

Consent Form

Instructions:

- Complete the consent form based on the research protocol.
- The consent form must begin with a concise presentation of Key Information. Therefore, this consent form includes a section for Key Information and a section for Detailed Information.
 - Key Information should be limited, as prompted, to the information that is most likely to assist a prospective participant or legally authorized representative in understanding the reasons why one might or might not want to participate in the research.
 - If the summary information in the Key Information section includes all relevant information for subjects, then delete the corresponding information from the Detailed Information section. If not, then provide the remaining non-summary information in the Detailed Section.
- Some items in this template are optional or based on certain types of studies (noted in red text). Review the guidance throughout the template.
- Refer to HRP-090 Informed Consent Process for Research, and HRP-091 Written Documentation of Consent in the [HRPP Toolkit Library](#).
- For additional resources on drafting a consent form, consider the following:
 - [Clear Language and Design](#)
 - [Health Literacy in Clinical Research](#)
 - [Alternative Word Suggestions](#)
 - [Readability calculator](#) (use Flesch-Kincaid score)
 - [OHRP Informational Videos for Research Volunteers](#)
- Remove help text and instructions before submitting the consent form draft to the IRB.

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Title of Research Study: *[insert title of research study here with protocol number]*

Investigator Team Contact Information: *[insert name of principal investigator]*

For questions about research appointments, the research study, research results, or other concerns, call the study team at:

Investigator Name: Investigator Departmental Affiliation: Phone Number: Email Address:	Student Investigator Name (if applicable): Phone Number: Email Address: Study Staff (if applicable): Phone Number: Email Address:
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Supported By: *[List all monetary and/or non-monetary support for this research.]* This research is supported by _____.

Financial Interest Disclosure: *[Include if there is a personal and/or institutional financial interest to disclose. Otherwise delete.]* The following disclosure is made to give you an opportunity to decide if this relationship will affect your willingness to participate in this research study:

Key Information About This Research Study

The following is a short summary to help you decide whether or not to be a part of this research study. More detailed information is listed later on in this form. *[You should aim for the entire Key Information section to be no longer than three (3) pages once you have removed all instructions.]*

What is research?

- The goal of research is to learn new things in order to help people in the future. Investigators learn things by following the same plan with a number of participants, so they do not usually make changes to the plan for individual research participants. You, as an individual, may or may not be helped by volunteering for a research study.

[Include if the investigator is also the participant's treating physician. Otherwise delete.] Your doctor, who is also responsible for this research study, [or, If your doctor is also the person responsible for this research study, please note that s/he...] is interested in both your clinical care and the conduct of this research study. You have the right to discuss this study with another person who is not part of the research team before deciding whether to participate in the research.

Why am I being invited to take part in this research study?

We are asking you to take part in this research study because _____. *[Fill in the circumstance or condition that makes participants eligible for the research, including how participants have been identified by the research team as potentially eligible.]*

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What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?

[Include brief descriptions of the following elements in this section. Each element should be no longer than two (2) sentences in easily understandable language. You may introduce technical terminology as needed later in this form.]

- (1) Tell the participant the purpose of the research in terms that can be understood by people not in the field of study.
- (2) Explain the background of the research problem/question.
- (3) Explain any potential benefits to others.

How long will the research last?

We expect that you will be in this research study for _____ [insert as hours, days, months, weeks, years, until a certain event. Estimate of total participation time should be included as well as time spent in specific activities (e.g. interview will require approximately 60 minutes).].

What will I need to do to participate?

You will be asked to _____ [include a high-level summary of the procedures that will be done. For example: You will view images of people and be asked to come for 1 study visit. You will fill out questionnaires asking about how you feel about the images of people.]

More detailed information about the study procedures can be found under “What happens if I say yes, I want to be in this research?”

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

[This beginning section of the consent form should identify the most important risks, with a particular emphasis on how those risks are changed by participating in the study. For example, information shared about illegal behaviors or immigration status may damage a participant’s reputation or place them at risk of legal action. If there are no foreseen risks of research participation, you must include a statement in this section. It should never be deleted.]

[Studies that include questionnaires or interview questions about mental health, psychological functioning, or mood, or includes participants that are at elevated risk of suicide, must include the following or similar language. Otherwise, delete.]

“As part of the research, we may ask questions about how <you feel> <your child feels> mentally and emotionally. We are providing a list of resources to you <your child> in case you <they> would like to talk to someone and get help. If you are thinking about hurting yourself or someone else, please tell someone who can help immediately. Call the toll-free 24-hour National Suicide Prevention Lifeline at 1-800-273-TALK (1-800-273-8255) to talk to a counselor near you.”

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[Include if there are additional risks that were not selected as part of the key information, include the statement below. Otherwise delete.] More detailed information about the risks of this study can be found under *“What are the risks of this study? Is there any way being in this study could be bad for me? (Detailed Risks)”*

Will being in this study help me in any way?

[This beginning section of the consent form should identify one or more likely benefits resulting from participation in the study; in doing so, you should not overemphasize the benefits. If you need to discuss benefits in additional detail, add an additional section later in the consent document]

[Include if there are benefits to participation. Otherwise delete.] We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include _____. [First describe any direct benefits to the subject, then any possible benefits to others. If benefits from participation may not continue after the research has ended, describe them here. Monetary reimbursement for participation is not a benefit.]

[Include for a study with no benefits to participation. Otherwise delete.] There are no benefits to you from your taking part in this research. We cannot promise any benefits to others from your taking part in this research. However, possible benefits to others include _____. [Describe any possible benefits to others. Monetary reimbursement for participation is not a benefit.]

[Include for research involving prisoners] Taking part in this research study will not improve your housing or correctional program assignments. Your taking part in this research study will not improve your chance of parole or release.

[Include if there are additional benefits described below. Otherwise delete.] More detailed information about the benefits of this study can be found under *“Will being in this study help me in any way? What happens if I do not want to be in this research?”*

Include if there are alternatives other than participating.]

[No Specific Alternatives: Include this statement]

There are no known alternatives, other than deciding not to participate in this research study.

[Specific Alternatives Available/Known: Include this statement]

You do not have to participate in this research. Instead of being in this research study, your choices may include: [List alternatives procedures. For student participant pools, describe alternatives for course credit.

For clinical trials, describe the options that you would normally offer a patient.

If applicable, include supportive care as an option.]

Detailed Information About This Research Study

The following is more detailed information about this study in addition to the information listed above.

How many people will be studied?

We expect about _____ people here will be in this research study out of _____ people in the entire study nationally [or internationally].

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What happens if I say “Yes, I want to be in this research”?

[In terms that can be understood by people not in the field of this research, tell the participant what to expect. Whenever appropriate include the following items:

- A timeline description of the activities that will occur, such as a schedule.
- The length and duration of visits, activities, and procedures.
- With whom the participant will interact.
- Where the research will be done.
- When the research will be done.
- List experimental procedures and therapies and identify them as experimental.
- How often activities or procedures will be performed.
- What is being performed as part of the research study.
- What is being performed as part of standard care (if the study involves any type of clinical care, e.g. mental health care)
- 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 whole genome or exome sequence of that specimen).
- When applicable, indicate that the participant will be asked to provide permission to be contacted for future research.
- When applicable, describe whether audio and/or video recording of any research activities will be done. Include whether an agreement to be recorded is required for participation or if it is optional.

[Include this statement for a clinical trial or other research that involves randomization. Otherwise delete.] The experimental treatment you get will be chosen by chance, like flipping a coin. Neither you nor the investigator will choose what experimental treatment you get. You will have a(n) _____ [equal / one in three /etc.] chance of being given either experimental treatment.

[For double-blinded research add] Neither you nor the investigator will know which experimental treatment you are getting.

[For single blinded research add] You will not be told which experimental treatment you are getting, however your investigator will know.

What are my responsibilities if I take part in this research?

[Delete this section if not applicable.]

If you take part in this research, you will be responsible for: [Describe any responsibilities of the participant, such as returning a study computer, Fitbit, etc.]

What happens if I say “Yes”, but I change my mind later?

You can leave the research study at any time and no one will be upset by your decision.

[Include if there are potential adverse consequences to withdrawing from the research. Otherwise delete] If you decide to leave the research study, [Describe the adverse consequences.]

If you decide to leave the research study, contact the investigator so that the investigator can [Describe the procedures for orderly termination by the participant, if any.]

Choosing not to be in this study or to stop being in this study will not result in any penalty to you or loss of

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benefit to which you are entitled. This means that your choice not to be in this study will not negatively affect your right to **[Insert as applicable]** any present or future medical care, your academic standing as a student, or your present or future employment.

[For research that is not FDA-regulated, describe what will happen to data collected up to the point of withdrawal. Describe whether participants will be asked to explain the extent of their withdrawal and whether they will be asked for permission to collect data through interaction or collection of private identifiable information. For example, a participant may wish to withdraw from the experimental procedure because of unacceptable side effects, but may agree to undergo follow-up procedures and data collection.]

What are the risks of being in this study? Is there any way being in this study could be bad for me? (Detailed Risks)

[If there are no risks in addition to what was included in the Key Information section above, then delete this section. Otherwise, describe in sufficient detail each of the following risks, if appropriate. If known, describe the probability and magnitude of the risk. The risks of procedures may be presented in a table form.]

- Physical risks
- Side effects of drugs and devices
- Psychological risks
- Privacy and confidentiality risks: There is some risk of a data breach involving the information we have about you. We comply with the University's security standards to secure your information and minimize risks, but there is always a possibility of a data breach.
- Legal risks
- Social risks
- Economic risks
- Group or community risks

If the research involves the use of CMRR, refer to the [CMRR template](#) for information that should be included.

Distinguish between the risks presented by participation in the research and the risks associated with any procedures, such as clinical care or classroom lessons, that would occur regardless of participation in the research. Also, do not include results of animal studies unless there is no other known risk information and inclusion would aid with understanding.]

This research may hurt you in the following ways: _____.

[Include for research that involves procedures whose risk profile is not well known, including all research involving an investigational product. Otherwise delete.] In addition to these risks, this research may hurt you in ways that are unknown. These might be minor or be severe as to cause death.

Will it cost me anything to participate in this research study?

In developing this section of the consent:

- Describe any research-related costs that are not covered by the study and how they will be paid.
- Describe any tests, procedures, treatments, etc. related to standard care that will be billed to

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subjects/their insurance, e.g. routine safety labs, routine imaging, drugs, devices.

- Describe any costs related to (if applicable):
 - additional procedures performed because of the research
 - treatment of side effects
 - fees for preparing or administering study drugs
 - pharmacy costs
 - incidental expenses such as transportation, food, childcare.
- Describe any costs that will be covered by the study including tests, procedures, transportation, etc.
- Encourage potential subjects to check with their insurance companies for information about coverage for research procedures. This includes suggesting pre-authorization, where appropriate.

Choose the option(s) most appropriate for your study. DELETE options that do not apply:

- There will be no cost to you for any of the study activities or procedures.
- There will be no cost to you for the [describe types of activities covered by study, e.g.] lab tests, diagnostic tests, drugs, clinic visits that are done for research purposes only and are not part of your regular care.
- You will have to pay for basic expenses like any childcare, food, parking, or transportation related to study activities.
- You or your insurance company will have to pay for all costs for medical care related to participation in this study, including copayments and deductibles. You will have to pay for any costs your insurance does not cover. If you have any questions about these costs, or what out-of-pocket expenses you may have to pay, you should contact your insurance company. If you do not have health insurance, you will have to pay all costs for your medical care just as you would if you did not take part in this study.
- If you need treatment for side effects while you are on the study, you or your insurance will need to pay for this treatment.

Will being in this study help me in any way? (Detailed Benefits)

[Delete this entire section if there are no benefits in addition to what was included in the Key Information section above.]

[Include whether there are benefits to participation. Otherwise delete.] We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include _____. [Describe the potential benefits of participation. First describe any direct benefits to the participant, then any benefits to others. If benefits from participation may not continue after the research has ended, describe them here. Monetary reimbursement for participation is not a benefit.]

[Include for a clinical trial with no benefits to participation. Otherwise delete.] There are no benefits to you from your taking part in this research. We cannot promise any benefits to others from your taking part in this research. However, possible benefits to others include _____. [Describe any benefits to others. Monetary reimbursement for participation is not a benefit and should be described in a later section.]

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete confidentiality. Organizations that may inspect and copy your information include the Institutional Review Board (IRB), the committee that provides ethical and regulatory oversight of research, and other

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representatives of this institution, including those that have responsibilities for monitoring or ensuring compliance. [Add to this list other organizations that may have access to the participants records such as the medical service providers (for clinical trials), US Department of Defense Health and Human Services, when the research is conducted or funded by DHHS, the sponsor, contract research organization, sponsor's agent and other collaborating institutions.]

We may publish the results of this research or sharing the resulting data. However, we will keep your name and other identifying information confidential.

[Include for all studies that involve, as part of their protocol, ANY clinical intervention that takes place within a MHealth Fairview Facility. Otherwise, delete.] If you agree to participate in this research study, a signed copy of this consent document and the HIPAA authorization form *may* be filed in your electronic medical record (EMR) and your study participation *may* be added to your EMR. This information will be used for your care and treatment and for healthcare operations, which may include billing and payment. Federal and state privacy laws give patients the right to access information about their care and treatment contained in their medical record. During this study, you may not be able to access certain information related to this study in your EMR until the study is complete to ensure that the study remains unbiased. By consenting to participate in this study, you are also consenting to this possible temporary withholding of your research records.

[Studies that include questionnaires or interview questions about mental health, psychological functioning, or mood, or includes participants that are at elevated risk of suicide, must include the following or similar language. Otherwise, delete.]

Anonymous Surveys (results are NOT individually identified): "We will not be able to link your responses to you <your child>, so we will not be able to provide you <your child> with personal feedback or referrals based on your <your child's> responses to questions. If you are concerned about your <your child's> mood, please refer to the attached resource referral information sheet. Please tell someone who can help right away. You can call also call the toll-free 24-hour National Suicide Prevention Lifeline at 1-800-273-TALK (1-800-273-8255) to talk to a counselor near you."

Results Individually Identifiable/In-Person: "The study team may break confidentiality in an effort to keep you <or your child> safe, which may include informing parents, local authorities, and/or health care professionals."

"If <you tell> <your child tells> us that you <they> are thinking about hurting yourself <themselves> or others, the research staff may ask more questions. Depending on how intense your <their> thoughts are or how much you <they> feel like hurting yourself <themselves> or others, the research staff may give you <them> referrals for treatment, work with you <them> to contact a personal doctor, trusted family member, or therapist to discuss your <their> thoughts of harming yourself <themselves>. We may need to work with you <them> on a plan that might include getting to a medical facility for safety."

Additional sharing of your information for mandatory reporting [Include one of the following Mandated or permitted Reporter Language statements if applicable. In studies in which investigators are probing for or likely to elicit information about child or vulnerable adult abuse or neglect, the State of Minnesota requires or permits investigators to report such information to authorities.]

If we learn about any of the following, we may be required or permitted by law or policy to report this information to authorities:

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- Current or within the preceding three years child or vulnerable adult abuse or neglect;
- Communicable, infectious or other diseases required to be reported under Minnesota's Reportable Disease Rule;
- Certain wounds or conditions required to be reported under other state or federal law; or
- Excessive use of alcohol or use of controlled substances for non-medical reasons during pregnancy.

Consent and Data Rights Under the European General Data Protection Regulation (GDPR)

[Include if participant is likely to be located in the European Economic Area. Otherwise delete this section.]

[If included, do not alter any of the following text.] Your participation in this research will involve the collection and processing of your personal data, as described above and in any HIPAA Authorization Form we have provided to you. Please indicate whether you consent to the collection and processing of your personal data by placing your initials underneath the appropriate selection.

☐ Yes, I consent to the collection and processing of my personal data.

☐ No, I do not consent to the collection and processing of personal data.

(Your consent is entirely voluntary, but declining to provide it may materially impede your ability to participate in this research and receive any treatment.)

To the extent your personal data are protected by the GDPR, you have the right to—

- Know what data we are collecting, where they will be processed, and how they will be used;
- View and correct your personal data;
- Obtain and transfer your personal data to another organization;
- Have certain personal data destroyed (except when data retention is otherwise required or authorized under the GDPR or other controlling legal authority);
- Withdraw your consent to the continued collection of your personal data; and
- Certain other actions described in Chapter III of the GDPR.

Certificate of Confidentiality

[Include the following statement if the research is being conducted under a Certificate of Confidentiality. Otherwise delete.]

To help protect your privacy, the National Institutes of Health has granted a Certificate of Confidentiality. The researchers can use this Certificate legally to refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below. It is unclear if the Certificate will work in foreign countries.

The Certificate does not prevent a researcher from reporting information learned in research when required by other state or federal laws, such as mandatory reports to local health authorities for abuse or neglect of children or vulnerable adults, or information to the Food and Drug Administration (FDA) when required in an FDA audit. However, the Certificate limits the researcher from disclosing such information in follow up civil, criminal, legislative or administrative legal proceedings if the information was created or compiled for purposes of the research.

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You also should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.

Data or Specimens Collected

[If data or specimens will be retained after the study for future research, explain where the data or specimens will be stored, who will have access to the data or specimens, and how long the data or specimens will be retained.]

[If identifiable private information or identifiable specimens will be collected during the research, add one of the following statements.] If identifiers are removed from your identifiable private information or identifiable samples that are collected during this research, that information or those samples could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent. **OR** Your information or samples that are collected as part of this research will not be used or distributed for future research studies, even if all of your identifiers are removed.

[Include when applicable.] Your information and samples (both identifiable and de-identified) may be used to create products or to deliver services, including some that may be sold and/or make money for others. If this happens, there are no plans [or replace with plans when using identifiable information/samples] to tell you, or to pay you, or to give any compensation to you or your family.

Genetic Information

[Include for research involving genetic information. Otherwise delete.] A federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

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

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

[Include for research where the sponsor may pay for medical expenses of the participant.] If the sponsor pays any of your medical expenses, we may be required to give the sponsor your name, date of birth, and Medicare ID or social security number.

[Include for a clinical trial. Otherwise delete.] The sponsor, monitors, auditors, the IRB, the University of Minnesota Research Compliance Office and other University compliance units, the US Office of Research

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Integrity (ORI), the US Office for the Protection of Human Research Protections (OHRP), the US Food and Drug Administration (FDA) may be granted direct access to your medical records to conduct and oversee the research. By signing this document you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

[[Section 801 of the Food and Drug Administration Amendments Act \(FDAAA 801\)](#) (PDF) requires Responsible Parties to register and submit summary results of clinical trials with [ClinicalTrials.gov](#). The law applies to certain clinical trials of drugs (including biological products) and medical devices. For more information see [CT.Gov Guidance](#).] A description of this clinical trial will be available at <http://www.ClinicalTrials.gov>, as required by U.S. Law or other guidelines. 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.

[Include for research involving prisoners. Otherwise delete.] If you are a prisoner, your medical records may also be given to officials and agencies within the criminal justice system when necessary and permitted by law.

Will I receive research test results?

[When applicable, include whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and for research involving biospecimens,] *If clinically relevant research results will be shared with research participants, include the content located under "Yes." If clinically relevant research results WILL NOT be shared with research participants, only include the content under "No results will be shared section"."*

YES

Most tests done on samples in research studies are only for research and have no clear meaning for health care. If the research with your identifiable information or samples gives results that do have meaning for your health, the investigators will contact you to let you know what they have found. If the investigators return genetic test results to you, it may be because they think you could have a health risk and want to recommend that the test should be re-done by a certified clinical laboratory to check the results. If this happens, then you may want to get a second test from a certified clinical laboratory, consult your own doctor, or get professional genetic counseling. You may have to pay for those additional services yourself.

NO

Most tests done on samples in research studies are only for research and have no clear meaning for health care. The investigator(s) will not contact you or share your individual test results.

For studies involving genetic testing, please reference and include relevant text below.

[Specific to genetic testing: When providing only aggregate and not individual results]

Only results of a **group** of study participants will be returned to you. When reviewing the results for the entire group of study participants, you will not be able to identify yourself or any other study participant. Results for the group may not provide results that are relevant to you as an individual. You will not receive individual information even if a medically significant result should be discovered and even if the testing reveals information that could be used by you to make healthcare or lifestyle changes that could prolong your life or prevent or delay the development of a life-threatening condition.

[Specific to genetic testing: Results verified in CLIA laboratory]

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The research laboratory is a CLIA certified laboratory. This means that the results regarding “**condition X**” can be shared with you and you may share these results with your physician to make medically relevant decisions if applicable.

or

[Specific to genetic testing: Results from a research laboratory only]

Our laboratory is a research laboratory. This means that our studies are being performed to learn about genes that cause “**condition X**”. If our laboratory should identify a genetic variation that impacts your medical care, we will ask your physician to have the result verified in a Clinical Laboratory Improvement Amendments (CLIA) certified Orphan Disease laboratory. We will provide information to the Orphan Disease laboratory to allow them to complete the testing. This additional testing in a clinical CLIA laboratory will usually require a new sample and be charged to your insurance as a clinical laboratory test.

[Specific to genetic testing: PI discretion related to return of results- if primary target is the only result disclosed]

The analysis of genetic data will be focused on the cause of “(**name condition X**)”. Only genetic results regarding this target condition will be reported. No other results that are related to other diseases or conditions will be reported, even if that genetic variant can be associated with cancer, neurologic disease or another condition.

[Specific to genetic testing: returning variants of uncertain clinic significance]

The investigators may disclose results to you that may or may not have clinical significance at this time. However, these genetic variants may have significance in the future that are not anticipated at this time.

[Specific to genetic testing: incidental findings not disclosed]

The testing in some cases may reveal information not anticipated. For some DNA testing this includes information about paternity or blood relationship between the people being tested. The DNA test may reveal private information about blood relationships.

[Specific to genetic testing: Disclosure of complete dataset]

You will receive a complete dataset of your genomic data completed by the investigators of this study. You will assume all future costs associated with interpretation, medical costs associated with evaluation and treatment for conditions beyond the scope of this study, genetic and emotional counseling and use of any web-based tools to analyze your genomic data.

NO Results will be shared

Most tests done on samples in research studies are only for research and have no clear meaning for health care. The investigator(s) will not contact you or share your individual test results.

[Specific to genetic testing: If not returning results to participants]

NO genetic results will be shared with you, even if a medically significant results should be discovered and even if the testing reveals information that could be used by you to make healthcare or lifestyle choices that could prolong your life or prevent or delay the development of a life threatening condition.

What will be done with my data and specimens (if applicable) when this study is over?

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(Use one of the following three options regarding the use of data and/or specimens for future research. Please note that this section does NOT constitute broad consent.):_

NO secondary (future) research with or without identifiers:

Your data and/or samples (include as applicable) will not be used for any future research after this study is complete.

Secondary (future) research without identifiers (include this if data sharing is indicated in a Data Management or Data Management and Sharing Plan for funded research):

We will use and may share data and/or specimens for future research. Data collected in this study may be made available for others to use, including for future research studies on similar or different topics, teaching, or other purposes. This could include for profit companies. Our goal is to make more research possible. We will not ask for your consent before using or sharing them. We will remove identifiers from your data and/or specimens, which means that nobody who works with them for future research will know who you are. Therefore, you will not receive any results or financial benefit from future research done on your specimens or data. *[Consider providing participants with a data sharing information sheet for full understanding of the process, including which repositories will manage the data and the access restrictions applied, if applicable. See [template provided by the University Libraries & Liberal Arts Technology and Innovation Services](#).]*

Secondary (future) research with identifiers:

If there is ANY chance of using the data and/or specimens for future research and they are linked to identifiers or identifiable information; either

- include an “Optional Future Use of Data and/or Specimens” section (see the next section of the template). Or
- if future use of individually identifiable specimens/data is mandatory for study enrollment, then this must be explicitly stated below (the header and option to document consent to the future use should be deleted).

Optional Consent for Future Use of Identifiable Data or Specimens

This section is specifically for studies that intend to retain identifiable data or specimens including coded specimens that can be relinked back to the individual and used for future research. The heading to this section should reflect whether this additional research is optional or a required element of the primary study. If identifiable data or specimens will be retained for future secondary research, then subjects must consent to its use. Edit the following section as appropriate and also indicate whether identifiers would only be maintained at UMN or might be shared outside of UMN.

At the completion of this research study, we would like to store and be able to use and share your identifiable <specimens and/or health information> with researchers at the University or affiliated hospitals for other research related to **[specify disease area –]**. Any research that involves identifiable information will be reviewed by an Institutional Review Board (IRB), which is the committee that provides ethical and regulatory oversight of research at the University, prior to use. Because these specimens and/or health information are identifiable, we are asking your permission to store, use and share these for other research. *(Delete the following sentence if not applicable to this research: You can still take part in the research study even if you say “no” to this optional request.)*

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We may not ask for your consent before using or sharing your identifiable specimens or data. You will not receive any results or financial benefit from the future research done on your specimens or data. We may share your identifiable specimens or data with outside researchers who will use them for future research.

If you leave the study, you can ask to have the data collected about you removed or the samples destroyed. You can also ask us to remove information that identifies you from the data or samples. This may not be possible if your samples and data have already been shared.

Please indicate whether you will allow the identifiable **data or samples** to be used for future research by putting your initials next to one of the following choices:

_____ (initials) NO, my identifiable **(data and/or specimens)** may not be used for future research. They may be used for this study only.

_____ (initials) YES, my identifiable **(data and/or specimens)** may be used for other future research studies

Will anyone besides the study team be at my consent meeting?

[Depending on the nature of the research protocol, there may be consent observation by the Post Approval Review Program or other monitoring entity. Some studies also include a provision of a third-party observer, such as a bioethicist.] You may be informed by the study team that an auditor may observe your consent meeting (or a recording of your consent meeting [remove if not applicable – only applicable if consent meetings are being systematically recorded by the study team for this study]). Observing the consent meeting is one way that the University of Minnesota makes sure that your rights as a research participant are protected. The auditor is there to observe the consent meeting, which will be carried out by the people on the study team. The auditor will not document any personal (e.g. name, date of birth) or confidential information about you. The auditor will not observe your consent meeting (or a recording of your consent meeting [remove if not applicable – only applicable if consent meetings are being systematically recorded by the study team for this study]) without your being informed ahead of time.

Whom do I contact if I have questions, concerns or feedback about my experience?

To reach the research team: Please see the “Investigator Contact Information” section at the beginning of this form.

To reach someone outside of the research team: This research has been reviewed and approved by an IRB within the Human Research Protections Program (HRPP). To share feedback privately with the HRPP about your research experience, call the Research Participants’ Advocate Line at 612-625-1650 (Toll Free: 1-888-224-8636) or go to z.umn.edu/participants. You are encouraged to contact the HRPP if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You are having difficulty reaching the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide feedback about this research.

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Will I have a chance to provide feedback after the study is over?

The HRPP may ask you to complete a survey that asks about your experience as a research participant. You do not have to complete the survey if you do not want to. If you do choose to complete the survey, your responses will be anonymous.

If you are not asked to complete a survey, but you would like to share feedback, please contact the study team or the HRPP. See the “Investigator Contact Information” of this form for study team contact information and “Whom do I contact if I have questions, concerns or feedback about my experience?” of this form for HRPP contact information.

Can I be removed from the research?

[Delete this section if not applicable.]

[Include for research where this is a possibility. Otherwise delete.] The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include [describe reasons why the participant may be withdrawn, if appropriate.]

[Include for research where this is a possibility. Otherwise delete.] We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

What happens if I am injured while participating in this research?

[If the research involves the potential for injury, one of the following three statements regarding appropriate compensation for injury must be included, as indicated on the medical application form.]

[Option 1 - Non-Sponsor Funded Compensation]

In the event that this research activity results in an injury, treatment will be available, including first aid, emergency treatment and follow-up care as needed. Care for such injuries will be billed in the ordinary manner, to you or your insurance company. If you think that you have suffered a research related injury let the study physicians know right away.

[Option 2 - Sponsor Funded Compensation]

In the event that this research activity results in an injury, treatment will be available, including first aid, emergency treatment and follow-up care as needed. Care for such injuries will be billed in the ordinary manner, to you or your insurance company. The sponsor of the study has some funds available to pay for care for injuries resulting directly from being in this study. If you think that you have suffered a research related injury and that you may be eligible for reimbursement of some medical care costs, let the study physicians know right away.

[Option 3: If the preferred injury compensation language is unacceptable to the study sponsor, the following alternative language may be used.]

In the event that this research activity results in an injury, treatment will be available, including first aid, emergency treatment and follow-up care as needed. Care for such injuries will be billed in the ordinary manner, to you or your insurance company. Under some circumstances the sponsor of the study will pay for care for injuries resulting directly from being in the study. If you want information about those circumstances

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or if you think you have suffered a research related injury let the study physicians know right away.

Will I be compensated for my participation?

[Include if participants will be paid. Otherwise delete.] If you agree to take part in this research study, we will pay you _____ [indicate amount] for your time and effort. [Indicate if the amount is pro-rated for research visit completion.]

[Include if the study will utilize Greenphire ClinCard for compensating participants. Otherwise delete.] Payment will be made using a pre-paid debit card called Greenphire ClinCard. It works like a bank debit card. We will give you a debit card and each time you receive a payment for participation in this study, the money will be added to the card after each completed visit.

You may use this card at any store that accepts MasterCard or you can use a bank machine to remove cash. However, there may be fees drawn against the balance of the card for cash withdrawals (ATM use) and inactivity (no use for 6 months). We will give you the ClinCard Frequently Asked Questions information sheet that answers common questions about the debit card. You will also receive letters with additional information on how you can use this card and who to call if you have any questions. Be sure to read these letters, including the cardholder agreement, for details about fees.

The debit card system is administered by an outside company. The company, Greenphire, will be given your name, address, birthdate and [if not applicable remove the SSN statements] social security number. They will use this information as part of the payment process. Greenphire will only need your social security number if the payment exceeds \$599. Greenphire will not receive any information about your health status or the study in which you are participating.

[Use the following language if the subject will be receiving appointment reminders and/or payment reminders or updates via text messaging or email via Greenphire.]

Additionally, you will have the option to receive updates related to appointment reminders and payment reminders and updates via text message and email message (Standard text messaging rates will apply). You will have the opportunity to opt-in to receive these messages, you are not required to provide your cell phone or email address to be enrolled in the study or use a ClinCard. If you choose to receive messages and decide at a later date that you want to stop these messages, you will have the ability to opt-out.

Payment you receive as compensation for participation in research is considered taxable income. If payment to an individual equals or exceeds \$600 in any one calendar year, the University of Minnesota is required to report this information to the Internal Revenue Service (IRS). Research payments to study participants that equal or exceed \$600 during any calendar year will result in a FORM 1099 (Miscellaneous Income) being issued to you and a copy sent to the IRS.

[Include for Department of Defense (DOD) research that targets military personnel where participants will be paid. Otherwise delete.] Military personnel should check with their supervisor before accepting payment for participation in this research.

[Include for research involving prisoners where there may be a need for follow-up examination or care after the end of participation. Otherwise delete.] If you are released from jail before you finish this research study,

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you should take steps to get insurance or Medicaid coverage. Regular office visits and standard clinical care will be billed to you or your health insurance. You may continue in the research study after your release from prison. If you move out of the area, we will help you make arrangements to be followed by a physician.

Use of Identifiable Health Information

[Include if HIPAA Authorization is required. Otherwise delete this section.]

[If included, do not alter any of the following text, except as indicated.] We are committed to respect your privacy and to keep your personal information confidential. When choosing to take part in this study, you are giving us the permission to use your personal health information that includes health information in your medical records and information that can identify you. For example, personal health information may include your name, address, phone number or social security number. Those persons who get your health information may not be required by Federal privacy laws (such as the 1099

Rule) to protect it. Some of those persons may be able to share your information with others without your separate permission. Please read the HIPAA Authorization form that we have provided and discussed.

The results of this study may also be used for teaching, publications, or for presentation at scientific meetings.

Optional Elements:

[Include for any optional elements of the research approved by the IRB. Otherwise delete.] The following research activities are optional, meaning that you do not have to agree to them in order to participate in the research study. Please indicate your willingness to participate in these optional activities by placing your initials next to each activity.

Yes, I agree	No, I disagree	
_____	_____	The investigator may audio or video record me to aid with data analysis. The investigator will not share these recordings with anyone outside of the immediate study team.
_____	_____	The investigator may audio or video record me for use in scholarly presentations or publications. My identity may be shared as part of this activity, although the investigator will attempt to limit such identification. I understand the risks associated with such identification.
_____	_____	The investigator may contact me in the future to see whether I am interested in participating in other research studies by <Name of Principal Investigator>

_____ I would like to receive reminders using Greenphire.

If yes, provide the following contact information:

Email Address: _____

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Phone Number: _____

[There are three sets of signature options listed below. Use the signature block appropriate for your study. Delete those that do not apply. Omit the signature page if there is no written documentation of consent.]

Signature Block for Capable Adult:

Your signature documents your permission to take part in this research. You will be provided a copy of this signed document.

Signature of Participant

Date

Printed Name of Participant

Signature of Person Obtaining Consent

Date

Printed Name of Person Obtaining Consent

WITNESS STATEMENT:

The participant was unable to read or sign this consent form because of the following reason:

- ☐ The participant is unable to read the information
- ☐ The participant is visually impaired
- ☐ The participant is non-English speaking
- ☐ The participant is physically unable to sign the consent form. Please describe:

☐ Other (please specify):

For the Consent of Non-English Speaking Participants when an Interpreter is Used:

As someone who understands both English and the language spoken by the subject, I represent that the English version of the consent form was presented orally to the subject in the subject's own language, and that the subject was given the opportunity to ask questions.

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Signature of Interpreter

Date

Printed Name of Interpreter

OR:

Statement from a Non-Interpreter:

As someone who understands both English and the language spoken by the subject, I represent that the English version of the consent form was presented orally to the subject in the subject's own language, and that the subject was given the opportunity to ask questions.

Signature of Individual

Date

Printed Name of Individual

Signature Block for Adult Unable to Consent:

Your signature documents your permission for the named participant to take part in this research.

Printed Name of Participant

Signature of Legally Authorized Representative

Date

Printed Name of Legally Authorized Representative

Date

Signature of Person Obtaining Consent

Date

Printed Name of Person Obtaining Consent

Date