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

INFORMED CONSENT FORM (ICF)
Reference Information

SOURCE:

45 CFR 46.116 and 117[1]
45 CFR 46.408
21 CFR 50.20 (Subpart B)[2]

APPLICABILITY:

Research Investigators

INSTITUTIONAL POLICY:

No investigator may involve a human being as a subject in research unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative (LAR). Exceptions must be approved by the IRB.

It is a requirement that the investigator propose an assent plan as part of a research protocol that includes children as subjects. If the investigator believes that assent is not appropriate for children over the age of six, a waiver must be specifically requested, described, and justified in the protocol and subsequently approved by the IRB.

FEDERAL REGULATIONS (45 CFR 46.116 & 45 CFR 46.117)

The goal of 46.116 (and 46.117) is to facilitate a prospective subject's or legally authorized representative's understanding of the reasons why an individual might or might not want to participate in the research.

[1] (OHRP - https://www.hhs.gov/ohrp/regulations-and-policy/regulations/finalized-revisions-common-rule/index.html)
[2] (FDA - https://www.fda.gov/ForPatients/ClinicalTrials/InformedConsent/default.htm)

General requirements for Informed Consent: Federal Regulations required the following (45 CFR 46.116(a)):

(1) Before involving a human subject in research covered by this policy, an investigator shall obtain the legally effective informed consent of the subject or the subject's legally authorized representative (LAR).

(2) An investigator shall seek informed consent only under circumstances that provide the prospective subject or the legally authorized representative sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence.

(3) The information that is given to the subject or the LAR shall be in language understandable to the subject or the LAR.

(4) The prospective subject or the LAR must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.

(5) Except for broad consent obtained in accordance with 45 CFR 45.116(d):

> (i) Informed consent must begin with a concise and focused presentation of the **key information** that is most likely to assist a prospective subject or LAR in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.
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> (ii) Informed consent as a whole must present information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or legally authorized representative's understanding of the reasons why one might or might not want to participate.

(6) No informed consent may include any exculpatory language through which the subject or the LAR is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

Basic Elements of Informed Consent (45 CFR 46.116(b)):

The following information shall be provided to each subject or the LAR (Except as provided in 45 CFR 46.116 (d), (e), or (f)):

(1) A statement that the study **involves research**, an explanation of the **purposes of the research** and the **expected duration of the subject's participation**, a description of the **procedures** to be followed, and identification of any **procedures that are experimental**;

(2) A description of any **reasonably foreseeable risks** or **discomforts** to the subject;

(3) A description of any **benefits to the subject or to others** that may reasonably be expected from the research;

(4) A **disclosure of appropriate alternative procedures** or courses of treatment, if any, that might be advantageous to the subject;

(5) A statement describing the **extent, if any, to which confidentiality of records identifying the subject** will be maintained;

(6) For research involving more than minimal risk, an explanation as to whether **any compensation** and an explanation as to whether **any medical treatments** are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

(7) An explanation of **whom to contact for answers** to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject;

(8) A statement that **participation is voluntary**, **refusal to participate will involve no penalty** or loss of benefits to which the subject is otherwise entitled, and the **subject may discontinue participation at any time** without penalty or loss of benefits to which the subject is otherwise entitled; and

(9) One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:

> (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
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> (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.

Additional Elements of Informed Consent (45 CFR 46.116(c)):

One or more of the following elements of information, when appropriate, shall also be provided to each subject or the legally authorized representative (LAR) (Except as provided in 45 CFR 46.116(d), (e), or (f)):

(1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) that are currently unforeseeable;

(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or the legally authorized representative's consent;

(3) Any additional costs to the subject that may result from participation in the research;

(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

(5) A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject;

(6) The approximate number of subjects involved in the study;

(7) A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;

(8) A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and

(9) For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (*i.e.,* sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

Elements of BROAD CONSENT for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens (**45 CFR 46.116 (d)**)

Broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens (collected for either research studies other than the proposed research or nonresearch purposes) is permitted as an alternative to the informed consent requirements in 45 CFR 46.116 (b) and (c). If the subject or the LAR is asked to provide broad consent, the following shall be provided to each subject or the subject's LAR:

(1) The information required in 45 CFR 46.116 (b)(2), (b)(3), (b)(5), and (b)(8) and, when appropriate, (c)(7) and (c)(9) of this section;

(2) A general description of the types of research that may be conducted with the identifiable private information or identifiable biospecimens. This description must include sufficient information such that a reasonable person would expect that the broad consent would permit the types of research conducted;

(3) A description of the identifiable private information or identifiable biospecimens that might be used in research, whether sharing of identifiable private information or identifiable biospecimens might occur, and the types of institutions or researchers that might conduct research with the identifiable private information or identifiable biospecimens;

(4) A description of the period of time that the identifiable private information or identifiable biospecimens may be stored and maintained (which period of time could be indefinite), and a description of the period of time that the identifiable private information or identifiable biospecimens may be used for research purposes (which period of time could be indefinite);

(5) Unless the subject or LAR will be provided details about specific research studies, a statement that they will not be informed of the details of any specific research studies that might be conducted using the subject's identifiable private information or identifiable biospecimens, including the purposes of the research, and that they might have chosen not to consent to some of those specific research studies;

(6) Unless it is known that clinically relevant research results, including individual research results, will be disclosed to the subject in all circumstances, a statement that such results may not be disclosed to the subject; and

(7) An explanation of whom to contact for answers to questions about the subject's rights and about storage and use of the subject's identifiable private information or identifiable biospecimens, and whom to contact in the event of a research-related harm.

Posting of clinical trial consent form:

ClinicalTrials.gov is a publicly available registry and results database of federally and privately supported clinical trials conducted in the United States and around the world. The purpose of ClinicalTrials.gov is to disclose to the public key information about clinical trials that are currently available or that have been conducted. ClinicalTrials.gov captures significant summary protocol information before and during the trial as well as summary results and adverse event information of a completed trial. Registration is required for trials that meet the FDAAA 801 definition of an "applicable clinical trial" and were either initiated after September 27, 2007, or initiated on or before that date and were still ongoing as of December 26, 2007 (https://clinicaltrials.gov/ct2/manage-recs/fdaaa).

OHRP regulations **(45 CFR 46.116(h)):**

(1) For each **clinical trial** conducted or supported by a Federal department or agency, one IRB approved informed consent form used to enroll subjects **must be posted** by the awardee or the Federal department or agency component conducting the trial on a publicly available Federal Web site that will be established as a repository for such informed consent forms.

(2) If the Federal department or agency supporting or conducting the clinical trial determines that certain information should not be made publicly available on a Federal Web site (*e.g.* confidential commercial information), such Federal department or agency may permit or require redactions to the information posted.

(3) The informed consent form must be posted on the Federal Web site **after the clinical trial is closed to recruitment**, and **no later than 60 days after the last study visit by any subject**, as required by the protocol.

Wording that must be included in the informed consent document of each clinical trial conducted or supported by a Federal department or agency:

[ENGLISH]

"*A description of this clinical trial will be available on http://www.ClinicalTrials.gov , as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time*."

[SPANISH]

"*Habrá una descripción de este ensayo clínico disponible en http://www.ClinicalTrials.gov, según lo exigen las leyes de los Estados Unidos. Este sitio web no incluirá información que permita identificarle. A lo sumo, incluirá un resumen de los resultados. Puede buscar en este sitio web en cualquier momento*."

Documentation of Informed Consent (45 CFR 46.117 (a)(b)(c))

(a) Except as provided in paragraph (c) of this section, informed consent shall be documented by the use of a written informed consent form approved by the IRB and signed (including in an electronic format) by the subject or the subject's legally authorized representative. A written copy shall be given to the person signing the informed consent form. [Note: "Written", or "in writing", for purposes of this regulation (45 CFR 45.102(m)), refers to writing on a tangible medium (e.g., paper) or in an electronic format.]

(b) Except as provided in paragraph (c) of this section, the informed consent form may be either of the following:

(1) A **written informed consent form** that meets the requirements of §ll.116. The investigator shall give either the subject or the subject's legally authorized representative adequate opportunity to read the informed consent form before it is signed; alternatively, this form may be read to the subject or the subject's legally authorized representative.

(2) A **short form written informed consent form** stating that the elements of informed consent required by §ll.116 have been presented orally to the subject or the subject's legally authorized representative, and that the key information required by §ll.116(a)(5)(i) was presented first to the subject, before other information, if any, was provided. The IRB shall approve a written summary of what is to be said to the subject or the LAR. **When this method is used, there shall be a witness to the oral presentation**. Only the short form itself is to be signed by the subject or the subject's legally authorized representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the subject's legally authorized representative, in addition to a copy of the short form.

(c) This section includes two points about waive the requirement for the investigator to obtain signed ICF:

(1) An IRB may waive the requirement for the investigator to obtain a signed informed consent form for some or all subjects if it finds any of the following:

(i) That the only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject (or LAR) will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern;

(ii) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context; or

(iii) If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

(2) In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects or legally authorized representatives with a written statement regarding the research (Information Sheet).

KEY INFORMATION (45 CFR 46.116(a)(5)(i))

A new approach to consent is requiring that the "key information" essential to decision making receive priority by appearing at the beginning of the consent form and being presented first in the consent discussion.

This new requirement states that the informed consent process must begin with "key information" that is most likely to assist a prospective subject or LAR in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.

According to the preamble of the Final Rule, a brief description of five "factors" (elements) at the beginning of an informed consent process (and consent form) would encompass the **key information** including a concise explanation of the following (HHS 2017, 7149-274)[3]:

1. The fact that consent is being sought for research and that participation is voluntary.
2. The purposes of the research, expected duration of the prospective subject's participation, and procedures to be followed in the research.
3. The reasonably foreseeable risks or discomforts to the prospective subject.
4. The benefits to the prospective subject or others that may reasonably be expected from the research.
5. Appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the prospective subject

ADDITIONAL INFORMATION THAT SHOULD BE CONSIDER AND INCLUDE IN THE INFORMED CONSENT FORM (ICF) (IF APPLICABLE)

RESEARCH INVOLVING MINORS AS SUBJECTS

When children or minors (<21 years of age in Puerto Rico) are involved in research, the regulations require the assent of the child or minor and the permission of the parent(s), in place of the consent of the subjects. The Parental Permission Form is a document that must contain the same elements as a typical Consent Form but is directed to the parent.

For studies that both, parent and minor, participate in the research, and minor is 15 to 20 years old, it may use the same ICF for both adult and pediatric subjects. The following text may be used through the ICF: "***You, or your child***". In this type of ICF, the sign section must include the sign of both, adult and child.

[3] Final Rule Material: Comprehensive Guide to Informed Consent Changes. (2017) Gary L. Chadwick, PharmD, MPH, CIP, University of Rochester (Emeritus) and HRP Consulting Group, CITI Program.

RESEARCH INVOLVING PRISONERS AS SUBJECTS

HHS regulations at 45 CFR part 46, subpart C provide additional protections pertaining to biomedical and behavioral research involving prisoners as subjects. The regulations are applicable to all biomedical and behavioral research conducted or supported by HHS. See 45 CFR 46.301.
The regulations define "**prisoner**" as follows:

"Prisoner" is defined by HHS regulations at 45 CFR part 46.303(c) as "any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing."

Minimal risk is also defined differently:

Prisoner Minimal Risk is defined in **45 CFR 46.303(d)** as follows: Minimal risk is the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.
According to OHRP:

The subpart C definition compares the **probability and magnitude of harm** in the research to the probability and magnitude of those harms normally encountered in daily life, or in routine medical, dental, or psychological examinations, rather than in daily life or routine physical or psychological examinations or tests as in subpart A.

The subpart C definition identifies healthy persons as the comparison group against which the risks of the research should be measured, rather than leaving the comparison group unspecified, as in subpart A. OHRP interprets the term healthy persons in this definition as referring to healthy persons who are not prisoners.

Federal Regulation (**45 CFR 46.305(a)**) required that the information in the ICF must be presented in language which is understandable to the subject population. Also, required adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and that each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole.

Suggested Wording to section "PARTICIPATION AND WITHDRAWAL VOLUNTEERS": [**ENGLISH**]

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 before you reach the end, the services you receive by the Department of Correction and Rehabilitation of Puerto Rico will not be affected.

Suggested Wording to section "PARTICIPATION AND WITHDRAWAL VOLUNTEERS": [SPANISH]

Su participación en este estudio es voluntaria. De ser necesario, su participación en este estudio puede ser detenida en cualquier momento por la investigadora del estudio sin su consentimiento. Usted no recibirá beneficios directos por participar del estudio ni recibirá bonificaciones que afecten la duración de su sentencia. Su participación no será tomada en consideración para procesos de libertad bajo palabra. Usted puede negarse a responder a las preguntas que le hagan sentir incómodo o dejar de participar de este estudio en cualquier momento sin ser penalizado por ello. Si rehúsa o desea finalizar la entrevista antes de llegar al final, no se afectarán los servicios que usted recibe por el Departamento de Corrección y Rehabilitación de Puerto Rico.

RESEARCH INVOLVING GENETICS PROCEDURES

Genetic testing is a type of medical test that identifies changes in chromosomes, genes, or proteins. The results of a genetic test can confirm or rule out a suspected genetic condition or help determine a person's chance of developing or passing on a genetic disorder. More than 1,000 genetic tests are currently in use, and more are being developed.[4]

Genetic research will lead to improved diagnosis and treatment of diseases. Researchers are creating new types of drugs based on what we know about genes. Because these newer drugs target certain sites in the body, they may have fewer side effects than many of today's medicines. Other new types of medicines will be tailored to an individual's unique genetic profile.

What is considered genetic information?
Genetic Information include:

- Information of a person's genetic tests (any laboratory test of human DNA, chromosomes, genes, or gene products to diagnose the presence of a genetic variation linked to a predisposition to a genetic disease or disability in the individual or individual's offspring; such term shall also include DNA profile analysis)
- Genetic tests of a person's family members
- Disease or disorder in a family member
- Participation of a person or family member in research that includes genetic testing, counseling, or education
- Tests for BRCA1/BRCA2 (breast cancer) or HNPCC (colon cancer) mutations
- Classifications of genetic properties of an existing tumor to help determine therapy
- Tests for Huntington disease mutations
- Carrier screening for disorders, such as cystic fibrosis, sickle cell anemia, spinal muscular atrophy, and the fragile X syndrome

How can risks to subjects be minimized?
Consider nonphysical risks including psychosocial risks. Examples of minimizing risks:

- de-identification/anonymous samples or results;
- not disclosing results to subject or their representatives;
- limiting the number of staff who have access to identifiable results;

[4] Help Me Understand Genetics Genetic Testing (https://ghr.nlm.nhi.gov)

- not placing identifiable records such as signed consent documents or results in the medical record;
- obtaining a certificate of confidentiality for identifiable results;
- avoiding storage of specimens for future testing.
- Information should be included if genetic counseling will be necessary and plan included on how this process is to be completed.

The consent process in research that involve genetic test must be described clearly. In the ICF should be included:

- The kind of information they will be provided and at what point in the study.
- That they may find out things about themselves or their family that they did not really want to know, or that they may be uncomfortable knowing.
- That information about themselves may be learned by others in the family.
- Whether information they learn or generated about them during the study may compromise their insurability.
- That actions they may take as a result of their participation may expose them to risks (submitting insurance claim forms for reimbursement for costs of genetic counseling or procedures whose costs are not covered by the protocol).
- About what assurances can be given to protect confidentiality and what lack of assurance can be given.
- About the rights they retain and the rights they must give up regarding control over what can be done with tissue they donate (blood samples).
- What the consequences of withdrawal from the study will be.
- Of any costs associated with participation (including, for example, the cost of genetic and/or psychological counseling, if those costs will not be covered by the investigator or the institution).
- Protecting Privacy and maintaining Confidentiality in Genetic Research
- Description of all staff who may access identifiable subject data.
- Will results be provided to subjects or others.
- What are the implications to others besides the subjects including relatives of the participant and the group the subject may be identified with such as racial and/or ethnic?

Genetic Information Nondiscrimination Act (GINA) 2008

GINA is a Federal law that prohibits discrimination in health coverage and employment based on genetic information. GINA, together with already existing nondiscrimination provisions of the Health Insurance Portability and Accountability Act, generally prohibits health insurers or health plan administrators from requesting or requiring genetic information of an individual or an individual's family members, or using such information for decisions regarding coverage, rates, or preexisting conditions. GINA also prohibits employers from using genetic information for hiring, firing, or promotion decisions, and for any decisions regarding terms of employment.

When investigators develop, and IRBs review, consent processes and documents for genetic research, they should consider the protections provided by GINA, particularly with respect to the following elements of informed consent that must be provided to subjects (unless an IRB has approved an alteration or waiver

of these requirements in accordance with the requirements of HHS regulations at 45 CFR 46.116(c) or (d))[5]:

- A description of any reasonably foreseeable risks or discomforts to the subjects (45 CFR 46.116(a)(2)); and
- A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained (45 CFR 46.116(a)(5)).

OHRP recommends that for genetic research undergoing initial or continuing review investigators and IRBs consider whether consent processes and documents should include language regarding the protections provided by GINA, and if so, ensure that such language accurately describes the impact of GINA on the risks and confidentiality protections for such research.

The following is one example of **sample language** regarding the protections provided under GINA that investigators could consider including in informed consent documents for such research:

[**ENGLISH**]

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 GINA (Genetic Information Nondiscrimination Act). 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.

[**SPANISH**]

Sus datos personales derivados de los resultados de las pruebas genéticas realizadas en este estudio son protegidos por las provisiones del Título II de la ley GINA (Genetic Information Non-discrimination Act). Esta nueva ley federal GINA generalmente lo protegerá a Usted de las siguientes maneras:

- *Las compañías proveedoras de seguros médicos y planes de salud no pueden solicitar información sobre los resultados de sus pruebas genéticas realizadas como parte de este estudio.*
- *Las compañías proveedoras de seguros médicos y planes de salud no pueden usar la información sobre los resultados de sus pruebas genéticas realizadas como parte de este estudio para tomar decisiones sobre su elegibilidad o primas.*
- *Empleadores con 15 o más empleados no pueden usar la información sobre los resultados de sus pruebas genéticas realizadas como parte de este estudio para tomar decisiones sobre su empleo, contrataciones, promoción o despido; o cuando establecen los términos de su empleo o contrato de empleo.*

Tenga en cuenta que esta ley federal no lo protege a Usted de discrimen genético por compañías que venden seguros de vida, seguros de cuidado a largo plazo o seguros por discapacidad.

RESEARCH THAT APPLY TO ISSUE A CERTIFICATE OF CONFIDENTIALITY (CoC)

Effective October 1, 2017, **all research, NIH-funded and conducted research, that was commenced or ongoing on or after December 13, 2016 and is within the scope the NIH Policy** is deemed to be issued a Certificate of Confidentiality. The NIH Policy is included in the NIH Grants Policy statement as a standard term and condition of award effective October 1, 2017 for new and non-competing awards.

The NIH Policy applies to all biomedical, behavioral, clinical, or other research funded wholly or in part by the NIH, whether supported through grants, cooperative agreements, contracts, other transaction awards, or conducted by the NIH Intramural Research Program, that collects or uses identifiable, sensitive information.

For studies in which **informed consent is sought**, NIH expects investigators to inform research participants of the protections and the limits to protections provided by a Certificate issued by this Policy. It is necessary to include language relating to the protections afforded by the Certificate and any exceptions to that protection. [Please, read the CoC policy to learn more (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-109.html)]

Suggested Consent Language Describing the CoC Protections:

[**SPANISH**]

Si usted elige participar en este estudio, el investigador obtendrá información sobre usted y su salud. Para ayudar a proteger su privacidad, hemos obtenido un Certificado de Confidencialidad de National Institutes of Health (NIH). Los investigadores pueden utilizar este certificado para negarse legalmente a revelar información que pueda identificarle en un proceso, federal, estatal, local civil, criminal, administrativo, legislativo, o algún otro procedimiento, por ejemplo, una citación de la corte. El investigador puede utilizar el certificado para resistir cualquier demanda de información que le pueda identificar, excepto por lo que se explica abajo.

*[**Use the following language as applicable**] El certificado no se puede utilizar para resistir una demanda de información del personal del gobierno federal o estatal de los Estados Unidos que esté auspiciando el proyecto, o por información que deba ser revelada para cumplir con los requisitos de la Administración de Drogas y Alimentos (FDA por sus siglas en inglés).*

Debe comprender que el Certificado de Confidencialidad no previene que usted revele voluntariamente información acerca de usted mismo o su participación en este estudio. Si un asegurador, proveedor de servicios de cuidado médico u otra persona obtiene un consentimiento escrito de usted para recibir información acerca de la investigación, entonces los investigadores no podrán utilizar el certificado para negar el proveer información.

El Certificado de Confidencialidad no se podrá utilizar para prevenir que el investigador provea información a las autoridades locales o estatales sobre, abuso infantil o negligencia y daño a usted o a otras personas.

Reference: [**https://humansubjects.nih.gov/coc/suggested-consent-language**]

Suggested Consent Language Describing the CoC Protections:

[**ENGLISH**]

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.

Reference: [**https://humansubjects.nih.gov/coc/suggested-consent-language**]