PROFESSIONAL UNIVERSITY
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PUDCJBR

INSTITUTIONAL COMMITTEE FOR THE REVIEW OF RESEARCH PROTOCOLS (CIRPI)

Professional University Dr. Carlos J. Borrero Ríos (PUDCJBR) is committed to guaranteeing maximum protection to people who participate in research as study subjects. PUDCJBR does not approve, endorse, or fund research without the appropriate review and authorization from the Institutional Committee for the Review of Research Protocol (CIRPI), also known as the institution's Institutional Review Board (IRB).

This review and authorization are mandatory when the research involves human subjects as participants or study subjects, and when it is funded by the PUDCJBR. This process applies to any professor, researcher, student, employee, or agent of the PUDCJBR, regardless of the source of funding. In addition, it applies when the participants or subjects of the study are students or employees of the PUDCJBR, or when information protected by the PUDCJBR about individuals is used.

STEPS TO FOLLOW TO REQUEST PROTOCOL REVIEW

Key research personnel must complete the necessary training, which is available free of charge on the U.S. Department of Health and Human Services website under the title Human Research Protection Foundational Training. This course consists of five lessons that must be completed, and at the end of each of them, a certificate will be awarded.

If the individual is a student and his/her project is part of a course, he/she must ensure that the proposal is approved following the procedure established by his/her professor. You will need to send the following documents to your professor:

- Initial Review Request Form
- Consent or assent forms (or equivalent documents) that include all the elements required by CIRPI.
- Instruments to be used to collect the data, such as question or interview guides, questionnaires, observation guides, lists of variables in a database, etc. If electronic forms will be used, the link and a PDF copy of the content that participants will see must be submitted.

If the project is not part of a course, the documents must be sent to the Dean of Academic Affairs and Accreditation. The documents that must be submitted are as follows:

- Initial Review Request Form

- Consent or assent forms (or substitute documents) that meet the requirements established by CIRPI.
- Instruments that will be used to collect the data, including question or interview guides, questionnaires, observation guides, lists of variables from a database, among others. If electronic forms will be used, the link and a PDF copy of the content as seen by participants must be submitted.
- Certificates from Human Research Protection Foundational Training.

PROTOCOL EVALUATION PROCEDURE

The Dean of Academic Affairs and Accreditation receives and conducts a preliminary evaluation of the documents. If the documentation or information is incomplete, the outstanding documentation or information will be requested in approximately 5 business days.

Then, the corresponding revision type is determined:

- **Administrative Review:**
  - It does not have a deadline for submission, but the CIRPI recess period should be considered.
  - The research must fall into the "exempt" research categories. However, there are investigations that qualify for administrative review but may require expedited review or review by a member of CIRPI.
  - The evaluation takes approximately 7 business days after the application is completed.
  - The research is declared exempt from further review by CIRPI.
  - The authorization does not have an expiration date, so it does not need to be renewed.
  - Even if the research is declared exempt, it must follow ethical principles and comply with applicable institutional or legal regulations.
  - The research statement exempt from CIRPI regular review is only valid for the protocol described in the application. Any changes to the protocol must be notified immediately using the protocol modification form. They will be informed whether the amendment requires further review by CIRPI.
  - Upon completion of the investigation, a notification of protocol termination should be submitted.
- **Expedited Review:**
  - It does not have a deadline for submission, but the CIRPI recess period should be considered.
  - They only qualify minimal risk research.
  - The investigation must correspond to exempt categories that require limited or expedited review.
  - They are evaluated by a member or a panel of CIRPI members.
  - The CIRPI member conducting the assessment does not have the authority to deny authorization of the protocol. If you feel that you should not authorize it, you

will refer it for consideration at the next available committee meeting. It will also refer to protocols that, due to their complexity or risks, should be evaluated by the full committee.
    - The result of the expedited review is notified in approximately 15 business days after the application is completed.
- **Review by the Full Committee:**
    - The protocol must be evaluated in a meeting with the quorum of the members of CIRPI.
    - The deadline for applications can be found on the CIRPI Calendar of Meetings.
    - The outcome of the protocol review is notified in approximately 7 business days after the date of the meeting.
    - The result of a protocol evaluation can be:

      to. Authorized with conditions. The protocol cannot begin until the conditions set by CIRPI to authorize it are met.

      b. Deferred Review. The protocol is incomplete or requires additional information. The protocol review is suspended until the required documents or information are submitted.

      c. Referred to the full committee. The reason for referring the protocol to the full committee is notified and scheduled for the next meeting.

      d. Not authorized by the full committee. The reason for not authorizing the protocol is notified. You can request a reconsideration in response to GIRPI's findings or file an appeal if you disagree, in whole or in part, with the decision.

Training

The primary mission of the PUDCJBR is to safeguard the human beings who participate as study subjects in research. Likewise, the institution is committed to promoting the training of research staff on issues related to ethics, integrity, well-being, rights and protection of the privacy of individuals.

Each research protocol submitted to the Institutional Committee for the Review of Research Protocols (CIRPI), regardless of the type of review, must be certified that key personnel involved in the research have completed Human Research Protection Foundational Training. The request for review will be considered incomplete without this evidence.

Key personnel include the principal investigator, co-investigators, student research supervisors, students, assistants, and employees involved in the research, who have direct contact with the participants or access private information that can directly or indirectly identify them. Supervisors of student research have responsibility for such research and should therefore have access to the raw data of the research.

Informed Consent

The process of obtaining informed consent is essential to protect individuals who voluntarily participate in research. It is unethical to conduct any research if people are not properly informed about what it entails to be a study subject or research participant.

Informed consent is carried out through a dialogue with the person considered as a possible participant in the research. During this process, the purpose of the research, the procedures to which the person will be exposed, the existing alternatives, the risks and possible benefits of the research are explained. It also discusses the rights of the individual, agrees on how their information or data will be handled and disclosed, and highlights that their participation is completely voluntary. It is verified that the person adequately understands all these aspects.

Typically, this process includes a document known as an "informed consent sheet," which contains all the elements required by CIRPI to communicate in a clear and understandable manner the details related to the individual's participation.

If the person agrees to participate in the research, they sign the informed consent form and receive a copy of it. This is the standard procedure for obtaining informed consent. However, if for some reason it is not feasible to follow this standard process in an investigation, waivers may be made as long as the required conditions are met and justified.

Examples of waivers in the standard informed consent process:

- Exempt the written document by an oral consent.
- Remove one or more of the elements from the standard consent form (official title of the research, signature of the participant, etc.).
- Providing partial or feigned information.
- Post-intervention consent taking.
- Obtain permission from only one parent or guardian of minors.
- Recruiting minors without the permission of their parental or legal representatives (e.g., college students).
- Some of the criteria for granting waivers:
- The research is of minimal risk.
- Research is not viable without the waiver.
- It does not infringe on the rights and safety of the participants.
- The purpose of the waiver is to protect the identity of individuals.
- Participants will receive appropriate information (e.g. the fact sheet in an electronic form).

If the person has limited autonomy or capacity for consent, as is the case with minors, the corresponding document is called an informed assent sheet. In this situation, minors or those with physical or mental limitations who are under the legal guardianship of others must give their consent to the extent that their capacity allows.

If you need the templates for the preparation of the Informed Consent Sheet, you can request them from the Dean of Academic Affairs and Accreditation.

Modifications to Authorized Protocols

All activities of an investigation must be carried out in accordance with the provisions of the protocol approved by CIRPI. Any modification to the authorized protocol, including changes to the consent or assent documents and instruments used, requires consideration and reauthorization by CIRPI.

The only exception to this rule is when a change is required to protect participants or study subjects and prevent potential harm. In such a case, CIRPI must be informed within two (2) working days after the occurrence of the event.

Protocol Termination Notification

Researchers are responsible for notifying the termination of the protocol authorized by CIRPI.

A research protocol is considered terminated when it is completed, transferred to another jurisdiction, or cancelled.

For CIRPI purposes, a protocol is considered complete when:

- The interaction or intervention with the participants and the data collection has been concluded, a primary analysis of the research has been carried out and it is concluded that it is not necessary to go back to the original source containing the identity of the subjects (people, files, raw data, list of participants, etc.) to collect more information.
- In student research projects such as theses and dissertations, the protocol is considered completed when the thesis or dissertation is approved by its corresponding committee or program of study.
- Before terminating a protocol, you also need to consider the specifications of the agencies that regulate or fund the research. These agencies may require the protocol to remain active for a longer period and have current CIRPI approval.

Researchers are responsible for using, storing, conserving, and disposing of the data, documents and materials related to the participants or subjects according to the conditions and time established in the protocol authorized by the CIRPI.