|  |
| --- |
| Adult Consent Form Template Version 1.12, 4/12/2024  **GENERAL INSTRUCTIONS** – delete this box from the submitted consent form  This template is for research involving adults. Do not use this template for research involving children; instead use “Parent Permission Form Template” if parents are not subjects and “Parent Consent and Permission Form Template” if parents as well as children are subjects.  Use this template as follows:   * Red text represents instructions to you – to be deleted from the final version. For example, when a section starts with “[Include if…],” you should read the red bracketed phrase, and either delete the whole section if not applicable to your study, or delete just the red bracketed phrase and retain the section if applicable to your study. * Blue text represents guidance on suggested content – to be edited and changed to black or replaced with black in the final version. The language should be understandable at an 8th grade reading level. * Black text represents text that should ordinarily be incorporated as-is, if applicable   If your study involves any of the following, see the specific instruction box at the end of this template:   * Genetic testing and/or collecting genetic information * Communication of pertinent and/or incidental findings to subjects and/or their physicians * Repositories or other retention of samples or data * ICH-GCP   There are five signature pages at the end of this template; use the one that is applicable and delete the remaining four.  Please note that you must enter the project title and PI name in black in the header on the second page.  The submitted version should have no red or blue text (including instruction boxes like this one) |

**RESEARCH CONSENT FORM**

**Basic Information**

Title of Project: Title

IRB Number: the “H number” of your submission

[Include if there is one or more external sponsor; otherwise, delete paragraph] Sponsor: External sponsor(s).

Principal Investigator: PI name

PI/study email

PI/study mailing address

[Include A or B]

[A. Include if the study is no more than minimal risk; otherwise, delete paragraph] Study Phone Number: phone number

[B. Include if the study is greater than minimal risk; otherwise, delete paragraph] Study-Related Phone Numbers: Regular business hours: phone number 24 hours: 24-hour number

**Overview**

We are asking you to be in a research study. A research study is an organized way of collecting information about scientific questions. This form will tell you what you should expect if you agree to be in the study. There are programs in place to make sure that investigators fulfill their obligations listed in this form.

It is your decision whether or not to join the study. We are doing the research to a one-sentence summary in lay language of the purpose of the study. We are asking you to be in this study because a one-sentence summary in lay language of why the subject is eligible for the study. If you agree, you will a one-sentence overview in lay language of what will happen in the study. You will be in the study for xx days, weeks, months if you decide to stay for the whole study. You will find more information about what will happen in this study later in this form.

The main risks of being in the study are a one-sentence overview in lay language of the risks that are most relevant to the potential subject’s decision about whether or not to join the study. You will find more information about risks later in this form.

[Include and complete if there is a potential direct benefit to subjects; otherwise, omit entire paragraph] You might benefit from being in the study because a one-sentence overview in lay language of the benefits that are most relevant to the potential subject’s decision about whether or not to join the study. You will find more information about benefits later in this form.

[Include and complete if there is a potential direct benefit to subjects and there are appropriate alternative procedures or courses of treatment that might be advantageous to the subject; otherwise, omit entire paragraph] If you decide not to be in the study, some other things that might help your condition are a one-sentence overview in lay language of the alternatives. You will find more information about alternatives later in this form.

[Include if the PI or any study investigator could also be the subject’s healthcare provider; otherwise, delete paragraph] Your doctor may also be an investigator in this research study. Being an investigator means your doctor is interested in both you and the study. Your doctor’s goal as an investigator is to collect information to answer the scientific questions asked in this research study, in order to help future patients. This is different from their role as your doctor, where their goal is to treat you as a patient. You may want to get another opinion about being in the study from a doctor who is not an investigator in this study. You can do so now or at any time during the study. You do not have to agree to be in this study even though it is offered by your doctor.

**Purpose**

A brief explanation of the background and purpose of the study, stating in lay language why the study is needed and what the study is designed to discover or establish. Do NOT copy from a grant application or other scientific description.

**What Will Happen in This Research Study**

A concise description of study procedures in enough detail to give a clear picture of what the subject will experience during the study. Explain the overall design of the study, and describe procedures to be followed (including pregnancy testing if applicable), the location and length of time for the procedures, the frequency of procedures, and, as appropriate, such study details as how subjects will be assigned to study groups, the method, dose, and frequency of medication administration, and specific tasks subjects will be expected to complete on their own. Any procedures which are experimental must be identified as such and differentiated from standard treatments. Technical language unfamiliar to the subject population should not be used. Subheadings may be inserted to make this section more readable.

[Include if subjects will be audio- or video-recorded at any point in the research; otherwise, omit sentence] We will make an audio OR a video recording of specify what will be recorded.

[Include if the approximate total number of subjects in the entire study would be relevant to the decision about whether or not to participate; for example, if the number of participants is small so that unknown risks are less likely to be identified and/or deductive identification of their participation is more likely; otherwise, delete sentence] You will be one of approximately number subjects who will be asked to be in the study.

**Risks and Discomforts**

A description of all reasonably foreseeable risks and discomforts, their likelihood of occurrence (when appropriate), and the steps you will take to minimize these risks. Include psychological, social, legal, and financial as well as physical risks. If applicable, identify any situations where the subject should seek immediate medical care.

[Include if the study is greater than minimal risk; otherwise, delete sentence] There may be unknown risks or discomforts involved.

[Include if there are any consequences of a decision to withdraw from the study or any necessary procedures for withdrawing; otherwise, delete paragraph] If you decide that you want to stop being in the study, we ask that you let us know. If you stop early, list risks of withdrawing. You are free to stop at any time, but if you tell us, we can do some things to help keep you safe. These things include list procedures for orderly withdrawal.

[Include and edit if subjects should not become pregnant because of risks to the fetus; otherwise, delete paragraph] If you get pregnant while you are in this study, it could be bad for the fetus/baby. You must use birth control if you are able to get pregnant and will have sex while you are in this study. [Include or modify time frame if applicable; otherwise, delete] You should also keep using birth control for three months after the study ends. Only some birth control methods work well enough to be safe while you are in this study. These methods are oral contraceptives (the pill), intrauterine devices (IUDs), contraceptive implants under the skin, contraceptive rings or patches or injections, diaphragms with spermicide, and condoms with foam. You should not be in this study if you are able to get pregnant and cannot use one of these birth control methods if you have sex.

[Include if the study involves wearable devices that are commercially available and have established instructions for use and safety information available; otherwise delete paragraph] The most common risks of the name of wearable device(s) in this study include list the most common risks. We will provide you with the instructions for use and safety information for the/each device and discuss the risks listed in the safety information with you before asking you to use the device(s).

There is a risk to the confidentiality of your health information. We take special efforts to protect your health information, but there is a small chance of a data breach. The ways we will protect your privacy and confidentiality are described in a separate section later in this form.

**Potential Benefits**

[Include A or B]

[A. Include if there is a potential direct benefit to subjects; otherwise, delete paragraph] The benefits of being in this study may be: list potential benefits. However, you may not receive any benefit. The primary goal of this research is to collect information about the scientific questions asked in this study. Your being in the study may help the investigators learn list what investigators may learn.

[B. Include if there is no potential direct benefit to subjects; otherwise, delete paragraph] You will receive no direct benefit from being in this study. The primary goal of this research is to collect information about the scientific questions asked in this study. Your being in this study may help the investigators learn list what investigators will learn.

[Include **Alternatives** if the study is expected to have a direct benefit and there are appropriate alternative procedures or courses of treatment that might be advantageous to the subject; otherwise, delete **entire** Alternatives section] **Alternatives**

The following alternative procedures or treatments are available if you choose not to be in this study: list of alternatives, including other methods to get potential direct benefits or palliative care if appropriate.

**Costs**

[Include A, B, or C]

[A. Include and edit this entire paragraph if the study uses any BMC clinical services (include the first sentence if the study uses a drug or device); otherwise, delete paragraph] The study drug/device will be provided by the Sponsor. There are no OR some additional costs to you for being in the study. [Include if there are additional costs; otherwise, delete] The additional costs are (describe). Items and services done only for study purposes will be provided at no cost to you. They won’t be billed to your health insurance either. You or your health insurance will be billed for all costs that are part of your normal medical care. These costs include co-payments and deductibles. You can ask any questions now about insurance coverage for this study or about the research activities paid for by the sponsor. You can also ask the investigator later, using the number on the first page of this form.

[B. Include if the study does not use BMC clinical services and subjects may incur any costs; otherwise, delete sentence] If you are in this study, you will have to pay for list costs

[C. Include if the study does not use BMC clinical services and subjects will not incur any costs; otherwise, delete sentence] There are no costs to you for being in this research study.

**Payment**

[Include A or B; include C if applicable]

[A. Include if subjects will be given any payment or reimbursement; otherwise, delete paragraph] You will receive description of amount, method, and timing, including how payment will be prorated if the subject withdraws. [Include if payments are > $400 for BMC study and > $600 for BU study and thus requires collection of SSNs/ITINs; otherwise, delete sentence] You must give us your Social Security Number or Individual Taxpayer Identification Number to receive this payment.

[B. Include if subjects will not receive any payment or reimbursement; otherwise, delete paragraph] You will not be paid for being in this study.

[C. Include if the research could lead to commercial products; otherwise, delete paragraph] The research may lead to the development of drugs, tests, or procedures that might have commercial value. You will not get any money if products are developed from the research.

**Confidentiality**

[Include the following paragraph and delete the remainder of the Confidentiality section if study does not record ANY information that would identify subjects; otherwise, delete paragraph] We will not record your name or any information that shows your identity. You will not be signing this form. Further explanation of measures to preserve anonymity, if appropriate.

We must use information that shows your identity to do this research. Information already collected about you will remain in the study record even if you later withdraw.

We will store your information in ways we think are secure. [Include next sentence if biospecimens are collected; otherwise, delete only next sentence] We will store biological samples taken from your body (such as urine, blood, or tissue) describe storage methods. We will store paper files in locked filing cabinets. We will store electronic files in computer systems with password protection and encryption. Only the people listed later in this section will be given access to your information. However, we cannot guarantee complete confidentiality.

[Include if study involves use of third-party software apps/programs/vendors that have access to subject data [sponsors are NOT third-parties]; otherwise delete] This study proposes to share data with name of third party. Data that is not stored at Boston Medical Center or Boston University is outside of our control. Your information could get out or be used by name of third-party for other purposes that are not related to the study.  Please carefully read and think about the name of third-party’s Terms of Service and Privacy Policies before agreeing to give them any of your information. [Include if sharing with third-party is mandatory to be in study; otherwise delete] If you do not want to share your data with name of third-party, that is completely acceptable, but you cannot be in the study. [Include if sharing with third-party is optional; otherwise delete] You do not have to agree to share your data with name of third-party to be in the study.

[Include if study proposes to give subjects the option of unsecure email or text communication; otherwise delete] This study gives you the option of communicating using describe which unsecure methods and why, such as unsecure email and/or text for appointment reminders and satisfaction surveys. This is because some people like the option of communicating by email and/or text message. It is important for you to understand that regular email and text are convenient but are generally not secure. As a result, information about you could be intercepted by someone not involved with the study. We will give you the option of using add secure and unsecure options such as secure email (Data Motion or BMC secure email), non-secure email, and/or non-secure text.

[Include if study has a Certificate of Confidentiality (edit if the CoC is from an agency other than NIH); otherwise, delete paragraph] This study is covered by a Certificate of Confidentiality (CoC) from the National Institutes of Health. [Include if study is NIH funded (check [list of NIH institutes](https://www.nih.gov/institutes-nih/list-nih-institutes-centers-offices) if in doubt); otherwise, delete sentence] All studies funded by the National Institutes of Health that involve identifiable information [if no biospecimens are collected, delete blue phrases] or biological samples are covered by a CoC**.** The CoC provides how we can share research information or biological samples. Because we have a CoC, we cannot give out research information or biological samples that may identify you to anyone that is not involved in the research except as we describe below. Even if someone tries to get your information or biological samples in connection with a legal proceeding, we cannot give it to them. The CoC does not prevent you from sharing your own research information. [Include if study information will be placed in medical records; otherwise, delete remainder of paragraph] We will record information from this study in your medical record, such as information related to your medical care. Please ask us if you have any questions about what information will be included in your medical records. You should know that once information has been put into your medical records, it is not covered by the CoC. However, information in your medical records is protected in other ways.

If you agree to be in the study, we will share information and biological samples that may show your identity with the following groups of people:

* People who do the research or help oversee the research, including safety monitoring.
* People from Federal and state agencies who audit or review the research, as required by law. Such agencies may include the U.S. Department of Health and Human Services, the Food and Drug Administration, the National Institutes of Health, and the Massachusetts Department of Public Health.
* [Include if study information will be placed in medical records; otherwise, delete bullet] People who see your medical records. [Include if study does NOT have a Certificate of Confidentiality; otherwise, delete sentence] Please ask us if you have any questions about what information will be included in your medical records.
* [Include and edit if identifiable study information or samples will be released to anyone not included in the above bullets (for example, investigators not included in the research team for this study); otherwise, delete bullet] People who will get information and biological samples from us describe who will get the information and why. These people are expected to protect your information and biological samples in the same way we protect it.
* Any people who you give us separate permission to share your information.

[Include and edit if study gathers information that requires mandatory reporting (this applies to studies where the information is or may be collected and to studies conducted by mandated reporters); otherwise, delete paragraph] You should know that we are required to report certain information that we might learn in this study to state or other agencies. The information includes list information such as child abuse or neglect; elder abuse; specific reportable diseases; harm to others.

[Include if study gathers information on self-harm; otherwise, delete paragraph] If you are in immediate danger of hurting yourself at any time in the study, the study team will try to work with you on a plan to keep you safe. Because study staff will be trying to protect you, it is possible that your information will be shared with others as part of a plan for safety.

We will share research data where we have removed anything that we think would show your identity. There still may be a small chance that someone could figure out that the information is about you. Such sharing includes:

* Publishing results in a medical book or journal.
* Adding results to a Federal government database.
* Using research data in future studies, done by us or by other scientists.
* [Include if biospecimens are collected; otherwise, delete bullet] Using biological samples in future studies, done by us or by other scientists.

[Include and edit if the study involves focus groups; otherwise, delete paragraph] We will ask everyone in the focus group not to talk about the discussions outside the group. However, we can’t promise that everyone will keep what you say confidential.

[Include without editing if the study is a clinical trial that is sponsored by NIH or includes a drug, biologic or device (note – observational studies that monitor drug treatment but do not involve interventions are not clinical trials); otherwise, delete paragraph] A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

[Include **Use and Sharing of Your Health Information** if HIPAA authorization is required; otherwise, delete **entire** Use and Sharing of Your Health Information section] **Use and Sharing of Your Health Information**

The research team has to use and share your health information to do this study, including information that may identify you. By agreeing to be in this study, you are giving us your permission where needed to use and share your health information as described in this form.

Health information that might be used or shared during this research includes:

* Information that is in your hospital or office health records. The records we will use or share are those related to the aims, conduct, and monitoring of the research study.
* Health information from tests, procedures, visits, interviews, or forms filled out as part of this research study.
* [Include this closed bullet and all applicable open bullet(s) if the study involves any of the following types of information; otherwise, delete this closed bullet and all open bullets] The health information specifically includes:
* Mental health communications (with a psychiatrist, psychologist, clinical nurse specialist, marriage-, family-, rehabilitation-, or mental-health-counselor, or educational psychologist)
* Domestic violence counseling
* Social work communications
* Rape victim counseling
* HIV/AIDS information
* Sexually transmitted disease information
* Communicable disease information
* [IMPORTANT NOTE: Please consult with BMC or BU counsel about the need for specific written consent if the study intends to further disclose alcohol or drug use information] Alcohol or drug use disorder treatment records about list specific data to be used and shared
* Genetic testing

The reasons that your health information might be used or shared with others are:

* To do the research described here.
* To make sure we do the research according to certain standards set by ethics, law, and quality groups.
* To comply with laws and regulations. This includes safety-related information. [Include if the study DOES gather information that requires mandatory reporting; otherwise, delete sentence] As we explained above, we also have to share any information from you about list information such as child abuse or neglect; elder abuse; specific reportable diseases; harm to others.
* [Include if the study DOES gather information about self-harm; otherwise, delete entire bullet] To protect you. As we explained above, if you are in immediate danger of hurting yourself, it is possible that your information will be shared with others as part of a plan for safety.

The people and groups that may use or share your health information are:

* Researchers involved in this research study from Boston Medical Center, Boston University, and/or other organizations
* Other people within Boston Medical Center and Boston University who may need to access your health information to do their jobs such as for treatment, research administration, payment, billing, or health care operations
  + People or groups that the researchers use to help conduct the study or to provide oversight for the study
  + The Institutional Review Board that oversees the research and other people or groups that are part of the Human Research Protection Program that oversees the research
  + Research monitors, reviewers, or accreditation agencies and other people or groups that oversee research information and the safety of the study
  + [Include if applicable; otherwise delete bullet] The sponsor(s) of the research study, listed on the first page, and people or groups they hire to help them do the research
  + [Include if applicable; otherwise delete bullet] Government agencies in other countries that are involved in the research
  + [Include if the study DOES gather information that requires mandatory reporting; otherwise, delete bullet] Public health and safety authorities who receive our reports about list information such as child abuse or neglect; elder abuse; specific reportable diseases; harm to others.
  + [Include if the study DOES gather information about self-harm; otherwise, delete entire bullet] Other care providers and public safety authorities who may be involved in helping to protect you if you express thoughts about hurting yourself.
  + [Include if applicable; otherwise delete bullet] list other group(s) that will have access to the subject’s health information

We ask anyone who gets your health information from us to protect the privacy of your information. However, we cannot control how they may use or share your health information. We cannot promise that they will keep it completely private.

The time period for using or sharing your health information:

* The time period is not known, because research is an ongoing process. We cannot give you an exact date when we will either destroy or stop using or sharing your health information.

Your privacy rights are:

* You have the right not to allow us to use and share your health information for research. If you do not agree, you cannot be in the research. This is because we need to use the health information to do the research. Your decision not to agree to be in this study will not affect any treatment, health care, enrollment in health plans, or eligibility for benefits.
* You have the right to withdraw your permission to use or share your health information in this research study. If you want to withdraw your permission, you must write a letter to the Principal Investigator at the address listed on the first page of this form. If you withdraw your permission, you will not be able to take back information that has already been used or shared with others. This includes information used or shared to do the research study or to be sure the research is safe and of high quality. If you withdraw your permission, you cannot continue to be in the study.
* When the study has been completed for everyone, you have the right to request access to the health information that we used or shared to make your treatment or payment decisions. If you ask for research information that is not in your medical record, we might not give it to you, but we will explain why not. You may use the contact information on the first page of this form to find out how to get your health information. You may also contact the HIPAA Privacy Officer at [choose applicable privacy contact] Boston Medical Center at [DG-privacyofficer@bmc.org](mailto:DG-privacyofficer@bmc.org) / Boston University at [HIPAA@BU.EDU](mailto:HIPAA@BU.EDU).

[End of Use and Sharing section]

[Include **Compensation for Injury** if the study is greater than minimal risk; otherwise delete **entire** Compensation for Injury section] **Compensation for Injury**

Insert language approved by sponsor and BMC Clinical Trial Office or BU Office of Sponsored Programs if available; otherwise use and edit the following:

If you think that you have been injured by being in this study, please let the Principal Investigator know right away. Use the phone number on the first page of this form. If you have a health emergency, get care first. You can seek treatment for the injury at Boston Medical Center, the BU School of Dental Medicine, or at any healthcare facility you choose. Tell the doctors that you are in this study.

There is no program to provide compensation for the cost of care for research related injury or for other expenses. Other expenses might be lost wages, disability, pain, or discomfort. You or your insurance will be billed for the medical care you receive for a research injury. You are not giving up any of your legal rights by agreeing to be in this research study.

[Include **Re-Contact** if you might re-contact the subjects after their participation in the study has ended (delete any categories that are not applicable to your study); otherwise, delete **entire** Re-Contact section] **Re-Contact**

We would like to ask your permission to contact you again in the future. This contact would be after your participation in the study has ended. Please initial your choice below:

\_\_\_\_Yes \_\_\_\_No You may contact me again to ask for additional information related to this study

\_\_\_\_Yes \_\_\_\_No You may contact me again to ask for additional biological samples related to this study

\_\_\_\_Yes \_\_\_\_No You may contact me again to let me know about a different research study

\_\_\_\_Yes \_\_\_\_No You may contact me again to list reason – or delete line

**Subject’s Rights**

By consenting to be in this study you do not waive any of your legal rights. Consenting means that you have been given information about this study and that you agree to participate in the study. You will be given a copy of this form to keep.

If you do not agree to be in this study or if at any time you withdraw from this study you will not suffer any penalty or lose any benefits to which you are entitled. Your participation is completely up to you. Your decision will not affect your ability to get health care or payment for your health care. It will not affect your enrollment in any health plan or benefits you can get. [Include if subjects will be given any payment or reimbursement; otherwise, delete sentence] You will only be paid for the study activities that you complete before withdrawing.

[Include if the study involves more than one visit AND is greater than minimal risk; otherwise, delete sentence] During this study, we may find out something that might make you not want to stay in the study. If this happens, we will tell you as soon as possible. You should also tell us if you ever have concerns about being in the study.

[Include if the study has the potential for direct benefit or if the subjects are being paid; otherwise, delete sentence] We may decide to have you stop being in the study even if you want to stay. Some reasons this could happen are if staying in the study may be bad for you, or if the study is stopped.

**Questions**

The investigator or a member of the research team will try to answer all of your questions. If you have questions or concerns at any time, contact name at phone number. Also call if you need to report an injury while being in this research. [Include if the study is greater than minimal risk; otherwise, delete sentence] Contact name at phone number if there is no answer at that phone number or if you are calling after normal business hours.

You may also call 617-358-5372 or email [medirb@bu.edu](mailto:medirb@bu.edu). You will be talking to someone at the Boston Medical Center and Boston University Medical Campus IRB. The IRB is a group that helps monitor research. You should call or email the IRB if you want to find out about your rights as a research subject. You should also call or email if you want to talk to someone who is not part of the study about your questions, concerns, or problems.

[Include and edit if this is an international study also overseen by a local Ethics Board; otherwise, delete sentence] You may also contact information for the local Ethics Board

|  |
| --- |
| **SPECIAL DIRECTIONS** – delete this box from submitted consent form  You are ready to select and edit the signature page, unless your study involves any of the following, in which case, copy the required language to the indicated sections. Delete this entire text box from the submitted version.   1. Genetic testing and/or collecting genetic information    * In **What Will Happen in This Research Study**, describe:    * If the research will or might include whole genome sequencing of biospecimens, include language such as the following:   We will perform a whole examination of your DNA or genome. Usually researchers study just a few areas of your genetic code that are linked to a disease or condition. In whole genome studies, all or most of your genes are examined and used by researchers to study links to a disease or condition.   * + Plans for future use of genetic samples and genetic data   + The plans for return of pertinent and incidental findings (see 2. below), or a statement that no findings will be returned to subjects   + In **Risks**, describe the psychological and socioeconomic risks related to generating personal genetic information (including risks to genetic relatives)   + If individually identifiable results will be returned to subjects, include the following language in **Risks**:   There is a potential risk that your genetic information could be used to your disadvantage. For example, if genetic research findings suggest a serious health problem, that could be used to make it harder for you to get or keep a job or insurance. Both Massachusetts state laws and federal laws, particularly the Genetic Information Nondiscrimination Act (GINA), generally make it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. These laws will generally protect you in the following ways:   * + 1. Health insurance companies and group health plans may not request your genetic information that we get from this research.     2. Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.     3. Massachusetts employers with 6 or more employees (or 15 or more employees in other states, under GINA) 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 neither Massachusetts law nor GINA protects you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. Thus, life insurance, disability insurance, and long-term care insurance companies may legally ask whether you have had genetic testing and deny coverage for refusal to answer this question.   * + If data will be sent to an NIH database such as dbGaP, add and edit the following language to **Confidentiality**:   Samples that are collected from you in this study will be analyzed to find out information about your genetics. Your genetics and health information, without your name or other data that could easily identify you, will be put in a database run by the National Institutes of Health (NIH). [Include if the study involves whole genome sequencing; otherwise, delete sentence] This may include your whole genome information. Other researchers can ask the NIH to get your information from the database. You should know that it is possible that your genetics information might be used to identify you or your family, though we believe it is not too likely that this will happen. Once your information is given to the NIH database, you can ask to have NIH stop sharing it, but NIH can’t take back information that was already shared.   1. Communication of pertinent and/or incidental findings to subjects and/or their physicians    * In **What Will Happen in This Research Study**, describe:  * The anticipated findings that will be communicated and/or the criteria that will be used to determine which findings will be communicated if there may be unanticipated findings * To whom and by whom the findings will be communicated, when, and how * The reliability and limitations of the information provided by any findings that are not standard measurements. * If applicable, further diagnosis or other actions may be required based on the findings, including their risks and costs to the subject (and to their relatives if applicable) * Whether or not subjects can request not to have some or all of the findings returned to themselves or to their physicians, and if so, the categories of findings they can choose and the considerations relevant to making those choices * If applicable, the resources such as counseling available to subjects to help with receiving and interpreting findings   As applicable, edit and add the following when pertinent findings may be returned, either as a stand-alone paragraph or incorporated into the study-specific discussion:  The research measurements we make are not necessarily the same as tests done by your doctor. We are collecting information on many people to answer our research questions. Not everyone doing the research tests is a doctor or a nurse. You or your doctor should not rely on the research measurements to make any diagnosis, treatment, or health planning decisions. If you or your doctor decides that follow-up tests and treatments are necessary, then you or your insurance will be billed for the costs.  As applicable, edit and add the following when incidental findings from imaging may be returned, either as a stand-alone paragraph or incorporated into the study-specific discussion:  The imaging test you will have in this study is for research purposes only. However, we might see something that could be important to your health. If we do, we will ask you if you want us to explain what we noticed. If you would like, we will also tell your doctor. You or your doctor should not rely on the research measurements to make any diagnosis, treatment, or health planning decisions. If you or your doctor decides that follow-up tests and treatments are necessary, then you or your insurance will be billed for the costs.  As applicable, edit and add the following when no findings will be returned to subjects or their physicians:  The tests we are doing in this study are for research purposes only. We will not tell you the results because explain the reason, such as it is not known if the results mean anything.   1. Repositories or other retention of samples or data    * In **What Will Happen in This Research Study**, describe:  * How samples or data will be obtained * What types of research will use the samples or data * Whether genetic information will be included * Plans for release of samples or data from the repository, including: * What types of researchers may request release (from BMC or BU, external universities, industry, government, etc.) * Who will review requests for release to ensure the research is consistent with the aims of the repository * What sample or data handling procedures will the researchers be required to agree to * For release of samples, what information will accompany the samples (demographics, diagnosis, etc.) * If the study has the potential for direct benefit to the subject, a statement that agreeing to the retention of samples or data is optional and that the subject can agree to participate in the main study but not agree to having their samples retained   + In **Confidentiality**:   + Add: The repository has standard operating procedures to protect your confidentiality. A description of how specimens and/or data are stored and shared.   + Add the following bullet to the bulleted list of people who will receive identifiable samples/data: * People who will get your data and your biological samples as we described in the section **What Will Happen in This Research Study**. These people are expected to protect your information and biological samples in the same way we protect it.  1. ICH-GCP (note that the IRB does NOT perform an ICH-GCP compliant review; if this is an issue, contact the IRB at 617-358-5372 or medirb@bu.edu): If your study protocol says that the consent form complies with ICH-GCP:    * In the **What Will Happen in This Research Study** section, the number of subjects is REQUIRED, not optional. Also include the subject’s responsibilities and the probability of random assignment, if applicable    * In the **Alternatives** section, include any clear advantages or disadvantages of the alternatives.    * In the **Confidentiality** section, include statements that the subject’s Primary Care Provider will be informed of their participation in the research, unless specifically requested not to do so by the subject and that the monitor(s), auditor(s), IRB, and regulatory authorities will be granted direct access to the subject’s original medical records for verification of research procedures and/or data.    * In the **Subject’s Rights** section, the following statements are REQUIRED, not optional: During this study, we may find out something that might make you not want to stay in the study. If this happens, we will tell you as soon as possible. AND We may decide to have you stop being in the study even if you want to stay. Some reasons this could happen are if staying in the study may be bad for you, or if the study is stopped.    * In the **Signature** page, a witness signature and date is REQUIRED if limited- or non-readers are enrolled. |

|  |
| --- |
| **SIGNATURE PAGES** – delete this box from submitted consent form  Five signature pages follow. Select and edit the one that is applicable to your study, and delete the other four pages.   1. No subject signature (waiver of documentation of consent), or subject signature is obtained but no signature of person conducting consent discussion 2. Signature of subject only and person conducting consent discussion 3. Signature of subject/ Legally Authorized Representative (LAR) and person conducting consent discussion 4. Signature of subject – limited- or non-readers excluded and person conducting consent discussion 5. Signature of subject/LAR – limited- or non-readers excluded and person conducting consent discussion   Limited- or non-readers**: should be included** unless there are specific reasons to exclude them. For research that is greater than minimal risk, to assure comprehension if limited- or non-readers are included, either an impartial witness must be present during the consent process or some other method will be used and documented, as described in the INSPIR application.  Subjects physically unable to write: a subject who is physically unable to provide a signature on a consent form may provide consent or assent by requesting another person to sign in their presence. The person signing the form on behalf of the subject must be an adult and may not be the person conducting the consent discussion. The person signing the form on behalf of the subject must provide a statement to this effect on the page with their signature, such as “[Name] is unable to sign and has directed me to sign in their presence – [printed name of person signing].” If the study is likely to enroll subjects physically unable to write, the investigator may include a pre-printed statement to the signature page to be used in such circumstances. |

|  |
| --- |
| **1. NO SUBJECT SIGNATURE OR NO INVESTIGATOR SIGNATURE** – delete this box from submitted consent form |

[Include if subject signature is waived or subject signature is obtained electronically; otherwise, delete first two paragraphs below]

By agreeing to be in this research, you are indicating that you have read this form (or it has been read to you), that your questions have been answered to your satisfaction, that you permit the use and sharing of information that may identify you as described, [include if health information is obtained and HIPAA authorization is not waived; otherwise, delete blue phrase] , including your health information, and that you voluntarily agree to participate in this research study.

[Include if subject signature is obtained electronically and edit as-needed to reflect your proposed language for documenting electronic consent; otherwise, delete blue text below] Please type your name into the box below to indicate your consent to participate in the study and click “Next” to continue.

[Include if written “wet ink” subject signature is obtained but investigator signature is not obtained; and if so ensure you deleted the two above paragraphs); otherwise, delete all text below]

**Subject:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed name of subject

By signing this consent form, you are indicating that

* you have read this form (or it has been read to you)
* your questions have been answered to your satisfaction
* you voluntarily agree to participate in this research study
* you permit the use and sharing of information that may identify you as described [include if health information is obtained; otherwise, delete blue phrase] , including your health information.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_

Signature of subject Date

NOTE: THE PRINCIPAL INVESTIGATOR MUST KEEP THE ORIGINAL SIGNED, DATED CONSENT FORM [Include unless the requirement to provide the subject with a copy of the consent form is specifically waived or modified by the IRB; if this requirement has been waived or modified, please delete] AND MUST DOCUMENT THAT A COPY OF THE CONSENT FORM WAS GIVEN OR OFFERED TO THE SUBJECT

|  |
| --- |
| **2. SIGNATURE OF SUBJECT – NO LARs** – delete this box from submitted consent form |

**Subject:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed name of subject

By signing this consent form, you are indicating that

* you have read this form (or it has been read to you)
* your questions have been answered to your satisfaction
* you voluntarily agree to participate in this research study
* you permit the use and sharing of information that may identify you as described [include if health information is obtained; otherwise, delete blue phrase] , including your health information.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_

Signature of subject Date

**Researcher:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed name of person conducting consent discussion

I have personally explained the research to the above-named subject and answered all questions. I believe that the subject understands what is involved in the study and freely agrees to participate.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_

Signature of person conducting consent discussion Date

[For the enrollment of limited- and non-readers, studies that are greater than minimal risk must either include a plan to have an impartial witness who is present throughout the consent process, or propose some other method, such as a quiz or a “teach-back” process, to ensure comprehension. Include if a witness is the method that will be used to ensure comprehension by limited- and non-readers; otherwise, delete all text below] *To be completed by witness if researcher reads this form to the subject*

This consent form was read to and apparently understood by the subject in my presence.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed name of witness (a person not otherwise associated with the study)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_

Signature of witness Date

NOTE: THE PRINCIPAL INVESTIGATOR MUST KEEP THE ORIGINAL SIGNED, DATED CONSENT FORM [Include unless the requirement to provide the subject with a copy of the consent form is specifically waived or modified by the IRB; if this requirement has been waived or modified, please delete] AND MUST DOCUMENT THAT A COPY OF THE CONSENT FORM WAS GIVEN OR OFFERED TO THE SUBJECT

|  |
| --- |
| **3. SIGNATURE WITH LARs** – edit depending on whether all signatures are by LARs or whether some signatures are by subjects – delete this box from submitted consent form |

**Subject:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed name of subject

By signing this consent form, you are indicating that

* you have read this form (or it has been read to you)
* your questions have been answered to your satisfaction
* you voluntarily agree to participate in this research study
* you permit the use and sharing of information that may identify you as described [include if health information is obtained; otherwise, delete blue phrase] , including your health information.

[Include if some subjects may consent for themselves; otherwise, delete through *To be completed by LAR if subject does not personally sign*] *To be completed by subject if personally signing*

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_

Signature of subject Date

*To be completed by LAR if subject does not personally sign*

I am providing consent on behalf of the subject.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed name of Legally Authorized Representative (LAR) Relationship to Subject

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_

Signature of Legally Authorized Representative Date

**Researcher:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed name of person conducting consent discussion

[Include if some subjects may consent for themselves; otherwise, delete through “*To be completed by researcher if subject* ***does not personally sign****”*] *To be completed by researcher if subject personally signs*

I have personally explained the research to the above-named subject and answered all questions. I believe that the subject understands what is involved in the study and freely agrees to participate.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_

Signature of person conducting consent discussion Date

*To be completed by researcher if subject does not personally sign*

I have personally explained the research to the above-named subject’s Legally Authorized Representative and answered all questions. I believe that the Legally Authorized Representative understands what is involved in the study and freely agrees to have the subject participate. [Include if some subjects are capable of providing assent; otherwise delete sentence and two checkboxes – retain signature of researcher] I consider that the above-named subject (check one):

🞏 is capable of understanding what is involved in the study and freely agrees to participate.

🞏 is not capable of understanding what is involved in the study.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_

Signature of person conducting consent discussion Date

[For the enrollment of limited- and non-readers, studies that are greater than minimal risk must either include a plan to have an impartial witness who is present throughout the consent process, or propose some other method, such as a quiz or a “teach-back” process, to ensure comprehension. Include if a witness is the method that will be used to ensure comprehension by limited- and non-readers; otherwise, delete all text below] *To be completed by witness if researcher reads this form to the subject/LAR*

This consent form was read to and apparently understood by the subject/Legally Authorized Representative in my presence.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed name of witness (a person not otherwise associated with the study)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_

Signature of witness Date

NOTE: THE PRINCIPAL INVESTIGATOR MUST KEEP THE ORIGINAL SIGNED, DATED CONSENT FORM [Include unless the requirement to provide the subject with a copy of the consent form is specifically waived or modified by the IRB; if this requirement has been waived or modified, please delete] AND MUST DOCUMENT THAT A COPY OF THE CONSENT FORM WAS GIVEN OR OFFERED TO THE SUBJECT

|  |
| --- |
| **4. SIGNATURE OF SUBJECT – NO LARs – LIMITED- AND NON-READERS EXCLUDED** – delete this box from submitted consent form |

**Subject:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed name of subject

By signing this consent form, you are indicating that

* you have read this form
* your questions have been answered to your satisfaction
* you voluntarily agree to participate in this research study
* you permit the use and sharing of information that may identify you as described [include if health information is obtained; otherwise, delete blue phrase] , including your health information.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_

Signature of subject Date

**Researcher:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed name of person conducting consent discussion

I have personally explained the research to the above-named subject (who has read this consent form) and answered all questions. I believe that the subject understands what is involved in the study and freely agrees to participate.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_

Signature of person conducting consent discussion Date

NOTE: THE PRINCIPAL INVESTIGATOR MUST KEEP THE ORIGINAL SIGNED, DATED CONSENT FORM [Include unless the requirement to provide the subject with a copy of the consent form is specifically waived or modified by the IRB; if this requirement has been waived or modified, please delete] AND MUST DOCUMENT THAT A COPY OF THE CONSENT FORM WAS GIVEN OR OFFERED TO THE SUBJECT

|  |
| --- |
| **5. SIGNATURE WITH LARs – LIMITED- AND NON-READERS EXCLUDED** – edit depending on whether all signatures are by LARs or whether some signatures are by subjects – delete this box from submitted consent form |

**Subject:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed name of subject

By signing this consent form, you are indicating that

* you have read this form
* your questions have been answered to your satisfaction
* you voluntarily agree to participate in this research study
* you permit the use and sharing of information that may identify you as described [include if health information is obtained; otherwise, delete blue phrase] , including your health information.

[Include if some subjects may consent for themselves; otherwise, delete through “*To be completed by LAR if subject* ***does not personally sign****”*] *To be completed by subject if personally signing*

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_

Signature of subject Date

*To be completed by LAR if subject does not personally sign*

I am providing consent on behalf of the subject.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed name of Legally Authorized Representative (LAR) Relationship to Subject

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_

Signature of Legally Authorized Representative Date

**Researcher:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed name of person conducting consent discussion

[Include if some subjects may consent for themselves; otherwise, delete through “*To be completed by researcher if subject* ***does not personally sign****”*] *To be completed by researcher if subject personally signs*

I have personally explained the research to the above-named subject (who has read this consent form) and answered all questions. I believe that the subject understands what is involved in the study and freely agrees to participate.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_

Signature of person conducting consent discussion Date

*To be completed by researcher if subject does not personally sign*

I have personally explained the research to the above-named subject’s Legally Authorized Representative (who has read this consent form) and answered all questions. I believe that the Legally Authorized Representative understands what is involved in the study and freely agrees to have the subject participate. [Include if some subjects are capable of providing assent; otherwise delete sentence and two checkboxes – retain signature of researcher] I consider that the above-named subject (check one):

🞏 is capable of understanding what is involved in the study and freely agrees to participate.

🞏 is not capable of understanding what is involved in the study.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_

Signature of person conducting consent discussion Date

NOTE: THE PRINCIPAL INVESTIGATOR MUST KEEP THE ORIGINAL SIGNED, DATED CONSENT FORM [Include unless the requirement to provide the subject with a copy of the consent form is specifically waived or modified by the IRB; if this requirement has been waived or modified, please delete] AND MUST DOCUMENT THAT A COPY OF THE CONSENT FORM WAS GIVEN OR OFFERED TO THE SUBJECT