INTER AMERICAN UNIVERSITY OF PUERTO RICO
INSTITUTIONAL REVIEW BOARD (IRB)
APPLICATION FOR PROTOCOL REVIEW
IAUPR-IRB FORM REV 01/2019

Research Study Title:	
If protocol is a sponsored Project:	Name of Sponsor or Agency: Grant or Contract Number:

Principal Investigator:

Name:

Postal Address:

Telephone:

Email:

Institution: Campus:

Department:

If Student, Degree and Program of Study: ___ Doctoral ___ Master's ____ Bachelor's ____ Other

Program:

Co-Principal Investigator:

Name:

Postal Address:

Telephone:

Email:

Institution: Campus:

Department:

If Student, Degree and Program of Study: ___ Doctoral ____ Master's ____ Bachelor's

Program:

Student Faculty Research Advisor:

Name:

Postal Address:

Telephone:

Email:

Institution: Campus:

Department:

PI and Co PI Assurance:

I/We certify that the information provided in this application is complete and correct. **I/We** understand that as Principal Investigator and Co- Principal Investigator, are responsible for the conduct and ethical performance of this project, the protection of the rights and welfare of human subjects, and strict adherence to any stipulations imposed by the IAUPR Institutional Review Board.

I/We agree to comply with all policies and to:

- ***accept responsibility for the scientific and ethical conduct of this research study;***
- ***obtain prior approval from the Institutional Review Board before amending or altering the research methodology or implementing changes in the approved consent form;***
- ***immediately report to the Institutional Review Board any serious adverse reaction and/or unanticipated effects on subjects which may occur as a result of this study;***
- ***obtain a legally effective Informed Consent form from human subjects or their legally responsible representative, and using only the currently approved, stamped, consent form;***
- ***complete, on request by the Institutional Review Board, the Continuation/Final Review Forms***

Principal Investigator (printed name)	Signature	Date
Co-Principal Investigator (printed name)	Signature	Date

Student Faculty Research Advisor Assurance:

I certify that I have reviewed this research protocol and **that I attest to the scientific merit** of this study and the competency of the investigator(s) to conduct the project.

Faculty Name (Typed/printed)	Signature	Date

Department Chair Assurance*:

I certify that I have reviewed this research protocol and **that I attest to the scientific merit of this study** and the competency of the investigator(s) to conduct the project.

Chairperson Name (Typed/printed)	Signature	Date

**applicable to protocols presented by PI's and Co-PI's of sponsored research projects and independent researchers. If the PI or Co-PI is also the chair of the Department the Dean or Supervisor must sign this assurance.*

Research Protocol Information:

Research procedures Time period[1]:	Start Date:	End Date:

Research Methodology: *Select all that apply*

Methodology	
____Quantitative Design ____Qualitative Design ____ Survey/questionnaire designed by researcher(1) ____Survey/questionnaire (standardized or developed by another researcher (2) ____Interviews ____Behavior observation(3) ____Testing or validation of instruments or procedures (2) ____Individual observation or group behavior or characteristics (3) 1. ***Provide evidence of the process for developing and validating the instrument.*** 2. ***Provide evidence of authorization to use the existing research instruments, data, samples, translation of instrument or materials.*** 3. ***Provide evidence of authorization or collaboration from organizations if research activities are not done in public settings. DEPR process documents should be presented for research in school settings.***	____Experimental or cuasi-experimental research ____ Action research (3) ____Evaluation of persons, groups or organizations (3) ____Observation of exercise or other physical activities done for research purposes in laboratory or natural settings (3) ____Potential development of commercial product from research instrument or research data/findings ____ Clinical studies (3) ____ Internet research or research using social media ____ Records with Identifiers (student records, medical records) ____ Other

What are your **research objectives or research questions**?:

[1] Dates should be after IRB approval.

What are your **research hypothesis or expected research findings** or contributions?:

Research Population:

Number of Participants for: ____ Pilot Study ____ Formal Research
Age Range: ____ Experimental Group ____ Control Group
Sex: ___ M ___ F

Please select all that apply:

Who are the Participants?	
____ IAUPR students or employees*	____ Elderly
____ DEPR students, parents or teachers*	____ Pregnant women
____ Prisoners**	____ Victims of violence (domestic, sexual abuse, war or other violent scenarios)
____ Mentally impaired or institutionalized*	____ Low income or marginalized populations
____ Emergency or hospitalized patients*	____ Culturally or ethnical populations (specific ethnic groups)*
____ Employees in their workplace (teachers, salesmen, administrative staff, etc.)	_____ Other (provide details)
____ Minors (less than 21 years)	
***Use of private information in patient's records must comply with HIPAA and use of student's records information must comply with FERPA.**	
** Needs to be reviewed with the Prisoner's Advocate during a Full Board Meeting	

From the sample selected **who** will be the **primary participants** and who will be the **secondary participants**?

Explain in detail the inclusion and exclusion criteria?

Data and Research Materials	
____ Use of private information *	____ Controlled substance (2)
____ Use of private data/records* (2)	____ Study of diagnostic specimens(2)
____ Use of information in data repository (2)	____ Study of pathological specimens (2)
____ Personal identifying links to data	____ Study of bodily materials from living individual or fetus(2)
____ Culturally or socially sensitive issues	____ Genetic notification
____ Study of existing documents (2)	____ Materials or tissues obtained specifically for this project/study (3)
____ Audio visual/tape recordings or photographs	____ Micro-organisms or recombinant DNA (2)
____ Deception	____ Genetic research/analysis (2)
____ Pilot study (1)	____ Human tissue analysis (2)
____ Copy of Screenshots or links to social media or internet documents	____ HIV/Aids, Hepatitis/TB/STD
____ ON LINE data gathering (survey monkey, google docs, blackboard)	____ Venipuncture (<450cc)
***Use of private information in patient's records must comply with HIPAA and use of student's records information must comply with FERPA.**	____ Exposure to radiation or carcinogenic or pathological substances
**** Needs to be reviewed with the Prisoner's Advocate during a Full Board Meeting**	____ Human in vitro fertilization
***** FDA applies to clinical trials or studies**	____ Investigational drugs, devices or materials
	____ Tools or devices developed specifically for this study
	____ Potential development of commercial products from human biological material or from tools and devices

1. ***Provide evidence of the process for developing and validating the instrument.***
2. ***Provide evidence of authorization to use the existing research instruments, data, samples or materials.***
3. ***Provide evidence of authorization or collaboration from organizations if research activities are not done in public settings. DEPR process documents should be presented for research in school settings.***

Research Site:

Where will the research take place?

Will the research take place at the researcher's workplace? ____ yes ____ no
(Explain and provide evidence that the researcher has been granted access to the research site)

Participant Identification, Recruitment and Contact:

Explain in detail who will identify, recruit and contact possible participants?

Detail **how** the participants will be identified, contacted and recruited (include copy of advertisements, flyers, social media marketing material to be used):

Explain **how will confidentiality and privacy** of participants be handled?

Documentation of Informed Consent/Assent Process:

Who will consent the participants?

Describe **the activities** that will be carried out to consent/assent participants:

Will the researcher adopt a waiver (dispensa de firma) of documentation of signed consent/assent process?
____ Yes (please explain) ___ No

Provide detailed description about how will confidentiality and privacy will be protected:

How will the researcher **eliminate undue influence and coercion** to assure that participant's rights are protected?

Risk and Benefits:

Describe potential risk associated with the research:

___ Minimal ___ Moderate ___ High

Select all that apply regarding the following:

____ Physical risks (health) ___ Psychological risks ____ Economical risk ____ Social risk ____ Legal risk

Provide explanation regarding your selection of type of risk:

What steps will the researcher take to minimize or eliminate completely risks associated with the research procedures?

What are the potential benefits to participants?

Will there **be any compensation** to participants?

Conflict of Interest:

Describe the **researcher relationship** with the research site, the research site staff, and research sponsor if any:

Adverse Events:

Explain **how** will adverse events will be handled?; Include information of **who** will assist the researcher.

Describe immediate intervention procedures to be used and the referral process if applicable:

Data Management Plan:

Type of data:

____ Video ____ Audio recordings _____Digital Data ____ Informed consent/assent documents

____ Other

How will data be managed to assure protection of privacy and confidentiality during the research process?

How will it be stored? (provide storage period); How will it be destroyed?

Digital Data: **Where** will it be stored?, **How** will it be protected?