University of Puerto Rico • Medical Sciences Campus
Human Research Subjects Protection Office (HRSPO)

INFORMED CONSENT FORM (ICF)
UPR MSC TEMPLATE
English Version

The following is an example of a consent form. All language is sample language, except those sections that are identified as required institutional language. Please, refer to document "*Informed Consent Form Reference Information"* (http://irbrcm.rcm.upr.edu/) for detailed information about the federal regulations requirements in the consent process and the specifications in the Informed Consent Form (ICF). In that document of reference, you will find the following information:

1) A description of the Institutional Policy concerning the ICF
2) A description of Federal Regulations requirements:
    a) General requirements for Informed Consent
        i) Key Information
    b) Basic Elements of Informed Consent
    c) Additional Elements of Informed Consent
    d) Elements of BROAD CONSENT for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens
    e) Posting of clinical trial consent form
    f) Documentation of Informed Consent
3) Additional Information that should be considered and include in the ICF (IF APPLICABLE)
    a) Research Involving Minors as Subjects (under 21 years old)
    b) Research Involving Prisoners as Subjects
    c) Research Involving Genetics Procedures
    d) Research that apply to issue a Certificate of Confidentiality (CoC)

Some important remarks to consider when working with the ICF Template:

1. Carefully review the comments included in some of the ICF sections.
2. Remove *italics* that do not apply and insert study specific information in place of the italics.
3. UPR MSC IRB requires the use of this format and structure for the ICF. In the event that this format cannot be adapted to your study, a justification is required.
4. Always use the same font type and size throughout the form. Do not use a very small font size. We recommend the use of Arial 11 or Times New Roman 12.
5. Language must be at eighth (8^{th}) grade student reading and comprehension level.
6. Header in all pages should include the following information:
    a. Page number (Format "Page # of #")
    b. Version (date or version number)
    c. Study Title (abbreviated) or Official Protocol Number
7. The bottom page margin should be 2 inches to allow for the placement of the **IRB STAMP.**
    a. Electronic system requires the document to be save in WORD 97-2003 with extension ".doc" to STAMP.

UNIVERSITY OF PUERTO RICO
MEDICAL SCIENCES CAMPUS
SCHOOL OF [*Specify the School to which the Principal Investigator (PI) belongs or that endorses the study***]**
DEPARTMENT OF [*Specify the Department to which the PI belongs or that endorses the study***]**

INFORMED CONSENT FORM TO PARTICIPATE IN RESEARCH STUDY AND AUTHORIZATION FOR USE AND DISCLOSURE OF HEALTH INFORMATION

[*Indicate the group to be addressed (i.e. Parents, Control Group, etc.). If no identifiable health information will be collected, delete the header "AUTHORIZATION FOR USE AND DISCLOSURE OF HEALTH INFORMATION".***]**

TITLE: [*The study title must match on all the submitted documents (IRBWise application, protocol, consent, documents). If the ICF is in Spanish, the title must be in Spanish.***]**

PROTOCOL NUMBER: [*If applicable, add the study identification number assigned by the sponsor. If there is no sponsor, include the official number of the Protocol assigned by the IRB (do not use the number beginning with "H" because this is a temporary number).***]**

INVESTIGATOR: [*Include names, degrees and institutional affiliation of the PI and Co-PIs.***]**

SPONSOR: [*Include this line, if applicable.***]**

SITE(S): [*Identify the site(s) where the study will be conducted. Include any collaborating site(s). Always include the full name of the institution (UPR-RCM) and then add the other sites where study processes will be conducted, if applicable.***]**

STUDY-RELATED PHONE NUMBER(S): [*If there is more than one number, include name of the person(s) to contact. Include a 24-hour phone number, if applicable***]**

If your study involves children as subjects (under 21 years old), include the following wording: "Throughout this consent "you/your" will be used to refer to either you or your child". Include the text of the assent and the signature lines at the end of this ICF if there are minors between 15 and 20 years of age. Otherwise delete this text and the signature lines at the end of this document. In addition to the parents' consent form, a separate assent form is required for children 7-14 years of age.

This consent form may contain words that you do not understand. Please ask the study investigator or the study staff to explain any words or information that you do not clearly understand. You may take home an unsigned copy of this consent form to think about or discuss with your doctor, family or friends before making your decision.

I. INTRODUCTION AND KEY INFORMATION

You have been invited to participate in a research study. This study is being conducted *[include a brief statement foreshadowing the purpose for the research].* When you are invited to participate, you have the right to be informed about the study procedures so that you can decide whether you want to consent to participate. Before you agree to take part in this study, please read this consent form carefully and ask as many questions as you need to in order to be sure you understand the study procedures, including risks and benefits.

Your participation is voluntary. You do not have to be in the study if you do not want to. You may refuse to be in the study and nothing will happen. If you do not want to continue to be in the study, you may stop at any time without penalty or loss of benefits to which you are otherwise entitled.

If your research is federally funded *informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or Legal Authorized Representative (LAR) in understanding the reasons why one might or might not want to participate in the research*.

Elements that should be included as part of the Key Information are:

1. *The purposes of the research (briefly), expected duration of the prospective subject's participation, and procedures to be followed in the research.*
2. *The reasonably foreseeable risks or discomforts to the prospective subject.*
3. *The benefits to the prospective subject or others that may reasonably be expected from the research.*
4. *Appropriate alternative procedures or courses of treatment, if any that might be advantageous to the prospective subject.*

II. PURPOSE OF THE STUDY

State in lay terms what the study is designed to examine, assess, or establish.

Briefly identify the criteria to participate in the study.

If the study involves an investigational drug or device, include this statement: "An [*INVESTIGATIONAL DRUG/DEVICE*] is one that is not approved by the U.S. Food and Drug Administration (FDA)".

III. STUDY PARTICIPANTS

Briefly describe the total number of participants. If this is a multi-site study, include the total number over all sites as well as the number at the MSC. For example, "300 subjects are expected to participate, 25 at the UPR Medical Sciences Campus and 275 at other sites around the United States". If the study includes different subject pools, note that also. For example: "100 total subjects (25 subjects with Alzheimer's disease and 75 healthy subjects)".

Briefly describe the criteria (such as age, gender, language spoken, etc.) that define who will be included or excluded in your study sample. Indicate specifically whether you will include or exclude any special populations: You may not include members of these populations as participants in your research unless you indicate this in your inclusion criteria. Include the expected duration of the subject's participation.

IV. PROCEDURES

Describe the procedures chronologically using simple language, short sentences, and short paragraphs. If there are several procedures or if they are complex, the use of subheadings may help organize this section and increase readability. The use of a summary table or flowchart may help.

Define and explain scientific or discipline-specific terms. Use language appropriate to the population.

If applicable, specify how the subjects will be assigned to the study groups.

Specify length of time for participation in each procedure or study activity, the total length of time for participation, frequency of procedures and location of the procedures to be done.

If prospective subjects will be recorded (audiotaped, videotaped, photos), describe the procedures to be used. If this action is optional, you must provide the alternatives for the subject to indicate whether or not to authorize being recorded / photographed.

Describe in lay terms the experimental/investigational procedures. Standard medical procedures must be clearly distinguished from the experimental procedures.

If there are optional procedures, please describe them in a separate section and provide space for participants' initials (if authorized or if not authorized). For example, some studies could take additional samples (i.e. blood, tissue, etc.) for storage or future studies related to the subject of the study, and ask participant's authorization to be contacted to invite them for futures studies.

[*For double-blind randomized trials, include the following language*:]
You will be "randomized" into one of the study groups described below. Randomization means that you are put into a group by chance. It is like flipping a coin. Which group you are put in is done by computer. Neither you nor the investigator or study staff will choose what group you will be in. You will have a(n) (*equal/one in three/etc.*) chance of being placed in any one group. The groups are: (*explain in one or two sentences what the groups are*).

Note: When study is single-blind, modify the wording of the above paragraph as appropriate.

V. RISKS AND DISCOMFORTS

List the reasonably foreseeable risks, discomforts, hazards, or inconveniences related the subject's participation in the research. Describe the probability, magnitude, duration, and reversibility of the risks.

Consider physical, psychological, social, legal, and economic risks as well as community or group harms.

Include information regarding risks of study drug, devices or procedures. Include the possible known side effects and if applicable include that there may be side effects which are unknown at this time.

Please note that "none" or "not applicable" are not considered appropriate for this section, because even studies involving minimal risks have foreseeable risks, such as discomfort or inconvenience.

If conducting a study with drugs, include the following sentences if applicable:
Your [*disease, condition, symptoms*] may not get better or may become worse while you are in this study. Only you can take the study drug. It must be kept out of the reach of children and persons who may not be able to read or understand the label.

This is a required MSC pregnancy language for drug studies. Other pregnancy language supplied by the sponsor might be used subject to IRB approval:

If you become pregnant during this study, there may be other risks to you and your unborn child that are not known. If you are female and able to become pregnant, you must use two (2) contraceptive methods throughout the study and for at least 4 weeks after you stop taking the study medication. One of the methods should be an acceptable barrier method (diaphragm with spermicidal jelly, condoms, etc.). No sexual intercourse is an acceptable method of birth control; if you become pregnant during the course of the study, you must stop taking your study medication immediately, and contact your study doctor.

If applicable, include an explanation of how to minimize the foreseeable risks and discomforts. You can refer to a ***Crisis Management Plan*** *suggested by the IRB in the following web page: (http://irbrcm.rcm.upr.edu/docs/Crisis-Management-Plan.pdf).*

VI. BENEFITS

Note: *Participation in the research itself and payment or other compensation from participating in the research are not benefits and should not to be discussed in this section.*

*It is suggested you begin this section with the following sentence: "*You may not receive any personal benefits from being in this study".

Your [*disease, condition or symptoms*] may improve as a result of your participation in this study. However, there is no guarantee of this.

*State the potential benefits, if any, to science or society expected from the research: "*The information from this research study may lead to a better treatment in the future for people with [*disease, condition, or symptoms*]".

VII. COSTS

Specify if study drug(s) will be provided by the sponsor. (If applicable)

Specify if the participant or the insurance will be billed for any cost related to the study. (If applicable)

Specify who will be responsible if the insurance doesn't pay. (If applicable)

*If there will be no charges, include this sentence: "*There are no charges or costs for you for your participation in this study".

VIII. COMPENSATION FOR PARTICIPATION

Include the amounts and conditions of payment. Investigators are advised that payments to prospective subjects should be prorated, and the amount earned to date should be paid even when subjects withdraw from the study prematurely.

You will receive a stipend of $____ for each completed study visit to cover [*transportation and meals expenses*]. If you do not complete the study, you will be paid for the visits you have completed.

If there is no payment or stipend, include this sentence: "You will not receive any stipend for taking part in this study".

IX. ALTERNATIVE TO PARTICIPATE

Describe any appropriate alternative therapeutic, diagnostic, or preventive procedures that should be considered before the prospective subject decides whether or not to participate in the study. If there are no efficacious alternatives, state that an alternative is not to participate in the study.

If you decide not to enter this study, there are other treatments available. These include *[List of major drugs and/or therapies]*. The study doctor will discuss these with you. You do not have to be in this study to be treated for *[disease, condition, symptoms]*.

If there is not an alternative option, add that an alternative is to not be in this research study: "You also have the option of not participating in this study, and will not be penalized for your decision".

X. PRIVACY AND CONFIDENTIALITY

This section corresponds to the Authorization to Use or Disclose (Release) Health Information that Identifies the participant for a Research Study.

This is required institutional language for studies that involve protected health information, and is subject to HIPAA.

Provide a description of who will be the custodian of the research data, where the data will be saved and for how long.

Otherwise this paragraph may be modified; researchers can edit the information in this section as applicable to the study.

Information in the bulleted section should be added or deleted as applicable to the study.

If you choose to be in this study, the investigator and the study staff will get personal information about you. This may include information that might identify you such as (*specify identifiers, such as name, address, birth date, phone number, email, etc.*). The investigator may also get information about your health including:

[*Select the ones that apply to your study*]

- Past and present medical records
- Research records about study visits
- Records about phone calls made as part of this research
- Information obtained during this research about:
  - Transmitted diseases such as HIV / AIDS, Hepatitis infection or other sexually transmitted diseases
  - Other reportable infectious diseases
  - Physical exams
  - Laboratory, x-ray, and other test results

- Diaries, questionnaires and other instruments
- The diagnosis and treatment of a mental health condition

• Records about any study drug you received
• Records about the study device

This information about you and your health that may identify you may be disclosed to others as part of this research study. *Select the ones that apply to your study or add others.*

These include:

- The U.S. Food and Drug Administration (FDA)
- Department of Health and Human Services (DHHS) agencies
- Governmental agencies to whom certain diseases (reportable diseases) must be reported

Information about you and your health that might identify you may be given to others to carry out the research study. It may also be given to governmental agencies in other countries. The sponsor will analyze and evaluate the results of the study. In addition, people from the sponsor and its consultants will be visiting the research site. They will follow how the study is done, and they will be reviewing your information for this purpose. The records will be safeguarded as Health Insurance Portability and Accountability Act (HIPAA) regulations.

Your information may be disclosed to the above-mentioned agencies so that the sponsor can receive approval for the marketing of new products resulting from this investigation. The information may also be used to meet the reporting requirements of governmental agencies. The results of this research may be published in scientific journals or presented at medical and professional meetings, but your identity will not be disclosed.

The information may be reviewed by the University of Puerto Rico, Medical Sciences Campus Institutional Review Board (UPR MSC IRB). UPR MSC IRB is a group of people who perform independent reviews of research as required by regulations.

Your personal health information will be kept as confidential as possible under the law. However, your personal health information may no longer be protected by the privacy rule once it is disclosed to our associates, and may be shared with others.

This Authorization does not have an expiration date [*or as appropriate, insert expiration date or event, such as "end of the research study"*]. You may cancel this authorization at any time by sending a written notice to the principal investigator at the following address:

[*Principal Investigator's name*]
[*Mailing Address – Not residential or physical address*]

If you cancel this authorization, the principal investigator will no longer use or disclose your personal health information under the authorization for this study, unless he/she needs to use or disclose some of your personal health information to preserve the scientific integrity of the study. Information submitted before you cancel this authorization can still be used by the associates.

The Authorization for Use and Disclosure of Protected Health Information for research purposes is completely voluntary. However, if you do not sign this document you will not be able to participate in this study. If in the future you cancel this authorization, you will not be able to continue participating in this study.

POSTING OF CLINICAL TRIAL (*If applicable*)

Refer to document "Informed Consent Form Reference Information" (http://irbrcm.rcm.upr.edu/) for detailed information about this section.

Wording that must be included in the informed consent document of each clinical trial conducted or supported by a Federal department or agency: A description of this clinical trial will be available on http://www.ClinicalTrials.gov , as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

The website could include the IRB-approved informed consent used to enroll subjects in the study.

COLLECTION OF IDENTIFIABLE PRIVATE INFORMATION OR IDENTIFIABLE BIOSPECIMENS (*If applicable*)

If the research study involves the collection of identifiable private information or identifiable biospecimens, one of the following statements should be included:

> *(i) A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the LAR, if this might be a possibility; or*
>
> *(ii) A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.*

RESEARCH INVOLVING GENETICS PROCEDURES TRIAL (*If applicable*)

Refer to document "Informed Consent Form Reference Information" (http://irbrcm.rcm.upr.edu/) for detailed information about this section.

Suggested sample language regarding the protections provided under Genetic Information Nondiscrimination Act 2008 (GINA) that investigators could consider including in the informed consent documents for such research:

Your personal data derived from the results of the genetic tests conducted in this study are protected by the provisions of Title II of the Genetic Information Nondiscrimination Act (GINA). This new federal law, GINA will generally protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research.

- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Be aware that this new Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

RESEARCH THAT IS ISSUED A CERTIFICATE OF CONFIDENTIALITY (CoC) (*If applicable*)

Refer to document "Informed Consent Form Reference Information" (http://irbrcm.rcm.upr.edu/) for detailed information about this section.

Suggested Consent Language Describing the CoC Protections:

If you choose to participate in this study, the researcher will obtain information about you and your health. To help protect your privacy, we have obtained a National Institutes of Health (NIH) Certificate of Confidentiality. Investigators may use this certificate to legally refuse to disclose information that may identify you in a federal, state, local civil, criminal, administrative, legislative, or other proceeding, for example a subpoena of the court. Researchers may use the certificate to withstand any demand for information that may identify you, except as explained below.

Use the following language as applicable: The certificate cannot be used to withstand a request for information from US federal or state government personnel who are sponsoring the project, or for information that must be disclosed to comply with the requirements of the Food and Drug Administration (FDA).

You should understand that the Certificate of Confidentiality does not prevent you from voluntarily disclosing information about yourself or your participation in this study. If an insurer, health care provider, or other person obtains written consent from you to receive information about the investigation, then the investigators may not use the certificate to deny providing information.

The Certificate of Confidentiality may not be used to prevent investigators from providing information to local or state authorities about child abuse or neglect and harm to yourself or others.

XI. COMPENSATION FOR INJURY

This is required institutional language. Determine which paragraph is applicable and do not include both.

If the UPR Medical Sciences Campus is responsible for compensation in case of injury, include this paragraph:

In the event of physical and/or mental injury resulting from this research study, you will receive medical treatment free of charge at the University Hospital/Pediatric Hospital/UPR Hospital Dr. Federico Trilla (*select the applicable hospital or hospitals according to the study population and the study site*

specifications) or any other hospital designated by the Chancellor of the Medical Sciences Campus of the University of Puerto Rico. The University of Puerto Rico has no plans to provide any form of compensation directly to you. However, by signing this consent form you do not give up any legal rights.

If the UPR MSC and the sponsor are responsible for the research participant and the sponsor will compensate the research participant in case of injury:

If you suffer a physical or mental injury as a result of receiving the study drug or any medical procedures required by the study, the principal investigator will treat you or refer you for treatment. You will be reimbursed by the sponsor for reasonable and customary fees and medical expenses actually incurred to treat such injury, but only to the extent such fees and expenses are not paid by your health insurance or governmental coverage. You will not be offered any financial compensation from the University of Puerto Rico Medical Sciences Campus. Your health insurance may not pay costs of treating a research related injury. No other provision has been made for payments of any other forms of compensation for a research related injury, such as for lost wages, lost time, or discomfort. By signing this consent form you do not give up any legal rights.

XII. VOLUNTARY PARTICIPATION AND WITHDRAWAL

Your participation in this study is voluntary. You may decide not to participate or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are entitled.

[*If applicable*] You will also be informed of any new information discovered during the course of this study that might influence your health, welfare, or willingness to be in this study.

Describe anticipated circumstances under which participants will be withdrawn from the research without their consent.

Describe the use of data after subject withdrawal

If it is necessary, your participation in this study may be stopped at any time by the investigator [*or the sponsor, if applicable*] without your consent if circumstances arise which warrant doing so.

RESEARCH INVOLVING PRISONERS AS SUBJECTS (*If applicable*)

Refer to document "Informed Consent Form Reference Information" (http://irbrcm.rcm.upr.edu/) for detailed information about this section. Suggested wording to section:

Participation in this study is voluntary. If necessary, your participation in this study may be stopped at any time by the study investigator without your consent. You will not receive direct benefits for participating in the study or receive bonuses that affect the length of your sentence. Your participation will not be taken into consideration for parole proceedings. You may refuse to answer questions that make you feel uncomfortable or stop participating in this study at any time without being penalized for it. If you refuse or wish to end the interview/participation before you reach the end, the services you receive by the Department of Correction and Rehabilitation of Puerto Rico will not be affected.

XIII. SOURCE OF FUNDING FOR THE STUDY (*If the research is funded*)

The study doctor is being paid by *[the sponsor] [may include other wording, as appropriate]* to conduct this research.

XIV. QUESTIONS

If you have any questions about this study or your participation in this study or if at any time you feel you have experienced a research-related injury [*or a reaction to the study medication, if applicable*], contact:

[*Name and contact information of the Principal Investigator*]

If you have questions about your rights as a research participant, you may contact:

Human Research Subjects Protection Office (HRSPO)
University of Puerto Rico
Medical Sciences Campus
Telephone: 787-758-2525 Exts. 2510 to 2515
E-mail: opphi.rcm@upr.edu

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

If you agree to be in this study, you will receive a signed and dated copy of this consent form with the stamp of the IRB approval in each sheet for your records.

XV. CONSENT AND SIGNATURE

I have read the information in this consent form (*or it has been read to me, if applicable*). All my questions about the study and my participation in it have been answered. My signature below means that I freely consent to be in this research study.

If the study involves protected health information and is subject to HIPAA, use the following sentence:

I authorize the use and disclosure of my health information to the parties listed in the authorization section of this consent for the purposes described above.

By signing this consent form, I have not given up any of my legal rights.

_____
Name of Participant

_____ _____
Signature of Participant Date

_____
Name of Person Conducting Informed Consent Discussion

_____ _____
Signature of Person Conducting Informed Consent Discussion Date

If the study involves children as subjects, you must request the signature of the parents.

NOTE: If the research involves greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition, Federal Regulations require to obtain permission from both parents, unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child. In this case, an additional signature line may be used for the second parent's signature, if required.

_____
Name of Father or Mother

_____ _____
Signature of Father or Mother Date

_____
Name of Legally Authorized Representative

_____ _____
Signature of Legally Authorized Representative Date

_____
Relationship of Legally Authorized Representative with Participant

Legally authorized representative (LAR) means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research. If there is no applicable law addressing this issue, legally authorized representative means an individual recognized by institutional policy as acceptable for providing consent in the nonresearch context on behalf of the prospective subject to the subject's participation in the procedure(s) involved in the research.

********** *Impartial Witness* **********

If this consent form (addendum) is read to the subject because the subject (or legally authorized representative) is unable to read the form, an impartial witness not affiliated with the research or the investigator must be present during the consent process and sign the following statement:

I confirm that the information in the consent form (addendum) and any other written information was accurately explained to, and apparently understood by, the subject (or the subject's legally authorized representative). The subject (or the subject's legally authorized representative) freely consented to be in the research study.

NOTE: A translated ICF in the primary language of prospective subjects and approved by the IRB should be used if applicable. The mechanism of impartial witness can't substitute a translated ICF.

_____
Name of Impartial Witness

_____ _____
Signature of Impartial Witness Date