The AHRQ Informed Consent and Authorization Toolkit for Minimal Risk Research

The Agency for Healthcare Research and Quality (AHRQ) has developed the *Informed Consent and Authorization Toolkit for Minimal Risk Research* to facilitate the process of obtaining informed consent and Health Insurance Portability and Accountability Act (HIPAA) authorization from potential research subjects. This toolkit contains information for people responsible for ensuring that potential research subjects are informed in a manner that is consistent with medical ethics and regulatory guidelines.

Note: This Toolkit has not been updated since the revised Common Rule became effective January 21, 2019. It therefore does not cover changes in the Common Rule, such as new requirements for the informed consent form and process regarding the information that must be given to prospective research subjects. You can access the Final Rule, 45 CFR 46, at https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML.

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Background

Why a Toolkit? The goal of this toolkit is to help make informed consent and HIPAA authorization for potential research subjects more meaningful. This toolkit is needed because there is significant evidence that current practice does not fulfill ethical and regulatory standards.

Common shortcomings of current practices include:

- Documents are long and written at a reading level beyond the capacity of most potential subjects.[1]
- Institutional review boards (IRBs) fail to meet their own standards for readability in their own required boilerplate language.[2]
- Research subjects often do not understand fundamental concepts required for participation.[3-5]
- Research findings may be biased by failure to include vulnerable populations from whom it is difficult to obtain informed consent.[6-7]

This toolkit is designed to help both researchers and IRBs ensure that potential subjects are well informed. The guidance provided here is consistent with the regulations for obtaining and documenting informed consent for participation in minimal risk research and authorization for use of protected health information as required under HIPAA.

Highlights of the toolkit include:

- A model process for obtaining written consent and authorization.
- Sample easy-to-read consent documents for informed consent and authorization.
- A certification tool to promote the quality of the consent process.
- Links to resources from the Department of Health and Human Services.

Development of This Toolkit

This toolkit was developed by AHRQ staff and modified with input from experts in health literacy, clinical research, Federal regulations, HIPAA authorization requirements, and ethics. The toolkit was also tested by researchers at Boston University Medical School (ACTION Network Field Partnerships for Applied Research, awarded by AHRQ in 2007, Principal Investigator: Michael Paasche-Orlow, M.D., M.A., M.P.H.) with a diverse group of research subjects, researchers, and IRB professionals. To refine and validate the language of the sample consent documents in this toolkit, research subjects with different levels of literacy were interviewed in English and Spanish in focus groups and one-on-one session in five cities (Atlanta, GA; Baltimore, MD; Boston, MA; Tucson, AZ; and Waukegan, IL). These materials are not copyright protected.

This toolkit will need to be adapted to meet local and State regulations, as well as by each investigator according to the specifics of each protocol. The toolkit does not specifically address issues related to assent by minors, special classes of vulnerable populations (e.g., prisoners), sponsors, or specific study considerations (e.g., genetics, repositories, certificates of

confidentiality). But the consent process and sample consent documents presented can inform the alterations that will be needed so that they can conform to the overarching aim of this toolkit, to advance patient comprehension.

Please send comments and suggestions to informed consent@ahrq.hhs.gov.

Informed Consent, HIPAA Authorization, and Adult Health Literacy

The Department of Health and Human Services (HHS) has promulgated regulations that define the process for obtaining and documenting informed consent in research supported by HHS (45 CFR 46.116 and 45 CFR 46.117). In addition, researchers who want to use and report on protected health information may be subject to the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA), or may have to receive protected health information from a covered entity that is subject to the HIPAA Privacy Rule. In either case, the researcher (or the covered entity that maintains the health information) would have to obtain a HIPAA authorization from his or her research subjects. Researchers conducting nonexempt human subjects research must first obtain approval for the research from an IRB and then obtain the informed consent of each research subject, unless the requirement for obtaining informed consent has been waived appropriately by the IRB. Additionally, researchers may seek from an IRB approval for a waiver of, or alteration to, the required HIPAA authorization form.

Obtaining informed consent and HIPAA authorization are two separate but parallel activities. Both activities should be designed to inform potential subjects about the research and the use and sharing of their health information in terms that they can understand. The process is an educational activity in which potential subjects are the learners. **Researchers have a responsibility to ensure that potential subjects understand the information provided.**

This task can be challenging due to the complex nature of medical research and the limited literacy skills of many potential subjects. According to the National Assessment of Adult Literacy, 41% of American adults have basic or below basic literacy skills and do **not** have the proficiency necessary to perform more than basic literacy activities while working independently.[8] While research subjects with limited literacy have been shown to benefit from easy-to-read consent documents, consent procedures to promote comprehension are also needed. Furthermore, more than 8% of U.S. residents do not speak English well. To safeguard potential subjects:

- Provide **very** easy-to-read consent and authorization documents.
- Use an informed consent and HIPAA authorization process that does not rely on subjects' literacy.
- Use an informed consent and HIPAA authorization process that does not rely on subjects' English proficiency (in research not exclusively conducted with English speakers).

In addition, certain vulnerable populations may not be accustomed to or comfortable with signing written materials.[9] When written formats are inadequate, investigators ought to consider supplementing the informed consent process with additional materials (e.g., diagrams, pictures, videos). IRBs must approve these supplemental materials. Investigators also need to be sensitive

to the fact that many potential subjects are not familiar with basic concepts related to research and the researcher-subject relationship.[10]

How To Improve Informed Consent and Authorization

Improving the Process

Adopting New Processes and Documents in Your Institution

This section of the toolkit offers some strategies for those who seek to serve as change agents in their organizations to improve the informed consent and authorization process.

Raise Awareness:

- Share examples of readable informed HIPAA consent and authorization documents that have been used succesfully by other IRBs.
- Educate IRB members, institutional lawyers, and researchers on regulatory requirements.
- Identify sections of documents that are not required and distract from the primary purpose of the documents.
- Host experts on health literacy, informed consent, and research ethics to educate the research and IRB communities.
- Conduct interactive workshops and online training on writing understandable documents and how to conduct the informed consent and authorization discussion.
- Create a forum to discuss ways to identify and address liability concerns outside the informed consent and authorization process.
- Share research findings regarding malpractice and communication.

Identify Leaders and Partners:

- Invite researchers and IRB officials from other communities or accrediting institutions such as the Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP) to model new approaches and demonstrate that changing the process for obtaining informed consent and authorization is feasible and worthwhile.
- Identify opinion leaders who can advocate change among their colleagues.
- Enlist technical assistance from the DHHS Office for Human Research Protections to resolve questions on whether informed consent document simplification complies with regulations.
- Review the Web site of the DHHS Office for Civil Rights for general HIPAA Privacy Rule information, as well as specific information related to the HIPAA Privacy Rule and research.
- Review the Web site of the National Institutes of Health regarding research and the HIPAA Privacy Rule.
- Solicit ideas from outside resources such as Public Responsibility in Medicine and Research (PRIM&R), the Association of American Medical Colleges (AAMC), and AAHRPP for ideas and support.

Identify Mechanisms for Change:

- Post AHRQ sample documents on your IRB Web site and encourage researchers to use them as templates.
- Establish a mechanism that researchers can easily use to test their documents and processes with potential research subjects.
- Create a community advisory board to review template language at your institution.
- Have the IRB office sponsor catered training, education, and feedback meetings that include topics related to evaluation and integration of methods to promote comprehension.
- Significantly increase the training and participation of IRB members who can represent the perspectives of research subjects, who are unaffiliated with the institution, and who are not scientists.

Address Common Concerns About the Proposed Changes

Common concerns appear below, along with responses that can be used to educate the community.

1. **Objection:**
   Legal clauses protect our institution against lawsuits.

   Response:
   Including legalistic clauses does not afford protection against lawsuits. On the contrary, complex consent forms have been the basis of legal action by research subjects even in the absence of physical harm.[11]

2. **Objection**
   Regulations require use of technical terms.

   Response:
   Regulations require the use of language that is understandable to the potential subject.[12]

3. **Objection:**
   A small font and long paragraphs keep the documents short.

   Response:
   Well-written documents do not have to be long. Also, documents that use large fonts, short lines, lots of white space, bulleted lists, and headings to break the text into manageable pieces are easier to read than short, dense documents.

4. **Objection:**
   Most people are familiar with common medical and research terms.

Response:
Most people who participate in research do not understand common medical and research terms.[13-14]

5. **Objection:**
   These documents have been used for years, so they must be fine. Subjects would not sign the documents if they didn't understand.

   Response:
   Research has shown that most research subjects did not understand all the information contained in consent documents they had signed.[15]

6. **Objection:**
   It will take too long to verify comprehension.

   Response:
   This is possible; however, assessing comprehension can identify subjects who need further instruction to participate.

7. **Objection:**
   There is no reason to focus too much on the written materials because informed consent is a process and investigators will communicate what is needed.

   Response:
   High-quality consent materials can lead to an improved consent process and provide information that subjects, family, and friends can refer to as the study continues to help ensure continuing comprehension and consent.

Improving the Informed Consent and Authorization Process

AHRQ recommends the following process for all study personnel who will be obtaining written informed consent and authorization. The objective is to teach potential subjects about research protocols and confirm their comprehension.

Create a Research Culture To Promote the Process

Many of the safeguards that have been put in place to protect subjects' rights can be easily subverted if research personnel are not motivated to perform their duties with integrity. Professionalism needs to be modeled. In addition, some of the activities needed to promote the consent process require preparation and training. If the activities described below are presented in a fashion that exhibits the ethical and regulatory importance of the consent process, investigators will be able to communicate these values to their staff.

Staff Training

- **Create a teaching version of your Informed Consent and Authorization documents**. These are educational materials. Researchers can create a companion teaching version with embedded prompts (e.g., "stop here and ask for questions") to serve as a teacher's guide. Give a copy of this teaching version to personnel in contact with subjects and potential subjects. Use the teaching version in a supervised simulation of the consent process and give feedback about what worked well and what did not work well.

- **Review the Informed Consent and Authorization Certification document** prior to beginning the discussion with a potential research subject. It serves as a reminder of the topics to discuss with the potential subject. When supervising a simulated or actual consent process, use the certification document as a checklist to keep track of what was or was not done.

- **Take steps to differentiate between clinical care and research**. Research personnel need to approach the informed consent and authorization process in a fashion that helps potential subjects understand that they can freely refuse to participate. Research personnel should avoid activities that falsely impart the impression of a therapeutic relationship, such as wearing a white coat. Investigators who are clinicians need to be especially careful to separate their clinical and research roles and, whenever possible, should not be directly involved with the consent and authorization process.

Physical Environment

- **Conduct the discussion in a private and quiet place**. The informed consent discussion should be held in a private setting, unless the potential research subject would like to include other people (e.g., family, friend). An exception may be made when providing information to a group of potential subjects at the same time, as is frequently the case when focus groups are conducted.

- **Be prepared to accommodate potential subjects with disabilities**. For example, people with visual impairment often can benefit from materials with large font, high contrast, adequate illumination, and reduced glare. People with hearing impairment benefit from interactions in private quiet environments and may need sign language interpreters. The physical route people take to interact with research staff should be accessible. Research staff should be taught about accommodating disabilities and should prepare in advance for these possibilities.

Communication To Promote Comprehension

- **Plan for potential subjects with limited English proficiency.** If the researcher anticipates that a portion of potential subjects will not be fluent in English, translated forms and bilingual staff are needed. In such circumstances, care should be taken that

informed consent not only meets appropriate standards, but also ensures that all survey instruments will provide valid data for such subjects.

  - In some settings, if no study personnel are fluent in the appropriate language, a qualified interpreter can be used.
  - For any subject who does not understand English, the consent form to be signed by the subject must be translated into a language understandable to the subject. Under the Office for Human Research Protections' guidance titled "Obtaining and Documenting Informed Consent of Subjects Who Do Not Speak English," this can be a short-form written consent document stating that the elements of informed consent required by 45 CFR 46.116 have been presented orally to the subject or the subject's legally authorized representative.
  - Study personnel who are fluent in the appropriate language or an interpreter should be used for any potential research subjects who request one, even if they appear to speak and understand English well.
  - If you cannot communicate with potential subjects, they may not be enrolled.

- **Offer to read the document with all research subjects**. There is no need to make any reference to reading ability. For example, the researcher could say, "Let's read this document together," or "It's my job to explain things clearly. If you like, I can read the document along with you to make sure all the information is clear." Do not rely on the document to provide the subject with the necessary information. **It is the explanation of what the document says that is important. The purpose of the consent form is to document what information has been disclosed to the subject and that the subject's consent was obtained.**

- **Give the potential research subject time** to review the document. There should be no time pressure. When possible, potential research subjects can be encouraged to take the document home and discuss their participation with family members, friends, and their primary care physician.

- **Verify and document that the potential research subject has understood** the document through use of the teach-back method.[16-17] The teach-back method is an interactive educational approach that can be used to confirm comprehension and is described in detail below. Study personnel should practice the teach-back method in simulated sessions prior to approaching potential subjects. If interpreters will be used, simulated teach-back sessions with the interpreters should be conducted. Other methods to evaluate comprehension, such as a written test, may be beneficial, but may be difficult for patients with limited literacy. People need to be excluded if they fail to understand key elements of the protocol despite multiple attempts to teach the material.

Teach-Back: Part 1

Start with phrases such as:

- "I want to make sure we have the same understanding about this research. Can you tell me what this project is about in your own words?"
- "It's my job to explain things clearly. To make sure I did this I would like to hear your understanding of the research project."

Teach-Back: Part 2

Make sure that the potential research subject has understood all the important elements of the study. Allow the potential research subject to consult the document when answering the questions. **The purpose is to check comprehension, not memory**. Listen for simple parroting; probe further if a potential research subject uses technical terms. Ask open-ended questions such as the following:

- **Goal of the Research and Protocol**
  - "Tell me in your own words about the goal of this research and what will happen to you if you agree to be in this study."

- **Benefit and Compensation**
  - "What do you expect to gain by taking part in this research?"

- **Risks**
  - "What risks would you be taking if you joined this study?"

- **Voluntariness**
  - **"**Will anything happen to you if you refuse to be in this study?"

- **Discontinuing Participation**
  - "What should you do if you agree to be in the study but later change your mind?"
  - "What will happen to information already gathered if you change your mind?"

- **Privacy**
  - "Who will be able to see the information you give us?"

- **Contact Information**
  - "What should you do if you have any questions or concerns about this study?"

Teach-Back: Part 3

Correct any misinformation until potential research subjects indicate that they have understood by correctly answering all the questions. Make clear that the need to repeat is due to the complexity of the material rather than the "fault" of the potential research subject.

For example, you could say, “Let’s talk about the purpose of the study again because I think I may have not explained it clearly.”

- Potential research subjects **should not be enrolled** if they cannot comprehend the study protocol, despite repeated attempts to explain the details.

- Document completion of the teach-back process on the Researcher’s Certification of Consent and Authorization.

- Ask the potential research subjects what questions they still have.
  - Avoid yes or no questions such as, “Do you have any questions?” and “Do you understand?”
  - Ask instead, “What questions do you still have?” and “What would you like to hear more about?”

- If the potential research subject signs the document (unless written consent and authorization have been waived), make a copy for him or her. Alternatively, have two copies and give one to the subject.
  - Emphasize that subjects should keep the document since it has important phone numbers in case they have any questions or concerns later.

- Complete and sign the Researcher’s Certification of Consent and Authorization.

Using the Tool for Researcher’s Certification of Consent and Authorization

The Researcher’s Certification of Consent and Authorization document is a tool to be completed by the person conducting the consent and authorization discussion. It can serve as:

- A checklist of all aspects of the process.
- Documentation that the correct process was used with each prospective research subject.
- A tool to help train research assistants.
- Protection for subjects in protocols that deserve special scrutiny.[18]

Improving the Forms

Using Sample Documents for Informed Consent and HIPAA Authorization

AHRQ has developed sample documents in both English and Spanish. They are written to maximize readability. Researchers should check with their IRB about combining the informed consent and authorization documents into a single document for both purposes.

- Sample Informed Consent Form (English)
- Sample HIPAA Authorization Forms (English)
  - For investigators who are in the same covered entity as the protected health information (PHI) of interest

    - For investigators who are in an institution that is covered by HIPAA but is not in the same covered entity as the PHI of interest
    - For investigators who are **not** in an institution that is covered by HIPAA to use PHI from a covered entity
- Sample Combined Informed Consent and HIPAA Authorization Documents (English)
    - For investigators who are in the same covered entity as the protected health information (PHI) of interest
    - For investigators who are in an institution that is covered by HIPAA but is not in the same covered entity as the PHI of interest
    - For investigators who are **not** in an institution that is covered by HIPAA to use PHI from a covered entity
- Sample Informed Consent Document (Spanish)
- Sample HIPAA Authorization Documents (Spanish)
    - For investigators who are in the same covered entity as the protected health information (PHI) of interest
    - For investigators who are in an institution that is covered by HIPAA but is not in the same covered entity as the PHI of interest
    - For investigators who are **not** in an institution that is covered by HIPAA to use PHI from a covered entity
- Sample Combined Informed Consent and HIPAA Authorization Documents (Spanish)
    - For investigators who are in the same covered entity as the protected health information (PHI) of interest
    - For investigators who are in an institution that is covered by HIPAA but is not in the same covered entity as the PHI of interest
    - For investigators who are **not** in an institution that is covered by HIPAA to use PHI from a covered entity

The Sample Informed Consent Document is designed for use when researchers only need to conduct informed consent and do not need HIPAA authorization to use protected health information (PHI).

The Sample HIPAA Authorization Documents are designed for use when researchers only need authorization to use PHI. There are three versions. Two are for researchers in institutions that are covered by HIPAA. The difference between these two documents depends on whether the researcher works at the same covered entity that has the PHI. The last version is for researchers in institutions that are not covered by HIPAA but want to use PHI from a covered entity.

The Sample Combined Informed Consent and Authorization Documents are designed for use with studies requiring both informed consent and HIPAA authorization. There are three versions. Two are for researchers in institutions that are covered by HIPAA. The difference between these two documents depends on whether the researcher works at the same covered entity that has the PHI. The last version is for researchers in institutions that are not covered by HIPAA but want to use PHI from a covered entity.

Highlighted brackets are used in the sample documents to provide instructions to researchers to guide their customization of the template.

These documents were developed for use in survey research and other types of minimal-risk research. They are templates that need to be adapted according to specific institutional and protocol parameters and may need to be revised based on any applicable State privacy laws. There are many opportunities, such as pictures and simple tables, to make the final consent and authorization forms that are derived from these templates even more engaging and easy to read. However, the addition of complex medical or legal jargon could easily subvert the goal of promoting informed consent. When complex terms are absolutely necessary, appropriate explanation in language understandable to the potential subjects should be included.

A significant portion of these templates is also relevant for research that involves more than minimal risk. Researchers who are implementing an intervention as part of their research (e.g., clinical trials) will need to add information to identify which procedures are experimental and alternatives. Researchers and IRBs can consult the National Cancer Institute's Recommendations for the Development of Informed Consent Documents for Cancer Clinical Trials. The report includes templates and samples of simplified informed consent documents for research trials.

In addition, researchers who are doing research that involves intervention (e.g., clinical trials) should consult the HIPAA Privacy Rule for additional requirements that may apply with respect to their authorizations for such research. For example, there is a prohibition on combining authorizations for multiple purposes where one of the authorizations conditions the research participant's receipt of research-related treatment on the participant signing the HIPAA authorization.[19]

Adapting and Testing AHRQ Sample Documents

AHRQ's sample documents are designed to be used as a template that researchers and IRBs can adapt according to the needs of State and local laws and regulations. While the sample documents were developed with minimal-risk health services research in mind, they can be adapted for use in other types of research settings.

Several publications listed in the Resources section of this toolkit can be helpful in adapting documents. When adapting the materials in the toolkit, keep in mind the following writing principles used to create easy-to-read materials.

Write in Plain Language

- Keep the reading level of consent documents low (Note: Grade level can be checked using one of several readability formulas. However, the main benefit of such formulas is to identify text that is overly complex. A low reading level on a readability formula does not ensure that potential research subjects will be able to read and understand the text. For example, most readability formulas involve counts of the number of syllables per word and the number of words per sentence, so these tests would find no problem with the sentence, "The argot was quite arcane.")

- Use the active voice.
- Use simple sentence structures.
- Use short sentences. Aim for no more than 8 to 10 words.
- Keep the object of the sentence close to the subject of the sentence.
- Do not use jargon. Ask people in your target audience to identify jargon and technical terms.
- When technical terms or abbreviations are essential, provide clear definitions.

Format to Promote Reading

- Use at least 14-point fonts if there is a chance that a potential subject is visually-impaired.
- Do not use ALL CAPS.
- Do not use *italics.*
- Break up text into manageable chunks using headings and subheadings.
- Use wide margins. A line length of 50 characters and spaces or fewer is easier to read.
- Use pictures, tables, and diagrams to help explain the text.

AHRQ recommends that before use, all adapted consent and authorization documents be tested with a diverse set of potential research subjects similar to those who will be approached to enroll in the study. Researchers are still responsible for ensuring that their documents meet the requirements of their IRB.

Regulatory Requirements

Informed Consent

An informed consent process must involve disclosure of the following topics in language that is understandable to the potential subject (45 CFR 46.116), unless an IRB has appropriately waived or approved an alteration in one or more of these requirements:

- The fact that the study involves research
- The purposes of the research
- The expected duration of subject participation
- What will happen during the study (i.e., the procedures to be followed)
- Which procedures are experimental
- Any reasonably foreseeable risks or discomforts (e.g., pain, anxiety from answering questions about sensitive topics)
- Any benefits to subjects or to society that may reasonably be expected
- Any alternative procedures or courses of treatment that might be advantageous to the subjects
- How the confidentiality of records identifying subjects will be maintained
- Whom to contact to answer questions about the research and subjects' rights
- Whom to contact in the event of a research-related injury
- The fact that participation is voluntary, refusal to participate will not compromise subjects' current access to health care (or employment status, if relevant) or result in any other penalty or loss of benefits to which the subject is otherwise entitled, and that

subjects may end their involvement in the research project at any time without penalty or loss of benefits to which they are otherwise entitled

If the IRB determines that a research study involves more than minimal risk, informed consent also must involve disclosure of whether any medical treatments or compensation are available if subjects are harmed and, if so, what they consist of, or where further information may be obtained.

In addition, when appropriate, subjects must be informed about the following (45 CFR 46.116):

- Risks that are currently unforeseeable
- Circumstances under which participation may be terminated by the investigator
- Any additional costs to the subject that may result
- Consequences of withdrawal from the research and procedures for termination
- The plan to provide subjects with significant new findings that develop during the course of the research that may influence subjects' willingness to continue participation
- The approximate number of subjects involved in the study

HIPAA Authorization

A successful authorization process will result in subjects understanding the following (*45 CFR 164.508(c)*):

- What protected health information will be used and/or shared
- From whom the protected health information will be obtained
- Who will use or have access to the protected health information
- With whom the protected health information will be shared
- The purpose of the use and/or sharing of the protected health information
- How long the protected health information will be used and/or shared
- The ability of subjects to revoke their authorization and how they can do so
- The limits on the subjects' ability to revoke their authorization (for example, information may still be used or disclosed as necessary to protect the integrity of the research study)
- Any consequences of refusing to sign the authorization
- The fact that the Privacy Rule may not protect health information that has been disclosed

Regulatory Exceptions

Waiver of Documentation of Informed Consent

In some research settings, obtaining consent is required but does not need to be documented. To do this, an IRB must formally grant a waiver of the requirement for the investigator to obtain a signed consent form for some or all subjects of documentation for consent (45 CFR 46.117). This does not decrease any obligation to obtain the subject's informed consent but does mean that the subject is not required to sign a written informed consent document.

A waiver of the usual requirements for documentation of informed consent requires that either:

(A) The only record linking the subject to the research would be the informed consent document, and the principal risk would be potential harm resulting from a breach of confidentiality; Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern;
or
(B) The research involves no more than minimal risk of harm to subjects and involves no procedures for which written consent would be required outside of the research setting.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

Waiver or Alteration of Informed Consent

An IRB can waive the requirement to obtain informed consent if it finds and documents the following:

- The research involves no more than minimal risk to the subjects.
- The waiver will not adversely affect the rights and welfare of the subjects.
- The research could not practicably be carried out without the waiver.
- Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Waiver or Alteration of HIPAA Authorization

The requirement for a covered entity to obtain HIPAA authorization in order to use or disclose protected health information for research can be waived or altered by an IRB or Privacy Board in the following circumstances:

- The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals, based on, at least:
    - An adequate plan to protect identifiers from improper use or disclosure;
    - An adequate plan to destroy the identifiers at the earliest opportunity, consistent with the needs of the research study, the subjects' health, and applicable law; and
    - Adequate written assurances from the researchers that the protected health information will not be reused or disclosed except as required by law, for authorized oversight of the research study, or for other research where the reuse or disclosure would be permitted by HIPAA
- The research could not practicably be conducted without the waiver or alteration; and
- The research could not practicably be conducted with access to protected health information.

Resources

Researchers and IRB officials will also find these resources from the Department of Health and Human Services helpful.

Creating Easy-To-Read Informed Consent Documents

Clear & Simple: Developing Effective Print Materials for Low-Literate Readers
National Cancer Institute

Simplification of Informed Consent: Recommendations for the Development of Informed Consent Documents for Cancer Clinical Trials
National Cancer Institute

Simply Put: Tips for Creating Easy-To-Read Print Materials That Your Audience Will Want To Read and Use (includes a description of the Fry Readability Scale)
Centers for Disease Control and Prevention

Consent for CDC Research: A Reference for Developing Consent Forms and Oral Scripts
(includes a description of the SMOG Readability Formula)
Centers for Disease Control and Prevention

Translation
Obtaining and Documenting Informed Consent of Subjects Who Do Not Speak English
Office for Human Research Protections

HIPAA Guidance
Health Services Research and the HIPAA Privacy Rule
National Institutes of Health

Office of Civil Rights – Research Guidelines on HIPAA Privacy Rules

Informed Consent Guidance
Informed Consent Checklist
Office for Human Research Protections

Tips on Informed Consent
Office for Human Research Protections

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Researcher's Certification of Consent and Authorization*

I have:

____ Conducted the informed consent and/or authorization discussion in private, or only in the presence of those people that the potential subject wanted to hear the discussion.

____ N/A

____ Noted that the potential subject is fluent in English or that the subject (check all that apply):

____ Signed form written in own language: _____

____ Was assisted by study personnel fluent in _____

____ Was assisted by a professional medical interpreter.

____ Was not enrolled because refused offer of professional medical interpreter.

____ Was not enrolled because study restricted to those fluent in English.

____ Read the Informed Consent and/or the Authorization Document with subjects who do not choose to read the document on their own. ____ N/A

____ Verified an adequate level of comprehension by:

Asking the potential research subject to restate his/her understanding of the research.

____ **Goal of the Research and Protocol**

- "Tell me in your own words about the goal of this research and what will happen to you if you agree to be in this study.

____ **Benefits and Compensation**

- "What do you expect to gain by taking part in this research?"

____ **Risks**

- "What risks would you be taking if you joined this study?"

____ **Voluntariness**

- "What do you think will happen to you if you refuse to be in this study?"

* This form is designed for minimal risk, noninterventional research only.

____ **Discontinuing Participation**

- "What should you do if you agree to be in the study but later change your mind?"
- "What will happen to information already gathered if you change your mind?"

____ **Privacy**

- "Who will be able to see the information you give us?"

____ **Contact Information**

- "What should you do if you have any questions or concerns about this study?"

____ Reviewed any misinformation (e.g., "Let's talk about the goal of the study again because I think I have not explained the project clearly.").

____ Asked the potential research subject to restate concepts not clearly understood.

____ Repeated this process until the potential research subject was able to exhibit comprehension.

____ Encouraged the potential research subject to ask questions.

____ Provided a copy of the Informed Consent and/or Authorization Document.

____ If all above items are not checked, note exceptions here:

_____

_____

____ Adequate level of Comprehension Confirmed

____ Not eligible due to lack of comprehension

_____
Signature

_____
Date

_____
Name (Print)

_____
Title

Sample Informed Consent Form*

Consent Form

Study Title

We are asking you to be in a research study.

You do not have to be in the study.

If you say yes, you can quit the study at any time.

Please take as much time as you need to make your choice.

Your medical care will not change in any way if you say no.

Why sign this document?

To be in this study, sign this document.

Why are you doing this research study?

We want to learn more about how to help people who have [insert condition]. This study will help us learn more about [insert specifics]. We are asking people like you who have [insert condition] to help us.

What happens if I say yes, I want to be in the study?

If you say yes, we will:

- Ask about [describe survey items, e.g., your health, what you eat, and if you exercise, smoke, or drink alcohol, and what medicines you take].
- Give you a form with questions for you to answer.
- Read the questions out loud and fill out the form with you, if you want.

* This form is designed for minimal risk, noninterventional research only.

There are no right or wrong answers to these questions. You can skip any question you do not want to answer.

How long will the study take?

The study will take about [insert time] of your time.

What happens if I say no, I do not want to be in the study?

No one will treat you differently. You will not be penalized. [**Note to researcher:** For studies with prospect of benefit add: While you would not get the benefit of being in this study, you will not lose any other benefits.] [**Note to researcher:** For studies with no prospect of benefit add: You will not lose any benefits.] The care you get from your doctor will not change.

What happens if I say yes, but change my mind later?

You can stop being in the study at any time. You will not be penalized. [**Note to researcher:** For studies with prospect of benefit add: While you would not get the benefit of being in this study, you will not lose any other benefits.] [**Note to researcher:**For studies with no prospect of benefit add: You will not lose any benefits.]The care you get from your doctor will not change.

Who will see my answers?

The only people allowed to see your answers will be the people who work on the study and people who make sure we run our study the right way. [**Note to researcher:** If there is a study sponsor that will have access to the data, name sponsor here.]

Your survey answers, health information, and a copy of this document will be locked in our files. We will not put your answers into your medical record.

When we share the results of the study [insert details here, e.g., in medical journals] we will not include your name. We will do our best to make sure no one outside the study will know you are a part of the study.

Will it cost me anything to be in the study?

No.

Will being in this study help me in any way?

Being in the study will not help you, but may help people with [insert condition] in the future.

Will I be paid for my time?

Yes. We will give you [insert amount]. This is to pay you for your time. You will get this money [insert detail, e.g., at the end of the survey today] even if you decide to skip some of the questions.

Is there any way being in this study could be bad for me?

Yes. There is a chance that:

- The questions could make you sad or upset.
- Someone could find out that you were in the study and learn something about you that you did not want them to know.
- You could have a legal problem if you told us about a crime such as child abuse [list other mandatory reporting required in your state] that we have to report.

We will do our best to protect your privacy.

[**Note to researcher:** Insert details on additional risks if relevant to the study, such as: You could have a legal problem if someone outside the study found out that you did something illegal.]

[Provide details regarding accommodation or referrals (e.g., for counseling) if relevant to the study.]

What if I have questions?

Please call the head of the study, [insert name and phone #] if you:

- Have any questions about the study.
- Have questions about your rights.
- Feel you have been injured in any way by being in this study.

You can also call the office in charge of research at [insert phone #] to ask questions about this study.

Do I have to sign this document?

No. You only sign this document if you want to be in the study.

What should I do if I want to be in the study?

You sign this document. We will give you a copy of the document to keep.

By signing the document you are saying:

- You agree to be in the study.
- We talked with you about the information in this document and answered all your questions.

You know that:

- You can skip questions you do not want to answer.
- You can stop answering our questions at any time and nothing will happen to you.
- You can call the office in charge of research at [insert phone #] if you have any questions about the study or about your rights.

_____
Your name (please print)

_____ _____
Your signature Date

If an interpreter was used:

_____
Name of interpreter (please print)

_____ _____
Signature of Interpreter Date

If someone is signing this form for the subject, explain why:

_____

_____
Name of legally responsible person (please print)

_____ _____
Signature of person signing for the subject Date

Relationship to you:

_____

_____
Name of person conducting the consent discussion (please print)

_____ _____
Signature of person conducting the consent discussion Date

Sample HIPAA Authorization Form*

Version for investigator who is in the same covered entity as the PHI of interest

Permission to Use and Share Your Protected Health Information

Study Title

We are asking you to let us use and share your health information in a research study.

Your medical care will not change in any way if you say no.

Why sign this document?

To let the researchers from [insert name of institution or organization] use and share your health information for this study, sign this document. We will give you a copy.

Why are you asking for my information?

We want to learn more about how to help people who have [insert condition]. This study will help us learn more about [insert specifics]. We are asking people like you who have [insert condition] to help us.

What information will you use and share for the study?

If you say yes, we will:

- Use and share information from [insert name of institution or organization].
- Use and share [describe in detail the information to be used, e.g., entire medical record, information from your record, such as how often you visited the doctor and the reason for your visits, what medicines you take, the results of lab tests, and your medical record number, sex, and date of birth].

* This form is designed for minimal risk, noninterventional research only.

The information we are asking to use and share is called “Protected Health Information.” It is protected by a federal law called the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA). In general, we cannot use or share your health information for research without your permission.

If you want, we can give you more information about the Privacy Rule. Also, if you have any questions about the Privacy Rule you can speak to our Privacy Officer at [insert phone #].

How will you use and share this information?

- We will use your information only for the study described in this document.
- We may share your information with [list anyone other than the researchers who will receive identifiable information. For example, if there is a study sponsor that will have access to the data, name sponsor here].
- [**Note to researcher:** If the information is being shared for any reason other than this research study that also requires a HIPAA authorization, this purpose needs to be described. For example: We may share your name with other people doing research on **[**insert condition**]** so they can contact you about being in other research studies.]
- We will do our best to make sure your information stays private. But, if we share information with people who do not have to follow the Privacy Rule, your information will no longer be protected by the Privacy Rule. Let us know if you have questions about this.

What happens if I say no?

We will not use or share your information for this study. The care you get from your doctor will not change.

What happens if I say yes, but change my mind later?

At any time, you can tell us to stop using and sharing health information that can be traced to you. We will stop, except in very limited cases if needed to comply with law, protect your safety, or make sure the research was done properly. If you have any questions about this please ask. [**Note to researcher:** After permission is revoked, researchers are permitted to use and disclose health information in very limited circumstances that relate to protecting the integrity of the research. For example, such use and disclosure is permitted to account for a subject's withdrawal from the research study, to conduct investigations of scientific misconduct, or to report adverse events.]

If you want us to stop, you have to tell us in writing. Write or email [insert name and address and email]. If you have any questions contact [insert name and phone # and email].

If you stop, the care you get from your doctor will not change.

How long will my health information be used?

We expect our study to take [insert number] years. We will not use or share your information after the study is done. [**Note to researcher:** If the information is being shared for any reason other than this research, that also requires a HIPAA authorization (e.g., sharing a person's contact information for recruiting to other research projects), include the expiration date for the authorized activity, if different from this expiration date.]

What if I have questions?

If you have any questions about the study call the head of the study, [insert name and phone #]. Please call if you have:

- Questions about your rights.
- Questions about how we will use and share your information.

You can also call the office in charge of research at [insert phone #] to ask questions about this study.

By signing the document you are letting us use and share your health information for this study. [Add other uses and disclosures referenced above. For example: By signing the document you are giving us permission to contact you about being in other research studies]

_____
Your name (please print)

_____ _____
Your signature Date

If an interpreter was used:

_____
Name of interpreter (please print)

_____ _____
Signature of Interpreter Date

If someone is signing this form for the subject, explain why:
_____

_____
Name of legally responsible person (please print)

_____ _____
Signature of person signing for the subject Date

Relationship to you: _____

_____
Name of person conducting the consent discussion (please print)

_____ _____
Signature of person conducting the consent discussion Date

Sample HIPAA Authorization Form*

Version for investigator who is in an institution that is covered by HIPAA but is not the covered entity that has the PHI of interest

Permission to Use and Share Your Protected Health Information

Study Title

We are asking you to let your health care providers share your health information for a research study.

We are also asking you to let us use and share your health information for this research study.

Your medical care will not change in any way if you say no.

Why sign this document?

To let your health care providers from [insert name of institution or organization] share your health information with the researchers from [insert name of institution or organization] and to let the researchers use and share your health information for this study, sign this document. We will give you a copy.

Why are you asking for my information?

We want to learn more about how to help people who have [insert condition]. This study will help us learn more about [insert specifics]. We are asking people like you who have [insert condition] to help us.

* This form is designed for minimal risk, noninterventional research only.

What information will you get from my provider, and use and share for the study?

If you say yes, we will:

- Send this permission form to your health care providers at [insert name of institution or organization].
- Get and use [describe in detail the information to be requested and used, e.g., entire medical record, information from your record, such as how often you visited the doctor and the reason for your visits, what medicines you take, the results of lab tests, and your medical record number, sex, and date of birth].

The information we are asking to use and share is called "Protected Health Information." It is protected by a federal law called the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA). In general, we cannot use or share your health information for research without your permission.

If you want, we can give you more information about the Privacy Rule. Also, if you have any questions about the Privacy Rule you can speak to our Privacy Officer at [insert phone #].

How will you use and share my information?

- We will use your information only for the study described in this document.
- We may share your information with [list anyone outside the researchers who will receive identifiable information. For example, if there is a study sponsor that will have access to the data, name sponsor here.].
- [**Note to researcher:** If the information is being shared for any reason other than this research study that also requires a HIPAA authorization, this purpose needs to be described. For example: We may share your name with other people doing research on [insert condition] so they can contact you about being in other research studies.]

- We will do our best to make sure your information stays private. But, if we share information with people who do not have to follow the Privacy Rule, your information will no longer be protected by the Privacy Rule. Let us know if you have questions about this.

What happens if I say no?

We will not get your information. The care you get from your doctor will not change.

What happens if I say yes, but change my mind later?

At any time, you can stop letting your health care providers share information with us. You can also tell us to stop using and sharing health information that can be traced to you. We will stop, except in very limited cases if needed to comply with law, protect your safety, or make sure the research was done properly. If you have any questions about this please ask. [**Note to researcher:** After permission is revoked, researchers are permitted to use and disclose health information in very limited circumstances that relate to protecting the integrity of the research. For example, such use and disclosure is permitted to account for a subject's withdrawal from the research study, to conduct investigations of scientific misconduct, or to report adverse events]

If you want us to stop getting and using your information, you have to tell us and your health care provider in writing. If you want us to tell your health care provider for you, let us know and we will do that. Write or email [insert name and address and email]. If you have any questions contact [insert name and phone # and email].

If you stop, the care you get from your doctor will not change.

How long will my health information be used?

We expect our study to take [insert number] years. After the study is done, your health care provider at [insert name of institution or organization] will no longer share your information with us and we will no longer use or share your information. [**Note to researcher:** If the information is being shared for any reason other than this research, that also requires a HIPAA authorization (e.g., sharing a person's contact information for recruiting to other research projects), include the expiration date for the authorized activity, if different from this expiration date.]

What if I have questions?

If you have any questions about the study call the head of the study, [insert name and phone #]. Please call if you have:

- Questions about your rights.
- Questions about how we will use and share your information.

You can also call the office in charge of research at [insert phone #] to ask questions about this study.

By signing the document:

- You are letting your health care provider share your health information with us.
- You are letting us use and share your health information for this study.

[**Add other uses and disclosures referenced above. For example:** By signing the document you are giving permission to be contacted about being in other research studies.]

_____
Your name (please print)

_____ _____
Your signature Date

If an interpreter was used:

_____
Name of interpreter (please print)

_____ _____
Signature of Interpreter Date

If someone is signing this form for the subject, explain why:
_____

_____
Name of legally responsible person (please print)

_____ _____
Signature of person signing for the subject Date

Relationship to you: _____

_____
Name of person conducting the consent discussion (please print)

_____ _____
Signature of person conducting the consent discussion Date

Sample HIPAA Authorization Form*

Version for investigator who is not in an institution that is covered by HIPAA to get PHI from a covered entity

Permission to Get Your Protected Health Information

Study Title

We are asking you to let your health care providers share your health information for a research study.

Your medical care will not change in any way if you say no.

Why sign this document?

To let your health care providers from [insert name of institution or organization] share your health information with the researchers in this study from [insert name of institution or organization], sign this document. We will give you a copy.

Why are you asking for my information?

We want to learn more about how to help people who have [insert condition]. This study will help us learn more about [insert specifics]. We are asking people like you who have [insert condition] to help us.

* This form is designed for minimal risk, noninterventional research only.

What information will you get from my health care providers?

If you say yes, we will:

- Send this permission form to your health care providers at [insert name of institution or organization].
- Get [describe in detail the information to be used, e.g., entire medical record, information from your record, such as how often you visited the doctor and the reason for your visits, what medicines you take, the results of lab tests, and your medical record number, sex, and date of birth].

The information we are asking to get is called "Protected Health Information." It is protected by a federal law called the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA). In general, your health care provider cannot share your health information for research without your permission.

If you want, we can give you more information about the Privacy Rule.

We will do our best to make sure your information stays private. But, once your information has been shared with us it will no longer be protected by the Privacy Rule. Let us know if you have questions about this.

What happens if I say no?

We will not get your information. The care you get from your doctor will not change.

What happens if I say yes, but change my mind later?

At any time, you can stop letting your health care providers share information with us. But, you have to tell your health care provider in writing. If you want us to tell your health care provider for you, let us know and we will do that. Write or email [insert name and address and email]. If you have any questions contact [insert name and phone # and email].

If you stop, the care you get from your doctor will not change.

For how long will my health care provider be allowed to share my information?

We expect our study to take [insert number] years. After the study is done, your health care provider at [insert name of institution or organization] will no longer share your information with us. [**Note to researcher:** Edit this statement if authorization ends at an earlier time.]

What if I have questions?

If you have any questions about the study call the head of the study, [insert name and phone #]. Please call if you have:

- Questions about your rights.
- Questions about how your health care providers will share your information with us.

By signing the document you are letting your health care provider share your health information with us.

_____
Your name (please print)

_____ _____
Your signature Date

If an interpreter was used:

_____
Name of interpreter (please print)

_____ _____
Signature of Interpreter Date

If someone is signing this form for the subject, explain why:

_____

_____
Name of legally responsible person (please print)

_____ _____
Signature of person signing for the subject Date

Relationship to you:

_____

_____
Name of person conducting the consent discussion (please print)

_____ _____
Signature of person conducting the consent discussion Date

Sample Combined Informed Consent and HIPAA Authorization Form*

Version for investigator who is in the same covered entity as the PHI of interest

Consent Form and Permission to Use and Share Your Protected Health Information

Study Title

We are asking you to be in a research study.

You do not have to be in the study.

If you say yes, you can quit the study at any time.

Please take as much time as you need to make your choice.

Your medical care will not change in any way if you say no.

Why sign this document?

To be in this study and let the researchers from [insert name of institution or organization] use and share your health information for this study, sign this document.

Why are you doing this research study?

We want to learn more about how to help people who have [insert condition]. This study will help us learn more about [insert specifics]. We are asking people like you who have [insert condition] to help us.

* This form is designed for minimal risk, noninterventional research only.

What happens if I say yes, I want to be in the study?

If you say yes, we will:

- Ask about [describe survey items, e.g., your health, what you eat, and if you exercise, smoke, or drink alcohol, and what medicines you take].
- Give you a form with questions for you to answer.
- Read the questions out loud and fill out the form with you, if you want.

There are no right or wrong answers to these questions. You can skip any question you do not want to answer.

How long will the study take?

The study will take about [insert time] of your time.

What information will you use and share for the study?

If you say yes, we will also:

- Use and share information from [insert name of institution or organization].
- We will use and share [describe in detail the information to be used, e.g., your entire medical record, information from your record how often you visited the doctor and the reason for your visits, what medicines you take, the results of lab tests, and your medical record number, sex, and date of birth].

The information we are asking to use and share is called "Protected Health Information." It is protected by a federal law called the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA). In general, we cannot use or share your health information for research without your permission.

If you want, we can give you more information about the Privacy Rule. Also, if you have any questions about the Privacy Rule you can speak to our Privacy Officer at [insert phone #].

How will you use and share my information?

- We will use your information only for the study described in this document.
- We may share your information with [list anyone other than the researchers who will receive identifiable information. For example, if there is a study sponsor that will have access to the data, name sponsor here].
- [**Note to researcher:** If the information is being shared for any reason other than this research study that also requires a HIPAA authorization, this purpose needs to be described. For example: We may share your name with other people doing research on [insert condition] so they can contact you about being in other research studies.]
- We will do our best to make sure your information stays private. But, if we share information with people who do not have to follow the Privacy Rule, your information will no longer be protected by the Privacy Rule. Let us know if you have questions about this.

What happens if I say no?

If you say no:

- We will not use or share your information for this study.
- No one will treat you differently. You will not be penalized.
- The care you get from your doctor will not change.
- [**Note to researcher:** For studies with prospect of benefit add: While you would not get the benefit of being in this study, you will not lose any other benefits.] [**Note to researcher:** For studies with no prospect of benefit add: You will not lose any benefits.]

What happens if I say yes, but change my mind later?

You can stop being in the study at any time. You will not be penalized. [**Note to researcher:** For studies with prospect of benefit add: While you would not get the benefit of being in this study, you will not lose any other benefits.] [**Note to researcher:** For studies with no prospect of benefit add: You will not lose any benefits.]

You can tell us to stop using and sharing health information that can be traced to you. We will stop, except in very limited cases if needed to comply with law, protect your safety, or make sure the research was done properly. If you have any questions about this please ask. [**Note to researcher:** After permission is revoked, researchers are permitted to use and disclose health information in very limited circumstances that relate to protecting the integrity of the research. For example, such use and disclosure is permitted to account for a subject's withdrawal from the research study, to conduct investigations of scientific misconduct, or to report adverse events.]

If you want us to stop, you have to tell us in writing. Write or email [insert name and address and email]. If you have any questions contact [insert name and phone # and email].

If you stop, the care you get from your doctor will not change.

Who will see my answers?

The only people allowed to see your answers will be the people who work on the study and people who make sure we run our study the right way. [**Note to researcher:** If there is a study sponsor that will have access to the data, name sponsor here.]

Your survey answers, health information, and a copy of this document will be locked in our files.

We will not put your answers into your medical record.

When we share the results of the study [insert details here, e.g., in medical journals] we will not include your name. We will do our best to make sure no one outside the study will know you are a part of the study.

Will it cost me anything to be in the study?

No.

Will being in this study help me in any way?

Being in the study will not help you, but may help people with [insert condition] in the future.

Will I be paid for my time?

Yes. We will give you [insert amount]. This is to pay you for your time. You will get this money [insert detail, e.g., at the end of the survey today] even if you decide to skip some of the questions.

Is there any way being in this study could be bad for me?

Yes. There is a chance that:

- The questions could make you sad or upset.
- Someone could find out that you were in the study and learn something about you that you did not want them to know.
- You could have a legal problem if you told us about a crime such as child abuse [list other mandatory reporting required in your state] that we have to report.

We will do our best to protect your privacy.

[**Note to researcher:** Insert details on additional risks if relevant to the study, such as: You could have a legal problem if someone outside the study found out that you did something illegal.]

[Provide details regarding accommodation or referrals (e.g., for counseling) if relevant to the study.]

How long will my health information be used?

We expect our study to take [insert number] years. We will not use or share your information after the study is done. [**Note to researcher:** If the information is being shared for any reason other than this research, that also requires a HIPAA authorization (e.g., sharing a person's contact information for recruiting to other research projects), include the expiration date for the authorized activity, if different from this expiration date.]

What if I have questions?

If you have any questions about the study call the head of the study, [insert name and phone #].
Please call if you have:

- Any questions about the study.
- Questions about your rights.
- Concerns that you have been injured in any way by being in this study.
- Questions about how we will use and share your information.

You can also call the office in charge of research at [insert phone #] to ask questions about this study.

Do I have to sign this document?

No. You only sign this document if you want to be in the study.

What should I do if I want to be in the study?

You sign this document. We will give you a copy.

By signing the document you are saying:

- You agree to be in the study.
- You are letting us use and share your health information for this study.
- [Add other uses and disclosures referenced above. For example: You are giving permission to contact you about being in other research studies]
- We talked with you about the information in this document and answered all your questions.

You know that:

- You can skip questions you do not want to answer.
- You can stop answering our questions at any time and nothing will happen to you.
- You can call the office in charge of research at [insert phone #] if you have any questions about the study or about your rights.

_____
Your name (please print)

_____ _____
Your signature Date

If an interpreter was used:

_____
Name of interpreter (please print)

_____ _____
Signature of Interpreter Date

If someone is signing this form for the subject, explain why:

_____

_____
Name of legally responsible person (please print)

_____ _____
Signature of person signing for the subject Date

Relationship to you:

_____

_____
Name of person conducting the consent discussion (please print)

_____ _____
Signature of person conducting the consent discussion Date

Sample Combined Informed Consent and HIPAA Authorization Form*

Version for investigator who is in an institution that is covered by HIPAA but is not the covered entity that has the PHI of interest

Consent Form and Permission to Use and Share Your Protected Health Information

Study Title

We are asking you to be in a research study.

You do not have to be in the study.

If you say yes, you can quit the study at any time.

Please take as much time as you need to make your choice.

Your medical care will not change in any way if you say no.

Why sign this document?

Sign this document if you want to:

- Be in this study.
- Let your health care providers from [insert name of institution or organization] share your health information with the researchers from [insert name of institution or organization].
- Let the researchers use and share your health information for this study.

* This form is designed for minimal risk, noninterventional research only.

Why are you doing this research study?

We want to learn more about how to help people who have [insert condition]. This study will help us learn more about [insert specifics]. We are asking people like you who have [insert condition] to help us.

What happens if I say yes, I want to be in the study?

If you say yes, we will:

- Ask about [describe survey items, e.g., your health, what you eat, and if you exercise, smoke, or drink alcohol, and what medicines you take].
- Give you a form with questions for you to answer.
- Read the questions out loud and fill out the form with you, if you want.

There are no right or wrong answers to these questions. You can skip any question you do not want to answer.

How long will the study take?

The study will take about [insert time] of your time.

What information will you use and share for the study?

If you say yes, we will also:

- Send this permission form to your health care providers at [name of institution or organization].
- We will use and share [describe in detail the information to be used, e.g., your entire medical record, information from your record how often you visited the doctor and the reason for your visits, what medicines you take, the results of lab tests, and your medical record number, sex, and date of birth].

The information we are asking to use and share is called "Protected Health Information." It is protected by a federal law called the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA). In general, we cannot use or share your health information for research without your permission.

If you want, we can give you more information about the Privacy Rule. Also, if you have any questions about the Privacy Rule you can speak to our Privacy Officer at [insert phone #].

How will you use and share my information?

- We will use your information only for the study described in this document.
- We may share your information with [list anyone outside the researchers who will receive identifiable information. For example, if there is a study sponsor that will have access to the data, name sponsor here.].
- [**Note to researcher:** If the information is being shared for any reason other than this research study that also requires a HIPAA authorization, this purpose needs to be described. For example: We may share your name with other people doing research on [insert condition] so they can contact you about being in other research studies.]
- We will do our best to make sure your information stays private. But, if we share information with people who do not have to follow the Privacy Rule, your information will no longer be protected by the Privacy Rule. Let us know if you have questions about this.

What happens if I say no?

If you say no:

- We will not get your information.
- No one will treat you differently. You will not be penalized.
- The care you get from your doctor will not change.

- [**Note to researcher:** For studies with prospect of benefit add: While you would not get the benefit of being in this study, you will not lose any other benefits.] [**Note to researcher:** For studies with no prospect of benefit add: You will not lose any benefits.]

What happens if I say yes, but change my mind later?

You can stop being in the study at any time. You will not be penalized. [**Note to researcher:** For studies with prospect of benefit add: While you would not get the benefit of being in this study, you will not lose any other benefits.] [**Note to researcher:** For studies with no prospect of benefit add: You will not lose any benefits.]

You can stop letting your health care providers share information with us. You can also tell us to stop using and sharing health information that can be traced to you. We will stop, except in very limited cases if needed to comply with law, protect your safety, or make sure the research was done properly. If you have any questions about this please ask. [**Note to researcher:** After permission is revoked, researchers are permitted to use and disclose health information in very limited circumstances that relate to protecting the integrity of the research. For example, such use and disclosure is permitted to account for a subject's withdrawal from the research study, to conduct investigations of scientific misconduct, or to report adverse events.]

If you want us to stop, you have to tell us in writing. Write or email [insert name and address and email]. If you have any questions contact [insert name and phone # and email].

If you stop, the care you get from your doctor will not change.

Who will see my answers?

The only people allowed to see your answers will be the people who work on the study and people who make sure we run our study the right way. [**Note to researcher:** If there is a study sponsor that will have access to the data, name sponsor here.]

Your survey answers, health information, and a copy of this document will be locked in our files. We will not put your answers into your medical record.

When we share the results of the study [insert details here, e.g., in medical journals] we will not include your name. We will do our best to make sure no one outside the study will know you are a part of the study.

Will it cost me anything to be in the study?

No.

Will being in this study help me in any way?

Being in the study will not help you, but may help people with [insert condition] in the future.

Will I be paid for my time?

Yes. We will give you [insert amount]. This is to pay you for your time. You will get this money [insert detail, e.g., at the end of the survey today] even if you decide to skip some of the questions.

Is there any way being in this study could be bad for me?

Yes. There is a chance that:

- The questions could make you sad or upset.
- Someone could find out that you were in the study and learn something about you that you did not want them to know.
- You could have a legal problem if you told us about a crime such as child abuse [list other mandatory reporting required in your state] that we have to report.

We will do our best to protect your privacy.

[**Note to researcher:** Insert details on additional risks if relevant to the study, such as: You could have a legal problem if someone outside the study found out that you did something illegal.]

[Provide details regarding accommodation or referrals (e.g., for counseling) if relevant to the study.]

How long will my health information be used?

We expect our study to take [insert number] years. After the study is done, your health care provider at [insert name of institution or organization] will no longer share your information with us and we will no longer use or share your information.

[**Note to researcher:** If the information is being shared for any reason other than this research, that also requires a HIPAA authorization (e.g., sharing a person's contact information for recruiting to other research projects), include the expiration date for the authorized activity, if different from this expiration date.]

What if I have questions?

If you have any questions about the study call the head of the study, [insert name and phone #].
Please call if you have:

- Any questions about the study.
- Questions about your rights.
- Concerns that you have been injured in any way by being in this study.
- Questions about how we will use and share your information.

You can also call the office in charge of research at [insert phone #] to ask questions about this study.

Do I have to sign this document?

No. You only sign this document if you want to be in the study.

What should I do if I want to be in the study?

You sign this document. We will give you a copy.

By signing the document you are saying:

- You agree to be in the study.
- You are letting your health care provider share your health information with us.
- You are letting us use and share your health information for this study.
- [Add other uses and disclosures referenced above. For example: By signing the document you are giving permission to contact you about being in other research studies.]
- We talked with you about the information in this document and answered all your questions.

You know that:

- You can skip questions you do not want to answer.
- You can stop answering our questions at any time and nothing will happen to you.
- You can call the office in charge of research at [insert phone #] if you have any questions about the study or about your rights.

_____
Your name (please print)

_____ _____
Your signature Date

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Name of interpreter (please print)

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Signature of Interpreter Date

If someone is signing this form for the subject, explain why:

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Name of legally responsible person (please print)

_____ _____
Signature of person signing for the subject Date

Relationship to you:

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_____
Name of person conducting the consent discussion (please print)

_____ _____
Signature of person conducting the consent discussion Date

Sample Combined Informed Consent and HIPAA Authorization Form*

Version for investigator who is not in an institution that is covered by HIPAA

Consent Form and Permission to Get Your Protected Health Information

Study Title

We are asking you to be in a research study.

You do not have to be in the study.

If you say yes, you can quit the study at any time.

Please take as much time as you need to make your choice.

Your medical care will not change in any way if you say no.

Why sign this document?

To be in this study and let your health care providers from [insert name of institution or organization] share your health information with the researchers in this study from [insert name of institution or organization], sign this document.

Why are you doing this research study?

We want to learn more about how to help people who have [insert condition]. This study will help us learn more about [insert specifics]. We are asking people like you who have [insert condition] to help us.

* This form is designed for minimal risk, noninterventional research only.

What happens if I say yes, I want to be in the study?

If you say yes, we will:

- Ask about [describe survey items, e.g., your health, what you eat, and if you exercise, smoke, or drink alcohol, and what medicines you take].
- Give you a form with questions for you to answer.
- Read the questions out loud and fill out the form with you, if you want.

There are no right or wrong answers to these questions. You can skip any question you do not want to answer.

How long will the study take?

The study will take about [insert time] of your time.

What information will you get from my health care providers?

If you say yes, we will also:

- Send this permission form to your health care providers at [insert name of institution or organization].
- We will get [describe in detail the information to be used, e.g., entire medical record, information from your record how often you visited the doctor and the reason for your visits, what medicines you take, the results of lab tests, and your medical record number, sex, and date of birth].

The information we are asking to get is called "Protected Health Information." It is protected by a federal law called the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA). In general, your health care provider cannot share your health information for research without your permission.

If you want, we can give you more information about the Privacy Rule.

We will do our best to make sure your information stays private. But, once your information has been shared with us it will no longer be protected by the Privacy Rule. Let us know if you have questions about this.

What happens if I say no?

If you say no:

- We will not get your information.
- No one will treat you differently. You will not be penalized.
- The care you get from your doctor will not change.
- [**Note to researcher:** For studies with prospect of benefit add: While you would not get the benefit of being in this study, you will not lose any other benefits.] [**Note to researcher:** For studies with no prospect of benefit add: You will not lose any benefits.]

What happens if I say yes, but change my mind later?

You can stop being in the study at any time. You will not be penalized. [**Note to researcher:** For studies with prospect of benefit add: While you would not get the benefit of being in this study, you will not lose any other benefits.]

You can stop letting your health care providers share information with us. But, you have to tell your health care provider in writing. If you want us to tell your health care provider for you, let us know and we will do that. Write or email [insert name and address and email]. If you have any questions contact [insert name and phone # and email].

If you stop, the care you get from your doctor will not change.

Who will see my answers?

The only people allowed to see your answers will be the people who work on the study and people who make sure we run our study the right way. [**Note to researcher:** If there is a study sponsor that will have access to the data, name sponsor here.]

Your survey answers, health information, and a copy of this document will be locked in our files. We will not put your answers into your medical record.

When we share the results of the study [insert details here, e.g., in medical journals] we will not include your name. We will do our best to make sure no one outside the study will know you are a part of the study.

Will it cost me anything to be in the study?

No.

Will being in this study help me in any way?

Being in the study will not help you, but may help people with [insert condition] in the future.

Will I be paid for my time?

Yes. We will give you [insert amount]. This is to pay you for your time. You will get this money [insert detail, e.g., at the end of the survey today] even if you decide to skip some of the questions.

Is there any way being in this study could be bad for me?

Yes. There is a chance that:

- The questions could make you sad or upset.
- Someone could find out that you were in the study and learn something about you that you did not want them to know.
- You could have a legal problem if you told us about a crime such as child abuse [list other mandatory reporting required in your state] that we have to report.

We will do our best to protect your privacy.

[**Note to researcher:** Insert details on additional risks if relevant to the study, such as: You could have a legal problem if someone outside the study found out that you did something illegal.]

[Provide details regarding accommodation or referrals (e.g., for counseling) if relevant to the study.]

How long will my health care provider be allowed to share my information?

We expect our study to take [insert number] years. After the study is done, your health care provider at [name of institution or organization] will no longer share your information with us. [**Note to researcher:** Edit this statement if authorization ends at an earlier time.]

What if I have questions?

If you have any questions about the study call the head of the study, [insert name and phone #].
Please call if you have:

- Any questions about the study.
- Questions about your rights.
- Concerns that you have been injured in any way by being in this study.
- Questions about how your health care providers will share your information with us.

You can also call the office in charge of research at [insert phone #] to ask questions about this study.

Do I have to sign this document?

No. You only sign this document if you want to be in the study.

What should I do if I want to be in the study?

You sign this document. We will give you a copy.

By signing the document you are saying:

- You agree to be in the study.
- You are letting your health care provider share your health information with us.
- [Add other uses and disclosures referenced above. For example: By signing the document you are giving permission to contact you about being in other research studies.]
- We talked with you about the information in this document and answered all your questions.

You know that:

- You can skip questions you do not want to answer.
- You can stop answering our questions at any time and nothing will happen to you.
- You can call the office in charge of research at [insert phone #] if you have any questions about the study or about your rights.

_____
Your name (please print)

_____ _____
Your signature Date

If an interpreter was used:

_____
Name of interpreter (please print)

_____ _____
Signature of Interpreter Date

If someone is signing this form for the subject, explain why:

_____

_____
Name of legally responsible person (please print)

_____ _____
Signature of person signing for the subject Date

Relationship to you:

_____

_____
Name of person conducting the consent discussion (please print)

_____ _____
Signature of person conducting the consent discussion Date

Ejemplo de formulario de consentimiento informado *

Formulario de consentimiento

Título del estudio

Le estamos pidiendo que participe en un estudio.

Usted no tiene que participar en el estudio.

Si dice que sí, puede dejar de participar en el estudio en cualquier momento.

Por favor tome todo el tiempo que necesite para decidir.

Su atención médica no cambiará de manera alguna si dice que no.

¿Para qué se firma este documento?

Lo firma para poder participar en el estudio.

¿Por qué se está haciendo este estudio de investigación?

Queremos saber más sobre cómo ayudar a las personas que tienen [inserte condición]. Este estudio nos ayudará a aprender más sobre [provea información específica]. Les estamos pidiendo a personas como usted, que tienen [inserte condición], que nos ayuden.

* Este formulario fue diseñado para investigación que no conlleva intervención, de riesgo mínimo.

¿Qué pasa si digo “sí, quiero participar en el estudio”?

Si dice que sí:

- Le preguntaremos sobre [describa las preguntas de la encuesta, por ejemplo, su salud, lo que come y si hace ejercicio, fuma o toma alcohol, y cuáles medicinas toma]
- Le daremos un formulario con preguntas para que usted las conteste.
- Si quiere, podemos leerle las preguntas en voz alta y escribir sus respuestas en el formulario.

Estas preguntas no tienen respuestas correctas o incorrectas. Puede saltar cualquier pregunta si no quiere contestarla.

¿Cuánto tiempo tomará el estudio?

El estudio tomará alrededor de [inserte tiempo] de su tiempo.

¿Qué pasa si digo “no quiero participar en el estudio”?

Nadie le tratará en manera diferente. A usted no se le penalizará. [**Nota para el investigador:** Si el estudio ofrece posibilidad de beneficio, añada: Aunque no recibirá el beneficio de estar en el estudio, no perderá ningún otro beneficio.] [**Nota para el investigador:** En el caso de estudios sin posibilidad de beneficio, añada: No perderá ningún beneficio.] La atención que recibe de su médico no cambiará.

¿Qué pasa si digo que sí, pero cambio de opinión más tarde?

Usted puede dejar de participar en el estudio en cualquier momento. A usted no se le penalizará. [**Nota para el investigador:** Si el estudio ofrece posibilidad de beneficio, añada: Aunque no recibirá el beneficio de estar en el estudio, no perderá ningún otro beneficio.] [**Nota para el investigador:** En el caso de estudios sin posibilidad de beneficio, añada: No perderá ningún beneficio.] La atención que recibe de su médico no cambiará.

¿Quién verá mis respuestas?

Las únicas personas autorizadas para ver sus respuestas son las que trabajan en el estudio y las que se aseguran de que éste se realice de manera correcta. [**Nota para el investigador:** Si el estudio tiene un patrocinador que tendrá acceso a los datos, nómbrelo aquí.]

Sus respuestas a la encuesta, su información médica, y una copia firmada de este documento se mantendrán bajo llave en nuestros archivos. No incluiremos sus respuestas en su expediente médico.

Cuando compartamos los resultados del estudio, [incluya detalles aquí, por ejemplo, en revistas médicas] no incluiremos su nombre. Haremos todo lo posible para que nadie fuera del estudio sepa que usted participó en él.

¿Me costará algo participar en el estudio?

No.

Participar en el estudio, ¿me ayudará de alguna manera?

Participar en este estudio no le ayudará, pero podría ayudar a personas con [inserte condición] en el futuro.

¿Me pagarán por mi tiempo?

Sí, le daremos [incluya cantidad]. Esto es para pagarle por su tiempo. Usted recibirá este dinero [provea detalles, por ejemplo, al final de la encuesta de hoy] aun si decide no contestar algunas preguntas.

Participar en este estudio, ¿pudiera ser malo para mí, de alguna manera?

Sí. Hay una posibilidad de que:

- Las preguntas le puedan hacer sentir triste o hacerle sentir mal.
- Alguien pudiera enterarse de que usted participó en este estudio y llegar a saber algo sobre usted que usted no quería que supiera.
- Podría tener un problema legal si nos cuenta sobre un delito, como el abuso de niños, [proporcione una lista de asuntos de notificación forzosa que se exijan en su estado] que tenemos que reportar.

Haremos todo lo posible para proteger su privacidad. [**Nota para el investigador:** Provea detalles sobre riesgos adicionales si son relevantes para el estudio, tales como un problema legal si alguien fuera de este estudio se enterara de que usted hizo algo ilegal.]

[**Nota para el investigador:** Provea detalles sobre asistencia o referidos (por ejemplo, consejería) si son relevantes para el estudio]

¿Qué debo hacer si tengo preguntas?

Por favor llame al director del estudio, [incluya el nombre y número de teléfono], si:

- Tiene alguna pregunta sobre el estudio.
- Tiene preguntas sobre sus derechos.
- Cree que se ha lesionado de alguna manera por participar en este estudio.

También puede llamar a la oficina encargada de investigaciones [incluya el número de teléfono] para preguntar sobre este estudio.

¿Tengo que firmar este documento?

No. Fírmelo solamente si desea participar en el estudio.

¿Qué debo hacer si quiero participar en el estudio?

Tiene que firmar este documento. Le entregaremos una copia.

Al firmar este documento está diciendo que:

- Está de acuerdo con participar en el estudio.
- Le hemos explicado la información que contiene este documento y hemos contestado todas sus preguntas.

Usted sabe que:

- No tiene que contestar preguntas que no quiera contestar.
- En cualquier momento, puede dejar de contestar nuestras preguntas y no le pasará nada a usted.
- Puede llamar a la oficina encargada de investigaciones al [incluya número de teléfono] si tiene alguna pregunta sobre el estudio o sobre sus derechos.

_____

Su nombre (en letra de molde)

_____ _____

Su firma Fecha

Si se utilizó un intérprete:

_____

Nombre del intérprete (en letra de molde)

_____ _____

Firma del intérprete Fecha

Si otra persona firma este formulario a nombre del participante, explique por qué:

_____

_____

Nombre del representante legal (en letra de molde)

_____ _____

Firma de la persona que provee el consentimiento en representación del sujeto Fecha

Relación o parentesco:

_____

_____

Nombre de la persona que explica el consentimiento (en letra de molde)

_____ _____

Firma de la persona que explica el consentimiento Fecha

Ejemplo del Formulario de Autorización HIPAA (Ley Federal de Portabilidad y Responsabilidad de los Seguros de Salud) *

Versión para el investigador que está en la misma entidad cubierta que la PHI de interés

Autorización para usar y compartir su información médica protegida

Título del estudio

Le estamos pidiendo usar y compartir información médica suya en un estudio de investigación.

Su atención médica no cambiará de manera alguna si dice que no.

¿Para qué se firma este documento?

Lo firma para permitir que los investigadores de [inserte el nombre de la institución u organización] usen y compartan la información médica suya para este estudio. Le entregaremos una copia.

¿Por qué me están pidiendo mi información?

Queremos saber más sobre cómo ayudar a las personas que tienen [inserte condición]. Este estudio nos ayudará a aprender más sobre [provea información específica]. Les estamos pidiendo a personas como usted, que tienen [inserte condición], que nos ayuden.

* Este formulario fue diseñado para investigación que no conlleva intervención, de riesgo mínimo.

¿Qué información se usará y compartirá en el estudio?

Si dice que sí:

- Usaremos y compartiremos información de [nombre del lugar o consultorio médico].
- Usaremos y compartiremos información de [describa en detalle la información que se usará; por ejemplo, su historial médico completo, información de su expediente, como con qué frecuencia ha ido al médico y el motivo de esas visitas, qué medicinas toma, los resultados de las pruebas de laboratorio, y su número de expediente médico, sexo y fecha de nacimiento].

La información que le pedimos que nos deje usar y compartir se conoce como "Información Médica Protegida". Está protegida por la ley federal llamada Regla de Privacidad (Privacy Rule, en inglés) de la Ley Federal de Portabilidad y Responsabilidad de los Seguros de Salud (Health Insurance Portability and Accountability Act, HIPAA, por sus siglas en inglés). En general, sin autorización suya, no podemos usar ni compartir información médica suya para los fines de la investigación.

Si quiere, le podemos dar una copia de la Regla de Privacidad. También, si tiene alguna pregunta sobre la Regla de Privacidad, puede hablar con nuestro Oficial de Privacidad, llamando al [incluya número de teléfono].

¿Cómo se usará y compartirá esta información?

- Usaremos su información sólo para el estudio que se describe en este documento.
- Podemos compartir su información con [mencione cualquier persona, aparte de los investigadores, que recibirá información que lo identifique. Por ejemplo, si hay un patrocinador del estudio que tendrá acceso a los datos, nómbrelo aquí].

- [**Nota para el investigador**: Si la información se comparte por razones ajenas al estudio de investigación, que también requieran autorización de la HIPAA, deberá explicarse el propósito. Por ejemplo: es posible que le demos su nombre a otras personas que investigan [inserte condición], para que se comuniquen con usted y le pregunten si le interesa participar en otros estudios de investigación.]
- Haremos todo lo posible para asegurarnos de que su información permanezca privada. Sin embargo, si compartimos información con personas que no estén obligadas a cumplir con la Regla de Privacidad, la información dejará de estar protegida por esta Regla de Privacidad. Díganos si tiene alguna duda al respecto.

¿Qué pasa si digo "no quiero participar en el estudio"?

No usaremos ni compartiremos su información en este estudio. La atención que recibe de su médico no cambiará.

¿Qué pasa si digo que sí, pero cambio de opinión más tarde?

En cualquier momento, puede pedirnos que dejemos de usar y compartir información médica que pueda identificarlo. Dejaremos de usar y compartir información, excepto en situaciones muy especiales, como cuando sea necesario para cumplir con la ley, para proteger su seguridad o para comprobar que la investigación se haya hecho en forma correcta. Por favor pregunte si tiene alguna duda al respecto. [**Nota para el investigador:** Después de que retire su autorización, los investigadores podrían usar y compartir su información médica en circunstancias muy especiales con el propósito de proteger la integridad de la investigación. Ese uso y revelación se permite, por ejemplo, cuando se quiere explicar por qué se retiró al sujeto del estudio, para investigar una conducta científica inválida, o para reportar eventos adversos.]

Si en algún momento desea retirarse, es necesario que lo pida por escrito. Envíe una carta o correo electrónico a [inserte nombre, dirección y correo electrónico]. Si tiene alguna duda, consulte con [inserte nombre, teléfono y correo electrónico)].

Si decide retirarse, seguirá recibiendo la misma atención de su médico.

¿Por cuánto tiempo se usará mi información médica?

Esperamos que nuestro estudio dure [incluya número] años. No usaremos ni compartiremos su información una vez terminado el estudio. [**Nota para el investigador:** Si la información se comparte por razones ajenas a la investigación que también requieran autorización de la HIPAA (como por ejemplo, compartir la información de contacto de una persona para invitarla a otros proyectos de investigación), incluya la fecha de vencimiento de la actividad autorizada, si difiere de esta fecha de vencimiento.]

¿Qué debo hacer si tengo preguntas?

Si tiene preguntas sobre el estudio, llame al director del estudio [incluya el nombre y número de teléfono]. Por favor llame si:

- Tiene preguntas sobre sus derechos.
- Tiene preguntas sobre cómo usaremos y compartiremos su información.

También puede llamar a la oficina encargada de investigaciones [incluya el número de teléfono] para preguntar sobre este estudio.

Al firmar este documento, nos está autorizando a usar y compartir su información médica para este estudio. [Añada otros usos y revelaciones mencionados anteriormente. Por ejemplo: al firmar este documento, acepta que le llamen o escriban para invitarlo a participar en otros estudios de investigación.]

_____
Su nombre (en letra de molde)

_____ _____
Su firma Fecha

Si se utilizó un intérprete:

_____
Nombre del intérprete (en letra de molde)

_____ _____
Firma del intérprete Fecha

Si otra persona firma este formulario a nombre del participante, explique por qué:

_____

_____
Nombre del representante legal (en letra de molde)

_____ _____
Firma de la persona que provee el consentimiento en representación del sujeto Fecha

Relación o parentesco:
_____

_____
Nombre de la persona que explica el consentimiento (en letra de molde)

_____ _____
Firma de la persona que explica el consentimiento Fecha

Ejemplo del Formulario de Autorización HIPAA (Ley Federal de Portabilidad y Responsabilidad de los Seguros de Salud)*

Versión para el investigador que está en una institución cubierta por la HIPAA pero distinta de la entidad cubierta que tiene la PHI de interés

Autorización para usar y compartir su información médica protegida

Título del estudio

Le estamos pidiendo que permita que sus médicos compartan información médica suya para un estudio de investigación.

También, le estamos pidiendo usar y compartir información médica suya en este estudio de investigación.

Su atención médica no cambiará de manera alguna si dice que no.

¿Para qué se firma este documento?

Lo firma para permitir que sus médicos de [inserte el nombre de la institución u organización] compartan su información médica con los investigadores de [inserte nombre de la institución u organización] y permitir que los investigadores usen y compartan la información médica suya para este estudio. Le entregaremos una copia.

* Este formulario fue diseñado para investigación que no conlleva intervención, de riesgo mínimo.

¿Por qué me están pidiendo mi información?

Queremos saber más sobre cómo ayudar a las personas que tienen [inserte condición]. Este estudio nos ayudará a aprender más sobre [provea información específica]. Les estamos pidiendo a personas como usted, que tienen [inserte condición] que nos ayuden.

¿Qué información se obtendrá de mi médico y se usará y compartirá para el estudio?

Si dice que sí:

- Enviaremos esta hoja de autorización a sus médicos de [inserte nombre de la institución u organización].
- Obtendremos y usaremos [describa en detalle la información que se usará; por ejemplo, su historial médico completo, información de su expediente, como con qué frecuencia ha ido al médico y el motivo de esas visitas, qué medicinas toma, los resultados de las pruebas de laboratorio, y su número de expediente médico, sexo y fecha de nacimiento].

La información que le pedimos que nos deje usar y compartir se conoce como “Información Médica Protegida”. Está protegida por la ley federal llamada Regla de Privacidad (Privacy Rule, en inglés) de la Ley Federal de Portabilidad y Responsabilidad de los Seguros de Salud (Health Insurance Portability and Accountability Act, HIPAA, por sus siglas en inglés). En general, sin autorización suya, no podremos usar ni compartir información médica suya para los fines de la investigación.

Si quiere, le podemos dar una copia de la Regla de Privacidad. También, si tiene alguna pregunta sobre la Regla de Privacidad puede hablar con nuestro Oficial de Privacidad, llamando al [incluya número de teléfono].

¿Cómo se usará y compartirá mi información?

- Usaremos su información sólo para el estudio que se describe en este documento.
- Podemos compartir su información con [mencione cualquier persona, aparte de los investigadores, que recibirá información que lo identifique. Por ejemplo, si hay un patrocinador del estudio que tendrá acceso a los datos, nómbrelo aquí].
- [**Nota para el investigador**: Si la información se comparte por razones ajenas al estudio de investigación que también requieran autorización de la HIPAA, deberá explicarse el propósito. Por ejemplo: es posible que le demos su nombre a otras personas que investigan [inserte condición], para que se comuniquen con usted y le pregunten si le interesa participar en otros estudios de investigación.]
- Haremos todo lo posible para asegurarnos de que su información permanezca privada. Sin embargo, si compartimos información con personas que no estén obligadas a cumplir con la Regla de Privacidad, la información dejará de estar protegida por esta Regla de Privacidad. Díganos si tiene alguna duda al respecto.

¿Qué pasa si digo "no quiero participar en el estudio"?

No obtendremos información de usted. La atención que recibe de su médico no cambiará.

¿Qué pasa si digo que sí, pero cambio de opinión más tarde?

En cualquier momento, puede retirar su permiso para que sus médicos nos den información. También puede pedirnos que dejemos de usar y compartir información médica que pueda identificarlo. Dejaremos de usar y compartir información, excepto en situaciones muy especiales, como cuando sea necesario para cumplir con la ley, para proteger su seguridad o

para comprobar que la investigación se haya hecho en forma correcta. Por favor pregunte si tiene alguna duda al respecto. [**Nota para el investigador:** Después de que retire su autorización, los investigadores podrían usar y compartir su información médica en circunstancias muy especiales, con el propósito de proteger la integridad de la investigación. Ese uso y revelación se permite, por ejemplo, cuando se quiere explicar por qué se retiró al sujeto del estudio, para investigar una conducta científica inapropiada o para reportar eventos adversos.]

Si desea que dejemos de obtener y usar su información médica, deberá pedirlo por escrito a su médico y a nosotros. Si prefiere que le avisemos a su médico, díganos y así lo haremos. Envíe una carta o correo electrónico a [nombre, dirección y correo electrónico]. Si tiene alguna duda, consulte con [inserte nombre, dirección y correo electrónico].

Si decide retirarse, seguirá recibiendo la misma atención de su médico.

¿Por cuánto tiempo se usará mi información médica?

Esperamos que nuestro estudio dure [incluya número] años. Una vez terminado el estudio, su médico de [inserte nombre de la institución u organización] dejará de darnos información suya y también nosotros dejaremos de usar y compartir su información. [**Nota para el investigador:** Si la información se comparte por razones ajenas a la investigación que también requieran autorización de la HIPAA (por ejemplo, compartir la información de contacto de una persona para invitarla a otros proyectos de investigación), incluya la fecha de vencimiento de la actividad autorizada, si difiere de esta fecha de vencimiento.]

¿Qué debo hacer si tengo preguntas?

Si tiene preguntas sobre el estudio, llame al director del estudio [incluya el nombre y número de teléfono]. Por favor llame si:

- Tiene preguntas sobre sus derechos.
- Tiene preguntas sobre cómo usaremos y compartiremos su información.

También puede llamar a la oficina encargada de investigaciones [incluya el número de teléfono] para preguntar sobre este estudio.

Al firmar este documento:

- Está autorizando a su médico a darnos información sobre su salud.
- Nos está autorizando a usar y compartir su información médica para este estudio.

[Añada otros usos y revelaciones mencionados anteriormente. Por ejemplo: Al firmar este documento, acepta que le llamen o escriban para invitarlo a participar en otros estudios de investigación.]

_____

Su nombre (en letra de molde)

_____ _____

Su firma Fecha

Si se utilizó un intérprete:

_____

Nombre del intérprete (en letra de molde)

_____ _____

Firma del intérprete Fecha

Si otra persona firma este formulario a nombre del participante, explique por qué:

_____

_____

Nombre del representante legal (en letra de molde)

_____ _____

Firma de la persona que provee el consentimiento en representación del sujeto Fecha

Relación o parentesco:

_____

_____

Nombre de la persona que explica el consentimiento (en letra de molde)

_____ _____

Firma de la persona que explica el consentimiento Fecha

Ejemplo del Formulario de Autorización HIPAA (Ley Federal de Portabilidad y Responsabilidad de los Seguros de Salud)*

Versión para el investigador que no está en una institución cubierta por HIPAA para obtener PHI de una entidad cubierta

Autorización para usar y compartir su información médica protegida

Título del estudio

Le estamos pidiendo que permita que sus médicos compartan información médica suya para un estudio de investigación.

Su atención médica no cambiará de manera alguna si dice que no.

¿Para qué se firma este documento?

Lo firma para permitir que sus médicos de [inserte el nombre de la institución u organización] compartan su información médica con los investigadores de este estudio de [inserte nombre de la institución u organización]. Le entregaremos una copia.

¿Por qué me están pidiendo mi información?

Queremos saber más sobre cómo ayudar a las personas que tienen [inserte condición]. Este estudio nos ayudará a aprender más sobre [provea información específica]. Les estamos pidiendo a personas como usted, que tienen [inserte condición], que nos ayuden.

* Este formulario fue diseñado para investigación que no conlleva intervención, de riesgo mínimo.

¿Qué información se obtendrá de mis médicos?

Si dice que sí:

- Mandaremos esta hoja de autorización a sus médicos de [inserte nombre de la institución u organización].
- Obtendremos [describa en detalle la información que se usará; por ejemplo, su historial médico completo, información de su expediente, como con qué frecuencia ha ido al médico y el motivo de esas visitas, qué medicamentos toma, los resultados de las pruebas de laboratorio, y su número de expediente médico, sexo y fecha de nacimiento].

La información que le pedimos que nos deje obtener se conoce como "Información Médica Protegida". Está protegida por la ley federal llamada Regla de Privacidad (Privacy Rule, en inglés) de la Ley Federal de Portabilidad y Responsabilidad de los Seguros de Salud (Health Insurance Portability and Accountability Act, HIPAA, por sus siglas en inglés). En general, sin autorización suya, su médico no puede compartir información médica suya para los fines de la investigación.

Si lo desea, podemos darle más información sobre la Regla de Privacidad.

Haremos todo lo posible para asegurarnos de que su información permanezca privada. Pero una vez que se nos transmita su información, dejará de estar protegida por la Regla de Privacidad. Díganos si tiene alguna duda al respecto.

¿Qué pasa si digo "no quiero participar en el estudio"?

No obtendremos información de usted. La atención que recibe de su médico no cambiará.

¿Qué pasa si digo que sí, pero cambio de opinión más tarde?

En cualquier momento, puede retirar su permiso para que sus médicos nos den información. Pero tiene que avisarle por escrito a su médico. Si prefiere que le avisemos a su médico, díganos y así lo haremos. Envíe una carta o correo electrónico a [inserte nombre, dirección y correo electrónico]. Si tiene alguna duda, consulte con [inserte nombre, teléfono y correo electrónico].

Si decide retirarse, seguirá recibiendo la misma atención de su médico.

¿Por cuánto tiempo se permitirá que mi médico comparta información mía?

Esperamos que nuestro estudio dure [incluya número] años. Una vez terminado el estudio, su médico de [inserte nombre de la institución u organización] dejará de compartir su información con nosotros. [**Nota para el investigador**: Modifique esta afirmación si la autorización termina antes.]

¿Qué debo hacer si tengo preguntas?

Si tiene preguntas sobre el estudio, llame al director del estudio [incluya el nombre y número de teléfono]. Por favor llame si:

- Tiene preguntas sobre sus derechos.
- Tiene preguntas sobre cómo sus médicos compartirán su información con nosotros.

Al firmar este documento está autorizando a su médico a darnos su información médica para este estudio.

_____

Su nombre (en letra de molde)

_____ _____

Su firma Fecha

Si se utilizó un intérprete:

_____

Nombre del intérprete (en letra de molde)

_____ _____

Firma del intérprete Fecha

Si otra persona firma este formulario a nombre del participante, explique por qué:

_____

_____

Nombre del representante legal (en letra de molde)

_____ _____

Firma de la persona que provee el consentimiento en representación del sujeto Fecha

Relación o parentesco:

_____

_____

Nombre de la persona que explica el consentimiento (en letra de molde)

_____ _____

Firma de la persona que explica el consentimiento Fecha

Ejemplo de formulario combinado de consentimiento informado y autorización*

Versión para el investigador que está en la misma entidad cubierta que la PHI de interés

Formulario de consentimiento y autorización para usar y compartir su información médica protegida

Título del estudio

Le estamos pidiendo que participe en un estudio.

Usted no tiene que participar en el estudio.

Si dice que sí, puede dejar de participar en el estudio en cualquier momento.

Por favor tome todo el tiempo que necesite para decidir.

Su atención médica no cambiará de manera alguna si dice que no.

¿Para qué se firma este documento?

Lo firma para poder participar en el estudio y permitir a los investigadores de [inserte el nombre de la institución u organización] usar y compartir la información médica suya para este estudio.

* Este formulario fue diseñado para investigación que no conlleva intervención, de riesgo mínimo.

¿Por qué se está haciendo este estudio de investigación?

Queremos saber más sobre cómo ayudar a las personas que tienen [inserte condición]. Este estudio nos ayudará a aprender más sobre [provea información específica]. Les estamos pidiendo a personas como usted, que tienen [inserte condición], que nos ayuden.

¿Qué pasa si digo "sí, quiero participar en el estudio"?

Si dice que sí:

- Le preguntaremos sobre [describa las preguntas de la encuesta, por ejemplo, su salud, lo que come y si hace ejercicio, fuma o toma alcohol, y qué medicinas toma]
- Le daremos un formulario con preguntas para que usted las conteste.
- Si quiere, podemos leerle las preguntas en voz alta y escribir sus respuestas en el formulario.

Estas preguntas no tienen respuestas correctas o incorrectas. Puede saltar cualquier pregunta si no quiere contestarla.

¿Cuánto tiempo tomará el estudio?

El estudio tomará alrededor de [inserte tiempo] de su tiempo.

¿Qué información se usará y compartirá en el estudio?

Si dice que sí, también:

- Usaremos y compartiremos información de [inserte el nombre de la institución u organización].

- Usaremos y compartiremos información de [describa en detalle la información que se usará; por ejemplo, su historial médico completo, información de su expediente, como con qué frecuencia ha ido al médico y el motivo de esas visitas, qué medicamentos toma, los resultados de las pruebas de laboratorio, y su número de expediente médico, sexo y fecha de nacimiento].

La información que le pedimos que nos deje usar se conoce como "Información Médica Protegida". Está protegida por la ley federal llamada Regla de Privacidad (Privacy Rule, en inglés) de la Ley Federal de Portabilidad y Responsabilidad de los Seguros de Salud (Health Insurance Portability and Accountability Act, HIPAA, por sus siglas en inglés). En general, sin autorización suya, no podremos usar ni compartir información médica suya para los fines de la investigación.

Si lo desea, podemos darle más información sobre la Regla de Privacidad. También, si tiene alguna pregunta sobre la Regla de Privacidad puede hablar con nuestro Oficial de Privacidad, llamando al [incluya número de teléfono].

¿Cómo se usará y compartirá mi información?

- Usaremos su información sólo para el estudio que se describe en este documento.
- Podemos compartir su información con [mencione cualquier persona, aparte de los investigadores, que recibirá información que lo identifique. Por ejemplo, si hay un patrocinador de estudios que tendrá acceso a los datos, nómbrelo aquí].
- [**Nota para el investigador:** Si la información se comparte por razones ajenas al estudio de investigación que también requieran autorización de la HIPAA, deberá explicarse el propósito. Por ejemplo, es posible que le demos su nombre a otras personas que investigan [inserte condición], para que se comuniquen con usted y le pregunten si le interesa participar en otros estudios de investigación.]

- Haremos todo lo posible para asegurarnos de que su información permanezca privada. Sin embargo, si compartimos información con personas que no estén obligadas a cumplir con la Regla de Privacidad, la información dejará de estar protegida por esta Regla de Privacidad. Díganos si tiene alguna duda al respecto.

¿Qué pasa si digo "no quiero participar en el estudio"?

Si dice que no:

- No usaremos ni compartiremos su información en este estudio.
- Nadie le tratará en manera diferente. A usted no se le penalizará.
- La atención que recibe de su médico no cambiará.
- [**Nota para el investigador:** Si el estudio ofrece posibilidad de beneficio, añada: Aunque no recibirá el beneficio de estar en el estudio, no perderá ningún otro beneficio.] [En el caso de estudios sin posibilidad de beneficio, añada: No perderá ningún beneficio.]

¿Qué pasa si digo que sí, pero cambio de opinión más tarde?

Usted puede dejar de participar en el estudio en cualquier momento. A usted no se le penalizará. [**Nota para el investigador:** Si el estudio ofrece posibilidad de beneficio, añada: Aunque no recibirá el beneficio de estar en el estudio, no perderá ningún otro beneficio.] [En el caso de estudios sin posibilidad de beneficio, añada: No perderá ningún beneficio.]

Puede pedirnos que dejemos de usar y compartir información médica que pueda identificarlo. Dejaremos de usar y compartir información, excepto en situaciones muy especiales, como cuando sea necesario para cumplir con la ley, para proteger su seguridad o para comprobar que

la investigación se haya hecho en forma correcta. Por favor, pregunte si tiene alguna duda al respecto. [**Nota para el investigador:** Después de que retire su autorización, los investigadores podrían usar y compartir su información médica en circunstancias muy especiales, con el propósito de proteger la integridad de la investigación. Ese uso y revelación se permite, por ejemplo, cuando se quiere explicar por qué se retiró al sujeto del estudio, para investigar una conducta científica inválida o para reportar eventos adversos.]

Si en algún momento desea retirarse, es necesario que lo pida por escrito. Envíe una carta o correo electrónico a [inserte nombre, dirección y correo electrónico]. Si tiene alguna duda, consulte a [inserte nombre, teléfono y correo electrónico].

Si decide retirarse, seguirá recibiendo la misma atención de su médico.

¿Quién verá mis respuestas?

Las únicas personas autorizadas para ver su información médica serán las que trabajan en el estudio y las que supervisan cómo realizamos el estudio. [**Nota para el investigador:** Si el estudio tiene un patrocinador que tendrá acceso a los datos, nómbrelo aquí.]

Las respuestas de su encuesta, su información médica, y una copia firmada de este documento se mantendrán bajo llave en nuestros archivos. No se incluirán sus respuestas en su expediente médico.

Cuando compartamos los resultados del estudio, [incluya detalles, por ejemplo, en revistas médicas] no incluiremos su nombre. Haremos todo lo posible para que nadie fuera del estudio sepa que usted participó en él.

¿Me costará algo participar en el estudio?

No.

Participar en el estudio ¿me ayudará de alguna manera?

Participar en este estudio no le ayudará, pero podría ayudar a personas con [inserte condición] en el futuro.

¿Me pagarán por mi tiempo?

Sí, le daremos [incluya cantidad]. Esto es para pagarle por su tiempo. Usted recibirá este dinero [provea detalles, por ejemplo, al final de la encuesta de hoy] aunque decida no contestar algunas preguntas.

Participar en este estudio, ¿pudiera ser malo para mí, de alguna manera?

Sí. Hay una posibilidad de que:

- Las preguntas le hagan sentirse triste o sentirse mal.
- Alguien pudiera enterarse de que usted participó en este estudio y llegar a saber algo sobre usted que usted no quería que supiera.
- Podría tener un problema legal si nos cuenta sobre un delito, como el abuso de niños [proporcione una lista de asuntos de notificación forzosa que se exijan en su estado], que tenemos que reportar.

Haremos todo lo posible para proteger su privacidad.

[**Nota para el investigador:** Provea detalles sobre riesgos adicionales si son relevantes para el estudio, tales como un problema legal si alguien fuera de este estudio se enterara de que usted hizo algo ilegal.]

[**Nota para el investigador:** Provea detalles sobre asistencia o referidos (por ejemplo, consejería) si es relevante para el estudio.]

¿Por cuánto tiempo se usará mi información médica?

Esperamos que nuestro estudio dure [incluya número] años. No usaremos ni compartiremos su información una vez terminado el estudio. [**Nota para el investigador:** Si la información se comparte por razones ajenas a la investigación que también requieran autorización de la HIPAA, (por ejemplo, compartir la información de contacto de una persona para invitarla a otros proyectos de investigación), incluya la fecha de vencimiento de la actividad autorizada, si difiere de esta fecha de vencimiento.].

¿Qué debo hacer si tengo preguntas?

Si tiene preguntas sobre el estudio, llame al director del estudio, [incluya el nombre y número de teléfono]. Por favor llame si:

- Tiene alguna pregunta sobre el estudio.
- Tiene preguntas sobre sus derechos.
- Cree que se ha lesionado de alguna manera por participar en este estudio.
- Tiene preguntas sobre cómo usaremos y compartiremos su información.

También puede llamar a la oficina encargada de investigaciones [incluya el número de teléfono] para preguntar sobre este estudio.

¿Tengo que firmar este documento?

No. Fírmelo solamente si desea participar en el estudio.

¿Qué debo hacer si quiero participar en el estudio?

Tiene que firmar este documento. Le entregaremos una copia.

Al firmar este documento nos está diciendo que:

- Está de acuerdo con participar en el estudio.
- Nos está autorizando a usar y compartir su información médica para este estudio.
- [Añada otros usos y revelaciones mencionados anteriormente. Por ejemplo: Al firmar este documento, acepta que le llamen o escriban para invitarlo a participar en otros estudios de investigación.]
- Le hemos explicado la información que contiene este documento y hemos contestado todas sus preguntas.

Usted sabe que:

- No tiene que contestar preguntas que no quiera contestar.
- En cualquier momento, puede dejar de contestar nuestras preguntas y a usted no le pasará nada.
- Puede llamar a la oficina encargada de investigaciones al [incluya número de teléfono] si tiene alguna pregunta sobre el estudio o sobre sus derechos.

_____
Su nombre (en letra de molde)

_____ _____
Su firma Fecha

Si se utilizó un intérprete:

_____
Nombre del intérprete (en letra de molde)

_____ _____
Firma del intérprete Fecha

Si otra persona firma este formulario a nombre del participante, explique por qué:

_____

_____
Nombre del representante legal (en letra de molde)

_____ _____
Firma de la persona que provee el consentimiento en representación del sujeto Fecha

Relación o parentesco:
_____

_____
Nombre de la persona que explica el consentimiento (en letra de molde)

_____ _____
Firma de la persona que explica el consentimiento Fecha

Ejemplo de formulario combinado de consentimiento informado y autorización*

Versión para el investigador que está en una institución cubierta por la HIPAA pero distinta de la entidad cubierta que tiene la PHI de interés

Formulario de consentimiento y autorización para usar y compartir su información médica protegida

Título del estudio

Le estamos pidiendo que participe en un estudio.

Usted no tiene que participar en el estudio.

Si dice que sí, puede dejar de participar en el estudio en cualquier momento.

Por favor tome todo el tiempo que necesite para decidir.

Su atención médica no cambiará de manera alguna si dice que no.

¿Para qué se firma este documento?

Firme este documento si desea:

- Participar en el estudio.
- Permitir que sus médicos de [inserte el nombre de la institución u organización] compartan su información médica con los investigadores de [inserte el nombre de la institución u organización].
- Permitir que los investigadores usen y compartan su información médica para este estudio.

* Este formulario fue diseñado para investigación que no conlleva intervención, de riesgo mínimo.

¿Por qué se está haciendo este estudio de investigación?

Queremos saber más sobre cómo ayudar a las personas que tienen [inserte condición]. Este estudio nos ayudará a aprender más sobre [provea información específica]. Les estamos pidiendo a personas como usted, que tienen [inserte condición], que nos ayuden.

¿Qué pasa si digo "sí, quiero participar en el estudio"?

Si dice que sí:

- Le preguntaremos sobre [describa las preguntas de la encuesta, por ejemplo, su salud, lo que come y si hace ejercicio, fuma o toma alcohol, y qué medicinas toma]
- Le daremos un formulario con preguntas para que usted las conteste.
- Si quiere, podemos leerle las preguntas en voz alta y escribir sus respuestas en el formulario.

Estas preguntas no tienen respuestas correctas o incorrectas. Puede saltar cualquier pregunta si no quiere contestarla.

¿Cuánto tiempo tomará el estudio?

El estudio tomará alrededor de [inserte tiempo] de su tiempo.

¿Qué información se usará y compartirá en el estudio?

Si dice que sí, también:

- Enviaremos esta hoja de autorización a sus médicos de inserte nombre de la institución u organización.

- Usaremos y compartiremos información de [describa en detalle la información que se usará; por ejemplo, su historial médico completo, información de su expediente, como con qué frecuencia ha ido al médico y el motivo de esas visitas, qué medicinas toma, los resultados de las pruebas de laboratorio, y su número de expediente médico, sexo y fecha de nacimiento].

La información que le pedimos que nos deje usar se conoce como "Información Médica Protegida". Está protegida por la ley federal llamada Regla de Privacidad (Privacy Rule, en inglés) de la Ley Federal de Portabilidad y Responsabilidad de los Seguros de Salud (Health Insurance Portability and Accountability Act, HIPAA, por sus siglas en inglés). En general, sin autorización suya, su médico no puede compartir información médica suya para los fines de la investigación.

Si lo desea, podemos darle más información sobre la Regla de Privacidad. También, si tiene alguna pregunta sobre la Regla de Privacidad puede hablar con nuestro Oficial de Privacidad, al [incluya número de teléfono].

¿Cómo se usará y compartirá mi información?

- Usaremos su información sólo para el estudio que se describe en este documento.
- Podemos compartir su información con [mencione cualquier persona, aparte de los investigadores, que recibirá información que lo identifique. Por ejemplo, si hay un patrocinador de estudios que tendrá acceso a los datos, nómbrelo aquí].
- [**Nota para el investigador:** Si la información se comparte por razones ajenas al estudio de investigación que también requieran autorización de la HIPAA, deberá explicarse el propósito. Por ejemplo, es posible que le demos su nombre a otras personas que investigan [inserte condición], para que se comuniquen con usted y le pregunten si le interesa participar en otros estudios de investigación.]

- Haremos todo lo posible para asegurarnos de que su información permanezca privada. Sin embargo, si compartimos información con personas que no estén obligadas a cumplir la Regla de Privacidad, la información dejará de estar protegida por esta Regla de Privacidad. Díganos si tiene alguna duda al respecto.

¿Qué pasa si digo "no quiero participar en el estudio"?

Si dice que no:

- No obtendremos información de usted.
- Nadie le tratará en manera diferente. A usted no se le penalizará.
- La atención que recibe de su médico no cambiará.
- [**Nota para el investigador:** Si el estudio ofrece posibilidad de beneficio, añada: Aunque no recibirá el beneficio de estar en el estudio, no perderá ningún otro beneficio.] [**Nota para el investigador:** En el caso de estudios sin posibilidad de beneficio, añada: No perderá ningún beneficio.]

¿Qué pasa si digo que sí, pero cambio de opinión más tarde?

Usted puede dejar de participar en el estudio en cualquier momento. A usted no se le penalizará. [**Nota para el investigador:** Si el estudio ofrece posibilidad de beneficio, añada: Aunque no recibirá el beneficio de estar en el estudio, no perderá ningún otro beneficio.] [**Nota para el investigador:** En el caso de estudios sin posibilidad de beneficio, añada: No perderá ningún beneficio.]

Puede retirar su permiso para que sus médicos nos den información. También puede pedirnos que dejemos de usar y compartir información médica que pueda identificarlo. Dejaremos de usar y compartir información, excepto en situaciones muy especiales, como cuando sea necesario para cumplir con la ley, para proteger su seguridad o para comprobar que la

investigación se haya hecho en forma correcta. Por favor, pregunte si tiene alguna duda al respecto. [**Nota para el investigador:** Después de que retire su autorización, los investigadores podrían usar y compartir su información médica en circunstancias muy especiales, con el propósito de proteger la integridad de la investigación. Ese uso y revelación se permite, por ejemplo, cuando se quiere explicar por qué se retiró al sujeto del estudio, para investigar una conducta científica inválida o para reportar eventos adversos.]

Si en algún momento desea retirarse, es necesario que lo pida por escrito. Envíe una carta o correo electrónico a [inserte nombre, dirección y correo electrónico]. Si tiene alguna duda, consulte a [inserte nombre, teléfono y correo electrónico].

Si decide retirarse, seguirá recibiendo la misma atención de su médico.

¿Quién verá mis respuestas?

Las únicas personas autorizadas para ver su información médica serán las que trabajan en el estudio y las que supervisan cómo realizamos el estudio. [**Nota para el investigador:** Si el estudio tiene un patrocinador que tendrá acceso a los datos, nómbrelo aquí.]

Las respuestas de su encuesta, su información médica, y una copia firmada de este documento se mantendrán bajo llave en nuestros archivos. No se incluirán sus respuestas en su expediente médico.

Cuando compartamos los resultados del estudio, [incluya detalles, por ejemplo, en revistas médicas] no incluiremos su nombre. Haremos todo lo posible para que nadie fuera del estudio sepa que usted participó en él.

¿Me costará algo participar en el estudio?

No.

Participar en el estudio ¿me ayudará de alguna manera?

Participar en este estudio no le ayudará, pero podría ayudar a personas con [inserte condición] en el futuro.

¿Me pagarán por mi tiempo?

Sí, le daremos [incluya cantidad]. Esto es para pagarle por su tiempo. Usted recibirá este dinero [provea detalles, por ejemplo, al final de la encuesta de hoy] aun cuando decida no contestar algunas preguntas.

Participar en este estudio, ¿pudiera ser malo para mí, de alguna manera?

Sí. Hay una posibilidad de que:

- Las preguntas le hagan sentirse triste o sentirse mal.
- Alguien pudiera enterarse de que usted participó en este estudio y saber algo sobre usted que usted no quería que supiera.
- Podría tener un problema legal si nos cuenta sobre un delito, como el abuso de niños [proporcione una lista de asuntos de notificación forzosa que se exijan en su estado], que tenemos que reportar.

Haremos todo lo posible para proteger su privacidad.

[**Nota para el investigador:** Provea detalles sobre riesgos adicionales si son relevantes para el estudio, tales como un problema legal si alguien fuera de este estudio se enterara de que usted hizo algo ilegal.]

[**Nota para el investigador:** Provea detalles sobre asistencia o referidos (por ejemplo, consejería) si es relevante para el estudio.]

¿Por cuánto tiempo se usará mi información médica?

Esperamos que nuestro estudio dure [incluya número] años. Una vez terminado el estudio, su médico de [inserte el nombre de la institución u organización] dejará de darnos información suya y también nosotros dejaremos de usar y compartir su información. [**Nota para el investigador:** Si la información se comparte por razones ajenas a la investigación que también requieran autorización de la HIPAA (por ejemplo, compartir la información de contacto de una persona para invitarla a otros proyectos de investigación), incluya la fecha de vencimiento de la actividad autorizada, si difiere de esta fecha de vencimiento.]

¿Qué debo hacer si tengo preguntas?

Si tiene preguntas sobre el estudio, llame al director del estudio, [incluya el nombre y número de teléfono]. Por favor llame si:

- Tiene alguna pregunta sobre el estudio.
- Tiene preguntas sobre sus derechos.
- Cree que se ha lesionado de alguna manera por participar en este estudio.
- Tiene preguntas sobre cómo usaremos y compartiremos su información.

También puede llamar a la oficina encargada de investigaciones [incluya el número de teléfono] para preguntar sobre este estudio.

¿Tengo que firmar este documento?

No. Fírmelo solamente si desea participar en el estudio.

¿Qué debo hacer si quiero participar en el estudio?

Tiene que firmar este documento. Le entregaremos una copia.

Al firmar este documento nos está diciendo que:

- Está de acuerdo con participar en el estudio.
- Está autorizando a su médico a darnos información médica.
- Nos está autorizando a usar y compartir su información médica para este estudio.
- [Añada otros usos y revelaciones mencionados anteriormente. Por ejemplo: Al firmar este documento, acepta que le llamen o escriban para invitarlo a participar en otros estudios de investigación.]
- Le hemos explicado la información que contiene este documento y hemos contestado todas sus preguntas.

Usted sabe que:

- No tiene que contestar preguntas que no quiera contestar.
- En cualquier momento, puede dejar de contestar nuestras preguntas y a usted no le pasará nada.
- Puede llamar a la oficina encargada de investigaciones, al [incluya número de teléfono] si tiene alguna pregunta sobre el estudio o sobre sus derechos.

_____

Su nombre (en letra de molde)

_____ _____

Su firma Fecha

Si se utilizó un intérprete:

_____

Nombre del intérprete (en letra de molde)

_____ _____

Firma del intérprete Fecha

Si otra persona firma este formulario a nombre del participante, explique por qué:

_____

_____

Nombre del representante legal (en letra de molde)

_____ _____

Firma de la persona que provee el consentimiento en representación del sujeto Fecha

Relación o parentesco:

_____

_____

Nombre de la persona que explica el consentimiento (en letra de molde)

_____ _____

Firma de la persona que explica el consentimiento Fecha

Ejemplo de formulario combinado de consentimiento informado y autorización*

Versión para el investigador que no está en una institución cubierta por la HIPAA

Formulario de consentimiento y autorización para usar y compartir su información médica protegida

Título del estudio

Le estamos pidiendo que participe en un estudio.

Usted no tiene que participar en el estudio.

Si dice que sí, puede dejar de participar en el estudio en cualquier momento.

Por favor tome todo el tiempo que necesite para decidir.

Su atención médica no cambiará de manera alguna si dice que no.

¿Para qué se firma este documento?

Este documento se firma para poder participar en el estudio y permitir que sus médicos de [inserte el nombre de la institución u organización] compartan la información médica suya con los investigadores de [inserte el nombre de la institución u organización].

* Este formulario fue diseñado para investigación que no conlleva intervención, de riesgo mínimo.

¿Por qué se está haciendo este estudio de investigación?

Queremos saber más sobre cómo ayudar a las personas que tienen [inserte condición]. Este estudio nos ayudará a aprender más sobre [provea información específica]. Les estamos pidiendo a personas como usted, que tienen [inserte condición], que nos ayuden.

¿Qué pasa si dice "sí, quiero participar en el estudio"?

Si dice que sí:

- Le preguntaremos sobre [describa las preguntas de la encuesta, por ejemplo, su salud, lo que come y si hace ejercicio, fuma o toma alcohol, y qué medicamentos toma].
- Le daremos un formulario con preguntas para que usted las conteste.
- Si quiere, podemos leerle las preguntas en voz alta y escribir sus respuestas en el formulario.

Estas preguntas no tienen respuestas correctas o incorrectas. Puede saltar cualquier pregunta si no quiere contestarla.

¿Cuánto tiempo tomará el estudio?

El estudio tomará alrededor de [inserte tiempo] de su tiempo.

¿Qué información obtendrán de mis médicos?

Si dice que sí, también:

- Enviaremos esta hoja de autorización a sus médicos de [inserte el nombre de la institución u organización].

- Obtendremos [describa en detalle la información que se usará; por ejemplo, su historial médico completo, información de su expediente, como con qué frecuencia ha ido al médico y el motivo de esas visitas, qué medicamentos toma, los resultados de las pruebas de laboratorio, y su número de expediente médico, sexo y fecha de nacimiento].

La información que le pedimos que nos deje obtener se conoce como "Información Médica Protegida". Está protegida por la ley federal llamada Regla de Privacidad (Privacy Rule) de la Ley Federal de Portabilidad y Responsabilidad de los Seguros de Salud (Health Insurance Portability and Accountability Act, HIPAA). En general, sin autorización suya, su médico no puede compartir información médica suya para los fines de la investigación.

Si lo desea, podemos darle más información sobre la Regla de Privacidad.

Haremos todo lo posible para asegurarnos de que su información permanezca privada. Pero una vez que se nos transmita su información, dejará de estar protegida por la Regla de Privacidad. Díganos si tiene alguna duda al respecto.

¿Qué pasa si digo "no quiero participar en el estudio"?

Si dice que no:

- No obtendremos información de usted.
- Nadie le tratará en manera diferente. usted no se le penalizará.
- La atención que recibe de su médico no cambiará.
- [**Nota para el investigador:** Si el estudio ofrece posibilidad de beneficio, añada: Aunque no recibirá el beneficio de estar en el estudio, no perderá ningún otro beneficio.] [**Nota para el investigador:** En el caso de estudios sin posibilidad de beneficio, añada: No perderá ningún beneficio.]

¿Qué pasa si digo que sí, pero cambio de opinión más tarde?

Usted puede dejar de participar en el estudio en cualquier momento. A usted no se le penalizará. [**Nota para el investigador:**Si el estudio ofrece posibilidad de beneficio, añada: Aunque no recibirá el beneficio de estar en el estudio, no perderá ningún otro beneficio.] [**Nota para el investigador:** En el caso de estudios sin posibilidad de beneficio, añada: No perderá ningún beneficio.]

Puede retirar su permiso para que sus médicos nos den información. Pero tiene que avisarle por escrito a su médico. Si prefiere que le avisemos nosotros, díganos y así lo haremos. Envíe una carta o correo electrónico a [inserte nombre, dirección y correo electrónico]. Si tiene alguna duda, consulte a [inserte nombre, teléfono y correo electrónico].

Si decide retirarse, seguirá recibiendo la misma atención de su médico.

¿Quién verá mis respuestas?

Las únicas personas autorizadas para ver su información médica serán las que trabajan en el estudio y las que supervisan cómo realizamos el estudio. [**Nota para el investigador:** Si el estudio tiene un patrocinador que tendrá acceso a los datos, nómbrelo aquí.]

Las respuestas de su encuesta, su información médica, y una copia firmada de este documento se mantendrán bajo llave en nuestros archivos. No se incluirán sus respuestas en su expediente médico.

Cuando compartamos los resultados del estudio, [incluya detalles, por ejemplo, en revistas médicas] no incluiremos su nombre. Haremos todo lo posible para que nadie fuera del estudio sepa que usted participó en él.

¿Me costará algo participar en el estudio?

No.

Participar en el estudio ¿me ayudará de alguna manera?

Participar en este estudio no le ayudará, pero podría ayudar a personas con [inserte condición] en el futuro.

¿Me pagarán por mi tiempo?

Sí, le daremos [incluya cantidad]. Esto es para pagarle por su tiempo. Usted recibirá este dinero [provea detalles, por ejemplo, al final de la encuesta de hoy] aunque decida no contestar algunas preguntas.

Participar en este estudio, ¿pudiera ser malo para mí, de alguna manera?

Sí. Hay una posibilidad de que:

- Las preguntas le hagan sentirse triste o sentirse mal.
- Alguien pudiera enterarse de que usted participó en este estudio y llegar a saber algo sobre usted que usted no quería que supiera.
- Podría tener un problema legal si nos cuenta sobre un delito, como el abuso de niños [proporcione una lista de asuntos de notificación forzosa que se exijan en su estado], que tenemos que reportar.

Haremos todo lo posible para proteger su privacidad.

[**Nota para el investigador:** Provea detalles sobre riesgos adicionales si son relevantes para el estudio, tales como un problema legal si alguien fuera de este estudio se enterara de que usted hizo algo ilegal.]

[**Nota para el investigador:** Provea detalles sobre asistencia o referidos (por ejemplo, consejería) si es relevante para el estudio.]

¿Por cuánto tiempo se permitirá que mi médico comparta mi información?

Esperamos que nuestro estudio dure [incluya número] años. Una vez terminado el estudio, su médico [nombre de la institución u organización] dejará de compartir su información con nosotros. **[Nota para el investigador:** Modifique esta afirmación si la autorización termina antes.**]**

¿Qué debo hacer si tengo preguntas?

Si tiene preguntas sobre el estudio, llame al director del estudio, [incluya el nombre y número de teléfono]. Por favor llame si:

- Tiene alguna pregunta sobre el estudio.
- Tiene preguntas sobre sus derechos.
- Cree que se ha lesionado de alguna manera por participar en este estudio.
- Tiene preguntas sobre cómo sus médicos compartirán su información con nosotros.

También puede llamar a la oficina encargada de investigaciones [incluya el número de teléfono] para preguntar sobre este estudio.

¿Tengo que firmar este documento?

No. Fírmelo solamente si desea participar en el estudio.

¿Qué debo hacer si quiero participar en el estudio?

Tiene que firmar este documento. Le entregaremos una copia.

Al firmar este documento nos está diciendo que:

- Está de acuerdo con participar en el estudio.
- Está autorizando a su médico a darnos información sobre su salud.
- [Añada otros usos y revelaciones mencionados anteriormente. Por ejemplo: Al firmar este documento, acepta que le llamen o escriban para invitarlo a participar en otros estudios de investigación.]
- Le hemos explicado la información que contiene este documento y hemos contestado todas sus preguntas.

Usted sabe que:

- No tiene que contestar preguntas que no quiera contestar.
- En cualquier momento, puede dejar de contestar nuestras preguntas y a usted no le pasará nada.
- Puede llamar a la oficina encargada de investigaciones, al [incluya número de teléfono] si tiene alguna pregunta sobre el estudio o sobre sus derechos.

_____
Su nombre (en letra de molde)

_____ _____
Su firma Fecha

Si se utilizó un intérprete:

_____
Nombre del intérprete (en letra de molde)

_____ _____
Firma del intérprete Fecha

Si otra persona firma este formulario a nombre del participante, explique por qué:

_____

_____
Nombre del representante legal (en letra de molde)

_____ _____
Firma de la persona que provee el consentimiento en representación del sujeto Fecha

Relación o parentesco:
_____

_____
Nombre de la persona que explica el consentimiento (en letra de molde)

_____ _____
Firma de la persona que explica el consentimiento Fecha