TEMPLATE

INFORMED CONSENT FORM[1]

Stage or phase of the study[2]

Research Title

Description

I invite you (You are invited) to participate in a research study about (briefly describe the research). This research is done by (name, status at UPR-RP or other institution). The purpose of this research is (describe the purpose of the research).

You are invited (selected or identified)[3] to participate in this research because (explain the eligibility criteria[4]). I expect approximately (amount) volunteers to participate in this research study.

If you agree to participate in this research study, (explain the procedures or what the participation will consist of).[5] Participating in this research study will take you approximately (indicate estimated time)[6]. [7]

(If applicable) The (interview, focus group, intervention, etc.) will be recorded with (indicate the tool) with the purpose of (specify the use to be made of the recording, e.g., transcription).

Risks and Benefits

The risks (or discomforts) associated with this research study are (describe the foreseeable risks, any discomfort or possible cost to the participant).[8, 9] (Explain the measures you will take to deal with or minimize them[10.]) This research study does not have direct benefits to the participants[11].

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[1] Draft the document in a language that is **simple and understandable** for any potential participant. This template is based on a generic standard consent-taking process. The contents must be adapted according to the particularities of the research. Verify that the document contains the required elements and use the Elements of a Standard Consent Form guide. You must also corroborate that it contains the required elements for research by remote means (see the guides for remote interviews or forms). If the document will not bear signatures, title it "**Information Sheet**" instead of "Informed Consent Form".

[2] If you will use multiple consent or assent documents, **distinguish each sheet** as best described (stage, phase, procedure, population, etc.) For phased or complex processes, split he information into separate paragraphs or subsections.

[3] If you directly identify, contact or select individuals because you have access to their contact information, indicate how you obtained or who provided the information. You do not have to explain if the person self-refers through an open call to a general population. Also, clarify whether the person was selected by random or probability sampling, if applicable.

[4] Ensure that the **selection criteria** are consistent with what is stated in the protocol, the invitation, the consent form, and the instrument you will use to collect the information.

[5] If applicable, include how people will be assigned to groups (e.g., experimental or control).

[6] If applicable, identify the **approximate time** it will take for the person to participate in each phase, session, procedure or activity.

[7] If applicable, notify **where** the study will take place.

[8] Keep in mind that participating in a research study entails at least minimal risk or discomfort; **avoid stating that there are no risks**.

[9] Internet-based research: (1) State if the person is required to download any application or program and whether it entails any cost; or whether the person may use their preferred means of communication. (2) State that there may be additional fees for the consumption of mobile data or internet connection. (3) Notify of the possible inconvenience of learning to use the tool, as well as the possibility of exhaustion from using the tool. If applicable, discuss with your potential participants whether they prefer to segment the interview into one or two one-hour slots or any other time frame you want to set.

Confidentiality[12]

Your identity will be protected (explain how and in the dissemination of the results).

Information or data that could directly or indirectly identify you will be handled confidentially. Raw data or data with identifiers will be accessible to or handled by (include the name[13] or their position[14]). Officials from the Río Piedras Campus of the

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[10] If the risks or discomforts are related to the susceptibility of the information, express that it will be handled with confidentiality; which you will detail in the next section. If the person receives any service or benefit that they understand or perceive may be affected by their decision to accept or decline to participate, clearly state that if they do not agree to participate, decide to withdraw from the study, or refuse to answer questions (as applicable), the services or benefits they receive will not be affected.

[11] If applicable, replace with a description of the direct benefits to participants. Avoid stating a benefit as a fact; express it as an expected benefit. Note that incentives or compensation for expenses are not benefits derived from the research. If you will provide incentives or compensation, state so elsewhere; they are not research benefits.

[12] If the purpose is to **disclose the identity** of the individuals, title the section "**Disclosure of Information**" instead of "Confidentiality". In this case, distinguish the identifiable information that will be publicly disclosed (names, images, audio, etc.) from that which will be handled confidentially (if any).
Confidentiality: Detail the measures you will take to handle confidentiality. Take into consideration that these may vary depending on the phase of the study such as recruitment, data collection and analysis, and publishing of results. Distinguish confidential from anonymous. **Confidential** means that the identity of the person is known due to interacting with them or because they share information with the agreement that their identity will not be disclosed. **Anonymous** means that it is not possible to identify the person, whether directly or indirectly. Avoid the mistake of implying that participation is anonymous if what you mean to express is that the results or data will be disclosed anonymously. If the identity of the person will be disclosed directly or indirectly, explain the conditions under which it will be published. When applicable, caution that although the person's name will not be published, they may be **indirectly identified** by the position they hold or by other characteristics which are unique to them or shared by very few people. If the information will be shared between participants (e.g., in **focus groups**), indicate that you cannot guarantee that the information shared in the group will not be disclosed by the participants. Encourage your participants to keep information confidential and not to record the session. If you will obtain information through the **internet**, include the following waning: *"The information you share electronically on the device (computer, cellphone or other) or platform you use may be tapped or reviewed by third parties. These individuals may have legitimate or illegitimate access to the device and its content; like a family member, employer, hackers or intruders, etc. In addition, the device you use may keep track of the information you access or send electronically."* If you need to collect the e-mail address, IP address (Internet Protocol address) or any other identifiable or geolocation information of the device from which the information was sent, state so and explain its purpose or use.
Limitations of confidentiality: If, due to the population or subject matter, information that must be notified by law or ethics may arise, state that confidentiality is limited by law or as long as there is no danger to the person participating in the research or to third parties.

[13] If the investigator is a student, include the name of the research, thesis or dissertation supervisor among those who will have access to raw research data.

University of Puerto Rico or federal agencies responsible for ensuring research integrity may require the investigator to provide the data obtained in this study, including this document.

The research documents, materials or data will be stored (explain storage conditions). The collected (documents, materials or data that will be kept for a fixed period) will be kept for (amount of time) years after the research is concluded. (Digital data will be deleted and printed documents will be shredded before disposal.) The (documents, materials or data that will be kept indefinitely) will be kept permanently for use in other research. They will also be shared with other researchers. (Explain the conditions for sharing the data in terms of whether it will be shared with or without identifiers or shared under a confidentiality agreement.)

Incentives (Only include if applicable.)

You will receive (amount or other non-monetary incentive) as an incentive for your participation[15].

Rights

If you read this document and decided to participate, please understand that your participation is completely voluntary and that you have the right to abstain from participating or to withdraw from the study at any moment, without any penalty.[16] You also have the right to refuse to answer any particular question. You are also entitled to a copy of this document[17].

If you have any questions or want more information about this research study, please contact (name of principal investigator) at (phone number and institutional email address[18])[19, 20].

If you have questions about your rights as a participant or a claim or complaint related to your participation in this research study, please contact the Compliance Officer of the Río Piedras Campus of the University of Puerto Rico at 787-764-0000, extension 86773 or cipshi.degi@upr.edu.

Your signature on this document means that you decided to participate in this research after reading and discussing[21] the information presented on this consent form[22] and that you received a copy of this document.[23]

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[14] If multiple people will have access and are yet to be identified or may change, mention them as "co-investigators", "research staff or team", "research assistants", etc.
[15] Explain the conditions for granting the incentive and when it will be disbursed.
[16] Remote interviews: When explaining the voluntary nature of participation, instruct on how to terminate participation or log out of the platform upon finishing the interview.
[17] If consent is obtained online, add a note exhorting participants to save or print the consent document.
[18] Use your institutional email address (@upr.edu).
[19] If you are a student, add your supervisor's name and contact information (phone number and institutional email [@upr.edu]).
[20] If applicable, include "In case of an emergency contact (name and contact information)." This only applies to research with emergency risks such as medical or psychological.
[21] Substitute the information if consent is not taken in person.
[22] If applicable, include a clause certifying that the person is of legal age—21 years or older—and that they have the legal capacity to consent.

Name of participant	Signature	Date

I discussed the contents of this consent form with the person signing above.[24]

Name of principal investigator or representative	Signature	Date

[23] If you offer multiple options for participation (e.g., interview with or without recording) or for the use of the data (e.g., identify or not identify the individual), itemize them in boxes before the participant's signature to check their authorization alternative.
[24] Adapt the content or remove if the consent process is not carried out in person.