



University of Puerto Rico  
Mayagüez Campus  
Dean of Academic Affairs  
Institutional Review Board

**Human Subject Research Approval Form  
New Project**

#Protocolo: \_\_\_\_\_

- Externo  
 Modificación

**Title of project**

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**I. Main researcher information**

Name:	
Institution:	
Faculty:	Department:
Status: <input type="checkbox"/> Faculty <input type="checkbox"/> Student (Please indicate your academic level)	
<input type="checkbox"/> Undergraduate <input type="checkbox"/> Master's <input type="checkbox"/> Doctoral	
Phone:	E-mail:

**Co-researchers**

Names	E-mail	Phone

**Student Advisor**

Name	E-mail	Phone

**Approval date of online training on the ethics of human subject research by personnel affiliated with the investigation (NIH or CITI course)**

Name	Relationship to researcher	Completed course	Date the course was completed
	Main researcher		

## II. Basic project information

Duration of project <sup>1</sup>	Estimated dates Beginning: _____ End: _____	
Purpose of the investigation	<input type="checkbox"/> Undergraduate <input type="checkbox"/> Master's Thesis <input type="checkbox"/> Doctoral Dissertation <input type="checkbox"/> Postdoctoral Project <input type="checkbox"/> Other _____ Date proposal was approved: _____	
Funds	<input type="checkbox"/> Institutional Sponsor:  <input type="checkbox"/> No funds	<input type="checkbox"/> External <sup>2</sup> Agency/Industry: Submission date: Approval date: Contract number:

## III. Place where the investigation will take place

<input type="checkbox"/> On Campus
<input type="checkbox"/> Off Campus <sup>3</sup> (Specify location): _____
<input type="checkbox"/> Outside of Puerto Rico (Specify location): _____ Do you have the necessary permits to visit and investigate in the host country? <sup>4</sup> <input type="checkbox"/> Yes <input type="checkbox"/> No
<b>Collaborating Agency or Institution</b> <sup>5</sup>
<input type="checkbox"/> Letter of support
<input type="checkbox"/> Letter of support
<input type="checkbox"/> Letter of support

## IV. Description of the Investigative Project

1. What is the theme and purpose of the study?

<sup>1</sup> The investigation request must be handed in no less than 10 days before the start of the investigation. No investigation will be allowed to begin without a Committee approval letter.

<sup>2</sup> Projects with external funding must submit an approval letter

<sup>3</sup> Research performed in the public education system requires an approval letter from the Department of Education

<sup>4</sup> Please submit the permits for approval

<sup>5</sup> Please submit letters of support

2. What are the objectives and/or research questions? Include a hypothesis if applicable.

Will your research gather or analyze sensitive information?

Yes No

- Medical history Information, including mental health and abortion
- Sexual preferences, attitudes, or practices
- Drug, alcohol, or controlled substance abuse
- Information regarding illegal conduct
- Information that endangers a participant's employment or finances
- Information that stigmatizes or damages a participant's reputation
- Information that could result in civil or criminal charges/processing against a participant

3. How would you prefer the letter?

- In Spanish     In English     E-mail     Postal mail

## V. Methodology

### 1. Your study is

- Qualitative     Quantitative     Mixed methods

### 2. Methods or techniques for gathering data and information (check all that apply)<sup>6</sup>:

- |   |  |
|---|--|
| <input type="checkbox"/> Surveys or questionnaires <sup>7</sup> | <input type="checkbox"/> Recording participants                        |
| <input type="checkbox"/> Self-administered                      | <input type="checkbox"/> Video   |
| <input type="checkbox"/> Completed by the researcher            | <input type="checkbox"/> Audio   |
| <input type="checkbox"/> By e-mail                              | <input type="checkbox"/> Experimental/quasi-experimental investigation |
| <input type="checkbox"/> Web page/platform                      | <input type="checkbox"/> Ethnography                                   |
| <input type="checkbox"/> Postal mail                            | <input type="checkbox"/> Case study                                    |
| <input type="checkbox"/> Interviews                             | <input type="checkbox"/> Active research                               |
| <input type="checkbox"/> In person                              | <input type="checkbox"/> Life history                                  |
| <input type="checkbox"/> Telephone                              | <input type="checkbox"/> Clinical history                              |
| <input type="checkbox"/> Group or focus groups                  | <input type="checkbox"/> Program or service evaluation                 |
| <input type="checkbox"/> Observation of individual or group     | <input type="checkbox"/> File/existing data analysis <sup>8</sup>      |

<sup>6</sup> Submit a copy of all instruments or methods you will utilize to collect data.

<sup>7</sup> Provide evidence of authorization if the instrument was developed by another researcher

<sup>8</sup> Submit a list of variables to which you will have access

- behavior
  - In public spaces
  - In private spaces
  - Others
- Public database
- Private database<sup>9</sup>
- Documents without direct or indirect identifiers

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

- Use of misleading/deceitful techniques
- Use of controlled substances
- Exercise programs/physical therapy
- Therapy or medical treatment
- Samples of:
  - Blood
  - Tissue
- Non-invasive testing
- Biological sample analysis
  - New<sup>10</sup>
  - Existing
- Use of medical device
- Taste test
- Workshops or training
- Development of products with a possibility of commercialization

**4. Provide a detailed description of data gathering procedures and activities:**

**5. Indicate whether participants will be afforded an insurance policy and what preventative measures have been planned in case of accident and/or complication**

<sup>9</sup> Submit an authorization letter of access and use of files and data

<sup>10</sup> Committee's authorization is required prior to gathering the samples

**during the study.**

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**VI. Describe your study's sample population**

1. Anticipated total of participants to be recruited:

Women/children    Men/children    Total

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Populations from which participants will be recruited

*University community*

- UPRM students -- underage students (under 21 years old) need consent from parents or legal guardians
- UPRM Faculty
- UPRM employees

*General community*

- Competent adults who can provide consent (over 21 years old)
- Underage students (under 21 years old) need consent from parents or legal guardians  
     Studies with children 10 years old or older: you must obtain the minor's consent)

*Populations that are considered vulnerable*

- Pregnant women
- Fetuses or newborns
- People with mental or physical disability
- People who are hospitalized or have terminal illness
- Institutionalized peoples
  - In jail/prison     Detention centers     Care centers (children, elderly)
- People in their workplace
- Researcher's student(s)
- Members of socially stigmatized or economically marginalized groups

2. Justify your selection of the sample population for your study. Explain participant inclusion and exclusion criterion.

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3. Anticipated duration of participant(s) in your study, including a follow-up period if applicable:

## VII. Identification and recruitment of participants

1. Who will identify and recruit participants?

- Main researcher or co-researcher(s)  
 Others (Identify who and why)

2. Provide a detailed description of participant identification and recruitment process, including the place and manner through which the informed consent will be collected.

- Any investigation performed online must justify how it will gather participant contact information and how it will obtain informed consent.
- Investigations with existing data and files must indicate who will authorize their access and use.

**\*Include a copy of your recruitment materials (flyers, brochures, e-mail, etc).**

**\*Include a copy of the informed consent form**

**Federal regulations allow researchers to alter or modify the standard format for informed consent format if the following criteria are met:**

- **The investigation is low-risk**
- **The exemption will not adversely affect the rights or well being of the participant(s)**
- **The investigation cannot be performed without this exemption**
- **Additional information will be offered to participant(s)**

3. Request to forgo requirements for standard format of informed consent:

- No  
 Yes, I request an exemption

Indicate the informed consent criteria that you are interested in modifying:

- Forgo use of informed consent form  
 Forgo the use of assent form  
 Forgo use of adult consent for research with minors form  
 Forgo collection of signature (online investigation).

Justify your request for exemption

4. Explain how the participant's privacy and confidentiality will be protected during the recruitment process.

5. Is there any existing relation between the researcher and the participant(s)?

- No
- Yes, there is a relationship between both parties

Explain the relationship and the measures that will taken in order to avoid coercion or wrongful influence

6. Will participants receive any incentives or compensation?

- No
- Yes (Please explain what they will be, their justification, and when they will be given to the participant(s))

**VIII. Benefits and risks of the investigation**

1. Classify the level of anticipated risk:

Definition: Minimal risk refers to any anticipated damage or discomfort in your study whose probability of occurrence and magnitude does not exceed that which humans normally confront during their daily routines or physical and/or psychological evaluations.

- Minimum
- Moderate
- Significant
- Unknown

2. Indicate the type(s) of potential risk(s) found in your study by marking yes or no below.

Yes No

- Physical (health)
- Psychological
- Economical (loss of employment or salary)
- Legal
- Stigmatization or social discrimination (loss of privacy or anonymity)

1. Describe the potential risks or inconveniences of your participant(s) in your investigation:

2. Describe how you plan to minimize these potential risks or inconveniences:

3. Research benefits:

- a. Directly to participants
- b. To society
- c. To the field of research

4. Explain in what way the anticipated risks and/or inconveniences are reasonable and acceptable in relation to the expected benefits of your investigation

**IX. Privacy and confidentiality oversight**

1. Describe the measures that will be taken in order to protect the privacy of all participants during the data gathering process:



2. Describe the measures that will be taken in order to protect the confidentiality of the consent forms and data during its storage, analysis, and disclosure (presentations or publications).
- Where and how will data be stored?
  - Who will have access to and how will access to data be controlled, especially for digital data?
  - Will the data be destroyed or stored in a permanent file?

#### **X. Conflict of Interest**

Explain and clarify if you have a relationship with any of the study's sponsors, the place or agency to be investigated, or the people to be investigated that might cause a conflict of interest or compromise your research.

#### **XI. Researcher's Commitment:**

I, \_\_\_\_\_, in my role of main researcher of this project, certify that the approved protocol and methods used for obtaining informed consent will be followed during the development period of this investigation. Any future modification will be submitted to IRB for consideration and approval before its application. I understand that this IRB approval does not commit the University to provide any resources. I also certify that all information presented in this form is, to my best understanding, true.

In turn, I also agree to:

1. Notify the IRB of any modification to the study's protocol. Include informed consent forms and instruments for their revision and authorization.
2. Report any event regarding unanticipated issues or adverse incidents that might/have harmed any of the participants or third parties.
3. Keep the thesis/dissertation/investigation's counselor, director, or supervisor informed of any changes made to the project's protocol as a result of the IRB's revision process (only valid for students.)

I also certify that I have completed the educational course on human subject research as required by the IRB, that the research on human subjects has not yet begun, and that it will not begin until it is properly authorized.

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Main researcher's signature

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Month/ Day / Year

## XII. Additional Signatures

As the thesis director, I **certify** that I have revised and approved the information listed here and that the student has submitted in this form. By signing, I am certifying that I have approved the following:

- The student passed the corresponding course
- The project's questions
- Methods, including data collection instruments
- Agreements with agencies/organizations inside and outside of campus fuera del Recinto
- Consent form and recruitment materials
- Procedures to ensure the confidentiality and privacy of the participant(s)

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Profesor or counselor's name (if the researcher is a student)

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Profesor or counselor's signature

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Date (Month / Day / Year)

## Checklist

### Necessary documents to request an IRB revision

1. It is required to hand in all listed documents
2. Any request submitted electronically must include all of the documents listed below as well as the corresponding signatures

<input type="checkbox"/>	Request for Revision to Investigation with Human Beings
<input type="checkbox"/>	Researcher's Signature
<input type="checkbox"/>	Ethics Certificate- Researcher and co-researchers must have this
<input type="checkbox"/>	Informed Consent Form for participants
<input type="checkbox"/>	Informed assent form for minors (under 21)
<input type="checkbox"/>	Data collection instrument(s) (i.e. questionnaires, interview guides)
<input type="checkbox"/>	If your instrument(s) is/are not your property, you must submit the owner's authorization for the use of the instrument(s)
<input type="checkbox"/>	Support letter from agency/company where the investigation will take place
<input type="checkbox"/>	Recruitment materials (brochures, flyers)
<input type="checkbox"/>	Approval Letter from the agency funding research
<input type="checkbox"/>	Letter from the Department of Education according to Circular Letter Num.13-2014-2015 (if applicable)
<input type="checkbox"/>	Approval letter (if applicable)