Allina Health

Research Consent 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.
- 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.

Key Information About This Study

This section is required for any studies approved by the Allina IRB on or after 01/21/2019 and should be specific to the research. When writing the "Key Information" section, include information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. Information should be organized in a way that facilitates comprehension. The IRB Office has provided a draft below that should be modified appropriately for the research.
Information presented in this section may be repeated in subsequent sections of the form but does not have to be.

You are invited to participate in a research study. The purpose of the research is to [INSERT STATEMENT DESCRIBING PURPOSE OF RESEARCH]. You are invited to be in this study because [INSERT EXPLANATION FOR WHY SUBJECT IS BEING ASKED TO PARTICIPATE]. Your participation in this research will involve [INSERT NUMBER OF VISITS] visits and last about [STATE DURATION IN HOURS, DAYS, OR MONTHS].

Attach Patient Sticker Here

Participation in this study will involve [E.G., INSERT INFORMATION COLLECTED, PROCEDURES, OTHER RESEARCH ACTIVITIES]. All research studies involve some risks. Some risks to this study that you should be aware of are [LIST MOST IMPORTANT RISKS DUE TO FREQUENCY OR MAGNITUDE]. You (MAY/MAY NOT) benefit from participating in this study by [LIST MOST LIKELY POTENTIAL BENEFITS, IF ANY].

Your participation in this study is voluntary. You do not have to be in this study if you do not want to, or you can stop being in this study anytime. You will not lose any services, benefits, or rights you would normally have if you choose not to participate or stop being in the study. There may be other choices if you do not want to participate. Some of those other choices may include [INSERT ALTERNATIVES, IF ANY].

The rest of this form contains more information about being in this study. Please read this whole form carefully. You can ask any questions if you need help deciding whether to join the study. The person in charge of this study is [PRINCIPAL INVESTIGATOR]. If you have questions or concerns or want to leave the study, you should let [PRINCIPAL INVESTIGATOR] know by contacting (HIM/HER) at:

[INSERT CONTACT INFORMATION]

If you have any questions about your rights as a volunteer in this research, contact the Allina Health Institutional Review Board Office at 612-262-4920.

If you are interested in learning more about this study, please continue to read below.

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.

Research Study

We are inviting you to be in a research study.

You do no 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.

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 say, "Yes, I want to be in the study"?

Attach Patient Sticker Here

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 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] in this study.

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

Your participation in this study is voluntary.

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].

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," but change my mind later?

You can stop being in the study at any time. You will not be penalized. 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].

Attach Patient Sticker Here

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.

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]

Attach Patient Sticker Here

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.

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.]

Attach Patient Sticker Here

Include this Billing Error Statement when the research involves procedures which 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.

For studies that offer a treatment or potential benefit, include a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous (for example, disclose if the treatment or benefit is available without participating).

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):

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?

Attach Patient Sticker Here

Yes. There is a chance that: [DESCRIBE FORESEEABLE RISKS OR DISCOMFORT TO SUBJECTS; THE FOLLOWING IS SAMPLE TEXT].

- 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.]

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.

Attach Patient Sticker Here

You know that: Sample Text, adjust or replace as appropriate

- 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)

Attach Patient Sticker Here

_____

_____ _____

Signature of person conducting the consent discussion Date

Attach Patient Sticker Here

Allina Health

HIPAA AUTHORIZATION TEMPLATE

- **This HIPAA authorization must be used for studies under the oversight of the Allina IRB or an external IRB under contract with Allina (e.g., Advarra, Western IRB).**
- **The HIPAA authorization should be attached to the end of the consent form after the signature lines for consent.**
- **This template includes instructions in red for creating the form. Prior to uploading this form for IRB review, delete or replace all template instructions (including these introductory instructions), and reformat the document so that the entire form is in black. (To do this, press Ctrl + A at the same time. In the menu bar, select black as the font color.)**

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HIPAA AUTHORIZATION FOR USE AND DISCLOSURE OF PROTECTED HEALTH INFORMATION

Research Study: [insert study title]

Subject Name: _____

Use and Disclosure of Your Health Information
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 study. Your information will be used only in accordance with the provisions of this authorization as outlined in this form or as required by law.

What Information Will Be Used or Disclosed?
The health information that we may use or disclose (release) for this research includes: **[Insert specific description of health information to be used or disclosed for the research project. This may include, for example, all information in a medical record, results of physical examinations, medical history, lab tests, x-rays, MRIs, or certain health information indicating or relating to a particular condition]. [Optional: It also includes all information you may provide us through [insert other information that may be obtained from patient (e.g., surveys), or otherwise.]**

Who Will Receive, Use, and/or Disclose the Information?
The following person(s), class(es) of persons, and/or organization(s) may use, receive, and/or disclose the information connected with this study listed below. These persons are authorized to use and disclose the information to the other parties on this list, to you or your personal representative, or as permitted by law. **[Add requested information on names/classes of recipients of PHI. Delete all categories that do not apply. Note that when the specific individual may change over the course of the project it is preferable to list their class as opposed to specific names. For example reference the "research coordinator" as opposed to the name of the current individual performing that role.]**

- The following health care facilities or research site(s) and research staff involved in this study: _____ **[list]**
- Health care providers at Allina Health System

Attach Patient Sticker Here

- Laboratories and other individuals and organizations that analyze your health information used in this study as outlined in the study protocol
- The following research sponsors: _____ **[list]**
- The United States Food and Drug Administration (FDA)
- The Office for Human Research Protections in the U.S. Department of Health and Human Services
- A Data Safety Monitoring Board or Committee (A DSMB or DSMC is an independent group who will review study data throughout the study)
- The members and staff of the Institutional Review Board (IRB) that approved this study
- Principal Investigator: _____ **[name]**
- Additional members of the Research Team **[individual names not required]**
- All persons and entities engaged by the Provider, Allina Health System, or the Research Team to assist in managing, analyzing, storing, or transmitting the information.
- Personnel within Allina Health System who are responsible for the administration or oversight of research.
- Others: _____

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.

How Will the Information be Used and Disclosed?
Your health information will be:

- Used and disclosed for purposes of the study, including [**describe how information will be used and disclosed for the study (for example, gathering information for the study, monitoring your safety and the overall safety of the study, and for analyzing study data.**]
- **[Insert the following, if applicable: *The researchers conducting this study would like to use your health information for future research purposes. Authorizing use of your health information for these additional purposes is voluntary and does not impact your ability to participate in this study. Please initial here to authorize the use of your health information for these additional purposes: _____ (Patient's Initials)*]**;
- Combined with information about other people who participate in the study;
- Placed in your medical record at Allina Health Systems; and
- Disclosed to persons listed in this authorization for purposes of the study or as otherwise permitted or required by law.

In order to participate in this study, you must agree to share your information with the groups above by signing this Authorization. You do not have to sign this Authorization, but if you do not, you will not be able to participate in this research study. Refusing to sign this authorization will not affect your current or future care at Allina Health System and will not cause any penalty or loss of benefits to which you are otherwise entitled.

When Access to Your Information May Be Limited

Attach Patient Sticker Here

[Choose appropriate language]
[*Your right to access your medical record is not affected by your participation in this project*.]
OR
[*You have the right to review and copy your health information related to this study for as long as the Research Team or institution holds this information. However, to ensure the scientific integrity of the study, you will not be able to review or copy some of the study information until after the study has been completed.*]

The Notice of Privacy Practices, available in the **[hospital, clinic, or office]** where this research is being conducted, provides general information on your rights to review, copy, and correct your health information.

Revocation (cancellation)
If you decide to end your participation in the study or if you are removed from the study by the principal investigator, you may cancel your authorization to use or disclose your health information by notifying **[insert individual to be contacted to terminate authorization]** in writing at **[insert address for contact]**. 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.

Expiration
This authorization for the use and/or disclosure of your health information will not expire unless or until you revoke it.

_____ Printed name of participant or participant's personal representative	_____ If applicable, description of the personal representative's authority to sign for participant
_____ Signature	_____ Date
_____ Printed name of person obtaining authorization	_____ Role in study
_____ Signature of person obtaining authorization	_____ Date

Attach Patient Sticker Here

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."*