Research Consent and HIPAA Authorization Form

Minimal Risk Study

Instructions

- This template can be used as a Consent Form or an Information Sheet (if subjects will not sign). If subjects will not sign a consent form, request a "Waiver of Documentation of Consent" from the IRB. Include the HIPAA Authorization title heading above and the HIPAA content indicated below only if HIPAA applies to the research.
- Enter all information below as it relates to your study. Sample text is provided; text should be adjusted as needed so that it is appropriate for your study. If any of the required elements of consent (see appendix) will not be included, request an "Alteration of Consent" from the IRB.
- Throughout this template, red text is instructions. Change the font color to black and delete these and other instructions before submitting this form to the IRB.
- A 1-inch margin must be maintained at the top of the page for the IRB stamp and the "patient sticker" field must be maintained unless a copy of the consent will not be added to the medical record.

Study Title

[INSERT THE FULL TITLE OF THE STUDY.]

Investigator

[INSERT THE INVESTIGATOR'S NAME AND HIS/HER HOSPITAL/CLINIC/ORGANIZATION.]

If applicable, indicate that the study is being conducted as part of an undergraduate project, graduate student project, thesis, or dissertation and include the student's name and affiliation in addition to the PI's.

Investigator Contact Information

E-mail, phone number, and include mailing address if a HIPAA Authorization is included.

Key Information about this Study

This section is required for any studies approved by the IRB on or after 01/21/2019 subject to the Common Rule. This section should be study-specific, concise, and focused presentation of the key information that is most likely to help a potential participant understand why they might or might not want to participate in the study.

We are asking you to take part in this research study. The purpose of this document is to fully inform you of the study's purposes and procedures. This section provides a summary of the study. It is important for you to understand why the research is being done and what it will involve before you decide to participate. Please take the time to read the entire consent form carefully and talk to a member of the research team before making your decision. You should not sign this form if you have any questions that have not been answered.

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Purpose	Your participation in this research study is voluntary. This project is being done to [insert brief purpose].
Length of Participation	You will be involved in this study for about [estimated time of the participant's involvement overall]. This project involves XX visits. Each visit may last from X to X hours. We would like to follow-up with you for [estimated length of follow-up].
Procedures	If you choose to participate, you will be asked to [describe information collected, procedures, and other research activities].
Risks	This is a brief list of the most common side effects and/or risks. The full consent form after this introduction contains a more complete list of potential research risks. List the most important risks due to frequency or magnitude.
Benefits	This study may or may not help you. Your condition may get better, stay the same, or even worsen. We hope that the information from this study will help [describe goal, e.g., develop better treatments for this condition]. OR There will be no direct benefit to you from participating in the study. However, this study will help us learn more about [describe].
Other Options	You do not have to be in this study if you do not want to, or you can stop being in this study at any time. You will not lose any services, benefits, or rights you would normally have if you decide to not participate or stop being in the study. Some alternative procedures or courses of treatment may include [routine care for this condition, joining another research project, etc.].

The rest of this form contains more information about being in this study. Please read this whole form carefully if you are interested in learning more about this study.

If you have any questions or concerns about this research project at any time, you can contact the Principal Investigator at Contact Information.

If you have any questions about your rights as a participant or want to report any problems or complaints, you can call the Allina Heath Human Research Protection Program at (612) 262-4920.

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Funding

If funded, identify the sponsor or funding agency. Include a conflict of interest statement from the Conflict Management Plan, if applicable. If there is no funding, then delete this section.

Why are we doing this research study?

We want to learn more about how to help people who have [INSERT CONDITION OR MODIFY THIS STATEMENT ACCORDING TO RESEARCH TOPIC]. This study will help us learn more about [INSERT SPECIFICS]. We are inviting people like you who have [INSERT CONDITION OR MODIFY THIS STATEMENT ACCORDING TO RESEARCH TOPIC] to help us.

What happens if I choose to participate?

This is a sample text that may be appropriate for studies involving a questionnaire and medical record review and it should be adapted, removed, or replaced with text that appropriately describes what the participants in your particular study are asked to do.

If the research includes any experimental procedures, these should be identified as such.

If you say yes, we will:

- Give you a form with questions for you to answer about [DESCRIBE QUESTIONNAIRE ITEMS, E.G., YOUR HEALTH, WHAT YOU EAT, AND IF YOUR EXERCISE, SMOKE, OR DRINK ALCOHOL, AND WHAT MEDICINES YOU TAKE]. There are no right or wrong answers to these questions. You can skip any question you do not want to answer.
- Read the questions out loud and fill out the form with you, if you want.
- Gather information from your medical records about [DESCRIBE].

How long will participating in the study take?

The study will take about [INSERT TIME] of your time. We will gather information from your records for up to [INSERT TIME FRAME].

How many people are participating in this study?

We expect to enroll about [INSERT NUMBER] people in this study.

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

If you say no, no one will treat you differently. You will not be penalized. [FOR STUDIES WITH PROSPECT OF BENEFIT, ADD: While you will not get the benefit of being in this study, you will not lose any other benefits you are entitled to]. [FOR STUDIES WITH NO PROSPECT OF BENEFIT, ADD: You will not lose any benefits you are entitled to].

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Include this sentence when patients are being recruited. If patients are not being recruited, delete or replace with an appropriate sentence. The care you get from your doctor [or Allina Health] will not change.

What happens if I say "yes" to participation but change my mind later?

You can stop being in the study at any time. To stop being in the study, contact the study team at [INSERT CONTACT INFORMATION]. [FOR STUDIES WITH PROSPECT OF BENEFIT, ADD: While you will not get the benefit of being in this study, you will not lose any other benefits you are entitled to]. [FOR STUDIES WITH NO PROSPECT OF BENEFIT, ADD: You will not lose any benefits you are entitled to].

Include this sentence when patients are being recruited. If patients are not being recruited, delete or replace with an appropriate sentence: The care you get from your doctor [or Allina Health] will not change.

If recommended procedures to safely manage subject withdrawal are needed (for example, referral to another service or provider), include a statement describing the recommended procedures.

If the investigator may choose to end a subject's participation independently (for example, because they are not attending enough visits), include a statement describing the anticipated circumstances under which the subject's participation may be terminated by the investigator.

If there are consequences to a subject's choice to withdraw (for example, they will not receive any remaining payments or will lose access to services only offered by the study), include a statement disclosing the consequences.

Who will see my information?

This is a sample text that may be appropriate for studies involving a questionnaire and medical record review and it should be adapted or replaced with text that is appropriate for this study.

The only people allowed to see your information will be the people who work on the study and people who make sure we run our study the right way. [IF THERE IS A STUDY SPONSOR THAT WILL HAVE ACCESS TO THE DATA, NAME SPONSOR HERE].

Your [list documents with subject information, e.g., such as survey results, health information, and a copy of this document will be locked in our files. We will not put your answers into your medical record.

[IF INFORMATION OR FORMS (E.G., CONSENT FORM, HIPAA AUTHORIZATION) WILL BE INCLUDED IN THE MEDICAL RECORD INSERT A SENTENCE DESCRIBING WHAT WILL BE INCLUDED.]

Include the following if the Excellian Research Functionality will be used:

Your participation in this study will be documented in Allina Health's electronic medical record system. This documentation provides health care providers with basic information about the study and information so that they can contact the study team to learn more, if important for your care. It can also be used by the study team and Allina Health Research Administration to assist with administrative processes such as tracking enrollment and participation in the study.

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If the study includes a Certificate of Confidentiality, include a paragraph describing the certificate and its purpose, protections, and limitations.

When we share the result of the study [INSERT DETAILS HERE, E.G. IN MEDICAL JOURNALS OR PRESENTATIONS] we will not include your name. We will do our best to make sure no one else will know you are part of the study.

Will my information or specimens be used for other purposes?

[INSERT STATEMENTS BELOW THAT ARE APPLICABLE TO THE RESEARCH]

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

If the study will produce any clinically relevant research results, describe whether these results will be given to the subjects, and if so, under what conditions. Describe whether and how subjects can opt out of receiving results.

For any research involving the collection of identifiable private information or identifiable biospecimens, a statement must be included regarding future use of the information or specimens.

If you will never use information and specimens from this study for future research, insert the following, or similar, language:

The information and/or biospecimens collected as part of this research will not be used or distributed for future research studies.

If it is possible that information and/or biospecimens from this study will be used for future research, insert the following, or similar, language:

The information and/or specimens that we obtain from you for this study might be used for future studies. We may remove anything that might identify you from the information and specimens. If we do so, that information and specimens may then be used for future research studies or given to another investigator without getting permission from you. It is also possible that in the future we may want to use or share study information that might identify you. If we do, a review board will decide whether or not we need to get additional permission from you.

If there are plans to store or share data and/or specimens for future research, such as submitting the data to a repository, describe those plans here including whether identifying information will be shared and the purposes for which the data and/or specimens will be used.

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Will it cost me anything to be in the study?

No.

If applicable, describe the costs that subjects may incur as a result of participating in the research. Otherwise, simply state "No."

You may be responsible for some costs, such as: [INSERT A LIST OF POSSIBLE COSTS SUCH AS CO-PAYS, LOSS OF INCOME WHEN TAKING TIME OFF FROM WORK, OR TRANSPORTATION COSTS OTHERWISE DELETE THE STATEMENT.]

Include this Billing Error Statement when the research involves procedures that might ordinarily result in a bill to the subject or the subject's insurer. If you believe you have received a bill in error during the research study, contact the investigator or study staff.

Will being in this study help me in any way?

Describe any benefits that subjects may reasonably accrue as a result of participating in the study. Compensation should not be described as a benefit.

If there is no benefit, state this (below is sample text that should be adjusted as needed for the study.)

Being in the study will not help you but may help people with [INSERT CONDITION] in the future OR may help us learn more about [STUDY AIMS].

Will I be paid for being in the research study?

If you are compensating subjects, describe the compensation; if not, delete this section or state "No."

Examples:

Yes, you will receive [DESCRIBE] for each visit to help cover your travel expenses.

Yes, as an incentive for participating in this study [DESCRIBE].

Yes, you will receive [DESCRIBE COMPENSATION AND INSERT DETAIL, E.G., AT THE END OF THE SURVEY TODAY] even if you decide to skip some of the questions.

Consider whether biospecimens collected for this study may ever be used for commercial profit. Consider all sources of profit for this study and future uses. If biospecimens (whether identifiable or deidentified) may be used for commercial profit, insert the following language:

The specimens we collect as part of this research may be used for commercial profit. [INSERT ONE OF THE FOLLOWING:]

There is no plan to share this profit with you OR there is plan to share this profit with you.

If the research includes compensation, include the following (adjust appropriately if the compensation isn't through Allina):

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Because you are being compensated for participating in this study, your name, address, and social security number may be released to the Accounting Office. If you receive payments that total $600 or more from Allina Health in a year, they will be reported to the Internal Revenue Service (IRS) as income.

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

Yes. There is a chance that: [DESCRIBE FORESEEABLE RISKS OR DISCOMFORT TO SUBJECTS; THE FOLLOWING IS SAMPLE TEXT THAT CAN BE REMOVED OR CHANGED AS APPLICABLE]**.**

- 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 others 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 and confidentiality.

If anything happens or we learn of anything that might impact your decision to stay in this study, we will let you know.

[INSERT DETAILS REGARDING ANY OTHER MEASURES TO MITIGATE RISKS SUCH AS REFERRALS FOR CARE OR COUNSELING IF RESPONSES INDICATE THAT A SUBJECT MAY BE AT RISK.]

Note: The following section is the HIPAA Authorization Language to be included when applicable (remove if HIPAA Authorization is not required)

How is my health information used and shared?

By signing this form, you are authorizing the use and disclosure (release) of your health information in connection with your participation in the above-named research project. Your information will be used only as stated in this authorization or as required by law. Your participation in this research is voluntary. Refusing to sign will not affect the present or future care you receive at Allina Health but you cannot participate in this study.

We (the investigators and research team) are requesting your authorization to review and collect information from your medical records about [include a description of the PHI that will be used and disclosed in a specific and meaningful summary, e.g., your past medical history, the results of past blood tests, etc.]. It may also include information you provide to us through [surveys, etc.]. We will use this information for the purposes of this study as described above. We may send this information to the following people, groups, and organizations who will be authorized to use and receive this information for the purposes of conducting this research, monitoring this study, and/or providing services:

- The investigators and research team of this research project
- All persons and entities from Allina Health engaged in managing, analyzing, storing, transmitting, or overseeing the information
- The U.S. Food and Drug Administration (FDA)

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- The Office for Human Research Protections (OHRP) in the U.S. Department of Health and Human Services
- The sponsor and their affiliates [list/name them]
- The National Institutes of Health (NIH)
- The Data Monitoring Committee or Data Safety Monitoring Board
- [list any other entity that may access identifiable information]

We cannot prevent re-disclosure of your health information by anyone who receives the information under this authorization, and the information may not be covered by state and federal privacy protections after it is released from Allina Health. This authorization will not expire unless or until you cancel it. You may change your mind and cancel your authorization to use or disclose your health information by notifying [insert individual to be contacted to terminate authorization] in writing at the address on the first page of this form. Your cancellation will be effective after the date it is received. Any health information about you that has already been collected may still be used or disclosed to maintain the integrity or reliability of the research.

What if I have questions?

If you have any questions about the study or feel that you have been injured in any way by being in this study, please contact: [INSERT NAME, PHONE NUMBER, AND/OR EMAIL ADDRESS OF THE PI AND STUDY CONTACT (WHEN APPLICABLE)].

The Allina Health Institutional Review Board (IRB) has reviewed this research study. If you have any concerns about your rights in this study, please contact the Allina Health IRB at 612-262-4920 or IRB@allina.com.

Do I have to sign this document?

Delete section if a waiver of documentation of consent is being requested.

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?

Delete section if a waiver of documentation of consent is being requested or modify to indicate next steps based on your study (e.g., Tell [insert name or role] that you would like to participate; or Complete the contact sheet and give it to the receptionist. A member of the study team will contact you to set up a time to talk).

You should make sure your questions and concerns have been answered, and then 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: Sample Text, adjust or replace as appropriate

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- 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.
- We will gather information about you from your medical records.

If study activities may begin on the same day as the subject signs consent, consider including a line for the time consent was obtained (to document that it was obtained prior to any study activities).

_____
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 Date

Relationship: _____

Name of person conducting the consent discussion (please print)

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_____

_____ _____

Signature of person conducting the consent discussion Date

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Below please find the Federal Elements of Consent as a reference. Please delete it from the final version of the consent document.

Federal Elements of Consent

(for researcher reference)

HHS:

Required Elements:
A statement that the study involves research
An explanation of the purposes of the research
The expected duration of the subject's participation
A description of the procedures to be followed
Identification of any procedures which are experimental
A description of any reasonably foreseeable risks or discomforts to the subject
A description of any benefits to the subject or to others which may reasonably be expected from the research
A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject
A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained
For research involving more than minimal risk, an explanation as to whether any compensation, and an explanation as to whether any medical treatments are available, if injury occurs and, if so, what they consist of, or where further information may be obtained
An explanation of (1) whom to contact for answers to pertinent questions about the research and (2) research subjects' rights, and (3) whom to contact in the event of a research-related injury to the subject
A statement that (1) participation is voluntary, (2) refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and (3) the subject may discontinue participation at any time without penalty or loss of benefits, to which the subject is otherwise entitled
One of the following statements about any research that involves the collection of identifiable private information or biospecimens: (i) A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research

studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or (ii) A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies
Elements that are required when applicable:
A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant), which are currently unforeseeable
Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent
Any additional costs to the subject that may result from participation in the research
The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject
A statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject
The approximate number of subjects involved in the study
A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit
For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen)
A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions

FDA regulated studies:

In addition to the above, the consent form must contain a statement that notes that the FDA may inspect the records.
This statement must be included verbatim for applicable clinical trials as defined in FDAAA 801: *"A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time."*