Elements of a Standard Consent Form

☐ 1. Official title of the research.

☐ 2. A description of the research, which must include:

- ☐ a. Invitation to participate in the study.
- ☐ b. Statement indicating that this is a research.
- ☐ c. Name of the principal investigator and their status at UPR-RP or other institution.
- ☐ d. An explanation of the purpose of the research.
- ☐ e. An explanation of why and how the person was selected.
- ☐ f. Expected number of participants.
- ☐ g. The approximate duration of the subject's participation.

☐ 3. A description of the procedures to which the participant will be exposed. If applicable, distinguish procedures that are experimental from those that might be the norm in another setting (e.g., routine treatment and care or accepted practice in the discipline). Explain the use of research methods such as random assignment to experimental and control groups and the use of placebos.

☐ 4. A description of any foreseeable risk or discomfort to the participant.

☐ 5. A description of the measures that will be taken in order to prevent or minimize the risks or discomforts.

☐ 6. A description of any benefit to the participant or to others, which may reasonably be expected from the research. If the research does not have direct benefits for the participant, state as such.

☐ 7. If applicable, information on any appropriate alternative procedures or courses of treatment that might be beneficial to the participant.

☐ 8. A description of the extent to which the information obtained, data or files will be kept confidential.

☐ 9. In the section on confidentiality:

- Indicate who will have access to the raw data or data that can directly or indirectly identify the participating persons. In **student research**, include your research supervisor among those who may have access to this data. Also, include the following clause: *Officials from the Río Piedras Campus of the 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.*
- Summarize the plan for the use, storage (time and security) and, as applicable, management of documents, materials and data.

As applicable:

- Include a statement that confidentiality is limited by law or as long as there is no danger to the participating person or third parties.
- If the information to be collected 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.
- In internet-based research, add the following warning: *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.*

☐ 10. For research that poses a greater than minimal risk, an explanation and description of any compensation or any medical treatment available if individuals are injured or harmed during their participation, including where they can get more information and who to contact in the event of a research-related injury. (Adapt to non-medical and non-physical risk situations.)

☐ 11. A mention of who to contact for answers to questions about the research. This includes the name, phone number, and institutional email address (@upr.edu) of the principal investigator.

- In **student research**, include the name, phone number, and email address of your supervisor.

☐ *12.* Mention of who to contact for information about the rights of participants or in case of complaint. All consent documents must include the following statement: *If you have questions about your rights as a participant or a claim or complaint related to your participation in this 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.*

☐ 13. Mention of who to contact in case of an emergency or harm related to the study (for research that applies).

☐ 14. Statement that participation is voluntary and that refusing to participate or the decision to withdraw from the research at any time does not represent any penalty or loss of benefits to which the person is entitled.

☐ 15. Statement that the participant has the right to receive a copy of the informed consent document.

If consent is obtained online, add a note exhorting participants to save or print the consent document.

☐ 16. Statement indicating that the person is making the decision to participate and that their signature means they have done so after having read and discussed the information presented. 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.

☐ 17. Names and signatures of both the participating person and the investigator or the person taking the informed consent. (To be signed at the time of consent).

☐ 18. Date of when informed consent is obtained.

☐ 19. Other appropriate and required elements according to the type of research.

☐ 20. Additional elements according to federal regulations. When appropriate, the participant must be informed of and the consent form must contain one or more of the following elements:

- ☐ a. A statement that a particular treatment or procedure may involve risks to the participating person (or to the embryo or fetus, if the person is or may become pregnant) not anticipated at the time consent is sought.
- ☐ b. The anticipated circumstances under which the researcher may terminate the person's participation without the need to seek their consent.
- ☐ c. Any additional cost to the individual that may result from their participation in the research.
- ☐ d. Consequences for the individual if they choose to withdraw from the research study and procedures for terminating their participation correctly.
- ☐ e. Statement that the person will be informed of new discoveries that occurred during the course of the study and that may influence the person's decision to continue with their participation.
- ☐ f. The approximate number of participants included in the study.

Formatting Guidelines for Standard Informed Consent Forms	
Writing	Information should be presented in a clear, simple and concise way that could be understood by anyone with the research participant's characteristics. For the general adult population, write at an eight-grade level. It must not contain exculpatory language or that could be interpreted as yielding of rights. Therefore, it should not be written in first person (me) from the participant's perspective. Preferably, use the second person (you). The first person may be used if it is from the perspective of the investigator (e.g., "I will ask you to participate in a focus group").
Official Stamping	On the first page, use the official stamp of the school, department, center, or office to which you are affiliated as a researcher. The UPRRP official stamps contain the unit's contact information and an equal opportunity clause. (Disregard this if you will use an information sheet in an electronic questionnaire format.)
Margins	At least ¾ of an inch on each side for easy reading.
Font Type and Size	Use a font type and size that facilitates reading. Recommended fonts are Times New Roman or Arial, among others. The font size should be at least 11 or 12. Also, consider the particularities of the reader. For example, children and people with visual impairments need a larger font size (e.g., 13 or 14).
Form Identification	If you will use multiple consent or assent forms, differentiate and identify them with a subtitle according to whom they are addressed or by the activity or the corresponding stage of the study.
Version Date	Include a footer on the first page with the document version date. Update the date each time you amend the document.
Page Numbering	Include a numbering identifying the total number of pages in sequence X of Y pages (e.g., "Page 1 of 3" and "Page 2 of 3").
Paper Size	Letter (8 ½" x 11")
Youth Assent Form	If the content of the consent form is comprehensible to a minor (approximately 13 years or older) and has all the elements required by CIPSHI, a single document may be used for taking both the consent of their fathers, mothers, or legal tutors and the assent. In this case, include the fields and meanings for the corresponding consent and assent signatures. Examples:

	Consent: Your signature in this document means you authorize your child to participate in this research study after reading and discussing the information presented in this document and that you received a copy of this document. **Assent:** Your signature in this document means that you decided to participate in this research study after reading and discussing the information presented in this document and that you received a copy of this document.
Elements of Child Assent Forms	Include only the following information in simple, age-sensitive sentences: • The purpose of the study. • The procedure or what their participation will consist of. • The possible discomforts or inconveniences. • Confidentiality in terms of whether or not they will be publicly identified. Avoid words, such as "secret", that may pose a dilemma for the child. • The voluntary nature of their participation and a statement that the minor can choose not to answer questions, stop participating in a certain activity, or withdraw at any time, as applicable. Also, explain, depending on the context, that refusing to participate will not affect the benefits or services the participant is receiving. • A sentence explaining the meaning of their signature (accepting to participate). Avoid using images with expressions that indicate joy or anger related to acceptance or denial. • Field to sign or mark assent.