NOTE TO INVESTIGATORS: This is the RSRB adult consent form template with required UR CABIN languageincluded.We request that you submit to the RSRB a consent form where the text you have added is in black and all blue text is left unchanged.

We acknowledge there may be some deviations from the established language (all blue text) based on the nature of your study. Be sure to delete all brackets and this page before submission. Delete the paragraphs within the brackets which are for clarification.

***Biomedical Template v. Jan, 2023***

***RSRB Requirements:***

* ***Information highlighted in yellow is guidance. Ensure ALL HIGHLIGHTED TEXT is deleted before submitting.***
* ***Use of “Subject”: The consent must use the term research “subject” rather than “participant” or “volunteer”.***
* ***Use of 2nd Person: The consent form must be written in the 2nd person (e.g., “You are being asked to take part in a research study about…”).***
* ***Document Footer: Upon approval, the RSRB watermarks all consent forms in the lower right-hand corner of the document. Do not include text on the right side of the document footer (it will be covered by the watermark once it is applied). A bottom margin of at least 1 inch should be maintained to provide space for the watermark.***
* ***Pagination: Maintain page numbering already inserted in the footer (e.g., “2 of 4”).***
* ***Version Date: Manually type the date in the footer, rather than selecting “Insert Date” from the toolbar to avoid automatic updates each time the document is opened.***

**CONSENT FORM**

**[Insert Title of Study]**

**Principal Investigator: [**Insert]

**This consent form describes a research study, what you may expect if you decide to take part and important information to help you make your decision. Please read this form carefully** **and ask questions about anything that is not clear before you agree to participate. You may take this consent form home to think about and discuss with family or friends.**

**Key Information**

[*The text below is provided as guidance; bullet points can be added/updated/removed, based on the nature of the research.* Key information should be a concise and focused summary of the study to provide the reasons why one might or might not want to participate*.*]

* Being in this research study is voluntary **– it is your choice**.
* You are being asked to take part in this study because [Specify condition, situation, circumstances or other reason for subject’s recruitment].
* The purpose of this study is [INSERT brief description of purpose, this should be consistent with the Purpose of the Study section below.].
* Taking part in this study will last for about [INSERT timeframe, e.g., hours, months, years, etc.].
* Procedures will include [INSERT primary activities]. Some of these procedures may be optional.
* There are risks from participating.
  + The most common risk is [INSERT].
  + One of the most serious risks is [INSERT].
  + See the “Risks of Participation” section in this consent form for more information. You should discuss these risks in detail with the research team.
* [Choose one of the following; the same benefit statement should be used in the Benefit section below.] You will not benefit from being in this study. OR You might not benefit from being in this research study. The potential benefit to you might be [INSERT].
* If you do not want to take part in this study… [Discuss appropriate alternative procedures or courses of treatment that might be available or advantageous to the subject, if they do not participate (e.g., standard treatment, no treatment, comfort care or taking part in another study). This should be consistent with the Alternative sections below. Delete if no alternatives]

**Purpose of Study**

The purpose of this study is to… [Describe the general purpose of the study and include relevant background information in lay terms. If possible, limit the explanation to why study is being done to one or two sentences.]

**Description of Study Procedures**

If you decide to take part in this study, you will be asked to… [Describe in plain language (i.e., using lay terms), step-by-step what will be done or required of the research subject. Be concise; avoid describing study procedures in lengthy narrative form. All procedures should be listed in the consent form. If there are multiple steps, use sub-headings, bullets, tables, pictures, etc. Include where the study procedures will take place. If different procedures will take place at different locations, specify accordingly.]

**[NOTE**: Sample language for certain procedures (e.g., blood draws, CT, MRI, X-ray, randomization, placebo, radiation, etc.) is provided in the [RSRB Consent Document Sample Language](http://www.rochester.edu/ohsp/documents/rsrb/word/Consent_Sample_Language_Guide.docx) guide. If the study will include genetic testing as defined in [Policy 608 Research Involving Genetic Testing and Gene Transfer](https://www.rochester.edu/ohsp/documents/ohsp/pdf/policiesAndGuidance/Policy_608_Genetic_Testing.pdf) refer to policy and associated guidelines for consent language.]

At visit [X and Y] you will have an MRI (Magnetic Resonance Imaging) done at UR CABIN. An MRI creates pictures of the inside of your body using strong magnets instead of x-ray energy. At the time of each scan you will be asked to fill out a screening form to verify that it is safe for you to have the scan. It is important that you provide us with an accurate and up-to-date medical history, and when unsure to ask clarifying questions so that we can proceed safely.You will also be asked to remove any metallic objects you may be wearing (for example, watches, earrings or piercings) and change into a hospital gown.Then you’ll be asked to lie on a narrow bed and special padding will be placed around your body to help keep you still and not touch the inside of the scanner. Once you are comfortable, the table will be moved into the scanner (the scanner is a long, narrow tube that is open at each end). You will need to lie still on the table during the scan which will take about [minutes/hours] to complete. You will hear normal “hammering” or clicking and squealing noises during the scan. You will be able to communicate with the techologist running the scan the entire time and will be provided an emergency button to squeeze at any time if you decide you want the scan to stop.

**Future Use of Information/Samples**

[Choose or modify **ONE** of the following sentences:]

Your [information / samples] collected as part of this research will not be distributed or used for future research studies.

-OR-

Your [information / samples] might be distributed or used for future research studies without additional informed consent. All identifiers will be removed before your [information / samples] are used or distributed. [INSERT LAST SENTENCE IF APPLICABLE] You will be given the option at the end of this consent form to decide if you would like your [information / samples] used for future research.

**eRecord, MyChart, and your participation in this study** (if applicable)

Taking part in this study and the results of any testing done for this study may be documented in your electronic health record (eRecord), and you and your designated proxies may see the results in MyChart. The following individuals may know you participated in research and may see study testing and results for this study:

* Staff at the University of Rochester Medical Center and its Affiliates (e.g., Strong Memorial Hospital, Highland Hospital, URMC primary care, specialist physician offices) who have a reason to access your electronic health record.
* Health care providers who are involved in your care at a facility that is not part of the University of Rochester Medical Center and its Affiliates and who have reason to access your electronic health record.
* Individuals who request a copy of information from your health record for activities such as treatment or payment (e.g., medical insurance companies, worker’s compensation).

The research team may be notified if you receive other health care services at URMC or any of its Affiliates (e.g., visit to the emergency room or urgent care).

If you have questions or concerns, you should discuss it with the research team.

**Return of Research Results** (If applicable)

[Include language below as applicable, to indicate whether clinically relevant research results will be disclosed, and, if so, under what conditions:]

[**No results returned**]

In general, we will not give you any individual results from taking part in the study. If we find something of urgent medical importance to you, we will inform you, although we expect that this will be a very rare occurrence.

-OR-

[**Aggregate results returned**]

Once the study is completed, we will send you a summary of the results and what they mean. You will not receive your individual results.

-OR-

[**Individual results returned (if optional, include as an optional research activity at the end of consent)**]

As part of this study, we may learn information relevant to you or your family's health. If this happens, we will only provide you information that would be clinically relevant [as soon as the information is known / once the study is completed]. You will be given the option at the end of this consent to decide if you would like to receive these clinically relevant results.

[Modify/include as applicable to the study]

Some things you should know about results:

* Sometimes the meaning of the results will be uncertain. It is important to know that our understanding of health is changing quickly, and in many cases, we may not know for sure what the results mean for your future health.
* Sometimes, even if you learn of a clear diagnosis, there will be no clear treatment.
* Any results we return to you will first be verified in a clinical lab.
* The results will be explained to you by a genetic counselor, a health professional who has training in genetics and counseling.
* For many subjects, only certain genes will be analyzed, so we will not find all gene variants that cause disease. You should not assume that if you are not contacted, that you do not have any gene variants that might be related to a disease.]

As a subject in this research study, the investigator will provide you with an electronic format single image of your [brain/other body part] if you are interested.

**This MRI is not a clinical evaluation.** The images of your [brain/other body part] collected in this study are strictly for research purposes. These images cannot be used to make a clinical diagnosis. A certified radiologist will **not**routinely look at your MRI images. Also, the MRI results will not become a part of your electronic health record. However, if the MRI technologist sees what could be an abnormality, they will tell the study’s principal investigator (PI). The PI will then discuss this with you. You will be given referral information so that you can have diagnostic tests.

**Risks of Participation**

[The risks identified in the consent form should be consistent with the risks described in the protocol. For each research procedure, describe both the immediate and long-term physical, psychological, social, legal and economic risks/discomforts. Provide sufficient description of the risks to enable subjects to decide if they want to participate. If appropriate, include information on probability of the risks and the magnitude and reversibility of harmful effects. Describe how the researchers are minimizing the risks/discomforts. If there are currently unforeseeable risks to the subject (or fetus, if the subject may become pregnant), this should be stated.]

**[NOTE**: Sample language for certain related risks (e.g., blood draws, CT, MRI, X-ray, randomization, placebo, radiation, etc.) is provided in the [RSRB Consent Document Sample Language](http://www.rochester.edu/ohsp/documents/rsrb/word/Consent_Sample_Language_Guide.docx) guide.]

*Metal*: The MRI scanner produces a constant strong magnetic field. The magnet could move objects within your body that contain metal such as implants, clips or pacemakers and demagnetize devices such as cochlear implants. If you have any of these items you should not participate in this study. Metal earrings, metal body piercings, and necklaces must be removed prior to the study. Tattoos with metallic inks can potentially cause burns. Please provide us with as much information as you can, for example if you had surgery in the past, so that we may decide whether it is safe for you to be a subject.

*Pregnancy*: Exposure to MRI scanning might be harmful to a pregnant female or an unborn child. Although there are no established guidelines at this time about MR and pregnancy, you should be informed that there is a possibility of a yet undiscovered pregnancy related risk. If you know or suspect you may be pregnant, you cannot take part in this research study.

*Inner ear damage*: MRI scanning produces a loud tone that can cause damage to the inner ear if appropriate sound protection is not used. Earplugs or close fitting headphones will be provided to protect your ears.

*Claustrophobia*: The MRI scanner surrounds your body. Your [head, or other body part] will also be positioned inside a close-fitting scanning coil. If you feel anxious in confined spaces you may not want to participate. If you decide to participate and begin to feel claustrophobic later, you will be able to tell us and we will discontinue the scan.

*Burns*: Rarely, contact with conductive materials (like wires) in the machine can result in excessive heating or burns during the scan. If you feel any heating or burning or sensations during the scan, please let the technologist know immediately.

Besides the risks listed above, there are no other known risks from the magnetic field or radio waves at this time. If new findings about the risks of the MRI technique become available during the time of the study, we will let you know about them.

[U.S. Public Law 110-85 requires registration of "Applicable Clinical Trials" at [www.ClinicalTrials.gov](http://www.ClinicalTrials.gov). Click [here](https://grants.nih.gov/ClinicalTrials_fdaaa/docs/Flow_chart-ACT_only.pdf) for a diagram to identify an "Applicable Clinical Trial".] 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 website for information related to this study by using this study’s identification number NCT[INSERT].

**Circumstances for Dismissal** (If applicable)

You may be withdrawn from the study if… [Describe the circumstances, if any, under which the subject’s participation may be stopped without their consent, e.g., if they do not keep appointments for study visits, are unable to complete study activities, their disease worsens, or if the investigator no longer feels participating in the research is in your best interests.]

**Early Termination** (If applicable)

If you decide to end your participation in the study before you complete it, to ensure your safety, you will be asked to… [Describe any consequences for early withdrawal and procedures for orderly termination of participation. E.g., “If you are asked to stop taking the study drug before you complete the study, to ensure your safety, you will be asked to return approximately 2 weeks after your last dose to complete a physical and neurological exam.”]

**Benefits of Participation** [Payment to subjects for participation is not considered a benefit, it is compensation for participation. Payment information can be provided in the Payment section below]

[Choose **ONE** of the following as appropriate to this specific study:]

You will not benefit from being in this research study.

-OR-

You might not benefit from being in this research study. The potential benefit to you from being in this study might be… [List any direct benefits to the subject that might reasonably be expected from the research.]

**Alternatives to Participation** (If applicable)

[If the only alternative is not to participate, delete this section.]

-OR-

[Use this section to discuss appropriate procedures or courses of treatment, if any, which might be advantageous to the subject (e.g., standard treatment, no treatment, comfort care, or participation in another study).]

**New Study Information** (If applicable)

[If significant new findings which may relate to subject’s willingness to continue participation]

If we discover any new information that might make you change your mind about continuing in the study, we will let you know.

**Number of Subjects**

Approximately [state total accrual goal (number) here] subjects will take part in this study. [If appropriate, give a short description about cohorts. If this is a multi-center study, provide figures for both the whole study and for local enrollment at UR (e.g., “Approximately 40 subjects from 4 study centers across the country will take part in this research. Locally, about 20 subjects will participate.”).]

**Sponsor Support**

[If the study is not funded by an external agency (i.e. departmental funds) this section may be deleted.]

The University of Rochester is receiving money from [insert sponsor name] to conduct this study.

**Financial Disclosure Statement** (If applicable)

[If the Principal Investigator or any other study personnel have a financial interest (e.g. receive honoraria, consultant fees, royalties, equity) with the study sponsor (e.g. COI Management plan or transparency checklist), this must be disclosed in the consent form. Insert the disclosure statement here.]

**Commercial Profit** (If applicable)

[Include language if research information could be used to develop commercial products, modify as applicable to the study:]

We will use your information and/or samples for research only. However, the results of this research might someday lead to the development of commercial products that could be sold by a company. You [will/will not] receive money from the sale of any such product.

**Compensation for Injury**

[If the study involves no more than minimal risk, delete this section.]

-OR-

[Include the following for greater than minimal risk studies only:]

If you think you have been injured as a result of taking part in this research study, tell the person in charge of this research study as soon as possible. The study investigator’s name and phone number are listed in this consent form. The University of Rochester and the study investigator will determine whether your injury was the result of your participation in the study.

We will offer you the necessary care to treat your injuries. The costs of treatment may be billed to you or your insurer just like any other medical costs, or covered by the University of Rochester or other third party, depending on a number of factors. If your insurance is billed, you may be responsible for deductibles and co-payments. There are no plans to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form.

If the care you receive as a result of your injury is paid for by the University of Rochester or another party, we will need to collect certain personal information about you for insurance or payment reporting purposes, such as your name, date of birth, gender, social security number or Medicare identification number and information related to this research study. We may be required to report this information to the Centers for Medicare & Medicaid Services. We will not use this information for any other purpose.

**Costs**

[Choose or modify **ONE** of the following sentences as appropriate to the specific study:]

There will be no cost to you to participate in this study.

-OR-

Some of the tests/procedures/exams [specify] you will receive are standard care. You and/or your insurance company will be responsible for paying for any tests/procedures/exams that are done as part of your standard care. You are encouraged to discuss your coverage with your insurance provider.

[If medications, tests and therapies are to be provided free as part of the study, please specify.]

**Payments**

[Choose **ONE** of the following options, plus additional applicable language, as appropriate to the specific study:]

You will not be paid for participating in this study.

-OR-

You will be paid $XX for taking part in this study. [If subjects are to be paid for participation, specify the amount, the schedule of payment and conditions for payment (e.g., “You will receive $100.00 for each completed study visit. You will not be paid for visits that you do not complete. You will be paid up to a total of $1200.00.”). When applicable, payments should be based on a prorated system.]

[**NOTE**: if using the [Advarra Participant Payments](https://sites.mc.rochester.edu/urmc-clinical-research/participant-payments/reference-materials/) include the following language:

You will be paid $XX for taking part in this study. For this study we use a subject payment system called Advarra Participant Payments. The system allows three ways to provide payment. You can choose: a reloadable debit card; direct deposit; or mailed paper checks. The study team will help you create a “subject profile” in the system. In order to provide payment, you will need to enter your name and date of birth into your subject profile. Depending on which payment method you choose, you may also need to enter your email address and banking information. If you already have an Advarra account (because you are in another study that uses this system), your existing profile will be used to provide payment. See the ‘Information Sheet for Advarra Participant Payments” for additional information.

**[NOTE:** If the study will provide $250.00 or more as payment, the following must be included:

Payment received for taking part in research is considered taxable income.  If you receive payment for your taking part in studies at the University of Rochester of $600.00 or more in any one calendar year, the University is required to report this information to the Internal Revenue Service (IRS) in a 1099 (Miscellaneous Income) form. You will be sent a copy of this form and a copy will be sent to the IRS. You may be asked to submit a W-9 form, which includes your Social Security Number. If you are asked to complete a W-9 form and we find that you are not a US citizen or permanent resident, we may need to withhold 30% of your payment for taxes consistent with tax requirements.

**Reimbursement for Travel Expenses** (If applicable)

[Include language regarding reimbursement for travel expenses, such as plane, taxi, hotel, mileage costs, and modify as applicable to the study:]

You will be reimbursed for reasonable out of pocket expenses after submission of receipts to the research team. You will only be reimbursed for actual expenses up to a maximum amount of $XX. Such reimbursed expenses are not taxable.

**Confidentiality of Records**

[For studies with **no** protected health information (PHI) collected or if you are not part of the [covered entity](https://sharepoint19.mc.rochester.edu/sites/HIPAA/Privacy/T-P15-2.pdf).]

The University of Rochester makes every effort to keep the information collected from you private. In order to do so, we will [insert protection measures]. Sometimes, however, researchers need to share information that may identify you with people that work for the University, regulators or the study sponsor. If this does happen we will take precautions to protect the information you have provided. Results of the research may be presented at meetings or in publications, but your name will not be used.

**Confidentiality of Records and Authorization to Use and Disclose Information for Research Purposes** [For studies with which protected health information (PHI) is being collected.]

The University of Rochester makes every effort to keep the information collected from you private. In order to do so, we will [insert protection measures]. Sometimes, however, researchers need to share information that may identify you with people that work for the University, regulators or the study sponsor.

If you have never received a copy of the University of Rochester Medical Center (URMC) and Affiliates Notice of Privacy Practices, please ask the investigator for one. [**Note to Investigators**: the Notice must be provided and receipt documented if this is the first contact with URMC and Affiliates ([copies available on web](https://www.urmc.rochester.edu/medialibraries/urmcmedia/privacy/documents/NoticeofPrivacyPracticesHIPAA.pdf)).]

***What information may be used and given to others?***

* The investigator will get your personal and medical information.
* Research records
* Records about phone calls made as part of this research
* Records about your study visits
* Past and present medical records related to the study, including records of external providers that are available via your electronic health record at URMC & Affiliates [include only if you will be collecting information from the medical record]
* Results of medical tests [include only if you will be conducting medical testing, labs, imaging, etc.]

***Who may use and give out information about you?***

* The investigator and the study staff
* URMC and Affiliates

***Your information may be given to:***

* The Department of Health and Human Services
* The University of Rochester
* [Include if sponsored] The Sponsor and companies working with, on behalf of, or collaborating with the Sponsor
* [Include every organization or individual where data is shared (i.e., Advarra Participant Payments, data monitoring committees, government agencies, foreign government regulatory agencies, companies, coordination centers, data management centers, other research sites, home health agencies, etc. who might receive, and/or use the information).]
* The U.S. Food and Drug Administration (FDA) may also need to inspect study records at some point during the study or even after it has been completed. In the event that this should occur, every effort will be made to keep identifying information about you private. [include for drug/device studies or studies funded by the Food and Drug Administration]

***Why will this information be used and/or given to others?***

* To do the research
* To study the results
* To see if the research was done correctly

If the results of this study are made public, information that identifies you will not be used.

***What if I decide not to give permission to use and give out my health information?***

Then you will not be able to be in this research study.

***May I review or copy my information?***

Yes, but only after the research is over.

***How long will this permission be valid?***

This permission will last indefinitely. [If you will destroy the records at a specific time point or when a milestone is reach, that should be stated instead; and must be consistent with what is listed in both your protocol and application.]

***May I cancel my permission to use and disclose information?***

Yes. You may cancel your permission to use and disclose your health information at any time. You do this by sending written notice to the investigator. Upon receiving the written notice, the research team will no longer use or disclose your health information and you will not be able to stay in this study. Information that has already been gathered may need to be used and given to others for the validity of the study.

***May I withdraw from the study?***

Yes. If you withdraw your permission to be in the study, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

***Is my health information protected after it has been given to others?***

No. There is a risk that your information will be given to others without your permission. Once your information is disclosed to the named entities or organizations listed above, it is possible that your medical information will be re-disclosed and will no longer be protected by U.S. federal privacy regulations.

**Certificate of Confidentiality** [If NIH funded, or study will request a certificate, insert the language depending on risk level below.]

*For greater than minimal risk studies:*

To help us further protect your privacy, the investigators have a Certificate of Confidentiality from the Department of Health and Human Services (DHHS).

With this Certificate, the investigators cannot be forced (for example, by court subpoena) to disclose or use research information, documents, or samples that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, other proceedings, or be used as evidence. Disclosure will be necessary, however, upon request of DHHS for audit or program evaluation purposes, or to other government agencies related to communicable diseases.

You 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, employer, or other person obtains your consent to receive research information, then the investigator may not use the Certificate to withhold that information. This means that you and your family must also actively protect your own privacy.

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others. Include the following only if applicable: The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities of child abuse and neglect, or serious harm to the subject or others.

*For minimal risk studies:*

The National Institutes of Health (NIH) issued a Certificate of Confidentiality (CoC) for this study. A Certificate of Confidentiality provides extra protection for you and any information and/or samples (blood, tissue, etc.) collected from you as part of this study because it prevents us from disclosing this information in a lawsuit or legal proceeding. We cannot release your study information in a lawsuit or legal proceeding unless you provide your consent for us to do so. This is an extra layer of protection above the already existing protections in place for you and any information and/or samples (blood, tissue, etc.) collected from you as part of this study. However, these protections do not apply in some situations. For example, we may have to release your information if a law requires us to do so, the Agency funding this study requests the information, or if the FDA tells us to release this information. You should visit the NIH website at <https://humansubjects.nih.gov/coc/faqs> to learn more.

**Use of E-mail and/or Text Messaging in Research** (If applicable)

You have the option to receive communications about this study via email and/or text messaging, by indicating your consent at the end of this form. [Insert purpose as applicable, e.g.: Messages will be limited to appointment reminders]

Email and/or text communications may be sent or received in an unencrypted (unprotected) manner. Therefore, there is a risk that the content of the communication, including your personal information, could be shared beyond you and the research team. Your consent below indicates that you understand this risk. The University of Rochester is not responsible for any interception of messages sent through email or texting.

[For email messages add] Email communications between you and the research team may be filed in your research record.

[For text messages add] You are responsible for any fees charged by your carrier’s service plan for text messaging. You may decide not to receive or send text messages with research study staff at any time, in person or by sending the research number a text message that says “**Stop Research Text**”. Your consent, and any request to stop email or text messaging, applies to this research study only.

**Contact Persons**

For more information concerning this research or if you feel that taking part in the study has resulted in any research relatedinjury, emotional or physical discomfort, please contact**:** [insert contact person’s name (for research related injury contact person must be a clinician)] at [telephone number and/or email address].

Please contact the University of Rochester Research Subjects Review Board at 265 Crittenden Blvd., CU 420628, Rochester, NY 14642, Telephone (585) 276-0005 or (877) 449-4441 [insert country code (001) if applicable] for the following reasons:

* You wish to talk to someone other than the research staff about your rights as a research subject;
* To voice concerns about the research;
* To provide input concerning the research process;
* In the event the study staff could not be reached.

[If there are additional informational sources related to the study (e.g., client representatives, subject advocate or individuals at other study sites as appropriate), list here with contact information.]

**Voluntary Participation**

Taking part in this study is voluntary. You are free not to take part or to withdraw at any time, for whatever reason. No matter what decision you make, there will be no penalty or loss of benefit to which you are entitled. In the event that you do withdraw from this study, the information you have already provided will be kept in a confidential manner.

[Additional student-subject wording [delete if not applicable]: Taking part will not affect your class standing or grades at the University of Rochester. You will not be offered or receive any special consideration if you take part in this research.]

[Additional employee-subject wording [delete if not applicable]: Taking part in this research is not a part of your University duties. Refusing to take part will not affect your job. You will not be offered or receive any special job-related consideration if you take part in this research.]

\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*

**Optional Research Activities:** [**Only** keep options applicable to the study, these must be described in the protocol and consent. If not applicable, ***DELETE***.]

Place your initials in the YES **OR** NO box, based upon your decision to take part.

**Communication with the Study Team**

|  |  |  |
| --- | --- | --- |
| **YES**  *(initial)* | **NO**  *(initial)* | *I consent to the use of* ***email*** *in this study. If yes, enter email address:*  *\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_* |
| **YES**  *(initial)* | **NO**  *(initial)* | *I consent to the use of* ***text messaging*** *in this study. If yes, enter phone number:*  *\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_* |

**Consent to Future Use and Re-Contact**

|  |  |  |
| --- | --- | --- |
| **YES**  *(initial)* | **NO**  *(initial)* | *I consent for the study doctor, or someone from the study team, to contact me in the future about using my information for research that is not described in this consent form.* |
| **YES**  *(initial)* | **NO**  *(initial)* | *I consent for the study doctor, or someone from the study team, to contact me in the future about participating in future research studies.* |

**Consent for Return of Individual Results**

|  |  |  |
| --- | --- | --- |
| **YES**  *(initial)* | **NO**  *(initial)* | *I consent for the study doctor, or someone from the study team, to contact me in the future about my individual research results.* |

**Consent for the Future Use of My Information and/or Samples**

|  |  |  |
| --- | --- | --- |
| **YES**  *(initial)* | **NO**  *(initial)* | *I consent for the study doctor or someone from the study team to share my [INSERT AS APPROPRIATE samples, health information, genomic information] with other researchers for future research not described in this consent.*  **Or**  *I consent for the study doctor or someone from the study team to share my [INSERT AS APPROPRIATE samples, health information, genomic information] with other researchers to study [INSERT FOR SPECIFIC DISEASES/DISORDERS] for future research not described in this consent.* |

**Consent for Audio/Video Recording**

|  |  |  |
| --- | --- | --- |
| **YES**  *(initial)* | **NO**  *(initial)* | *I consent to audio/video recording for this study.* |

**SignatureS/Dates [***Note that signature blocks should appear all on one page if possible.]*

After reading and discussing the information in this consent form you should understand:

* Why this study is being done;
* What will happen during the study;
* Any possible risks and benefits to you;
* Other options you may have instead of being in the study;
* How your personal information will be protected;
* What to do if you have problems or questions about this study.

**Subject Consent**

I have read (or have had read to me) the contents of this consent form and have been encouraged to ask questions. I have received answers to my questions. I agree to participate in this study. I have received (or will receive) a signed copy of this form for my records and future reference.

Subject Name (Printed by Subject)

Signature of Subject Date

[**INCLUDE THIS SIGNATURE BLOCK IF THE STUDY INCLUDES DECISIONALLY IMPAIRED WITH CONSENT FROM A LEGALLY AUTHORIZED REPRESENTATIVE**.]

Subject Name (Printed) Legally Authorized Representative’s Relationship to Subject

Legally Authorized Representative Name (Printed)

Legally Authorized Representative Signature Date

|  |  |
| --- | --- |
|  | This subject does not have the capacity to provide assent. |

**Assent:** This research study has been explained to me and I agree to be in this study.

Subject's signature for assent Date

**Person Obtaining Consent**

I have read this form to the subject and/or the subject has read this form. I will provide the subject with a signed copy of this consent form. An explanation of the research was given and questions from the subject were solicited and answered to the subject’s satisfaction. In my judgment, the subject has demonstrated comprehension of the information. I have given the subject adequate opportunity to read the consent before signing.

Name and Title (Print)

Signature of Person Obtaining Consent Date