SIT Study Abroad

School for International Training

Human Subjects Review Policy

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Preface

Welcome to the SIT Study Abroad Human Subjects Review Policy, the Application for Human Subjects Review, and the accompanying forms. Your Independent Study Project (ISP) constitutes a key learning outcome of your study abroad experience. Undergraduate research abroad involves many stakeholders that include students, host community, local staff and faculty, program partners, alumni, your home institution, the scientific community, and the public at large. You are responsible for ensuring that your ISP is conducted in strict observance of in-country ethical standards and the general norms of the scientific community in the United States. You are also responsible for staying in contact with your Academic Director and ISP advisor and ensuring your own safety and the safety of research participants while conducting your field study. Included in this handbook are guidelines, policies, and required forms to help you through the Local Review Board/Institutional Review Board HSR Application and research process.

Definitions

- Human Subjects Review (HSR): The process by which student proposals are developed and reviewed so as to protect participants from harm.

- Local Review Board (LRB): The program-level board charged with establishing appropriate standards and reviewing research proposals to insure compliance with these standards.

- Institutional Review Board (IRB): SIT's institution-wide board responsible for overseeing the implementation of ethical research.

Human Subjects Review Policies

SIT Study Abroad's Local Review Boards (LRBs) and SIT's Institutional Review Board (IRB) function as committees on the use of human subjects in research to partially fulfill the institution's ethical responsibilities within its stated mission and to, when indicated, satisfy requirements of the *Code Of Federal Regulations, Title 45, Part 46, Protection Of Human Subjects, Public Welfare, Department Of Health and Human Services, National Institutes Of Health, Office for Protection from Research Risks.*

In developing its statement of policies and procedures governing the use of human subjects in research, SIT has considered guidelines of various federal agencies, the ethical codes of principal scholarly associations and other relevant sources of information. The intent of these policies and procedures is to ensure that the rights and safety of human subjects in research are protected. Students are expected to fulfill their obligation to protect the rights of people involved in their research. Research that includes human subjects will be reviewed in terms of the ethical standards of a Local Review Board (LRB) at the program level and, when necessary, the Institutional Review Board (IRB) policies of SIT in Vermont. Human Subject Review policies apply to all research at World Learning, including that conducted by faculty, students, academic directors or other staff.

Students may **NOT** engage in research that involves:

- Procedures that might physically harm them or their research participants
- Activities that may be illegal or likely to offend prevailing standards of morality

Any research involving the following will need careful consideration of potential benefits and risks, and will not be approved unless adequate safeguards are fully in place.

- Procedures that deprive participants of necessary or accustomed resources
- Procedures that may cause mental stress
- The use of participants not able to give free and informed consent, including, but not limited to children
- Explicit, or implicit, deception of participants about any aspect of the research significant to them

The types of Human Subjects Review are provided in greater detail following the discussion of roles, below.

The Human Subjects Review (HSR) Process

The HSR review process involves the student, ISP advisor and Academic Director during the initial drafting of a proposal. Once the draft is submitted for approval, the review process involves the Academic Director, the Local Review Board and, if necessary, the Institutional Review Board at SIT Study Abroad in Vermont on particularly challenging issues. The roles and obligations of each party, as well as the steps that must be taken, are outlined below:

Student

- The student is ultimately responsible for conducting research within the HSR guidelines.
- The student makes a formal HSR application for proposed research, completes all required documentation, and submits the HSR application to the Academic Director.
- **The student is also responsible for checking with their home institution if a separate Institutional Review Board application process is required.**
- Please note that **ALL** ISP proposals must be submitted to the Local Review Board for review. When necessary, the proposal may be submitted for full review by SIT's IRB in Vermont.

Academic Director (AD)

- The AD reviews the policies and procedures with all students and counsels students on individual project questions to ensure that the rights of human subjects are protected in each project.
- The AD recommends which proposals merit exempt, expedited, or full review (discussed below) and signs the student's Application for Human Subjects Review.
- The AD submits the documentation to the program's Local Review Board and convenes the LRB to review all proposals.
- Any projects needing review by the SIT IRB in Vermont will be submitted by the AD.
- The academic director scans and emails the LRB/IRB Action Form, Ethics Review form, and Statement of Ethics form to their program associate in Vermont and keeps a copy at the program site so that an institutional record is maintained every semester. Each student's Application for Human Subjects Review, together with the Action Form, must be kept on file at each local SIT program office.

Local Review Boards (LRBs)

The Local Review Board consists of the program Academic Director and, additionally, at least two and up to four local faculty or professionals with expertise in the program theme and who do not work for SIT full-time. No other SIT staff should participate in the LRB. This measure provides for more objectivity/for a wider range of input. LRB members will not participate in the approval of projects in which they have a conflicting interest.

- The LRB reviews proposals within the context of the HSR guidelines and within the ethical and value systems of the local community as well as those set forth by World Learning.
- The LRB receives signed, formal HSR applications from the Academic Director and convenes to review the applications.
- The LRB approves or disapproves each project. The LRB can stipulate conditions for the conduct of any research involving human subjects and require certain changes in the research plan.
- If any cases are referred for full SIT IRB review in Vermont, the AD will submit these on behalf of the LRB.

SIT's Institutional Review Board (IRB)

The Institutional Review Board (IRB) The SIT IRB shall serve as a consultant and resource to all faculty/Academic Directors in interpretation of the procedures and policies of the human subjects review process. IRB members will not participate in the approval of projects in which they have a conflicting interest.

- The SIT IRB approves or disapproves each project submitted to it by the Academic Director, following initial review by the LRB. The IRB can also stipulate conditions for the conduct of any research involving human subjects and require certain changes in the research plan.
- The SIT IRB will convene and review proposals within a timeframe of one week from receipt of referral.

Types of Human Subjects Review: Exempt, Expedited, Full LRB, Full IRB

At SIT Study Abroad, there are four categories of Human Subjects Review for conducting field research:

Exempt

- Any Research that does not involve the participation of human subjects. The Exempt category DOES NOT mean that the study is exempt from LRB/IRB review. Rather, the Exempt category represents research that the LRB determines presents minimal risk to human subjects. For example, this would include research involving the collection or study of existing/archival data, documents, or records, 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.
- Research involving the observation of public behavior may also, at times, be exempt.
- Research involving animals is not covered by the HSR but should follow the general lines of doing no harm to the student or the animal. Similar concerns will be raised in terms of protecting the environment. In other words, no matter what the subject matter, even if

research does not involve direct analysis of human subjects, this does not make it exempt from ethical considerations.

Expedited

- Any research conducted in an established or commonly accepted educational setting and involving normal educational practices such as (a) research on regular and special education instructional strategies, or (b) research on the effectiveness of, or the comparison among, instructional techniques, curricula, or classroom management methods.
- Research involving the use of educational tests, if information taken from these sources is recorded in such a manner that participants cannot be identified, directly or through identifiers linked to the participants.
- Research involving elected or appointed public officials or candidates for public office.
- Research that involves "minimal risk," unless it involves children as participants. "Minimal risk" means that the risks of harm anticipated in the proposed research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Full Review by the LRB

Full reviews are conducted for topics such as:

- Research involving at-risk populations, children, deception, sensitive topics, and higher risks. Research with children is described in more detail below.
- Research that exposes human subjects to the risk of unreasonable harm shall not be conducted.

In a full review, the LRB must be satisfied that any research risks are mitigated through proper protocols.

Full Review by the SIT Institutional Review Board

Extremely sensitive topics or cases whereby a decision cannot be reached at the level of the LRB may be submitted for full review by the SIT IRB which functions as a committee on the use of human subjects in research to partially fulfill the institution's ethical responsibilities within its stated mission.

- Examples for Full Review by the SIT IRB: Research involving at-risk populations, children, deception, sensitive topics, and higher risks. Research that exposes human subjects to the risk of unreasonable harm shall not be conducted.
- Please note that while a proposal denied by the LRB may also be submitted to SIT's Institutional Review Board for review, it is unlikely SIT's IRB would approve a proposal that was denied by the Local Review Board. SIT Study Abroad upholds the principle that the LRB is the most qualified body to ensure observance of local norms of ethics and value systems.
- The SIT IRB reserves the right to turn down a research proposal even if the proposal was approved by the LRB if the IRB believes that that the proposal contradicts any of the U.S federal regulations and policies which regulate research on human subjects.

The Importance of Informed Consent

When planning research with human subjects, the student should obtain, in a culturally appropriate manner, the informed consent of all human subjects who participate in the study.

Obtaining consent includes the following:

- The student shall explain to subjects (prior to their participation) the objectives of the study, the procedures to be followed, and potential risks and benefits.
- The student shall not use individuals as subjects unless they, or those legally responsible for their well-being, consent to participation freely and with understanding of the consequences.
- Students shall respect the privacy of participants. They shall protect confidential information and advise participants of how their confidentiality will be protected.
- Subjects shall not be induced to participate by means or in circumstances that might affect their ability to decide freely.
- It shall be made clear to participants that they are free to withdraw from active participation in the research at any time, or may refuse to respond to any part of the research. Participants who desire to withdraw shall be allowed to do so promptly and without prejudice to their interests.
- The Participant Informed Consent Form must be written in a language and a style that the participant can read and understand (see SIT Study Abroad's Participant Informed Consent Form).

In some cases, a participant may be unable to provide written consent:

- In this case, the student shall still read the information in the Participant Informed Consent Form and explain the objectives of the study and its impact on the participant, and shall wait for the participant's oral consent to take part in the study.

Two cases when a Participant Informed Consent Form is not necessary:

- First, when the research solely involves observation of a person's behavior in locations where that person might reasonably expect that his/her behavior could be observed by another person.
- Second, when the subjects are only filling out an anonymous public questionnaire or survey, and they can choose not to participate by simply not returning the questionnaire.

Children and Human Subjects Research

The US standard specifies that subjects under the age of 18 may participate in research only with the signature of their parent or legal guardian, in addition to their own signature. This also applies to the completion of anonymous questionnaires since persons under 18 are not permitted legally to make the informed choice to participate. For more information on the US standard, please see: U. S. Department of Health and Human Services Office of Human Research Protections, http://www.hhs.gov/ohrp/policy/childrenfaqsmar2011.pdf

The following definitions hold:

- **"Children"** are persons who have not attained the legal age for consent to treatments or procedures involved in the research in the state/country where the study will be conducted. As the legal age for consent to participate in research in the US is, generally, 18, and though this age may differ in the many sites in which SIT is located, for the purposes of this Human Subjects Review and consent to participate in SIT research, children are defined as under 18 years of age.
- **"Assent"** means a child's affirmative agreement to participate in the research following an age-appropriate explanation of the research project. Mere failure to object shall not be construed as assent.
- **"Permission"** means the agreement of the parent(s) or guardian to the participation of their child in the research following an appropriate explanation of the research project in a language fully understood by the parent.

Standards for Children

1. When reasonable under the circumstances, students shall obtain assent from children in addition to obtaining permission from the child's parent or guardian. When obtaining permission from the parent, signed documents and the verbal explanation shall both be in a language fully understood by the parent. This may require document translation.
2. Final responsibility rests with the LRB which shall determine that adequate provisions are made for soliciting the assent of the children or, if the LRB determines that the children are not capable of providing assent based on age, maturity, psychological state or other factors, then the LRB will assure that the parents or other responsible party has done so in lieu of the children in a satisfactory manner.

Helpful Links

http://www.hhs.gov/ohrp/humansubjects/index.html

http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html

http://www.hhs.gov/ohrp/policy/childrenfaqsmar2011.pdf

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PARTICIPANT INFORMED CONSENT FORM

INDEPENDENT STUDY PROJECT TOPIC:
STUDENT NAME:

Thank you for taking the time to participate in this project.

My name is_____. I am a student with SIT Study Abroad _____ program. I would like to invite you to participate in a study I am conducting. However, before you agree to participate in this study, it is important you know enough about it to make an informed decision. If you have any questions, at any time, please ask me. You should be satisfied with the answers before you agree to be in the study.

Brief description of the purpose of this study
The purpose of this study is to _____.

Your participation will consist of _____and will require approximately _____of your time.

There are ____ foreseeable risks in participating in this study and no penalties should you choose not to participate; participation is voluntary. During the interview you have the right to not answer any questions or discontinue participation at any time.

Rights Notice
In an endeavor to uphold the ethical standards of all SIT ISP proposals, this study has been reviewed and approved by a Local Review Board or SIT Institutional Review Board. If at any time, you feel that you are at risk or exposed to unreasonable harm, you may terminate and stop participation. Please take some time to carefully read the statements provided below.

a. *Privacy* - all information you present in this interview may be recorded and safeguarded. If you do not want the information recorded, you need to let the interviewer know.

b. *Confidentiality* - all confidential information will be protected.

c. *Withdraw* – you are free to withdraw your participation in the project at any time and may refuse to respond to any part of the research. Participants who desire to withdraw shall be allowed to do so promptly and without prejudice to their interests

If you have any questions about your rights as a participant, you may visit the World Learning website and check its policies on Human Subjects Research at: http://studyabroad.sit.edu/documents/studyabroad/human-subjects-policy.pdf or contact the Academic Director at: _____.

If you have any questions or want to get more information about this study, please contact me at phone: _____ or email at: _____.

Please sign below if you agree to participate in this research study and acknowledge that you are 18 years of age or older.

Participant's signature _____Date_____

Researcher's signature _____ Date_____