Protocol #: _____

PROFESSIONAL UNIVERSITY
DR. CARLOS J. BORRERO RÍOS
PUDCJBR

INSTITUTIONAL COMMITTEE FOR THE REVIEW OF RESEARCH PROTOCOLS (CIRPI)

APPLICATION TO CONDUCT RESEARCH WITH HUMAN PARTICIPANTS

I. OVERVIEW

I-A. Title of the research

I-B. Type of review

☐ Full Committee
☐ Expedited or Administrative Review

I-C. Principal Investigator

Name:			
Academic Program:			
Telephone:		E-mail:	
Mailing Address:			
Last academic degree obtained: (B.A., M.A., Ph.D., Ed.D., J.D., M.D., R.N., etc.):			
Indicate your status			
☐ Faculty			
☐ Non-Faculty staff			
☐ Student:		Student number:	
☐ ☐ Undergrad	☐ Doctoral		
☐ ☐ Master	☐ Other specify:		

I-D. Co-investigator or supervisor of the research

Name:			
	Co-investigator		
	Supervisor of the research		
Academic Program:			
Telephone:		E-mail:	
Mailing Address:			
Last academic degree obtained: (B.A., M.A., Ph.D., Ed.D., J.D., M.D., R.N., etc.):			
Indicate your status			
	Faculty		
	Non-Faculty staff		
	Student:	Student number:	
	Undergrad	Doctoral	
	Master	Other specify:	

I-E. Personnel assigned to the investigation and dates of approval of the training on Human research

Name	Relationship to research	Date of completion of training (month/day/year)

(If the number of people is larger, use the same box for multiple people's information.)

I-F. Relationship with a member of CIRPI

☐ No
☐ Yes, identify the CIRPI member and describe the relationship:

_____

I-G. Nature of the research

☐	Project at the undergraduate level
☐	Master's project leading to academic degree
☐	Doctoral project leading to an academic degree
☐	Postdoctoral project
☐	Project with institutional funds
☐	Project with external funds
☐	Other, specify:

I-H. Research Funding

☐ Not applicable; No funds in addition to personal funds.

☐ Project with institutional or external funds, specify the source of the funds:

_____

I-I. Estimated duration of the project

I-I (1) Estimated dates for data collection (from initial contact with potential participants to completion of data collection):

From: ☐ Immediately upon approval of the CIRPI

☐ Another date, please specify:

____ ____ ____ ____

Month Day Year

Until: ____ ____ ____

Month Day Year

I-I (2) Estimated date for completion of the research (first report including results or presentation of your project):

____ ____ ____

Month Day Year

II. RESEARCH OVERVIEW AND METHODOLOGY

II-A. Research Overview (500 words or less)

II-B. Methods or techniques for obtaining or collecting the information or data

- ☐ Face-to-face activities
- ☐ Remote Activities
- ☐ Audio Recording
- ☐ Video Recording
- ☐ Photographs
- ☐ Electronic questionnaire
- ☐ Face-to-face questionnaire
- ☐ Face-to-face one-on-one interview
- ☐ Remote one-on-one interview
- ☐ Group interview, focus group, or face-to-face discussion
- ☐ Group interview, focus group, or remote discussion
- ☐ Public Conduct Observation
- ☐ Non-Public Conduct Observation
- ☐ Evaluation of teaching methods
- ☐ Workshops or trainings
- ☐ Evaluation of a program or
- ☐ Psychological therapy or intervention
- ☐ Taste Testing
- ☐ Physical therapy
- ☐ Medical treatment or therapy
- ☐ Blood sampling
- ☐ Analysis of existing biological samples
- ☐ Tissue sampling
- ☐ Existing individual-level data (not aggregated data) about individuals without direct or indirect identifiers. Include a description of the data and, if applicable, include the list of variables you will have access to.
- ☐ Existing data about individuals with direct or indirect identifiers. Include a description of the data and, if applicable, include the list of variables you will have access to and the Data Use Agreement.
- ☐ Other; Specify:

	service
	Non-invasive physical test or measurement
	Cognitive or perceptual experiment

II-C. Genetic analysis of biological samples

	It does not apply, will not use biological samples or specimens, nor will it do genetic analysis.
	Yes, they will perform genetic analysis. Explain the purpose or use and whether people will receive reports of the analysis. _____

II-D. Research Procedures or Activities

III. RESEARCH OVERVIEW AND METHODOLOGY

III-A. Population groups

	Adults and competent to consent (21 years of age or older**)**
	Vulnerable or special populations:
	Under 21 years of age, please specify the ages:
	Persons with physical or mental limitations under the guardianship of a legal representative
	Pregnant women, fetuses, or neonates
	Persons deprived of liberty or in the custody of a correctional institution or in a diversion program

	Patients of hospitals or outpatient clinics	
	Status in PUDCJBR:	
	Students	
	Faculty	
	Non-Faculty staff	
	Other groups, please specify:	_____

III-B. Inclusion or exclusion criteria

☐ Check whether it will include people regardless of their sex or gender.

Description of inclusion or exclusion criteria:

III-C. Expected number of participants

Expected total attendees:	
Subgroup 1 [Nurse. Anesth.]	
Subgroup 2 [*Description*]	
Subgroup 3 [*Description*]	
Subgroup 4 [*Description*]	
Subgroup 5 [*Description*]	

IV. RECRUITMENT

IV-A. Identification, contact and recruitment of participants.

IV-B. Incentives

☐ It will not give incentives.
☐ It will give incentives,
Specify:

_____

IV-C. Compensation for Recruiting Participants

☐ It will not compensate for reluctant participants.
☐ If it will be worth recruiting participants, explain:

_____

IV-D. Relationship with potential participants

☐ There is no relationship between key research personnel and potential participants.
☐ Yes, there is a relationship. Explain:

_____

IV-E. Relationship with the institution where the research will be carried out

☐ There is and was no relationship between the key research staff and the institution.
☐ Yes, there is or was a relationship. Explain:

_____

V. LOCATIONS WHERE THE RESEARCH WILL BE CONDUCTED

V-A. Places where the research will be carried out and its stages

Place	Stage of the investigation

VI. RISKS AND BENEFITS OF RESEARCH

VI-A. Risks of research

VI-B. Measures to minimize risks

VI-C. Direct benefits for participants

☐ No
☐ Yes, explain:

_____

VI-D. Expected Benefits or Returns from Research

VI-E. Follow-up of participants:

☐ No
☐ Yes, explain:

_____

VII. PRIVACY, CONFIDENTIALITY AND HANDLING OF DATA

VII-A. Use of Photos and Audio or Video Recordings

☐ It does not apply, it will not use photos, or audio or video recordings.

☐ Yes, you will use photos or audio or video recordings. Explain its purpose and use.

_____

VII-B. Dissemination of results

VII-C. Other Measures for Managing Privacy and Confidentiality

VII-D. Use, storage of documents, materials, and data

- **Documents, materials, or data:**

Responsible person or custodian:

⇨ **Document, material or data** ⇨ **With/without identifiers**	**Type: Printed (paper), digital, biological, ect.**	⇨ **Will be shared** ⇨ **Will not be shared with others in addition to key research personnel**	**The following will be shared:** ⇨ **With identifiers** ⇨ **Without identifiers**
If necessary, please provide any other related details:			

- **Documents, materials or data that you Will keep <u>permanently</u>**

Responsible person or custodian:

⇨ **Document, material or data** ⇨ **With/without identifiers**	**Type: Printed (paper), digital, biological, ect.**	⇨ **Will be shared** ⇨ **Will not be shared with others in addition to key research personnel**	**The following will be shared:** ⇨ **With identifiers** ⇨ **Without identifiers**

If necessary, please provide any other related details:

VIII. INFORMED CONSENT PROCESS

VIII-A. Capacity of Adults to Consent

☐ Not applicable, all adults are qualified to consent.

☐ Some or all adults have a limited capacity for consent and require the consent of their legal representative. Explain:

_____

VIII-B. Information you will offer to explain the protocol.

VIII-C. Understanding Information

VIII-D. Time and place to obtain Informed Consent

VIII-E. Person who will take Informed Consent

VIII-F. Consent or Informed Assent Forms

Quantity:

Consent or assent forms	Phase or stage of the research or target population

IX. REQUEST FOR WAIVER IN STANDARD INFORMED CONSENT

- ☐ No (Skip to section X.)
- ☐ Yes

IX-A. Items you want to delete or modify

IX-B. Justification for the waiver

a. Need for Dispensation

b. Waiver of signature on consent or assent form

c. Restriction of Information

d. URL:

X. SIGNATURES AND CERTIFICATIONS

X-A. Signature of supervisor of the research project

I hereby confirm that this research project has been approved and I have thoroughly reviewed as well as the information provided in this application and its annexes. In the same way, I attest to the academic merit of this study and the capacity of the researcher to carry out such research.

I am committed to monitoring any modifications that are made to the protocol because of the review process carried out by CIRPI. Likewise, I am responsible for ensuring that the researcher complies with the protocol authorized by CIRPI and that he or she does not make changes to the research without due authorization.

It is my sole responsibility to report any conflicts of interest or adverse incidents involving study participants. In addition, I will make sure to always keep the protocol authorization in place.

I remain available for any diligence related to this research and to provide the necessary support in the development of the project.

Name	Date
Signature	

X-C. Principal Investigator Certification and Signature

I certify that the information presented herein is complete and accurate. As the principal investigator, I take responsibility for safeguarding the rights and well-being of the individuals participating in this research, as well as ensuring the integrity and ethical performance of the study.

I agree to abide by the regulations and policies of the Professional University Dr. Carlos J. Borrero Ríos and the institutions where I will conduct the selection of participants and research, as well as applicable state and federal laws.

I also commit to:

- Inform CIRPI of any modifications to the protocol, including consent sheets, instruments, etc., for review and authorization.
- Obtain legal informed consent from each participant, when required.
- Report any unanticipated issues or adverse incidents that affect or may affect participants or third parties.
- Report any potential financial or non-financial conflicts of interest prior to or during the conduct of the investigation.
- Inform my research supervisor about changes made to the protocol because of the CIRPI review process. (This measure applies only to students.)
- If necessary, request the renewal of the CIRPI authorization.
- Notify Protocol Termination.

I confirm that I have completed the training required by CIRPI on research involving human subjects, and that the phase of research involving human involvement has not yet begun, nor will it begin until the protocol is duly authorized.

Signature	Date