Hope International University

Institutional Review Board (IRB) Handbook

A Manual & Guide for Investigators

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Institutional Review Board (IRB) Contact Information

IRB Webpage:

https://www.hiu.edu/current-students/irb/

Email:

IRB@hiu.edu

Director of IRB:

Brian Luhmann, Psy.D.

Phone Number:

714-879-3901 x 1261

Mailing Address:

Hope International University

2500 E. Nutwood Ave.

Fullerton, CA 92831

Policy Statement for Hope International University – Research with Human Subjects:

General Policy Statement

The Institutional Review Board (IRB) is a committee designed to assure the ethical standards associated with both faculty and student research using human subjects. Based on the 1974 passage of the National Research Act and the ethical guidelines developed in the *Belmont Report*, the IRB at Hope International University (HIU) will review research proposals utilizing human subjects ensuring their adherence to (a) respect, (b) beneficence, and (c) justice. HIU recognizes the dignity, autonomy, and privacy of persons who may become subjects of research that is conducted at the university. The protection of the rights and welfare of human subjects is the primary goal of this policy and the accompanying procedural guidelines.

Respect

There are two main aspects to the ethical principle of respect in research using Human Subjects. Investigators are required to seek voluntary, written informed consent from potential subjects. Voluntary informed consent means that subjects are given explicit assurances of the voluntary nature of their participation in terms that are easy to understand and are not under duress. The consent form also includes adequate information about the study that will assist subjects in intelligently deciding whether to participate in research. In addition, respect means honoring the privacy of individuals and maintaining their confidentiality. Respect for minors (defined by the *National Institute of Health* as those under the age of 21) and mentally disabled persons requires taking extra precautions to protect those individuals who are immature or incapacitated, perhaps even to the extent of excluding them from participation in certain research. The extent of protection depends on the risks and benefits of the research to the participants.

Beneficence

The principle of beneficence requires that researchers maximize the potential benefits to the subjects and minimize the potential risks of harm. Benefits to the subjects, or in the form of generalized knowledge gained from the research, should always outweigh the risks. Finally, if there are any risks resulting from participation in the research, then there must be benefits, either to the subject, or to humanity or society in general.

Justice

The principle of justice means that subjects are selected fairly and that the risks and benefits of research are distributed equitably. Investigators should take precautions not to systematically select subjects simply because of the subjects' easy availability, their compromised position, or because of social, racial, sexual, economic, or cultural biases institutionalized in society. Investigators should base inclusion criteria on those factors that most effectively and soundly address the research problem.

General IRB Description

Hope International University (HIU) has a moral and legal responsibility to safeguard the rights, welfare, and dignity of human subjects involved in research. HIU is committed to the ethical principles for the protection of human subjects and is committed to ensuring that all human subject research, regardless of funding source. HIU's IRB policies comply with the Code of Federal Regulations (Title 45 Part 46 of the Code of Federal Regulations [45 CFR 46]) issued by the U.S. Department of Health and Human Services Office for Human Research Protections (OHRP) requirements as set forth in faculty, students, and staff who conduct research under the auspices of Hope International University must receive written IRB approval prior to initiating

A vital safeguard of the privilege of conducting research involving human subjects is the institutional review of all research projects to minimize the possibility of unacceptable or unnecessary levels of risk to the rights, welfare, and dignity of human subjects. Careful review of this type also enhances the likelihood that any given research project will yield results that are accepted as valid by the scholarly community. Toward this end, and to comply with the requirements of federal law, HIU has created an Institutional Review Board (IRB). To assist the individual researcher in protecting the rights of human subjects and to minimize the potential legal liability of the investigator and the university should a human being be placed at risk, the IRB is instructed to review all projects involving human subjects.

Responsibilities of Institutional Review Board (IRB)

Federal and state regulations mandate that research involving human participants must be reviewed and approved by an Institutional Review Board (IRB) provided for in its assurance filed with the Office of Human Research Protections and will be subject to continuing review by the IRB. The IRB is responsible for providing guidance and oversight for the human participant protection program and for helping to maintain compliance with applicable laws, regulations, and policies.

The IRB is responsible for the following oversight functions:

A. Determine what activities constitute human participant research.

B. Review, approve, require modifications of (to secure approval), or disapprove all research activities covered by this policy prior to the commencement of the research.

C. Require that information given to participants as part of informed consent is in accordance with appropriate laws, regulations, and international standards. The IRB

may require that additional information be given to the participants when, in the IRB's judgment, the information would meaningfully add to the protection of the rights and welfare of participants.

D. Require documentation of *informed consent or waive documentation* in accordance with federal and state laws and regulations.

E. Notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. If the IRB decides to *disapprove* a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

F. Conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, (unless the research has been classified as "Exempt") and have authority to observe or have a third party observe the consent process and the research. Continuing review is the process of resubmitting for approval to continue a study. This is to ensure that the appropriate protections of human subjects initially approved are being upheld.

G. Suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to participants. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, supervising faculty, appropriate institutional official(s) and the department or agency head.

IRB Certification Requirement

Ongoing education in the ethical treatment of human subject research participants, the components of informed consent, and the handling of research materials and data is an integral component of research and scholarship. Training in human subject protection is required for IRB members, Principal and Co-Principal Investigators, and Faculty Advisors. Training must be completed before a protocol will be reviewed by the IRB. Individuals shall be required to complete a training review every 2-3 years (depending on role). This training on ethics for working with human subjects as well as explains the background and purpose of the IRB.

Research universities and institutions across the country require similar training with great success in improving research programs.

Please note that there are different training requirements depending on your role in the ethical research process. Please make sure to carefully review the section of this handbook to determine the training requirements for your role.

Additional resources are available at the Office for Human Research Participants (OHRP) website: https://www.hhs.gov/ohrp/index.html

IRB Committee and Functions

The IRB shall be composed as follows:

1. Five (5) members with varying backgrounds, experience, and expertise sufficient to the needs of the research normally conducted by Hope International University. The Vice President of Academic Affairs (VPAA) will appoint the chair of this committee. The chair will select committee members in consideration of race, gender, and cultural diversity as well as expertise in research methodology, subject to approval by the VPAA. This process will occur at the beginning of each academic year, and the appointments last for one academic year.

2. The committee shall include at least one member whose primary interests are in scientific areas, and at least one member whose primary concerns are in non-scientific areas.

3. No committee member may participate in a review process in which a conflict of interest exists.

4. If a committee member is submitting a project for approval or there is a conflict of interest, the chair will select a replacement member to review this project. If the chair of the committee is submitting a project for approval, then the Chair of the committee will select a replacement for this review.

5. Each committee member (permanent or replacement) will email IRB@hiu.edu with current certificates of completion for the "IRB Members" training from Collaborative Institutional Training Initiative (CITI). Certificates must be renewed every 3 years to stay current.

Meeting Frequency:

The IRB Chair will convene the committee as needed.

Responsibilities of the Committee:

Each board member will serve as a reviewer of IRB applications. The requirements of review will depend on the level of review needed for the research.

Exempt Review: The project will be reviewed by an individual reviewer to assure that this level of review is approved. If denied for this level of review, written documentation will be provided to detail reasons for denial.

Expedited Review: The project will be reviewed by an individual reviewer to assure that this level of review is approved. If denied for this level of review, written documentation will be provided to detail reasons for denial.

Full Board Review: The project will be reviewed by the entire board and an IRB board meeting will convene to deliberate a decision. A project must be approved by at least 3 out of 5 of the committee members to proceed. The committee will provide written documentation as to the rationale for either granting or denying approval of research proposals.

Review Process:

The IRB will consider:

1. The risks to the subjects.
2. The anticipated benefits to the subjects and others.
3. The selection of subjects is equitable.
4. The importance of the knowledge that may reasonably be expected to result.
5. The informed consent process to be employed; and
6. The confidentiality of data and privacy of subjects.

The IRB has the authority to approve, require modifications to secure approval, and disapprove all research activities overseen and conducted by the organization. The IRB has the authority to suspend, place restrictions, or terminate approval of research activities that fall within its

jurisdiction that are not being conducted in accordance with IRB requirements or that have been associated with serious harm to subjects. The IRB has the authority to observe or have a third party observe the consent process and/or the research if the IRB determines it to be indicated.

All projects that meet the federal definition of research with human subjects must be reviewed and approved, or receive an exempt determination, by an IRB prior to beginning data collection. The IRB staff initially screens submissions to determine the completeness and the appropriate type of review. Submissions may be returned to the study team for changes before the review type is assigned. The review type may be reassessed at any time during the review process.
There are three types of review paths for an IRB application:

- Exempt
- Expedited
- Full Board

The Office for Human Research Protections (OHRP) provide decision charts (https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts-2018/index.html) to researchers and others to decide whether an activity involves human subjects and the appropriate review type.

Exempt Review: No More Than Minimal Risk

Key information about exempt research studies:

- Research can qualify for an exemption if it is no more than minimal risk and all the research procedures fit within one or more of the exemption categories in the federal IRB regulations.
- Researchers do not make their own determination as to whether a research study qualifies for an exemption. The IRB issues exemption determinations.
- Although there are eight United States Department of Health & Human Services (HHS) exempt category regulations, HIU has opted to implement four (4) of those categories at this time (see the list below).
- Studies that qualify for an exemption *do not* undergo continuing review.

- Exemptions do not apply to research with prisoners, except for research aimed at involving a broader subject population that only incidentally includes prisoners. [45 CFR 46.104(b)(2)].
- Exemption 2 and Exemption 3 do not apply to research with children.

Exempt Categories

Category One

Research conducted in established or commonly accepted educational settings, that specifically involve normal educational practices such that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Examples:

- Evaluating the use of accepted or revised standardized tests
- Testing or comparing a curriculum or lesson

Category Two

Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording**) if at least one of the following criteria is met:**

1. The information obtained is recorded by the investigator in such a manner that **the identity of the human subjects cannot readily be ascertained**, directly or through identifiers linked to the subjects.

2. Any disclosure of the human subjects' responses outside the research **would not reasonably place the subjects at risk** of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation.

3. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through

identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination as required by the HHS.

Examples:

- Surveying teachers, nurses, or doctors about a technique or an outcome
- Interviewing managers about a management style or best practice
- Conducting a focus group about an experience or an opinion of a community program

Category Three

Research involving **benign behavioral interventions*** in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject **prospectively agrees to the intervention** and information collection and at least one of the following is met:

1. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects.

2. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation.

3. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subject, and an IRB conducts a limited IRB review to make the determination required by HHS. Children cannot be included.

*Benign Behavioral Intervention is brief, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing.

Category Four

Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, **if at least one of the following criteria is met:**

1. The identifiable private information or identifiable biospecimens are publicly available.
2. Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects.
3. The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164 (Health Insurance Portability and Accountability Act of 1996), subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b)
4. The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

Expedited Review: Minimal Risk

Federal regulations state that certain types of research may be considered for review through an expedited process (45 CFR 46.110). A primary criterion for expedited review is that the research be of minimal risk. The Office of Human Research Protections (OHRP) defines ***minimal risk*** *as risk where the probability and magnitude of harm or discomfort anticipated in the*

proposed research are not greater, in and of themselves, than that ordinarily experienced in daily life or during the performance of routine physical or psychological examinations. In addition, the purpose of the research must fit within a series of categories as stipulated by HHS regulations:
https://www.hhs.gov/ohrp/regulations-and-policy/guidance/categories-of-research-expedited-review-procedure-1998/index.html

A. The research activity poses no greater that minimal risk; and

B. The identification of the participant and/or their responses would not reasonably place the participant at risk of criminal or civil liability or be damaging to the participant's financial standing, employability, insurability, reputation, or be stigmatizing, unless appropriate protections will be implemented so that the risk related to invasion of privacy and breach of confidentiality are no greater than minimal; and

C. The project falls under one of the *expedited categories*.

1. Clinical studies of drugs and medical devices only when condition.

2. Collection of blood samples by finger stick, heel stick, ear stick or venipuncture from (a) healthy, nonpregnant adults who weigh at least 110 lbs.; (b) other adults and children.

3. Prospective collection of biological specimens for research purposes by noninvasive means.

4. Collection of data through noninvasive procedures (not involving anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. For example: (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

5. Research involving materials (data, documents, records, or specimens) that have been collected solely for non-research purposes (such as medical treatment or diagnosis.

6. Collection of data from voice, video, digital or image recordings made for research purposes.

7. Research on an individual or group characteristics or behavior (including but not limited to research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

Full Board Review: More than Minimal Risk

Federal regulations and institutional policy require an IRB Full Board Review for applications where the research involves **more than minimal risk** to human subjects or has been referred to the committee by an expedited reviewer or the IRB Chair. Regardless of risk level, the IRB may require full board review when the research involves:

- Vulnerable populations, particularly prisoners.
- Sensitive topics, including illegal behaviors which may require an NIH Certificate of Confidentiality [CoC] to protect subject data from compelled disclosure.
- Research involving genetic testing.
- A complex research design requiring the expertise of multiple board members to evaluate.

Defining Research

To determine if a project requires IRB review, read the following four questions:

1. Is it Research?

Research
Research is defined as a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

Generalizable Knowledge

Generalizable knowledge is defined as knowledge that is "expressed in theories, principles, and statements of relationships" that can be widely applied to our experiences. The information is collected to share with other people within a discipline and is created to make a broad statement about a group of people,

procedures, programs, etc. Generalizable knowledge includes one or more of the following concepts:

- The information contributes to a theoretical framework of an established body of knowledge.
- The primary beneficiaries of research are other researchers, scholars, and practitioners in the field of study.
- Publication, presentation, or other distribution of the results is intended to inform the field of study.
- The results are intended to be replicated in other settings

If your project IS research, then consider the next question.

2. Does your Research Involve Human Subjects?

Human Subject

A human subject is a living individual about whom an investigator (whether professional or student) is conducting research by:

1. Obtaining information or biospecimens through intervention or interaction with the individual, and using, studying, or analyzing the information or biospecimens OR
2. Obtaining, using, studying, analyzing, or generating identifiable private information or identifiable biospecimens.

Definition of Related Terms

- **Intervention**: both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

- **Interaction**: communication or interpersonal contact between investigator and subject.

- **Private information**: 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 that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).

- **Identifiable private information**: information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

- **An identifiable biospecimens**: the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

<u>If your research involves human subjects, you will need to submit an application.</u>

3. *Does Your Human Subject Research Study Qualify for an Exemption*?
When a study qualifies for an exemption, this means it is exempt from federal scrutiny. However, institutional policy requires that **<u>ALL</u>** human research studies are reviewed by HIU's IRB. Exempt studies are reviewed by designated IRB staff to determine approval. Exempt studies do not require an annual review and there is no expiration date.

Limited Data Set with a Data Use Agreement

Limited Data Sets include research that falls under Health Insurance Portability and Accountability Act of 1996 (HIPAA) regulations but does not require researchers to obtain authorization or waiver of authorization. Researchers can collect data that retains the following types of identifiers with a data use agreement:

- Admission, discharge, and/or service dates.
- Birth date.
- Date of death.
- Age (including over age 89).
- Geographic information (except street addresses) such as city, state, and five-digit zip code.

Researchers using a limited data set will be able to use the data only for research purposes but may not use the limited data set to contact subjects.

A data use agreement specifies covered entities obtaining satisfactory assurances that the recipient of the limited data set will use or disclose the Personal Health Information (PHI) in the data set only for specified purposes. Even if the person requesting a limited data set from a covered entity is an employee or otherwise a member of the covered entity's workforce, a written data use agreement meeting the Privacy Rule's requirements must be in place between the covered entity and the limited data set recipient.

The HIPAA Privacy Rule requires a data use agreement to contain the following provisions:

- Specific permitted uses and disclosures of the limited data set by the recipient consistent with the purpose for which it was disclosed (a data use agreement cannot

authorize the recipient to use or further disclose the information in a way that, if done by the covered entity, would violate the Privacy Rule).

- Identify who is permitted to use or receive the limited data set.
- Stipulations that the recipient will:
    - Not use or disclose the information other than permitted by the agreement or otherwise required by law.
    - Use appropriate safeguards to prevent the use or disclosure of the information, except as provided for in the agreement, and require the recipient to report to the covered entity any uses or disclosures in violation of the agreement of which the recipient becomes aware.
    - Hold any agent of the recipient (including subcontractors) to the standards, restrictions, and conditions stated in the data use agreement with respect to the information.
    - Not identify the information or contact the individuals.

Procedural Guidelines Governing Research with Human Subjects

Institutional Review Board (IRB) Application Process

I. *Introduction*:

a. It is the intention of the IRB at Hope International University (HIU) to ensure that faculty and student research is conducted with maximum care to protect and benefit human participants.

b. To ensure that respect, beneficence, and justice for research participants are maintained, it is the goal of the IRB to review all research conducted at HIU by students and faculty of Hope International University.

c. Procedural Guidelines Governing Research with Human Subjects lays the foundational process for reviewing research at Hope International University.

II. *Procedural Guidelines*: Research not requiring review:

a. A research project designed as a *pedagogical* tool for conducting research as an assignment in a class. For example, student research conducted **entirely** with in a Research Methodology class (researcher(s) and participant(s) are registered in the same class) does not need to go through the review process as (a) it is conducted for the students' education, and (b) it is supervised by the professor.

b. Student and faculty research conducted in partnership with another institution where the other institution has conducted an IRB review and approved the research. This exception is fulfilled by the HIU investigators providing the IRB approval documentation to the IRB Director at HIU by emailing it to IRB@hiu.edu

c. Statistical analysis of a secondary data set does not require a review. The process here requires: (a) Submit a research proposal in accordance with the procedures outlined below, and (b) it is clearly indicated in the proposal that a secondary analysis will be conducted. IRB will then confirm and document that this research proposal has been reviewed and does not require further approval.

III. *Procedural Guidelines*: Research requiring review:

a. Any projects using human subjects. Some examples:

i. Student's completing master's theses and dissertations.

ii. Any human subject research where HIU faculty, staff, or students are the *primary* investigators.

IV. *Application Overview*:

a. Investigators should submit research proposals containing (which is accomplished by fully completing the IRB application and all instructions found at: https://www.hiu.edu/current-students/irb/ . The application are to include the following areas:

i. Brief overview of research literature relevant to the topic.

ii. Clear identification of research questions and hypotheses.

iii. Specific research procedures and methods including sampling procedures, clear informed consent process, brief discussion of potential risks and benefits of research, and any surveys and instruments used in the research project.

iv. Clear description of analytic methods used.

v. Discussion of expected outcome of the research.

vi. Overview of the potential risks and benefits to participation in the study.

vii. Copies of any measures/instruments/documents participations will be using or interfacing with.

b. All researchers/investigators and faculty sponsors on a project must also provide certificates of completion for Human Subjects Training.

Ethical Research Training Certificates

HIU Students, Faculty, & Staff: complete the *"Social-Behavioral-Educational (SBE) Comprehensive"* ethical human research training

from the Collaborative Institutional Training Initiative (CITI). To get started following these steps:

1) Go to: https://www.citiprogram.org/index.cfm?pageID=154&icat=0&ac=0&region=1&message=0
2) Select 'Select Your Organization Affiliation"
3) Type 'Hope International University' and agree to the terms to Create a CITI Program account.
4) When creating your account use your HIU.edu email account (as the primary email) and the name you used when registering at HIU.
5) When you reach the 'Select Curriculum' page, Answer the questions in the following way:
   - Question 1: Human Subject Research
   - Question 2: Social & Behavioral Research Investigator
6) When you complete registration click the "View Courses" button.
7) Select the "Social-Behavioral-Educational (SBE) Comprehensive" and follow the instructions to complete the course.
8) Save the completion certificate after completing the modules and passing the quizzes (minimum score: 80). A new training certificate needs to be updated every 3 years.

Here is the CITI Program Guide for new users: https://support.citiprogram.org/s/article/updated-guide-to-getting-started#Loggingin

Non-HIU members: Complete the following *"Human Research Protection Foundational Training"* lessons from the HHS https://www.hhs.gov/ohrp/education-and-outreach/human-research-protection-training/human-research-protection-foundational-training/index.html :

- Lesson 1
- Lesson 2
- Lesson 4

Save the completion certificates. These training certificates need to be renewed every 2 years.

c. **Student research:** The IRB review will only occur after the application has been approved by their sponsoring faculty (examples: research methodology professor, thesis advisor, dissertation chair). Approval is granted by the faculty sponsor completing the "HIU Faculty Sponsor Approval Form". This completed form is to be submitted along with the application. The form can be found on the IRB webpage: https://www.hiu.edu/current-students/irb/

d. *Approval may be granted for one year only*. If research has not been completed, further approval is needed.

Contact the IRB for any questions about IRB Applications and submission procedures: irb@hiu.edu

Informed Consent Process

The informed consent is intended to be a process which informs the participants about the purpose of the study, any risks, possible benefits, and alternatives to participant or leaving study. The purpose of this process is to provide participants with the ability to make an informed decision about if they want to participate and their rights as a participant. The following consent processes will be informed by your research procedures:

Written Consent Process

Written Consent with an Informed Consent document is most used to fully inform potential participants of the project. All human subject research at HIU is to utilize written consent unless a Waiver or Alteration conditions are met (see following sections for specifics). The following are required elements of written consent:

1. A statement that the study involves research, the purpose of the research, estimate time of participant involvement, description of the procedures to be followed by participants.
2. Statement outlining and reasonably foreseeable risks and discomforts participants may experience by participating.
3. Statement of any possible benefits the participants may reasonably expect from the research.
4. The alternative procedures to participation, if any.
5. A statement describing how confidential records identifying the participants will be maintained.
6. Information about whom to contact for answers to questions about the research, participants rights, and whom to contact in the event of a research-related injury to participants.
7. Clear statement of that participation is voluntary. This is to include that by not participating or discontinuing participation at any time will not involve a penalty or a loss of benefit the participant would otherwise be entitled.
8. The document has the subject (or authorized legal person) sign the informed consent.

9. A member of the research team signs the consent form.
10. Participants are given a copy of the signed informed consent.

The HIU Informed Consent Templates can be downloaded from the HIU's IRB Webpage: https://www.hiu.edu/current-students/irb/

Waiver or Alteration of Consent Process

Some consent procedures may be approved by the IRB which do not include all the elements of the informed consent process. Additionally, the IRB may elect to waive the obtaining consent if **all the following criteria are met:**

1. The research involves no more than minimal risks to participants.
2. The rights and welfare of participants are not impacted by the waiver or alteration.
3. The research could not practically be done without the waiver or alteration.
4. The participants will be provided with any possible pertinent information after their participation in the research.

The HHS provides examples of Waivers and Alterations for Consent: https://www.hhs.gov/ohrp/sachrp-committee/recommendations/attachment-a-minimal-risk-informed-consent-models/index.html

Some instances are appropriate to obtain consent through non-written means (verbally, online, audio/video recording). If this is the case for a study, a waiver of consent documentation may be requested in the IRB application. The IRB may approve the waiver if either of the following are met:

1. The principal risks to participation are associated with a breach of confidentiality concerning being a participant in the research, and the consent document would be the only record linking the participant to the research.

2. Participation in the research presents minimal risk of harm to the participant(s) and the research involves no procedures requiring consent outside the context of participation.