SAGRADO
Universidad del Sagrado Corazón

Institutional Review Board

Guidelines for the Protection of Human Subjects in Research

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Table of Contents

Preamble	3
Legal Provisions	3
Institutional Roles and Responsibilities	4
Criteria for Submitting an Activity or Project to the IRB	6
Types of Reviews for Research Projects	7
Ethical principles	9
Composition of the IRB	9
Positions and Functions	10
Vacancies	12
IRB Responsibilities	13
Duties of IRB Members	14
Term	14
Confidentiality Agreement	14
Meetings	14
Quorum	15
Conflict of interest	15
IRB Procedures	15
IRB Location	19
Responsibilities of Principal Investigators	19
Checklist	21
Participant complaints and concerns	21
Questions about the guide	21
Reports of violations of the guide	21
Violations of the guidelines	22

Institutional Review Board (IRB)
Universidad del Sagrado Corazón

Preamble

Conscious of this mission, the Sagrado community is committed to protecting the rights and well-being of individuals participating in research involving human subjects.

One of Sagrado's goals is to provide an education of excellence by developing innovative and far-reaching research programs, activities, and co-curricular experiences. Our institution is committed to protecting the rights of individuals who participate in research projects. One way we fulfill this commitment to the protection of human subjects is through a thorough review of research proposals that involve their participation.

This *Guide and Procedures for the Protection of Human Subjects in Research* is part of the regulations governing research involving human subjects. Its purpose is to provide a comprehensive and systematic mechanism designed to protect the rights, dignity, and well-being of individuals who are research subjects.

To ensure compliance with these guidelines, Sagrado has established the *Institutional* Review *Board* (IRB) as an institutional oversight body, in accordance with the requirements set forth in *the Code of Federal Regulations* (CFR) 45 CFR §46 (January 21, 2019, as amended), the *Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (1979, updated in 2009) of the *National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research*, applicable federal, state, and local regulations related to the conduct of research involving human subjects, as well as the University's policies and procedures.

Legal Provisions

General Provisions

This document shall be titled *"Guidelines and Procedures for the Protection of Human Subjects in Research*." The interpretation of the general provisions of these guidelines shall be subject to the regulations in force at Sagrado, in accordance with the regulations set forth in 45 CFR 46.

Legal Framework

The Institutional Review Board (IRB) for the Protection of Human Subjects in Research at the Universidad del Sagrado Corazón is a body created by federal mandate for the purpose of evaluating all research involving human subjects. Its primary function is to ensure the protection of the rights and well-being of individuals participating in

research conducted by, or under the supervision of, its faculty, student body, staff, and/or contractors.

The IRB operates in accordance with the provisions of the Code of Federal Regulations, Title 45, Part 46 (45 CFR 46), known as the Common Rule, which establishes the ethical principles and legal requirements for the protection of human subjects in research. These regulations include specific provisions for the protection of vulnerable populations, such as minors, individuals with preexisting or chronic health conditions, and incarcerated individuals. Oversight and enforcement of these regulations are the responsibility of the Office for Human Research Protections (OHRP), part of the federal Department of Health and Human Services, which ensures compliance with 45 CFR 46.

When research involves products regulated by the Food and Drug Administration (FDA), the IRB also follows the regulations set forth in 21 CFR 50 and 56, which govern the protection of human subjects in research involving drugs, medical devices, and biological products. In this case, oversight and enforcement of these regulations are the responsibility of the FDA, which is responsible for ensuring compliance with 21 CFR 50 and 56.

In addition to these federal regulations, Sagrado's IRB complies with local and institutional regulations regarding privacy and the protection of personal data. In research involving protected health information (PHI) obtained from covered entities (such as hospitals and health plans), the Health Insurance Portability and Accountability Act (HIPAA) applies, which regulates the protection and confidentiality of health information.

The IRB is committed to ensuring that the risks associated with the research do not outweigh the potential benefits derived from it. In reviewing projects, it seeks to balance the risks to participants with the scientific knowledge to be gained, the potential benefits for both participants and society, and compliance with applicable regulations and policies.

Institutional Roles and Responsibilities

The purpose of this section is to establish guidelines for the institutional roles and responsibilities that different members of the university community will have in protecting human research participants.

Roles

a. Institutional Officer: Has the authority to sign documents on behalf of the Universidad del Sagrado Corazón. The role of Institutional Officer at Sagrado is held by the person serving as President.
b. Academic Affairs: The IRB will report to the Vice-Presidency for Academic Affairs, as delegated by the person serving as President.
c. The role of Assistant Vice President for Academic Research and Grants will serve as the IRB Administrator.

Responsibilities

Compliance with Federal and State Laws:

Universidad del Sagrado Corazón is responsible for all research involving human subjects conducted by or under the supervision of researchers from the institution, even if it is carried out off-campus. This includes compliance with federal and state laws applicable to such research.

In addition, the Institution will ensure that the IRB thoroughly reviews all research involving human participants prior to its approval. No research may begin until the protocol has been reviewed and approved, or exempted from future review by the IRB. Sagrado is responsible for registering the IRB with the Office *for Human Research Protections (OHRP*), part of the federal *Department of Health and Human Services* (*DHHS*).

It is also the institution's responsibility to maintain an IRB with at least five members, at least one of whom must come from a non-scientific field and one of whom must be a representative of the external community.

Another of Sagrado's responsibilities is to promote effective communication among IRB members, researchers, unit directors and administrators, research staff, research officers, and research participants, in order to establish and maintain an adequate level of understanding regarding the protection of human rights and the well-being of all participants.

The Institution will provide convenient space and the necessary resources to support the IRB's work in reviewing and maintaining its records, in accordance with the requirements of 45 CFR 46.103(b)(2).

Education and Training:

One of the IRB's responsibilities is to educate, train, and communicate with the university community involved in research involving human subjects. The IRB uses a multifaceted approach to carry out these tasks. Activities can take various forms and be delivered in different settings, ranging from the development of online resources and e-newsletters to formal, personalized instruction in the classroom or individual meetings with researchers. These training sessions are coordinated by the IRB coordinator at the Universidad del Sagrado Corazón.

In addition, individuals designated as principal investigators, supervisors, and/or co-investigators must complete and maintain a series of online training courses through the *Collaborative Institutional Training Initiative* (CITI Program). This training covers topics related to the protection of human subjects and responsible research conduct and is a prerequisite for the start of any project, regardless of the funding source. Likewise, faculty members who offer research courses and the cohort of students enrolled in those courses must meet this requirement and submit evidence of the corresponding certifications.

Criteria for Submitting an Activity or Project to the IRB at the

Faculty, students, staff, external researchers, and collaborators from other institutions who propose research involving human subjects—whether through intervention, interaction, or data collection—must seek IRB approval. To determine whether a project or activity qualifies as "research involving human subjects," the following three questions should be considered:

1. **Is it research?** Federal regulations define research as a systematic inquiry—including the development of methodologies, testing, and evaluation—designed to develop or contribute to generalizable knowledge. Research is generally described in a protocol, a formal document that establishes the research question or hypothesis and how it should be tested (methodology) to establish facts and reach conclusions.

2. **Is the goal** to **produce generalizable knowledge?** The intention to develop or contribute to generalizable knowledge transforms an activity into research. Generalizable knowledge is knowledge expressed in theories, principles, or statements of relationships that can be applied beyond a single case. Activities designed to contribute to this knowledge seek to draw general conclusions, inform policy, or generalize findings beyond a single person or an internal program. Information is collected with the intention of sharing it with the academic or professional community and is created to make general statements about groups, procedures, programs, or other aspects. Generalizable knowledge includes one or more of the following elements:

    a. The information contributes to an established theoretical framework or body of knowledge.
    b. The primary beneficiaries of the study are researchers, academics, and professionals in the field of study.
    c. The publication, presentation, or other dissemination of the results is intended to inform the field of study.
    d. The results are designed to be replicated in other contexts.

3. Does **it involve human subjects?** Although the question seems simple, determining whether an activity involves human subjects can be confusing, especially when dealing with coded private data or specimens. It is considered to involve human subjects when working with "living individuals" from whom the researcher obtains one or both of the following:

    a. Data through intervention or interaction: Intervention includes both the physical procedures by which data are collected (e.g., venipuncture) and manipulations of the environment or the participant for research purposes. Interaction includes any communication or interpersonal contact between the researcher and the participant, including surveys or other instruments.

b. Personally identifiable information: This includes information about behaviors that occur in contexts where the participant reasonably expects privacy, as well as information provided for specific purposes that is not intended to be disclosed (e.g., medical records). The private information must be individually identifiable (i.e., the participant's identity is known or can be easily determined by the researcher) for the activity to be considered research involving human subjects.

Types of reviews for research projects

Research projects are reviewed and categorized into one of three types of review: **exempt review, expedited review, and full committee review**. Regardless of where the research is conducted or the type of review, any research project involving human subjects must be submitted to the IRB for evaluation and approval. The IRB is responsible for determining whether the activity or project qualifies as research involving human subjects, or whether it qualifies for any of the exemptions established by law (45 C.F.R. §46.101(b)(4)). If there are doubts as to whether the activity meets the definition of research, the researcher must consult the person serving as Administrator or Coordinator of the Sagrado IRB.

Expedited Review:

Expedited reviews are conducted by at least one experienced member of the IRB. This procedure is carried out in accordance with 45 CFR 46.110 and 21 CFR 56.110. Examples of research that may qualify for expedited review include:

- Studies involving moderate exercise by healthy volunteers.
- Analysis of data collected through recordings (such as those made in speech disorder research).
- Linguistic and ethnographic studies.
- Studies involving focus groups.
- Collection of samples and data in a manner that is not anonymous and involves no more than minimal risk to individuals.

Exempt review:

To qualify for exempt review, the research project must fall under one of the six (6) categories outlined in federal regulations. It is important to clarify that **"exempt" does not mean the project is exempt from IRB review**. The exemption applies to research that poses minimal risk to individuals, minimized through the anonymity of responses, the use of publicly available data, or through non-invasive methodologies.

NOTE**:** Exempt review cannot be used for research involving convicted individuals or for certain studies in which the study population is

involving minors as participants. The determination of exempt review is based on three essential criteria:

- The source of the data (primary or secondary data).
- The researcher's ability or inability to link data or specimens to specific participants, either directly or indirectly through coding systems.
- The nature of the study participants (pregnant women, children, inmates) and the experimental procedures [tissue and blood collection, techniques involving physical interventions (heat, pressure, sound, light), chemical interventions (radiation), or clinical interventions (inoculation)].

Research involving only coded private information is not considered research involving human subjects if the following conditions are met:

1. The private information or specimens were not collected specifically for the current research project (i.e., they are pre-existing data).
2. The researcher cannot determine the identity of the person to whom the coded private information or specimens belong.

The exemption applies to research involving private information and specimens when:

1. The data already exists at the time the research is proposed and is publicly available.
2. The information is recorded by the researchers in such a way that participants cannot be identified directly or through linking identifiers.

Important: This exemption does not apply if, when obtaining existing personally identifiable information, records, or samples, researchers record the data or information in a coded manner that allows participants to be identified through linking identifiers. Some common examples of exempt research include:

- Instructional strategies in education.
- Educational tests (cognitive, diagnostic, aptitude, achievement), interview processes, questionnaire processes, and observational behavior.

<u>Full Committee Review:</u>

Research projects involving human subjects that do not qualify for exempt review or expedited review must be reviewed by the full IRB committee. Projects requiring full review are those that pose more than minimal risk to participants or involve vulnerable populations. Some examples of vulnerable populations are:

- People residing in correctional facilities, nursing homes, and/or mental health facilities.
- People with terminal medical conditions.
- People with disabilities.
- People with intellectual or cognitive disabilities.
- Children [under 21 years of age].
- Economically disadvantaged individuals.
- People belonging to a racial, ethnic, or gender identity minority.

Ethical Principles

Sagrado promotes research within its university community as a tool for generating knowledge and as a space where students can develop skills that enable them to apply scientific principles to everyday problems. Consequently, this institution is guided by the ethical principles that apply to all research involving human participants.

In 1979, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research published its report titled *Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (better known as the Belmont Report; April 18, 1979). The general principles identified by the National Commission in the Belmont Report are: respect for persons, beneficence, and justice. Although the Belmont Report includes the prohibition against causing harm under the principle of beneficence, subsequent bioethical reflection has distinguished between beneficence and non-maleficence (Cf. T. L. Beauchamp and James F. Childress, *Principles of Biomedical Ethics*, 5th edition, 2001). We adopt this latter formulation, establishing four general principles to guide all biomedical or behavioral research involving human subjects at this Institution: respect for persons, beneficence, nonmaleficence, and justice.

In addition, the requirements set forth in 45 CFR 46 (as amended) will be met for all applicable research funded by the Department of Health and Human Services (HHS) and all other research, regardless of the level and source of funding, with the exception of the requirement to report to HHS.

Composition of the IRB

The IRB will consist of six members representing Sagrado's academic units: School of Health and Sciences; School of Arts, Design, and Creative Industries; Ferré Rangel School of Communication; School of Business and General Education.

<u>Standing Members:</u>

1. A person whose primary interest lies in the field of behavioral sciences or education.
2. A person whose primary interest lies in the field of natural or basic sciences.
3. A person with a background in non-scientific subjects.

4. A member of the community who is not affiliated with the Institution and is not a close family member of anyone affiliated with the Institution. The unaffiliated person must be willing to discuss research from a community perspective and must not be intimidated or persuaded by other IRB members.
5. An expert or advisor to the IRB on the research topic, if necessary.

Alternate members:

1. The IRB shall have at least three individuals who will serve as alternate members.
2. Alternate members shall serve in the event of the absence of regular IRB members. They may only vote on proposals they have reviewed.
3. The Vice-Presidency for Academic Affairs will appoint the standing and alternate members, ensuring diversity within the body to foster respect for its decisions and recommendations regarding the protection of the rights and well-being of research participants.

All IRB members must provide evidence of having completed the *IRB Members* certification provided by the *Collaborative Institutional Training Initiative* (CITI Program), of which Sagrado is a member. Additionally, the names and credentials of IRB members will be public and available on the IRB portal within the institutional website.

Positions and Administrative Functions

IRB Administration:

The person responsible for overseeing the various tasks and activities related to IRB processes. Additionally, this individual is accountable to the federal *Department of Health and Human Services* (*DHHS*) for ensuring compliance with federal regulations regarding the protection of human subjects in research.

IRB Chair:

A person appointed by the Vice-Presidency for Academic Affairs to chair meetings. They must have an interest in human rights and ethical issues, as well as knowledge of the rules and regulations governing human participation in research. The IRB chair shall be appointed directly. The chair must be a recognized and respected member of the university community, impartial, and immune to external pressures.

a. Duties:
    1. Maintain a list of the members of the IRB, including details of their academic and professional background and experience, ensuring diversity and respect for their decisions.

2. Convene meetings and, if necessary, request the presence of the principal investigator for clarification.
3. Conduct expedited reviews of research involving minimal risk or minor changes to approved proposals. You may delegate these reviews to another IRB member.
4. Determine whether a review request requires an expedited review, a full committee review, or is exempt. May designate another IRB member for this purpose.
5. Refer requests to the IRB committee according to the established schedule.
6. Certify IRB approval to federal agencies or funding entities and sign such certifications.
7. Immediately report any incidents related to the research, such as injuries to participants, unforeseen problems, allegations of scientific misconduct, or regulatory violations.
8. Maintain records of the reasons for the revocation of prior approvals.

IRB Coordination:

Person responsible for managing documentation, maintaining records, and organizing the committee's administrative activities. Must possess knowledge of research ethics and regulations related to the protection of human subjects. Appointment to this position will be made by direct appointment. The person in this role is required to be organized, meticulous, and possess the skills to ensure confidentiality and regulatory compliance.

a. Duties:
    1. Take detailed minutes of meetings, recording attendance, actions taken, votes, reasons for requiring changes or disapproving proposals, and a summary of controversies and their resolution.
    2. Retain for three years documents such as review requests, ongoing review forms, correspondence between principal investigators and the IRB, lists of members who approved or disapproved research, and additional correspondence between investigators and participants.
    3. Review and edit the minutes before sending them to the chair for distribution.
    4. Keep files and documents submitted to the IRB for review up to date.
    5. Coordinate the process of submitting research proposals to the IRB, ensuring that applications comply with regulatory and institutional requirements.
    6. Organize and schedule IRB committee meetings, ensuring the timely review of research proposals.
    7. Prepare and distribute agendas and necessary materials for IRB meetings.
    8. Ensure that all research complies with applicable ethical and regulatory standards, including federal regulations on the protection of human subjects (45 CFR 46) and other state and local laws.

9. Stay current on changes to research regulations and communicate them to IRB staff and researchers, providing guidance on compliance with these regulations.
10. Provide technical support and advice to researchers in preparing proposals and complying with IRB procedures.
11. Facilitate training on ethical guidelines, review procedures, and good research practices.
12. Monitor the progress of approved research studies, ensuring that the conditions established by the IRB are met.
13. Conduct periodic follow-ups on ongoing studies, managing renewals, modifications, and incident reports related to research protocols.
14. Serve as a liaison between researchers, administrative staff, and the IRB, ensuring effective and smooth communication.
15. Coordinate with other departments within the institution (such as ethics, compliance, and grant administration) to ensure that research projects comply with applicable regulations.
16. Implement and maintain electronic systems or databases for the submission and tracking of research protocols.
17. Ensure that IRB records are accurate and accessible for audits and external reviews, as needed.

IRB Advisory or Expert Review:

When the IRB lacks sufficient expertise on a specific topic, an expert may be consulted to assist with the review. This person will not have voting rights.

Vacancies

If, for any reason, an IRB member is unable to complete their term, they must submit a written resignation to the Vice-Presidency for Academic Affairs. Vacancies on the IRB may also arise when a member:

a. Ceases to be a member of the faculty or regular staff at Sagrado.
b. Fails to attend two (2) IRB meetings without a valid reason.
c. Is removed from office for failing to comply with established rules and procedures, for a conflict of interest, or for breaching confidentiality.

The Vice-Presidency for Academic Affairs, at the request of the IRB Chair, shall make appointments to replace any member who resigns, whose term expires, or who is removed from office.

IRB Responsibilities

The Institutional Review Board is responsible for ensuring that in research projects:

- The voluntary participation and confidentiality of participants are guaranteed.
- Risks of physical, mental, or emotional harm, or any other type of harm, are minimized.
- Benefits are provided to humanity in general.

For this reason, the IRB must:

1. Review to approve, request modifications, or disapprove any research covered by Sagrado's policies and procedures on the protection of human subjects in research and in accordance with 45 CFR 46.
2. Act in accordance with the procedures established for Sagrado, as required by 45 CFR 46 and in this guide.
3. Require that the information provided to human subjects comply with the applicable regulations of 45 CFR 46.
4. Require or waive the requirement for informed consent documentation, as provided in 45 CFR 46.
5. Notify principal investigators (PIs) in writing of the IRB's decision to approve or not approve the research proposal or the modification required to ensure approval of the research activity. If the IRB decides, by vote, to disapprove a research proposal, the written communication must include the reasons for its decision and allow the principal investigator to respond in writing or in person to the IRB.
6. Conduct ongoing review of research covered by this guidance at intervals appropriate to the level of risk, at least once a year. The IRB shall have the authority to observe or assign an alternate member to observe the consent and data collection process.

Except when expedited review is used, approval of a research project involving human subjects must be granted by a majority vote of the members present at the meeting or via electronic voting, as previously arranged by the IRB chair.

To comply with federal regulations regarding the protection of human subjects in research and to ensure the ethical conduct of research conducted by students, faculty, and staff at Sagrado, all research proposals involving human subjects will fall under the jurisdiction of the individuals serving in the roles of IRB chair, administration, and coordination. This administrative team is responsible for determining whether the research proposal is exempt or whether it will be subject to expedited review or full committee review.

Duties of Members of the IRB

1. Review, examine, and comment on proposed research protocols at IRB meetings in order to discuss them, identify their shortcomings, and offer suggestions and modifications to address them.
2. If a proposed research protocol is unclear, IRB members shall seek clarification from the principal investigator or from subject matter experts consulted by the IRB.
3. Vote to approve, disapprove, or defer approval of the protocols for research proposals submitted to the IRB for review.
4. Visit the site where the clinical study is being conducted when requested to do so by the IRB chair.
5. If an IRB member is unable to attend an IRB meeting, they may designate an alternate and must provide the appropriate and necessary documentation and materials for the review of the protocol proposals.
6. If any IRB member has a conflict of interest, it must be documented, and the conflict of interest form must be completed.

Term

The term of office for IRB members will be two years. Members may be reappointed by the Vice-Presidency for Academic Affairs. If a member decides not to continue serving on the IRB, they may be consulted as an Advisory Member.

Confidentiality Agreement

Once appointed, IRB members will sign the following forms annually:

1. Declaration of Significant Financial Interests and Conflict of Interest.
2. Confidentiality and Non-Disclosure Agreement.

IRB Meetings

The IRB will meet once a month during the academic year to review proposals, except in July. In addition, it will meet at least once a year to review operating procedures. Proposals for changes to the IRB's operating procedures will be submitted by the IRB to the Vice-Presidency for Academic Affairs for approval.

The following individuals will be present at each meeting:

a. The members of the IRB.
b. The IRB chair.
c. Spokespersons representing the interests of the research participants, if necessary.
d. Individuals invited by IRB members who can review protocols, such as: medical doctors, nurses, licensed professionals, counselors, psychologists,

parents, among others. The IRB may consult any individual or group representing the community under study.

The meeting notice, the agenda, and any other relevant documents will be issued by the IRB coordinator.

Quorum

At every IRB meeting, all members must be present. However, if a member is unable to attend, they may be replaced by an alternate member.

Conflict of Interest

No IRB member may participate in the initial review or ongoing oversight of any project in which there is an actual or potential conflict of interest, but may provide information requested by the IRB. The IRB member shall not participate in or be present during voting procedures, and the minutes must reflect compliance with this requirement. The conflict of interest form must be completed.

IRB Procedures

General guidelines for researchers

1. All research conducted must be reported to the IRB Coordinator. The Coordinator serves as the initial reviewer of the protocol, ensuring that the documentation is complete and meets the established requirements. Once this initial review is complete, the Coordinator forwards the protocol to the Administrator and/or the Chair of the IRB, as appropriate. Subsequently, comments will be sent to the person designated as the principal investigator, if necessary. Once the comments have been addressed, the protocol may be approved, denied, require additional modifications, or be referred to the full IRB for review. The IRB Coordinator reports to the Assistant Vice President for Academic Research and Grants.
2. The IRB at the Universidad del Sagrado Corazón has an official website where all information related to required documentation, procedures, guidelines for researchers, frequently asked questions, and any relevant updates is available. It is the responsibility of researchers to regularly check this website to ensure compliance with current regulations and the requirements established by the IRB.
3. It is essential that researchers review and familiarize themselves with the established guidelines for the protection of human subjects in research to ensure that their protocol complies with all applicable ethical and regulatory requirements.
4. Each application to review research involving human subjects, including supporting documents, must be submitted electronically and signed by the

principal investigators, co-investigators, mentors, and thesis advisors and/or relevant units.

5. Individuals designated as principal investigators, supervisors, and/or co-investigators must maintain valid research ethics certificates issued by the *CITI Program*.
6. Any person participating in research involving human subjects and intended to produce generalizable knowledge must submit the required documentation and request review of their research protocol by the IRB.
7. Individuals planning to conduct research must disclose any potential conflicts of interest before initiating their study. The IRB will evaluate such disclosures.
8. All researchers must develop a plan to ensure the secure storage of collected data and the convenient disposal of information once the study is completed, in accordance with current regulations.
9. Any researcher who needs to make any modifications to a previously approved protocol must request an amendment from the IRB before implementing the changes. Unauthorized modifications may invalidate the protocol's approval.
10. Research projects that require the participation of active-duty staff and students affiliated with the Puerto Rico Department of Education (DEPR) must comply with the DEPR's specific provisions. In such cases, researchers must request a meeting with the staff responsible for the administration or chairmanship of the IRB.
11. When the study sample comes from a company, organization, university, government office, or other external entity, researchers must submit a letter of collaboration on letterhead, signed by authorized personnel. Likewise, if the entity provides the use of its facilities or equipment, a letter of collaboration must be included. In cases where the entity has its own ethics committee or IRB, the corresponding authorization must be submitted before the protocol is submitted to the Sagrado IRB.
12. The research protocol must clearly identify the person or organization responsible for intervening in the event that a participant experiences a crisis while taking the assessment. Researchers may not assume this role, even if they have training or certification in mental health.
13. The SOHO platform retains digital IRB applications for a maximum of 15 days. If the application and its supporting documents are not completed and submitted within this period, they will be automatically deleted, and the process will need to be restarted. It is the responsibility of researchers to ensure that all documentation is complete and submitted within this timeframe to allow for timely review by the IRB. The 15-day period includes both the days on which the application is completed and the days on which the IRB receives it. This timeframe is continuous and includes weekends and holidays.
14. Once the application and required documentation have been submitted, the IRB will have two weeks to complete its review and provide feedback or make decisions regarding the protocol. The IRB will review both the electronic application and the supporting documents, verifying that everything is complete and in compliance with established regulations. If necessary, the IRB may make comments or request additional modifications to the protocols before proceeding with approval. Researchers must address the comments and make the necessary corrections. The IRB may approve the protocol, deny it, or, if deemed necessary, refer it to the full IRB for final evaluation.

15. Researchers must report to the IRB any unexpected problems involving risks, serious or ongoing noncompliance with 45 CFR 46, or with the IRB's determinations, as well as any suspension or termination of the study. Adverse events or unexpected situations must be reported to the Institutional Review Board within seven (7) business days of the event, as required by the regulations for the protection of human subjects in research (45 CFR 46). Serious events must be reported within 24 hours of their occurrence, via telephone or email. In all cases, the adverse event or unexpected situation notification form must be completed, and a follow-up report must be submitted to the *Office for Human Research Protections* (OHRP) once corrective actions have been implemented.
16. Research protocols approved by the IRB are valid for one (1) year. If all data have not been collected within that period, researchers must submit a renewal request (*Continuing Review*) to the IRB thirty (30) days in advance.
17. Sagrado IRB staff may visit the locations where researchers indicated the sample would be stored to verify that the protocol is being carried out as submitted and approved.

Specific guidelines regarding the application process

Institutional and external research:

Research conducted within the Universidad del Sagrado Corazón and/or by members of the university community (such as faculty, staff, or students), as well as research proposed by organizations, agencies, external institutions, or independent researchers who wish to submit their protocols for review and approval by the Sagrado IRB, must meet the following requirements:

1. Protocols must be submitted with all documentation requested by the IRB, including the electronic signatures of the principal investigators, co-investigators, mentors, thesis advisors, and/or relevant units.
2. Researchers must complete the corresponding online application and submit all supporting documents within 15 days.
3. The supporting documents required to accompany the application are as follows: the template for creating the informed consent form, which must be fully tailored to the study's specific characteristics. If the data collected in a study is expected to be used for future research, in accordance with the criteria of 45 CFR 46, the broad consent section must be completed. If the research involves participants who are not adults, the template for creating the informed assent form must also be submitted. Additionally, it is essential to include the ethics certificate for each person who will work directly on the research, which must be obtained through the *CITI Program*.
4. Researchers must submit the research instruments to be used in the study. These instruments must be submitted in both their original format and as PDF files, and must be thoroughly proofread for grammar and spelling before being sent to the IRB.

Recruitment materials must also be included, and these must contain details such as the study title, the principal investigator's name, the purpose of the study, the basic eligibility criteria, the study site location, contact information (using institutional email), a summary of study activities (such as interviews), the time commitment required, a brief list of potential benefits (if applicable), and the protocol number assigned to the research by the IRB.

5. If the research involves collaboration with other institutions or entities, the corresponding collaboration letters, signed by authorized personnel from those entities, must be submitted. Similarly, if the research is funded by external entities, a letter detailing the funding and associated conditions must also be included.

Research in GIV courses:

The GIV courses at the Universidad del Sagrado Corazón are part of the academic program designed to promote the development of skills and competencies in research and social action. Students enrolled in GIV courses must adhere to the following guidelines:

1. The cohort of students enrolled in GIV courses will participate in an academic-practical process of drafting research protocols and preparing documents required by the IRB, as part of the course's assessment requirements. This exercise is intended solely for academic and training purposes; therefore, the documentation will not be submitted to the IRB for official review. However, if a student, in agreement with the course instructor, decides to submit their research for publication or to develop generalizable knowledge, they must follow the formal IRB application and approval procedure. In such cases, the student must comply with the same requirements established for institutional and external researchers, including ethical and methodological approval by the IRB and supervision by the course instructor.
2. Students who wish to submit their research for publication or to develop generalizable knowledge should review and adapt the draft application developed in the course, ensuring that it meets the IRB's official criteria and requirements. They must then submit the revised version of the application in PDF format to the course instructor for review and preliminary approval. The course instructor is responsible for verifying that the application meets established ethical and academic standards before authorizing its formal submission to the IRB with their signature.
3. Once the application has been approved by the course instructor, researchers must complete the digital application and submit all supporting documents within 15 days.
4. The supporting documents required to accompany the application are as follows: the template for creating the informed consent form, which must be fully tailored to the study's specific characteristics. If the data collected in a study is expected to be used for secondary purposes in future research, in accordance with the criteria of 45 CFR 46, the broad consent section must be completed. If the research involves participants who are not adults, the template for creating the informed assent form must also be submitted. Additionally, it is essential to include the ethics certificate for

each individual who will work directly on the research, which must be obtained through the *CITI Program*.

5. Researchers must submit the research instruments to be used in the study. These instruments must be submitted in both their original format and as PDF files, and must be thoroughly proofread for grammar and spelling before being sent to the IRB. Recruitment materials must also be included and must contain relevant information about the research, such as the study title, the principal investigator's name, the name of the GIV course instructor, the study's purpose, eligibility criteria, the study site location, institutional contact information, a summary of study activities, the time commitment required, and a brief list of potential benefits, if applicable.
6. If the research involves collaboration with other institutions or entities, the corresponding collaboration agreements, signed by authorized personnel from those entities, must be submitted. Similarly, if the research is funded, a letter detailing the funding and associated conditions must also be included.
7. Once the research projects of the student researcher community in the GIV courses have been completed, the supervisor must complete the list of students who have finished their research projects in order to maintain solid evidence of completion in the relevant files.

IRB Location

The IRB at the Universidad del Sagrado Corazón is currently located on the institution's campus at Calle San Antonio, corner of Calle Rosales, Parada 26.5, San Juan, PR 00914. It is located on the first floor of the San Miguel Building and is affiliated with the *A Culture of Research Achievement at Sagrado* (Co-RAS) program in the School of Health and Sciences.

Responsibilities of Principal Investigators ( )

The principal investigator is the primary guardian of the rights and safety of research participants. They are responsible for:

1. Submitting the research project for IRB review and ensuring approval is obtained before initiating any research activities.
2. Conduct the study in accordance with the approved protocol, using the informed consent form.
3. Notify the IRB and sponsors (if applicable) of any amendments to the protocol and the consent form before implementing any changes, except in cases of immediate danger to participants, which must be reported to the IRB immediately.
4. Ensure that all individuals responsible for the study's design and conduct are trained in human subjects protection prior to the project's start.
5. Ensure that CITI Program certifications are not expired at the time of submission to the IRB and throughout the duration of the research.

6. Oversee the informed consent process, ensuring that participants understand the study, the risks, and their rights.
7. Ensure that those obtaining consent are certified by the CITI Program and are knowledgeable about the study.
8. Implement additional safeguards to protect vulnerable communities from coercion or undue influence.
9. Verify that participants have the cognitive capacity to give consent.
10. Ensure that all consent forms are signed by the principal investigator or a designated person within 30 days of the participant's signature.
11. Conduct or personally supervise the study.
12. Maintain a protocol file containing the research project documentation.
13. Comply with federal and institutional record retention periods.
14. Recruit potential participants in an ethical and responsible manner.

The principal investigator must maintain a file containing the human subject research project documents. The file must include the following items:

1. A copy of the human subject research application submitted to the IRB, along with all IRB approvals, amendments, ongoing revisions, protocol deviations, and adverse events.
2. A copy of the sponsor's protocol (if applicable).
3. A copy of the federal grant application (if applicable).
4. A copy of the principal investigator's brochure for a new investigational drug (if applicable).
5. A copy of the investigational device exemption information (if applicable).
6. A copy of the consent form with the IRB stamp and expiration date.
7. The original of each consent form signed by each participant enrolled in the research.
8. A copy of all correspondence with the IRB, the sponsor, the funding source, or other agencies.
9. A copy of all data generated by the study (case report forms, computer data, adverse event reports, drug/device liability records, etc.).

The principal investigator is required to retain records associated with a human subject research project for a maximum of three (3) years. Record retention requirements vary depending on whether federal funds were provided for the project.

-Check Sheet

This section lists the documents required to complete the review of research involving human subjects. It is important to emphasize the following:

1. Submission of the documents listed here is required. The list includes links to templates for some of these documents.
2. Digital applications must be accompanied by the required documents and include the corresponding signatures.

Checklist of Required Documents	
Researchers	**Students**
• Application	• Application
• Informed consent	• Informed consent
• Informed consent (if applicable)	• Informed consent (if applicable)
• Ethics Certificate (current)	• Ethics Certificate (current)
• Instruments	• Instruments
• Recruitment materials	• Recruitment materials
• Letter of Collaboration (if applicable)	• Letter of collaboration (if applicable)

Complaints and concerns from participating individuals

The principal investigator is responsible for providing contact information on the informed consent form to allow participants the opportunity to voice complaints or concerns about study procedures or their participation. The contact information must be included on the consent form. Complaints received will be investigated and reported to the IRB and the appropriate institutional IRB officials. The principal investigator must retain documentation of the complaint, concern, and its resolution in the protocol file for a minimum of three years, in accordance with federal regulations. Serious complaints must be brought to the attention of the IRB as they occur, and all complaints must be reported at the time of ongoing review.

Questions about the “ ” guide

Questions regarding the scope and interpretation of this guide should be directed to the Institutional Review Board (IRB) Administrator at 787.728.1515, ext. 5232, or by email at irb@sagrado.edu .

Reports of violations of this guide

Violations of this Policy should be reported to the General Counsel at 787.728.1515, ext. 5436, or by email to cameliac.fernandez@sagrado.edu, or to the Compliance and Integrity Officer at cumplimiento@sagrado.edu. Any violation of this guide or procedure will be addressed in accordance with institutional policies and procedures.

Violations of the guidelines

La Universidad del Sagrado Corazón reserves the right to interpret this Policy in its administration, implementation, and enforcement. Any violation of this Policy by a student, faculty member, staff member, or any other person may result in disciplinary action, which may include expulsion from the University (students) or termination of employment (faculty and administrative staff), or other appropriate legal actions. If there is any ambiguity in any provision of this Policy, the University reserves the discretion to interpret it in accordance with the purpose for which it was established, the impact on the University's operations, and good faith, unless any law provides otherwise.

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INSTITUTIONAL REVIEW BOARD

Step-by-Step Guide for Registration and Access to CITI-Program Trainings

August 2025

Participant Manual
Step-by-Step Guide to Registration and Access to CITI-Program Trainings
Universidad del Sagrado Corazón

This manual was developed by Valerie Cora Polanco and reviewed by Stephanie M. Vega Flores, Sarah Patricia Abreu, Yara Flores Díaz, and Stephanie De Jesús Blasky

Content review July 2022: *Center for Academic Research*

Table of Contents

Collaborative Institutional Training Initiative (CITI) 1

Steps for Registration and Training in the CITI Program for Research Assistants, Faculty, and Administrative Staff 1

Registration 1

Training 17

Certification 24

Bibliography 26

Collaborative Institutional Training Initiative (CITI)

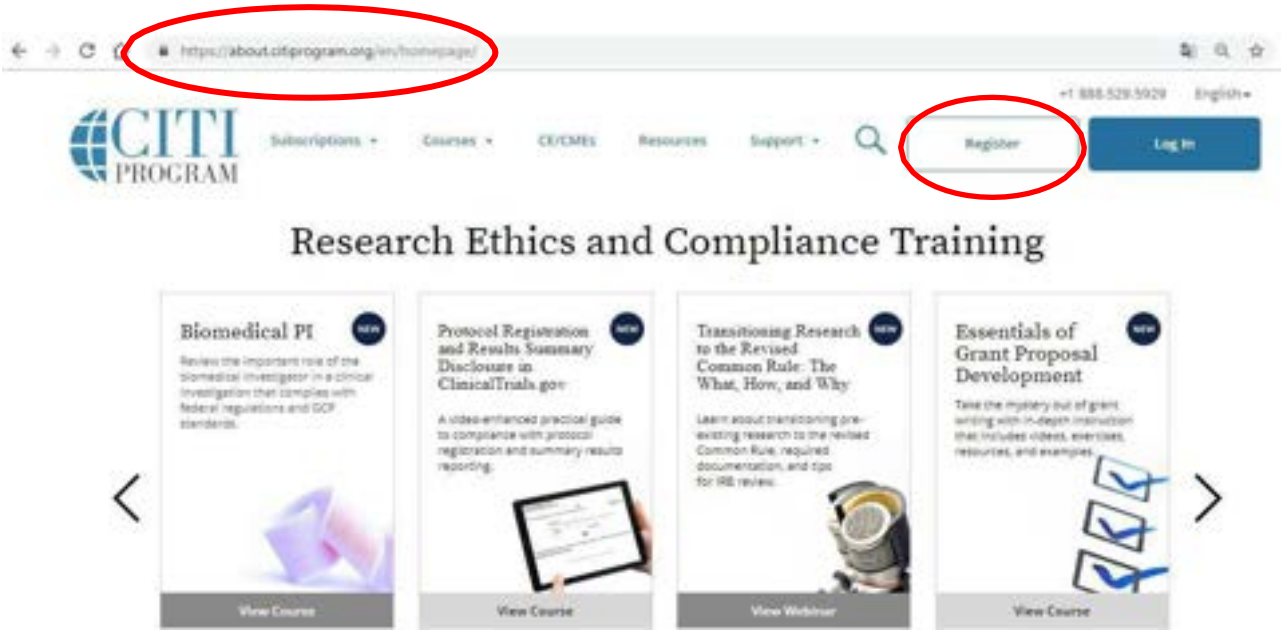
The CITI program is dedicated to meeting the training needs of colleges and universities, healthcare institutions, technology and research organizations, and government agencies, while promoting the integrity and professional development of their students. It provides researchers, faculty, and students with guidance to better understand and comply with the laws, guidelines, and institutional policies that govern human research activities at institutions participating in the program. The primary objective is to ensure that researchers are aware of the rights of human subjects participating in research and guarantee their protection.

Steps for CITI registration and training for research assistants, faculty, and administrative staff

The following outlines the steps to register and access the basic training modules on the protection of research participants, which include *short comprehension quizzes*, through the *Collaborative Institutional Training Initiative* (CITI) platform. This guide is designed to help faculty members and students enrolled in research courses obtain three basic certifications. It is mandatory for all faculty and students involved in any research process involving human subjects or specimens to obtain three certifications: *Responsible Conduct in Research* (RCR), Social Behavioral Research (SBR), and *Information Privacy Security* (IPS)

Registration

1. To register, visit https://about.citiprogram.org/



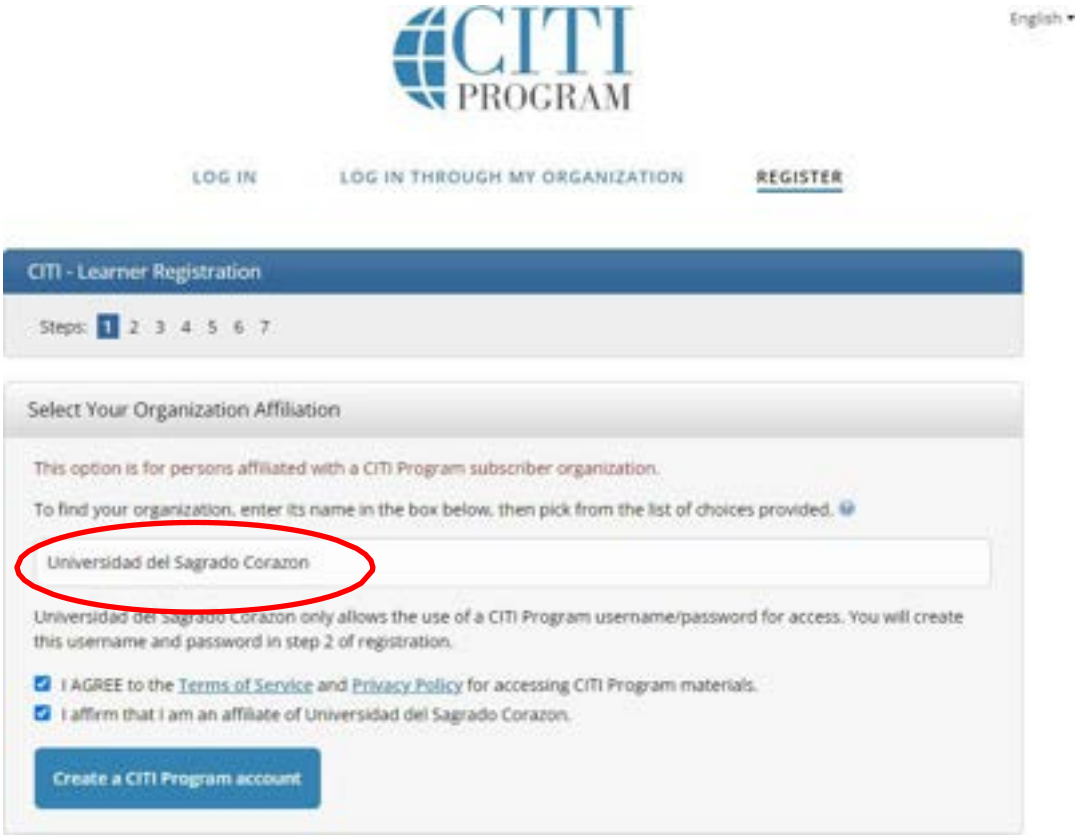
2. If you prefer, you can switch to your preferred language (as shown in the image in the upper right corner).

If you select **Spanish**, please note that only some instructions will appear in this language. However, the modules will only be available in **English**.

3. Click the "*Register*" button.

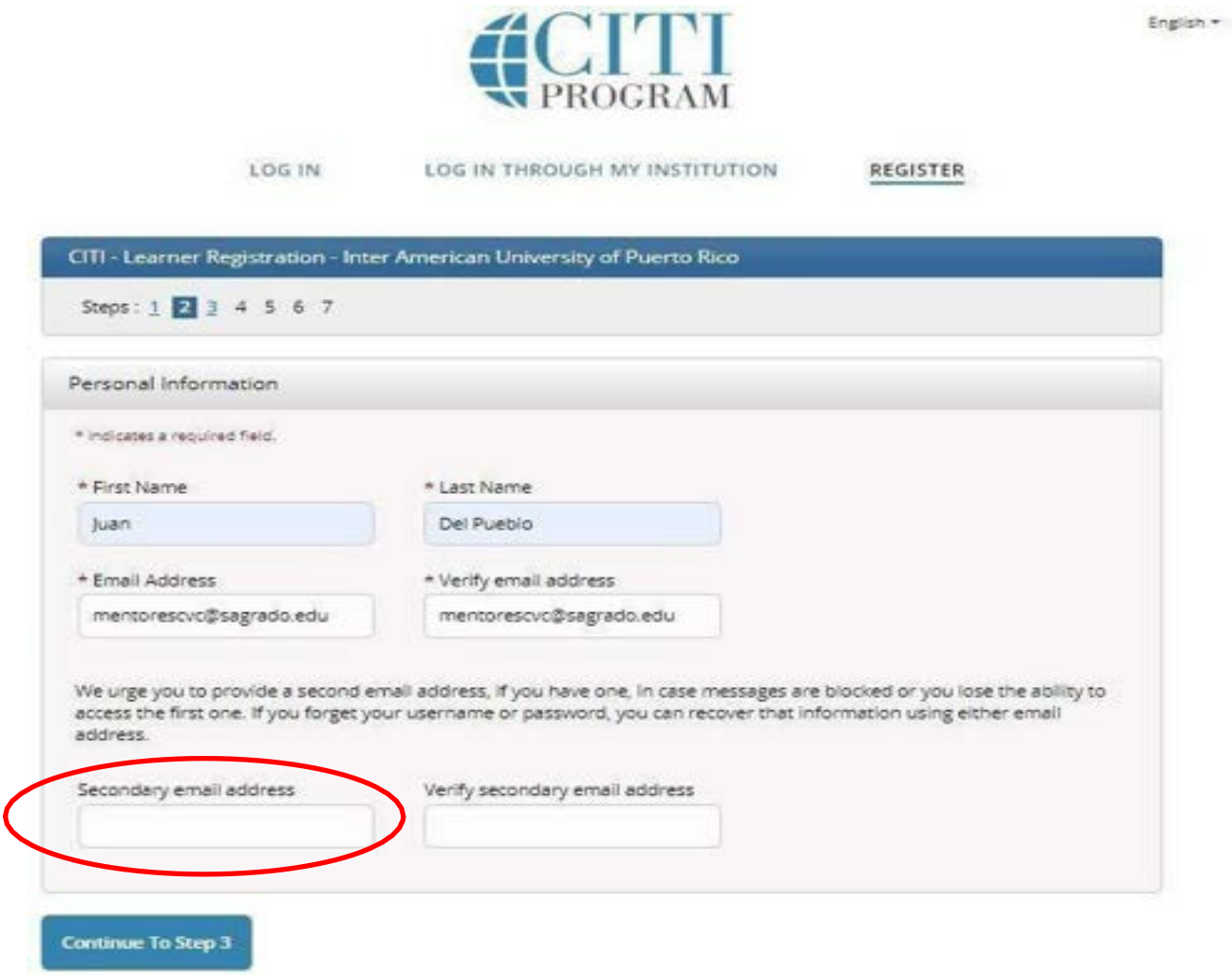
4. To affiliate with an institution, type ***Universidad del Sagrado Corazón*** (in Spanish) in the blank field and then check the following requirements to certify.

   I AGREE to the Terms of Service for accessing CITI Program materials I affirm that I am an affiliate of Universidad del Sagrado Corazón

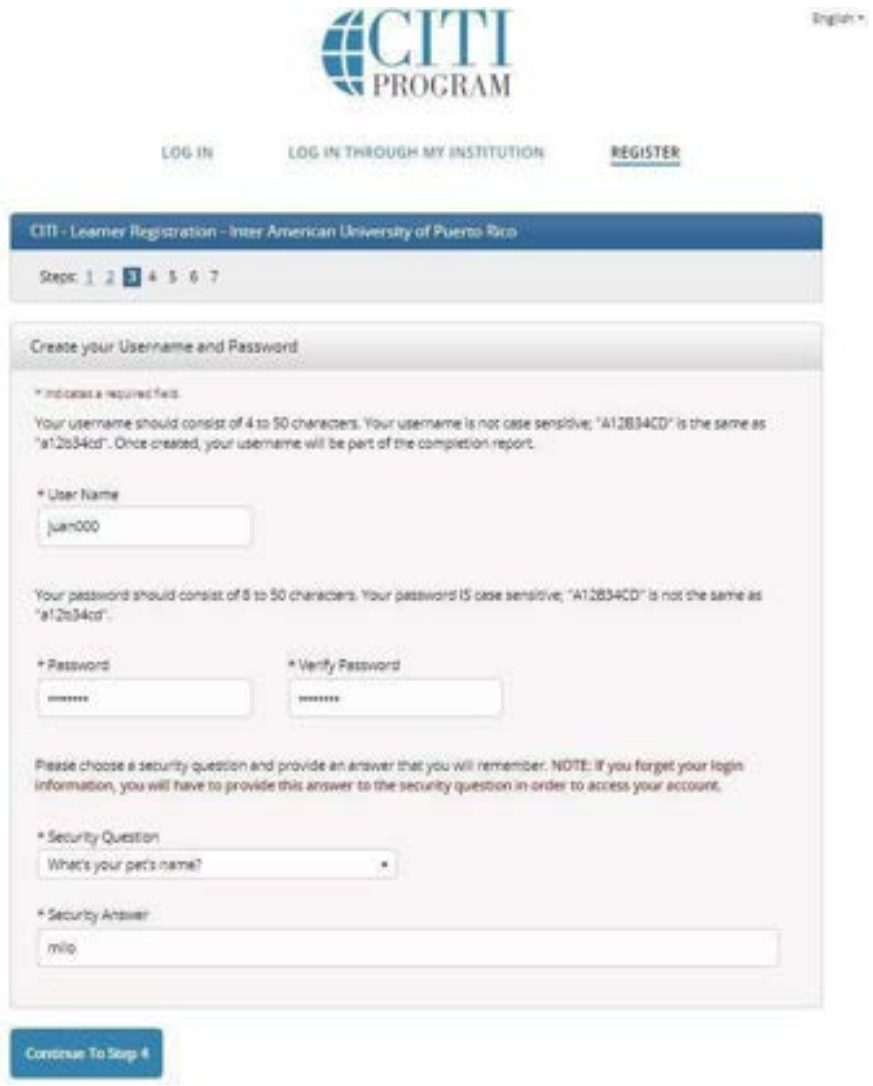


Next, click "*Continue to Create a CITI Program Account."*

5. Fill in the personal information requested during registration and provide a valid institutional email address. We also recommend that you enter an alternate email address (which can be a personal one) in the "*Secondary email address*" field in case your account is locked. Then click *Continue to Step 3*.

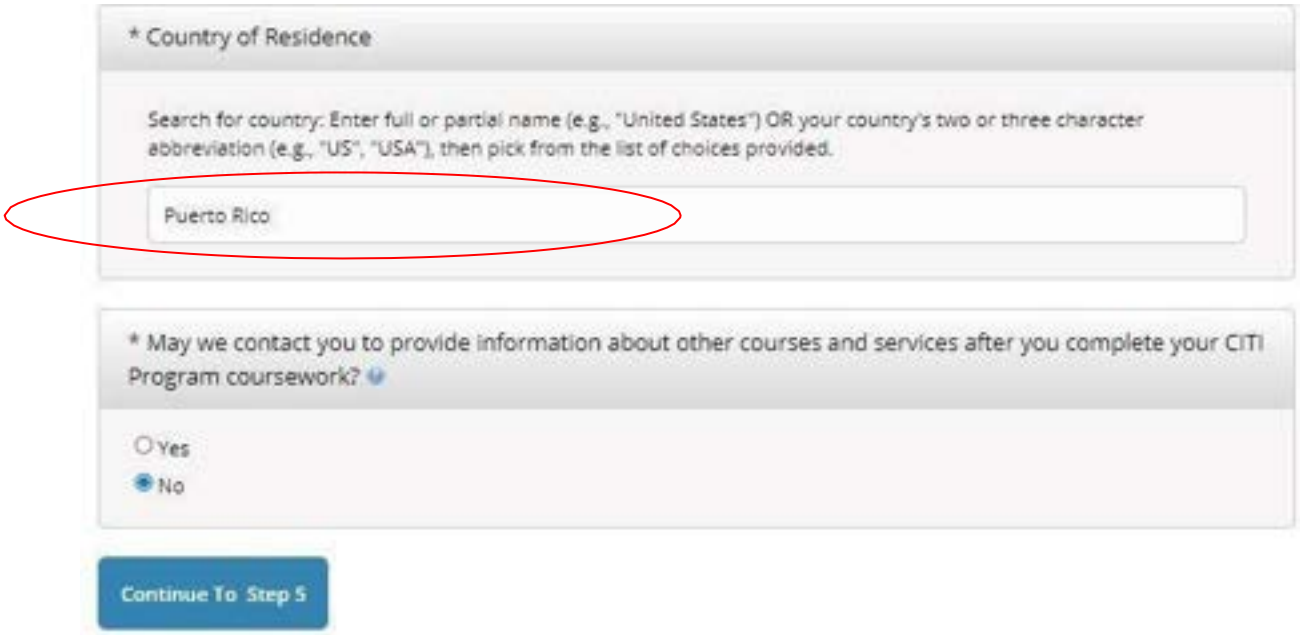


6. On the next screen, you must create your username and password. We recommend that you choose a convenient username, such as the initial of your first name and your last name (**JDelPueblo** or **J_Del_Pueblo**). We do not recommend using a nickname. The password must be between 8 and 50 characters long (be sure to use special characters [@ ¿? ¡!] to strengthen the security of your desired password). Password creation is case-sensitive. That is, if you create the password using uppercase letters, the platform will recognize it as such and not in lowercase. We recommend using a combination of numbers, letters, and symbols.



Be sure to save this information and double-check your password. Next, select a security question under *"Security Question" and enter* your **answer** in the box below. Save this information as well. Click *"Continue to Step 4."*

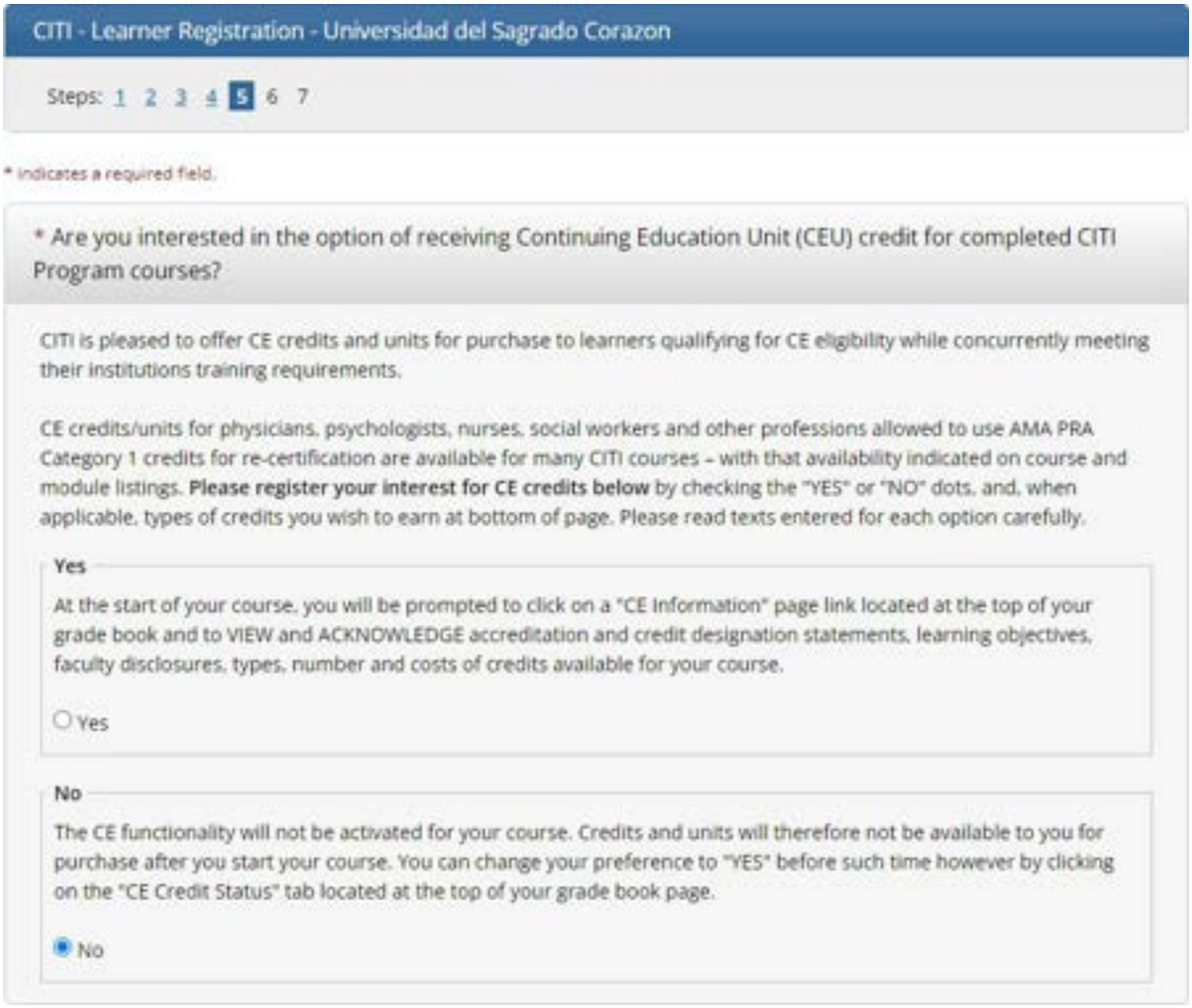
7. In Step 4, in the "*Country of Residence*" section, type the word "**Puerto Rico**" in the *search field***.**



Next, proceed to the question asking whether you consent to receiving information from CITI via email or wish to participate in CITI surveys. Select your preference. Your selection will not affect your *quiz* results or the issuance of your CITI certification.

Next, click *Continue to Step 5*.

8. On the next screen, select **NO** in the second box. This selection means that no credits will be awarded for taking the training, nor will there be a charge for it.

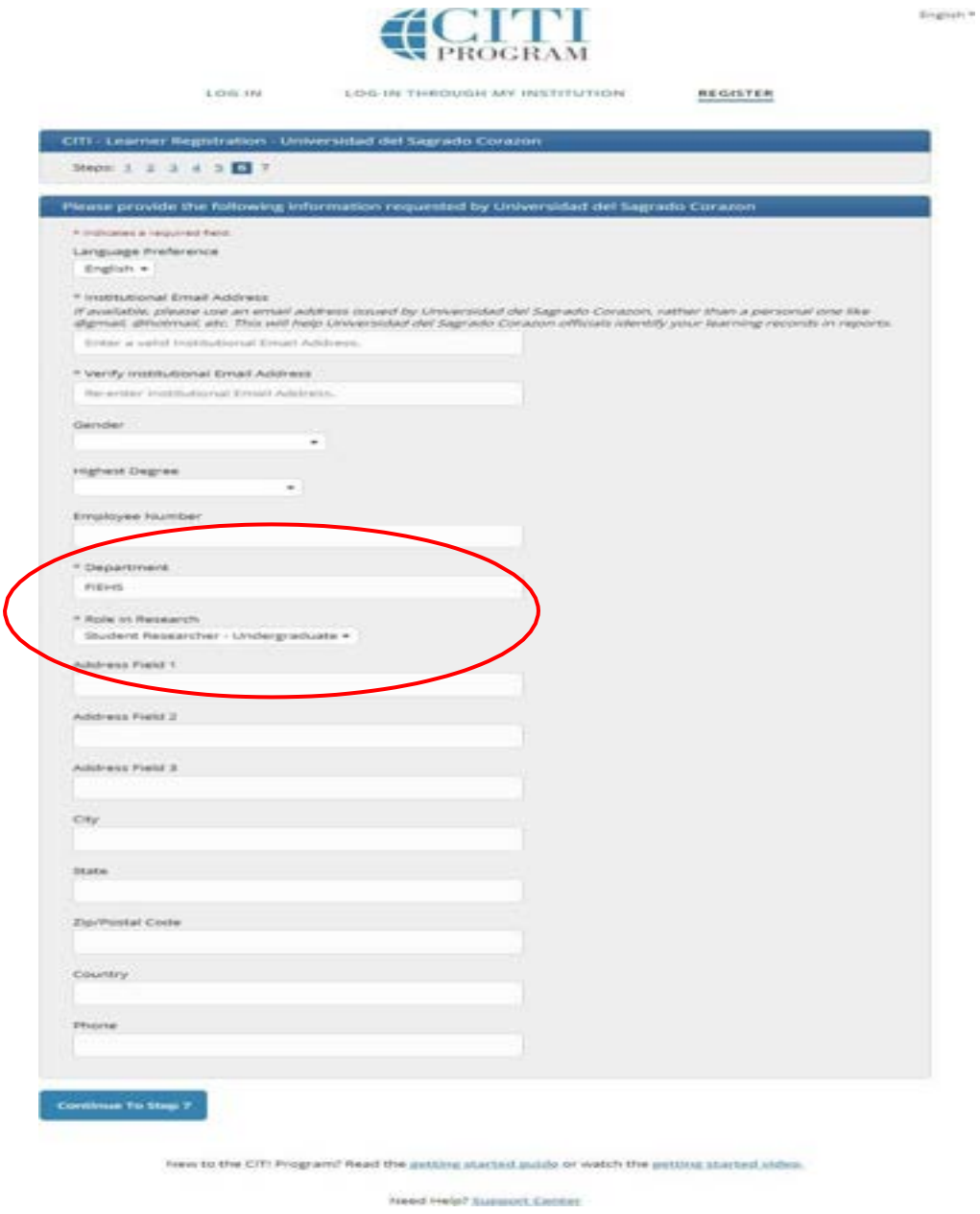


If you click "Yes," this box will appear:

Then, click *Continue to Step 6*.

9. The next screen will appear, asking for information required by the university. In this section, do the following:

- Under Language of your choice, select **English** (This is the only option available)
- In ***the Institutional email address field***, enter your Sagrado faculty or student email address.
- Select your gender from the ***Gender*** dropdown menu**.**
- Under ***Highest Degree***, select the highest degree you have earned.
- In ***the "Department*****" field,** enter **the school or department to which you belong.**
- Under "***Role in Research,"*** select "***Student Researcher—Undergraduate" or "Graduate."***
- If you are a faculty member or a non-faculty administrator, select the role that best describes your position.
    - Principal Investigator
    - Co-Investigator
    - Data Manager
    - Institutional Official
    - IRB Administrator
    - IRB Chair
    - IRB Member
    - Lab Research Staff
    - Research Assistant
    - Study Coordinator



Then, click *Continue to Step 7*.

Continue filling in the requested information about the training required of you in the ***Select Curriculum*** section.

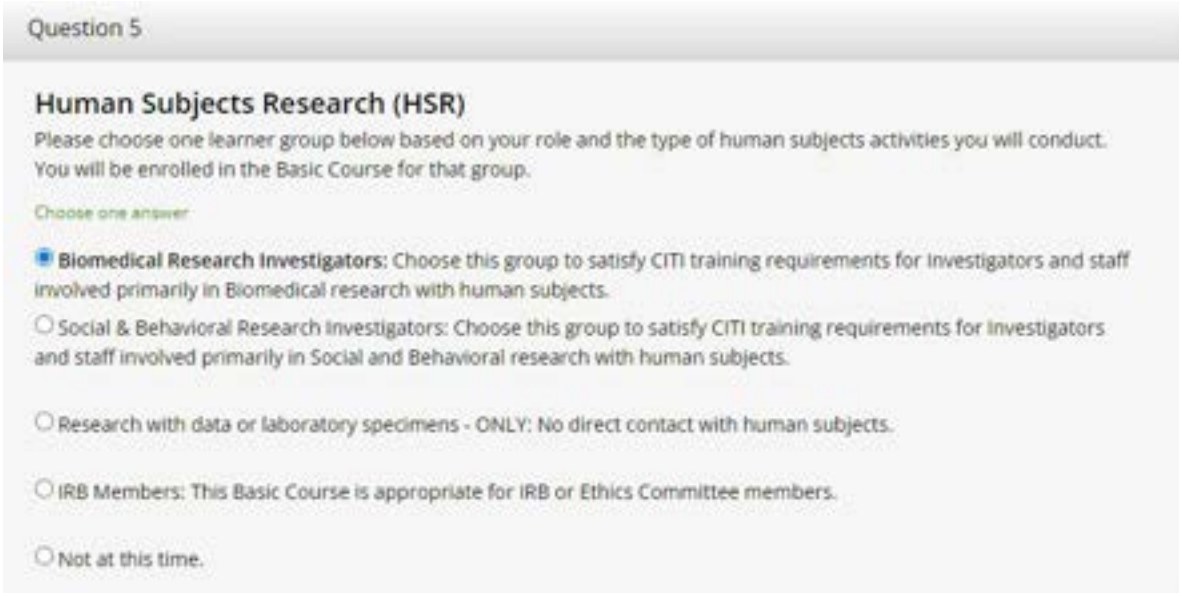
Leave question 1 blank.

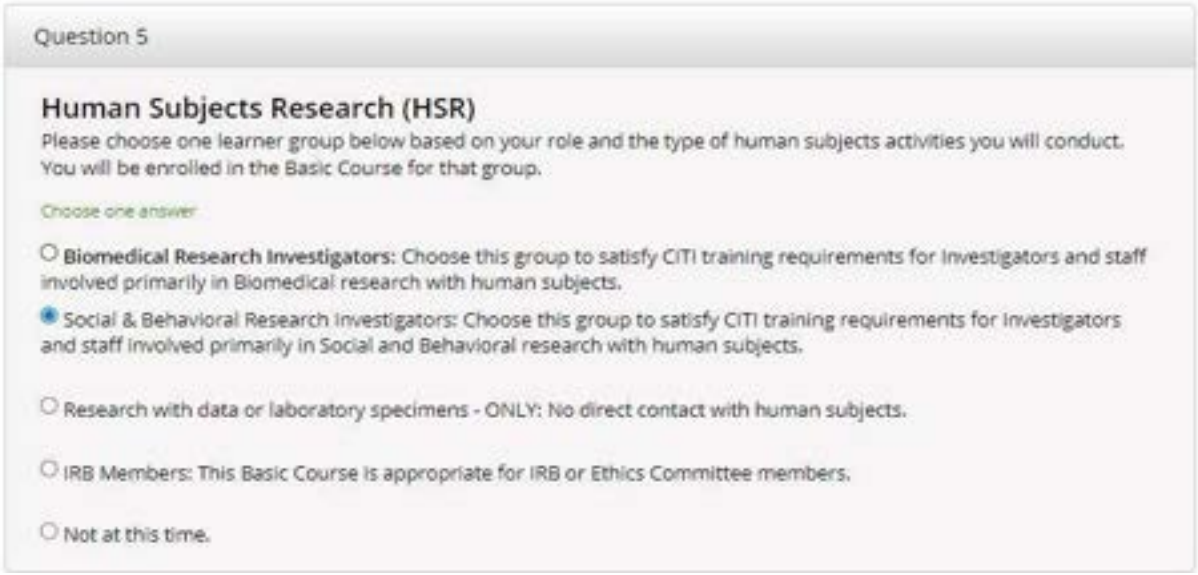
For question 2, ***Conflicts of Interest*** **(COI)**, select *Conflicts of Interest for Students* (if you are a student) or *Conflicts of Interest for Faculty* or *Conflicts of Interest for Staff* (if you are a faculty member or staff member).

Leave question 3 blank.

For question 4, ***Information Privacy Security*** **(IPS),** select *IPS for Students and Instructors* (if you are a student). If you are faculty or staff, select *IPS for Researchers.*

For question 5, ***Human Subjects Research*** **(HSR),** select *Social & Behavioral Research Investigators* or *Biomedical Research Investigators.* If you are conducting research with data (without contact with subjects) or laboratory specimens, select *Research with data or laboratory specimens.*



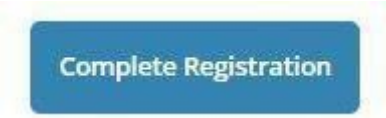


Leave question 8 blank.

For question 9, "***Responsible Conduct of Research* (RCR),"** select "*Social & Behavioral Responsible Conduct of Research."*

Leave question 10 blank. Click

Complete Registration.

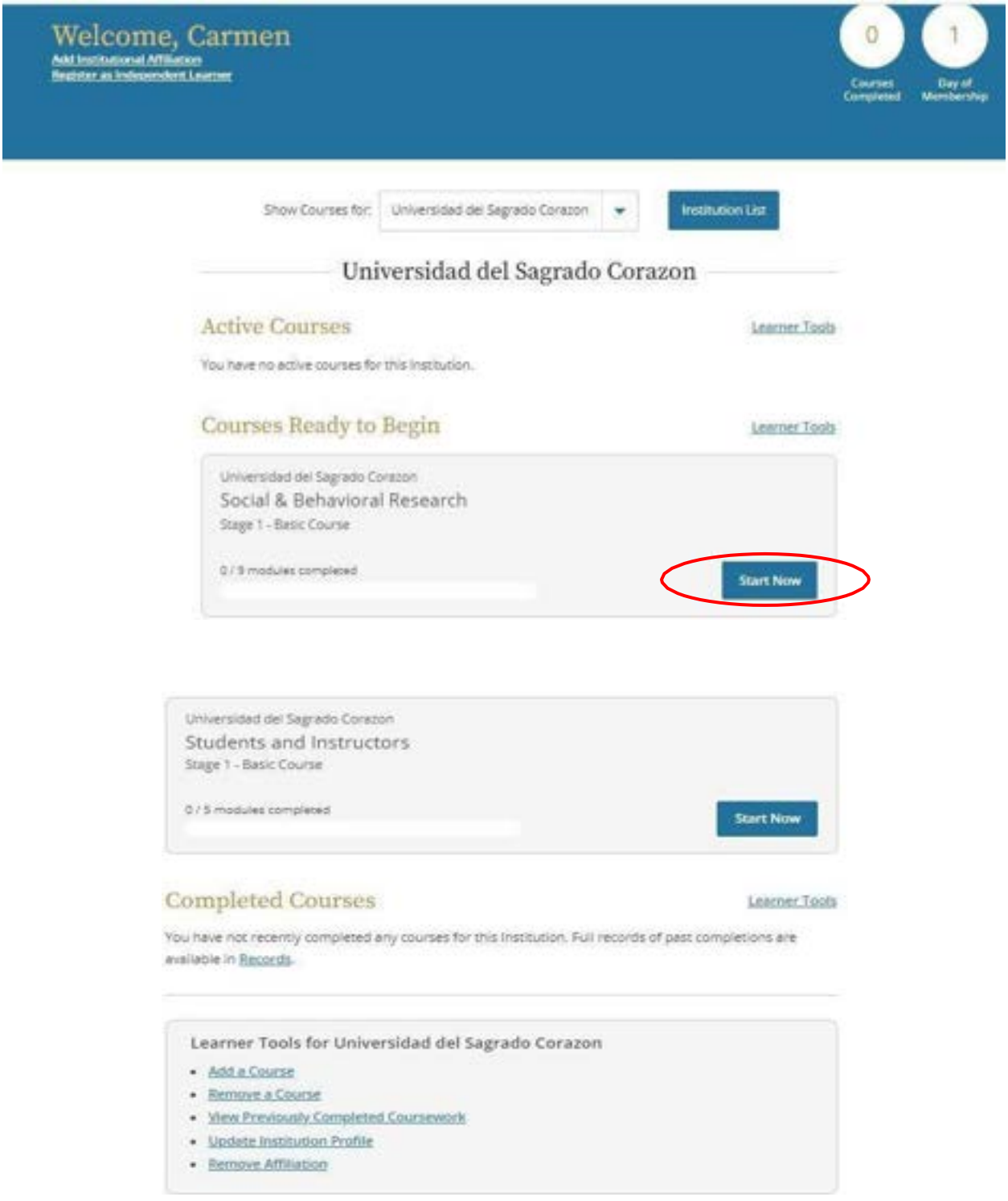


Then, click ***Finalize registration***.

10. Once registration is complete, the following screen will appear:

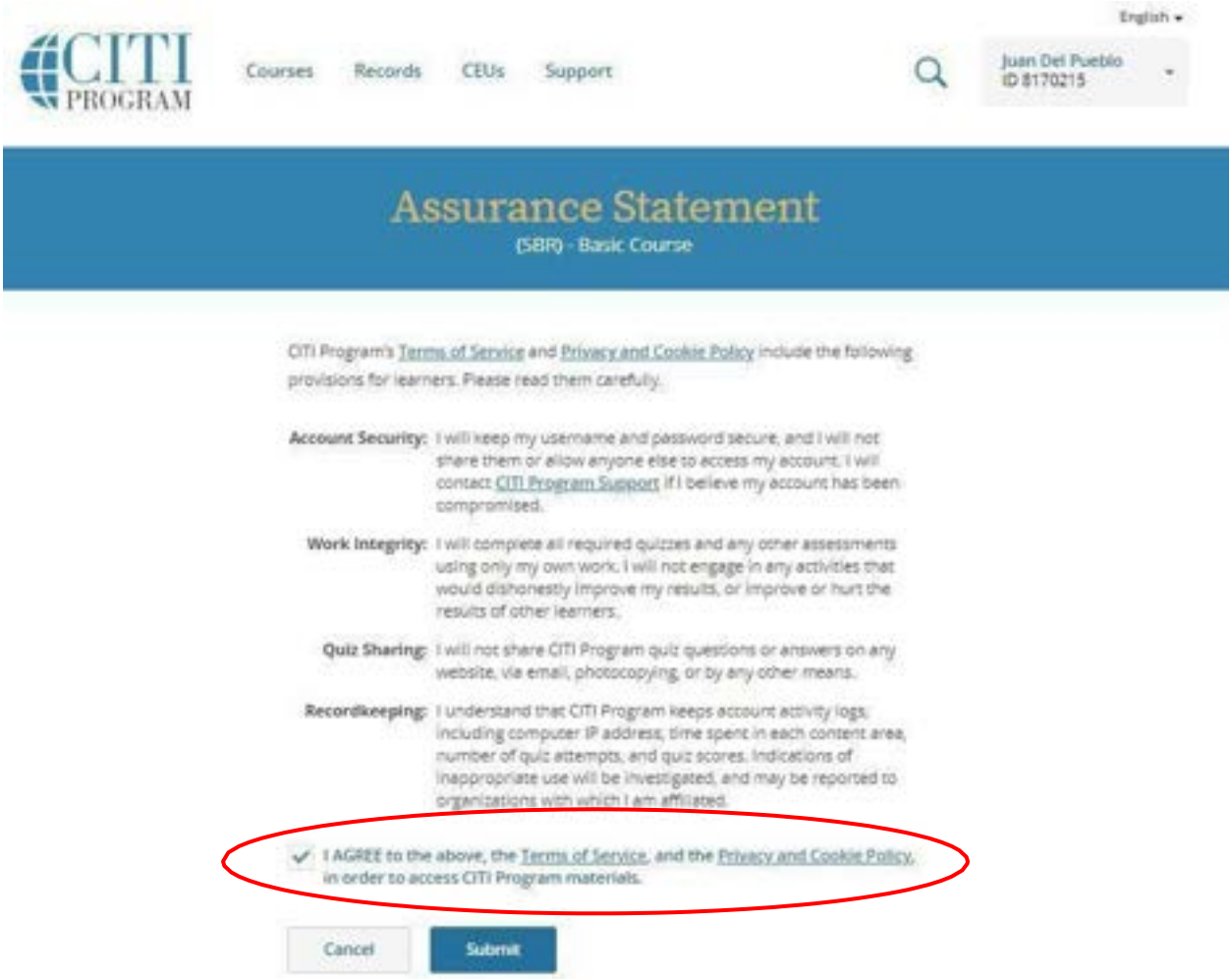
Click ***View Courses***.

11. When you click *View Courses*, the following screen will appear:



Select ***Start Now*** for the *Social and Behavioral Research* training.

12. The following screen will appear:



Please read the terms of use for the training carefully in the ***Assurance Statement*** and select the "***I AGREE"*** option.

Then click ***Submit*** to read the modules and complete the training.

Training Modules

1. Once you have completed the integrity assurance, you may begin viewing or reading and answering the modules that will appear on the screen. Each module contains readings or visual information, case studies, and a short quiz. You must complete all required modules. These must be taken in order. You may take elective or supplemental modules of your choice. The required modules are listed below.

You have unfinished required or elective modules remaining.

Required Modules

Complete all 9 required modules.

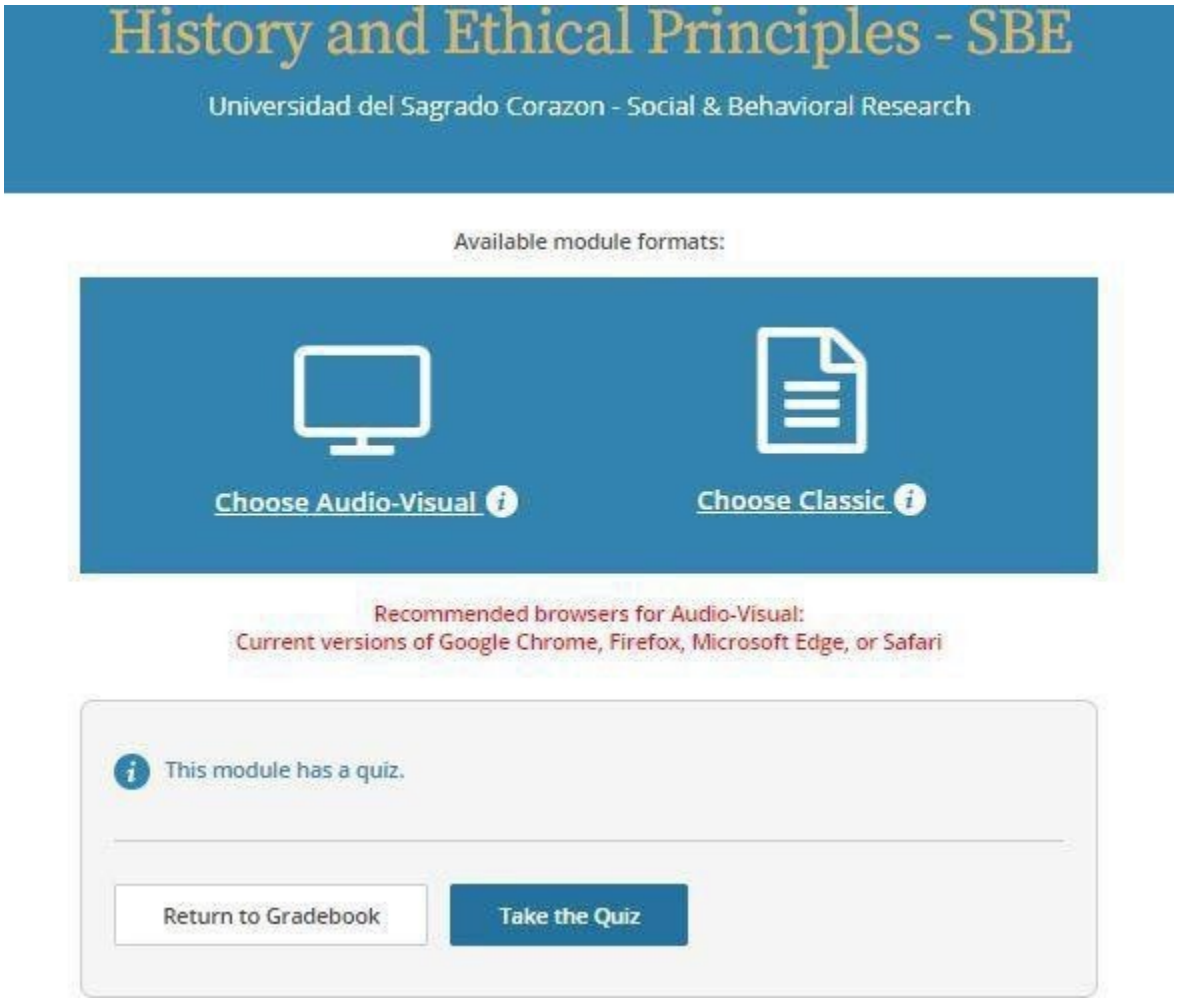
Modules	Completed	Score	
History and Ethical Principles - SBE (ID 490)	19-Aug-2020	0%	Review
Defining Research with Human Subjects - SBE (ID 491)	19-Aug-2020	20%	Review
The Federal Regulations - SBE (ID 502)	Incomplete	-	Start
Assessing Risk - SBE (ID 503)	Incomplete	-	Start
Informed Consent - SBE (ID 504)	Incomplete	-	Start
Privacy and Confidentiality - SBE (ID 505)	Incomplete	-	Start
Unanticipated Problems and Reporting Requirements in Social and Behavioral Research (ID 14928)	Incomplete	-	Start
Populations in Research Requiring Additional Considerations and/or Protections (ID 16680)	Incomplete	-	Start
Conflicts of Interest in Human Subjects Research (ID 17464)	Incomplete	-	Start

Supplemental Modules

Modules	Completed	Score

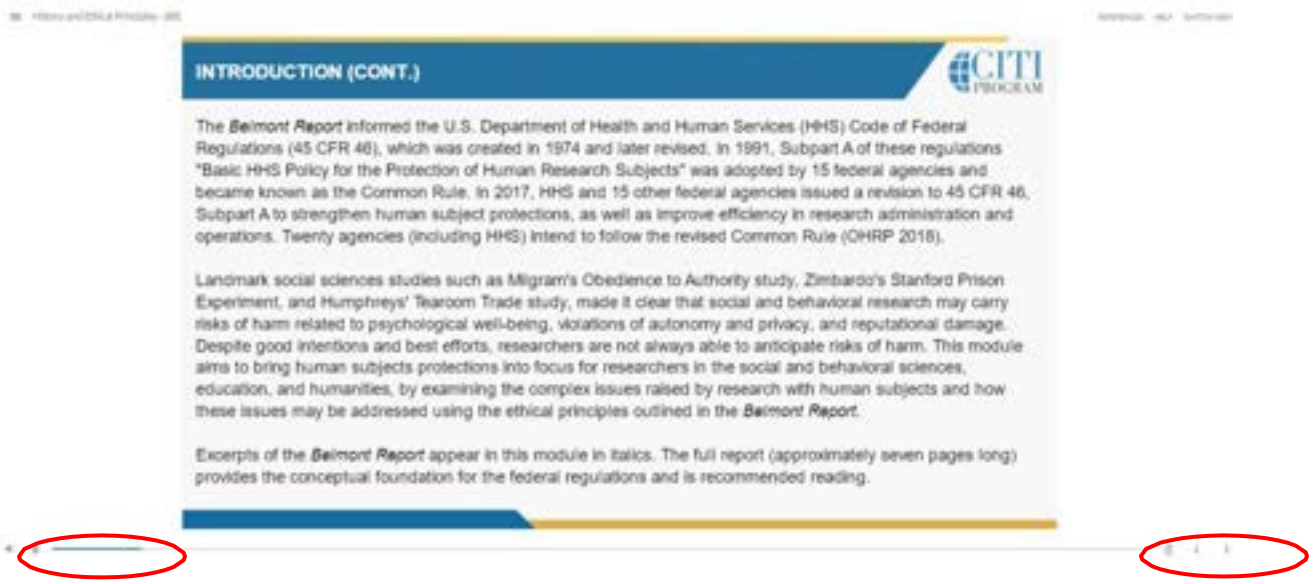
The modules will take you about 1–2 hours to complete. You must achieve a minimum score of 80% on the certification exam for it to be valid.

2. When you select the first module, the following will appear:



On this screen, you can choose to access the module in **audiovisual** or **text format**

If you select audiovisual**,** a video will appear as follows:

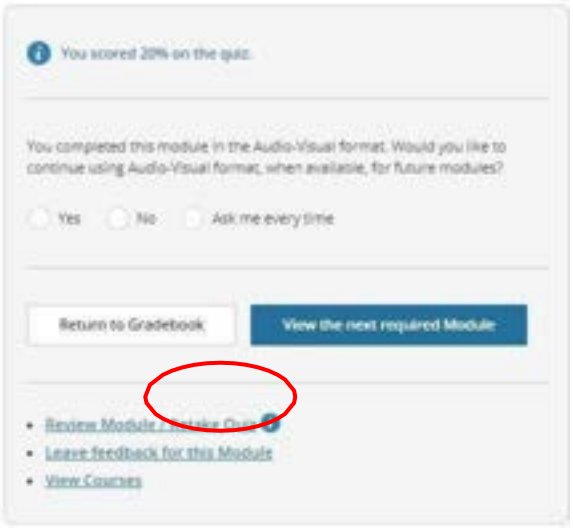


The first circle shows you how to pause the video. The second circle shows you how to continue watching the video. A summary of the module's key points is also provided. This summary is presented in both audiovisual and text formats.

3. After listening to or reading the information, select the ***"Take the quiz***" option at the bottom of the page. The short quizzes consist of approximately three (3) to five (5) questions testing your understanding of the information.

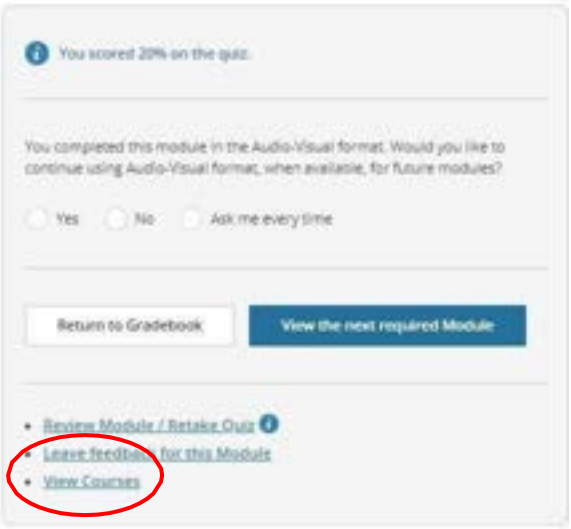
4. Once you have completed the short quiz, a screen will appear showing the correct and incorrect answers along with feedback on them.

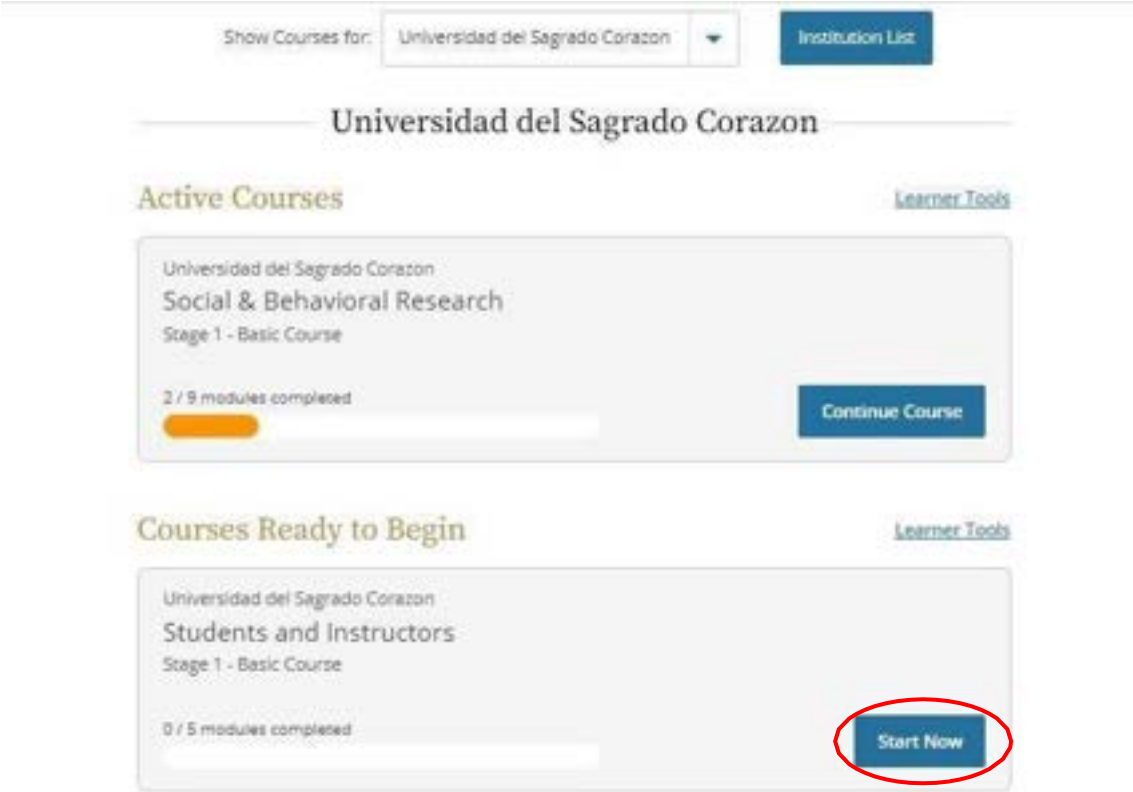
If you are not satisfied with your score on a module, you can retake it. To do so, click on the module you wish to repeat, review the information again, and select the ***"Retake the quiz"*** option**.** When you retake the *quiz,* you will be asked different questions related to the information provided in the module.



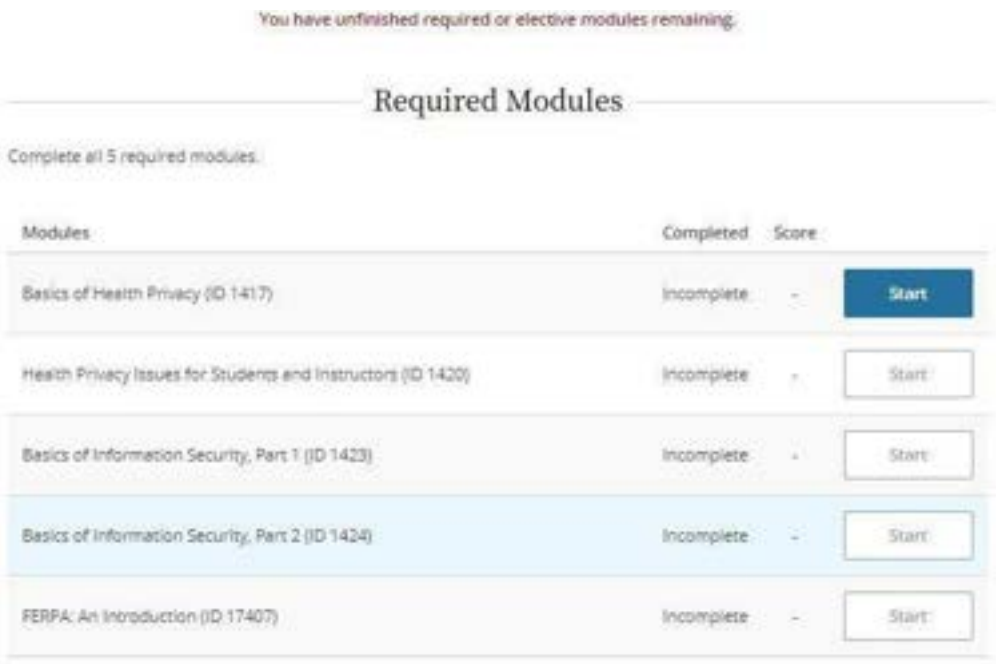
If you are satisfied with your score, you can move on to the next module.

5. After completing all the modules for the *Social and Behavioral Research or Biomedical Research* training (as applicable), click the *"View Courses"* link and select the *Information Privacy Security* (IPS) modules. This certification requires completion of five (5) modules. The modules are available only in text format and do not have an audiovisual option.





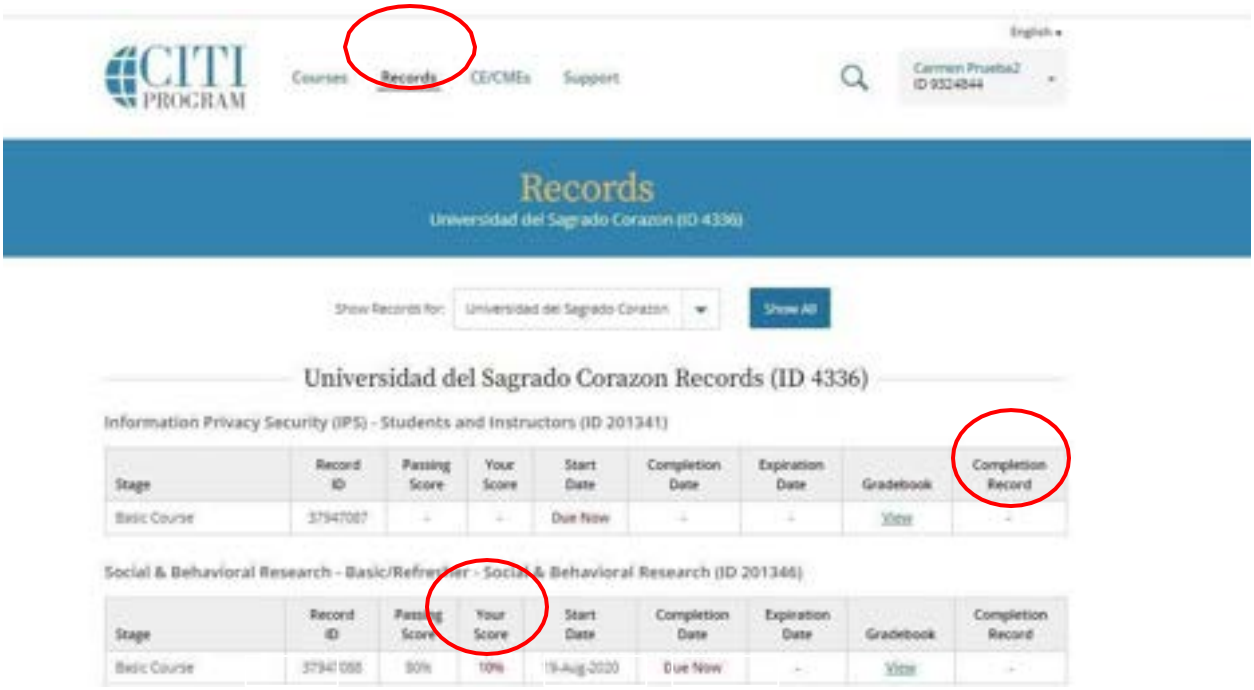
The required *Information Privacy Security* (IPS) modules are listed below.



Remember **to repeat steps 11 and 12** of this Guide before taking this training.

Certification

1. Once you have completed the *Social and Behavioral Research* and *Information Privacy Security* (IPS) training modules, go to the home page and select the ***"Records"*** option. Then, click the ***"Completion Record"*** link to obtain proof of your certification. This certification will be available in your CITI Program account.



Your certification will display your personal information, including your identification (ID) number. It will also list the modules you completed, along with the exam date and your score.

If you decide to complete all the modules of a training course to earn your certification and are not yet satisfied with your score, you can retake the modules to improve your score. However, in this case, you will have two certifications for the training course, one showing your previous scores and the other showing your most recent scores. The CITI program will calculate an average percentage (%) for the retaken training. This means that if the final result on the second attempt is 100%, the CITI program will average the results of the previous certification with the recent one. Your final result will likely not be 100%.

You can view your final score in the ***"Your Score"*** column on the ***Records*** screen. Remember that to pass the *Social Behavioral Research* and *Information Privacy Security* (IPS) certifications, you must score at least 80% on each one.

If you are a student, submit a copy of the final certificates and the scores obtained from both trainings to your professor to demonstrate your completion. If you are a faculty member or administrator, be sure to keep the certificates, as they will be required when you submit your research proposal to Sagrado's *Institutional Review Board*. **These will be valid for three (3) years starting from the date on which you pass the certification.**

Bibliography

Collaborative Institutional Training Initiative. (n.d.). https://about.citiprogram.org/en/homepage/

Collaborative Institutional Training Initiative. (February 6, 2022). *Guide to creating an account, selecting courses, and starting modules*. https://support.citiprogram.org/s/article/updated-guide-to-getting-started

Collaborative Institutional Training Initiative. (2021, June 15). *Updated Guide to Getting Started* [Video]. https://support.citiprogram.org/s/article/updated-guide-to-getting-started-video

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Universidad del Sagrado Corazón

INSTITUTIONAL REVIEW BOARD

Application for Review to Conduct Research Involving Human Subjects

I. General Information

1. Study Title:

2. Principal Investigator Information:
   a. Name: _____
   b. Institution: _____
   c. Department/School: _____
   d. Phone: _____
   e. Email: _____
   f. Status:

   ☐ Faculty
   ☐ Non-faculty staff
   ☐ Undergraduate student
   ☐ Graduate student
   Highest degree obtained:

   ☐ High school
   ☐ High school
   ☐ Master's
   ☐ Doctorate

3. Co-researchers, advisors, thesis or dissertation advisors:

Name	Role in the Study			Email	Phone
	Co-researcher	**Supervisor**	**Director**		

4. Dates of approval of training on the protection of human subjects in research (CITI Certificate) for study personnel.

Title of certificate completed	Relationship to the study	Date of completion
	Principal Investigator	

Certificates must be attached. If there are additional staff members, please include the attachment.

II. Basic Study Information:

1. Estimated duration of the study following protocol approval:
   a. Estimated start date _____
   b. Estimated completion date _____
2. Purpose of the study:

   ☐ Undergraduate
   ☐ Master's thesis
   ☐ Doctoral dissertation
   ☐ Other: _____
3. Proposed approval date: _____
4. Funding:

   ☐ No funding
   ☐ Internal
   ☐ External (Please complete the following):
   a. Sponsor: _____
   b. Date of funding request: _____
   c. Funding approval date: _____
   d. Contract number: _____

Please remember that the research application must be submitted 10 days prior to the start of the study. No study may begin conducting research without the Committee's approval letter. Projects funded by must submit a letter of approval.

5. Location where the study will be conducted:

☐ On the campus of the Universidad del Sagrado Corazón

☐ Off the Universidad del Sagrado Corazón campus (specify where): _____

☐ Outside of Puerto Rico (Please specify where): _____

a. Do you have the necessary permits in the host country? ☐ Yes ☐ No

b. Do you have an institutional partnership? ☐ Yes ☐ No

c. Please list the collaborating agency or institution: _____

☐ Online (Specify the platform): _____

Submit copies of permits and/or letters of collaboration or support from the collaborating agency or institution.

III. Study Summary

1. What is the topic of the study?

2. What is the purpose of the study?

3. What are the objectives of the study?

4. What are the research questions of the study?

5. What is the research hypothesis? (if applicable)

6. Will your study collect or analyze sensitive information?

   Yes No

   ☐ ☐ Medical history information, including mental health and abortions

   ☐ ☐ Sexual preferences, attitudes, or practices

   ☐ ☐ Use of alcohol, drugs, or other addictive substances

   ☐ ☐ Information about illegal behavior

   ☐ ☐ Information that could jeopardize participants' employment or finances

   ☐ ☐ Information that damages reputation or results in stigmatization

   ☐ ☐ Information that could lead to criminal or civil prosecution

IV. Study Methodology

1. Your study is:

   ☐ Qualitative
   ☐ Quantitative
   ☐ Mixed methods

2. Techniques for obtaining information or data (Check all that apply)

   ☐ Surveys or questionnaires:
      ☐ Self-administered
      ☐ Administered by researcher
      ☐ Online platform (Specify which): _____
   ☐ Experimental or quasi-experimental research
   ☐ Ethnography
   ☐ Case studies
   ☐ Participatory action research
   ☐ Life stories
   ☐ Clinical studies
   ☐ Program or service evaluation
   ☐ Interviews (Specify whether they will be group or individual): _____
      ☐ In-person
      ☐ By phone

☐ Virtual (Specify the platform): _____

☐ Focus group

☐ Behavioral observation

☐ Behavior in public spaces

☐ Behavior in private spaces

☐ Recording of participants

☐ Audio

☐ Video

☐ Analysis of existing records/data

☐ Public database

☐ Private database

☐ Documents without direct or indirect identifiers of individuals

☐ Documents containing direct or indirect identifiers of individuals

☐ Other, please specify _____

Please provide proof of authorization if the instrument was developed by other researchers. Submit the list of variables to which you will have and the authorization letter for access to and use of records or data.

***Submit copies of all instruments or guidelines you will use to collect data.**

3. Indicate whether your research will include any of the following procedures:

☐ Use of deceptive techniques

☐ Use of controlled substances

☐ Exercise program

☐ Physical exercise therapy

☐ Medical treatment or therapy

☐ Sample collection

☐ Blood

☐ Tissue

☐ Use of a medical device

☐ Taste test

☐ Non-invasive physical examination

☐ Workshops or training sessions

☐ Analysis of biological samples

☐ New

☐ Existing

☐ Development of potential products for commercialization

V. Description of your study sample:

1. Anticipated number of participants to be recruited:

Women or Girls	Men or Boys	Total Participants

2. Populations from which participants will be recruited:

a. **University community:**

☐ Sagrado students over the age of 21

☐ Sagrado students under 21 years of age (parental or guardian consent required)

☐ Sagrado faculty members

☐ Non-faculty employees at Sagrado

b. **General Public:**

☐ Adults capable of giving consent (21 years of age or older)

☐ Individuals under the age of 21 (require consent from a parent or guardian and the minor's own consent)

c. **Populations Considered Vulnerable:**

☐ Pregnant women

☐ Fetuses or newborns

☐ People with mental or physical disabilities

☐ Hospitalized individuals or those with terminal illnesses

☐ People in institutions:

- ☐ Incarcerated
- ☐ Detention centers
- ☐ Care facilities (children, elderly)

☐ People at their workplaces or places of employment

☐ Students of the researcher

☐ Members of economically marginalized or socially stigmatized groups

☐ Ethnic and racial minority populations

3. Justify your choice of population.

4. Explain how the study sample was determined and selected.

5. Explain the inclusion and exclusion criteria for participants.

6. Expected duration of participants in your study, including the follow-up phase, if applicable.

Phase	Time Required

7. Is there any relationship between the researchers and the participants?

☐ There is no relationship.

☐ Yes, there is a relationship between the researchers and participants.

8. Please explain the relationship and the measures you will take to prevent coercion or undue pressure:

VI. Identification and recruitment of participants:

1. Who will identify and recruit participants?

☐ Principal investigator or co-investigators

☐ Others (Please explain who and why) _____

2. Explain in detail the process for identifying and recruiting participants, including where and how informed consent/assent will be obtained.
   a. **For online research, explain how you will obtain participants' contact information and how you will ensure that informed consent is obtained.**
   b. **Research using existing records or data must indicate who will approve access to and use of the data.**

Include a copy of the recruitment materials (flyers, brochures, emails, etc.).
Include a copy of the consent form
informed.

3. Describe in detail the procedures and activities you will use to collect information or data once you have identified the participants.

4. Do the study participants have the capacity to consent?

   ☐ All participants are capable of giving consent.

   ☐ Some or all participants are not capable of giving consent (Explain):

Federal regulations allow for waivers to alter or modify the requirements of the standard informed consent form if the following criteria are met:

- The research involves minimal risk.
- The exemption does not adversely affect the rights or well-being of the participants.
- The research could not be conducted without an exemption from this requirement.
- Additional information will be provided to participants.

5. Request for exemption from the requirements of the standard informed consent form:

   ☐ No waiver is requested.

   ☐ Yes, a waiver was requested.

6. Please specify the elements of the informed consent form you wish to modify:

   ☐ Waiver of the use of the informed consent form

   ☐ Waiver of the Adult Consent Form

   ☐ Waiver of the adult consent form for research involving minors

   ☐ Waiver of signature requirement (online research)

7. Justify the request for a waiver:

8. Will incentives or compensation be offered to participants?

   ☐ No incentives or compensation will be offered.

   ☐ Yes, incentives and compensation will be offered. (Explain what they are, why they are justified, and when they will be provided to participants.)

VII. Risks and benefits of the research:

1. Classify the anticipated level of risk:

   ☐ Minimum ☐ Moderate ☐ Significant ☐ I don't know

Definition: Minimal risk refers to anticipated harm or discomfort in your research whose probability of occurrence and magnitude do not exceed those we normally face during our daily routine or during routine physical or psychological examinations.

2. Identify the types of potential risks in your study: Yes No

   ☐ ☐ Physical (health)

   ☐ ☐ Psychological

   ☐ ☐ Financial (loss of employment or income)

   ☐ ☐ Legal

   ☐ ☐ Stigmatization or social discrimination (due to loss of anonymity or privacy)

3. After classifying the risks in **question #2**, describe the potential risks or drawbacks for the participants in your study

4. Explain the measures to minimize the risks and inconveniences.

5. Do you have an agreement for medical care or to refer participants to a psychological support center?

   ☐ No

   ☐ Yes, please specify (provide evidence of this): _____

6. Identify and describe the benefits that may result from your study, as applicable.

   ☐ Direct benefits for participants. Specify:

☐ For society. Specify:

☐ For your field of research. Please specify:

7. Explain to what extent the anticipated risks and drawbacks are reasonable and acceptable in relation to the expected benefits of your research.

VIII. Privacy and Confidentiality Management:

1. Explain how the confidentiality and privacy of participants will be respected during the **recruitment process**.

2. Describe the measures that will be taken to protect participants' privacy during the **data collection** process.

Definition: Data collection is the process of systematically gathering information.

3. Where and how will the collected data be stored?

4. Who will have access, and how will access to the data be controlled, especially for digital data?

5. Will you be using photos, audio recordings, or video recordings?

   ☐ No photos, audio recordings, or video recordings will be used.

   ☐ Yes, photos and/or audio or video recordings will be used. (Describe their use and storage):

6. Will you permanently store the collected information or raw data?

   ☐ The collected information or raw data will not be retained.

   ☐ Yes, the collected information or raw data will be retained. (Justify and specify which information or raw data will be retained):

7. The minimum required retention period for the data is **3 years**. Indicate how long you will retain the data and describe the method you will use to delete it once that period has elapsed.

8. Describe the measures that will be taken to protect confidentiality during the **data analysis**.

9. Describe the measures that will be taken to protect confidentiality during the **publication**.

IX. Conflict of interest:

1. Please explain and clarify whether you have any relationship with the research sponsors, the location or agency under investigation, or the individuals under investigation that could give rise to a conflict of interest or compromise your research work.

X. Researcher's Commitment:

I, _____, in my capacity as the principal investigator of this project, certify that the protocol and methodology used to obtain informed consent, as approved by the Sagrado IRB, will be followed throughout the duration of this research. Any future modifications will be submitted to the IRB for consideration and approval prior to implementation. I understand that IRB approval does not obligate Sagrado to provide any institutional resources. I further certify that all information presented in this application is, to the best of my knowledge and based on the current status of the research, accurate.

I also agree to:

1. Notify the IRB of any changes to the protocol (including consent forms and instruments) for review and authorization.
2. Notify the IRB of the occurrence of any unanticipated problems or adverse events that affect or could affect participants or third parties.
3. Keep my supervisor informed of any changes I make to the research protocol as a result of the IRB review process. (For students only.) I certify that I have completed the educational course on the protection of human subjects in research required by the IRB, that the phase of the research involving human subjects has not yet begun, and that it will not begin until it is authorized.

_____ _____

Signature of the principal investigator **Date (day/month/year)**

XI. Additional Signatures:

I certify that as a professor, mentor, supervisor, or thesis advisor, I have reviewed and approved the information the student has submitted in this application. By my signature, I certify that I have approved the following:

☐ The student took the required ethics course.

☐ Research Questions
☐ Vulnerability of the population to be studied
☐ Methods, including instruments
☐ Risk Assessment in Research: Benefits vs. Risks
☐ Agreements with collaborating agencies/organizations on and off campus ☐ Consent form and recruitment materials

☐ Procedures to ensure confidentiality and privacy

_____

Name of the professor, supervisor, mentor, or thesis advisor

_____

Signature of the professor, supervisor, mentor, or thesis advisor

_____

Date (day/month/year)

Checklist of Required Documents	
Researchers	**Students**
☐ Application	☐ Application
☐ Informed Consent	☐ Informed Consent
☐ Informed Assent (if applicable)	☐ Informed Consent (if applicable)
☐ Certificate of Ethics (current)	☐ Certificate of Ethics (current)
☐ Instruments	☐ Instruments
☐ Recruitment Materials	☐ Recruitment Materials
☐ Letter of Collaboration (if applicable)	☐ Letter of Collaboration (if applicable)
☐ Other: _____	☐ Other: _____

Note: Researchers must attach all required documents in this section. The supervisor is responsible for reviewing the submitted documentation and completing the checklist, indicating in the corresponding boxes which documents were included in the application.