate approval; upon closer examination, the chair and additional IRB members may recommend the proposal must undergo a full review.

Full Review
A *full review* requires the entire IRB to review, discuss, and vote to approve the projects (via a majority vote) that involve more than minimal risk. Full reviews happen at fixed points on the academic calendar. Full reviews may disprove research proposals, i.e., disallow the commencement of data collection, and/or may, at the discretion of the board, instruct the applicant in the manner in which a proposal may be revised and re-submitted for consideration. Applicants may be contacted to be on-hand during full reviews to meet with the board.

Regardless of the category, a complete RPA (including all six sections: Overview, Funding, Human Participants, Research Plan, Informed Consent, and Pledge)must be received before a review can begin. It is common for the Board to request that a proposal be re-submitted with additional documentation or clarification prior to making a final approval decision. Researchers may not contact potential participants or commence data collection until the IRB issues a formal approval letter.

SECTION A: OVERVIEW

A.1 Title of Study:

A.2 Nature of Study:

(*Please select one from the following*):

☐ Master's Thesis ☐ Graduate Research ☐ Undergraduate Research ☐ Faculty Research ☐ Staff Research
☐ Other (specify): _____

A.3 Principal Investigator (PI) Contact Information	
First Name:	Last Name:
Mailing Address:	
SAIC Department:	Job Title (if applicable):
Phone:	Email:
Anticipated Graduation Year (if applicable):	Degree (if applicable):

A.4 Faculty Advisor Contact *(To be completed if PI is a SAIC student performing research for college credit.)*	
First Name:	Last Name:
Department:	Job Title (if applicable):
Phone:	Email:

A.5 Study Site Contact *(Identify the primary contact at the site of the study.)*	
First Name:	Last Name:
Mailing Address:	
Department:	Job Title (if applicable):
Phone	Email:
Fax:	Relationship to the investigator:

A.6 Other Key Personnel

Will anyone be assisting you in your research (e.g., persons enrolling participants, conducting consent processes, statistical analysis, or having access to information linking participants' names with their data)?

	Yes		No

Please check one

If yes, please list the other personnel and specify their role below:

Name	Role	Student?	SAIC?	Other Affiliation?

A.7 Additional Collaborating Institutions

Are you collaborating with any other institutions on this project?

	Yes		No

Please check one

If yes, please use the first table below to specify the name and location of the institution as well as the nature of the collaboration (data collection, student teaching, internship, etc.) and whether or not permission is enclosed.
Permission must be obtained from all collaborating institutions. Obtain all necessary verification(s), typically a letter from a representative of the institution, to submit with this application.

Name of Institution	Location of Institution	Nature of collaboration	Permission enclosed?

A.8 Collaborating IRBs

Is this being (or already has been) reviewed by any additional IRBs?

	Yes		No

Please check one

If yes, list the IRB(s) in the table below.

Name of IRB	Location of Institution*	Determination: Approve, Reject, or Pending?**

**For foreign research, approval from IRB or equivalent in country where research is conducted may be needed.*

***If approved, submit documentation of IRB acceptance with this application form.*

SECTION B: FUNDING

B.1 Project Funding

Use this section to describe the funding you will be using to conduct your research. Funding sources are defined as:

- *Departmental Funds*—Allocated for an individual's use by an academic or professional department of SAIC.
- *Faculty Grants*—Awarded to faculty for their use through a specific application process, typically vetted through the Office of the Deans and Division Chairs.
- *External Funds* (Federal, State, or Private)—Awarded to an individual through an institution other than SAIC
- *Investigator Funds (Out-of-Pocket)*—Supplied by the PI.

B.1-a Sources of Funds

Select all that apply from the following:

Departmental Funds	External Funds
Faculty Grants	Investigator Out-of-Pocket Funds

B.1-b External Funds
If study is externally funded, in whole or part, specify these sources in the second table.

Funding Institution	Are you PI for Funding?*	Funding Awarded or Pending?	If pending, what is date of decision?

**Copies of complete funding applications as well as award letters or funding contracts must be included with this application.*

B.1-c Participant Costs
Briefly describe the costs (if any) as well as the amount or method of compensation (if any) that will be incurred by or given to participants.

SECTION C: HUMAN PARTICIPANTS

C.1 Enrollment Statistics
Please use the spaces below to indicate the profile and sample size of the participants you plan to both approach and enroll in your study.

C.1-a Special Populations
Please indicate all the categories of participants you plan to solicit for enrollment in your study. Please indicate all that apply:

Population			
General Population		Members of the Armed Forces	
Minors		Non-English Speakers	
Prisoners		Critically Ill Individuals	
Pregnant Women/Babies		SAIC Students*	

Decisionally Impaired		SAIC Employees*	
Economically/Educationally Disadvantaged		Other special population(s):	

*Do you attend classes with, work with, teach, or supervise the SAIC students or employees you intend to solicit or enroll?

	Yes		No

Please check one

If yes, please address the necessity of enrolling these special populations in subsection **C.2**.

C.1-b Participant Count
Indicate the estimated number of prospective participants you plan to approach (ask) and the total number you anticipate actually enrolling. "Enrollment" is defined as participants who have completed written and oral consent to participate in your study.

Total number of individuals you plan to **approach**	Total Number of individuals you plan to **enroll**

C.2 Enrollment Methodology
In this subsection, provide a brief narrative that explains your strategy for identifying and selecting study participants.

C.2-a Participating Populations
Briefly describe the population(s) you anticipate enrolling in this study as well as the setting(s) in which the enrollment will occur. Indicate any specific demographic factors that would rule a potential in or out of your study.

C.2-b Participant Recruitment
How will you identify and recruit your participants? Written permission from collaborating institutions

(including SAIC) is required prior to starting participant recruitment and data collection.
Please include copies of any permission letters and recruitment/advertising materials to this application.

C.2-c Participant Justification
If you indicated that you would be targeting any of the special vulnerable populations listed in subsection **C.1**, please explain why such involvement is essential to this study below:

SECTION D: RESEARCH PLAN

Use this section to succinctly describe your Research Plan. This section forms the centerpiece of the approval process and is to be developed in consultation with your thesis advisor, collaborating institutions, and consulting experts as appropriate. Your description should be comprehensive but also concise. All ten subsections must be completed. The Board requires a clear and direct narrative in order to assess the ethics and safety of your plan. The Board is not charged with evaluating the usefulness of its research, so please keep this in mind as you describe your methodology.

D.1 Research Question - State the hypothesis or focal question for your research.

D.2 Purpose - State the rationale and goals of this study as related to the hypothesis or focal question.

D.3 Background - Provide a brief historical background of the project. State your personal experience as it relates to your research interests, and provide an overview of the pertinent literature that informs your research.

D.4 Design - Describe the study design, addressing all ethics and safety concerns. Indicate the sequence and timing of all study procedures. Pay particular attention to any interventions, procedures, technology, or equipment that are innovative, unusual, or experimental. Indicate what form(s) the data will take and how it will be collected. If the research involves the study of existing data, describe how the authorization to access data will be obtained. If you will be using photography or audio/video recording, provide justification for its use. If you will be developing or adapting instruments to collect data (e.g., survey forms, rating scales, etc.) please include examples.

D.5 Analysis - Explain how the data will be analyzed and presented (e.g., research paper). Describe how the proposed sample size and demographics are appropriate for achieving the anticipated results.

D.6 Inclusion/Exclusion - List and justify the major inclusion and exclusion criteria used in this study. Describe the conditions under which participants may be removed from the study.

D.7 Risks - Frankly describe any potential physical, psychological, social, legal, employment, and financial risks or discomforts to participants. Detail steps being taken to minimize those risks. If any data monitoring procedures are needed to ensure the safety of participants, describe them.

D.8 Benefits - Describe the anticipated benefits, if any, to the individual participants. Describe anticipated benefits to society (e.g., added knowledge to the field of study, or a specific class of individuals).

D.9 Confidentiality - Describe the provisions to protect the privacy of participants and to maintain the confidentiality of the data. Indicate how and where the data will be securely stored. Note the length of time for data storage and plan for destroying the data after its storage period.

D.10 Debriefing - If applicable to your Research Plan, please explain your method for debriefing participants at the end of your data collection. If you do not intend to offer debriefing please explain. (For example, you may clarify how you will inform participants of research results or explain any deception used in the design of the study.)

SECTION E: INFORMED CONSENT

Please use SAIC's *IRB Form 2: Informed Consent Template* (insert link) to complete the informed consent document. This is the document you will use in obtaining consent from your research participants. IRB Form 2 provides a template for completing the Informed Consent document. Once complete, please include the your final Informed Consent form here. (Use the identical layout and content that will be seen by your research participants.)

SECTION F: PLEDGE

F.1) Principal Investigator's Authorization

I understand the School of the Art Institute of Chicago's policies concerning research involving human participants, and I agree:

- *To comply with all Institutional Review Board's policies, decisions, conditions, and requirements;*
- *That this study has been designed, to the best of my knowledge, to protect human participants engaged in research in accordance with the standards set by the School of the Art Institute of Chicago, the United States Department of Health and Human Services, and any other sponsoring agency;*
- *To obtain prior approval from the Institutional Review Board before amending the research protocol or approved consent/assent form(s);*
- *To report to the Institutional Review Board any adverse event(s) and/or unanticipated problem(s) involving risk to participants;*
- *To submit the Re-Approval/Completion Form as needed;*
- *That the PI and each individual listed as study personnel in this application has: a) completed the required human subjects training; and b) are knowledgeable of the study procedures described in this protocol;*
- *That each individual listed as study personnel in this application possesses the necessary training and experience for conducting research activities in the role described for them in this research study.*

_____ _____

Signature of Principal Investigator *Date*

_____ _____

If PI is an SAIC student *Date*
Signature of Thesis Advisor or Faculty