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| Consent to Collect Data after Withdrawal Version 1.7, 10/14/2022**GENERAL INSTRUCTIONS** – delete this box from the submitted consent formThis template is for obtaining consent and authorization for continued follow-up and further collection of Protected Health Information from adult subjects who withdraw from a study (called “the main study” in the instructions for this template). If the subjects are children, edit by changing “you” to “your child” throughout the template. 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 necessary, change “you” to “your child” throughout the black text

There are two signature pages at the end of this template; use the one that is applicable and delete the other one. 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 of main study – Consent for Follow-Up

IRB Number: the “H number” of the main study

[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 main study is no more than minimal risk; otherwise, delete paragraph] Study Phone Number: phone number

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

**Background**

You have decided or been asked to withdraw from our study called “Title of main study.” We are asking your permission to continue to follow up with you. This will help us understand purpose of main study. But your decision about whether to let us follow up is completely up to you.

[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 allowing us to follow up with you from a doctor who is not an investigator in this study. You can do so now or at any time while we are following up with you. You do not have to agree to be followed even though it is offered by your doctor.

**Purpose**

We let you know when you joined our study that if you withdraw, we will keep using the data we collected about you while you were in the study. It would also be helpful to know about your health in the future, but we need your permission.

**What Will Happen if We Follow Up With You**

If you agree to the follow up, your doctors and hospitals will let us look at your medical information. You will not have any extra tests, visits, or procedures. This follow up will last for duration.

[Include if the main study involves a repository or other retention of samples or data; otherwise, delete paragraph] Your follow up data will/will not be included in the repository that we told you about when you joined the study.

**Risks and Discomforts**

You will not have any extra tests or procedures. The only risk is 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.

**Potential Benefits**

You will receive no direct benefit from allowing us to follow up with you. If you do allow follow up, your health information may help the investigators learn list what investigators will learn.

**Costs**

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 follow up period. You can also ask the investigator later, using the number on the first page of this form.

**Payment**

You will not be paid for allowing us to follow up with you.

[Include if the main 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**

We must use information that shows your identity to follow up with you. Follow up 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. 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 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 are covered by a CoC**.** The CoC provides how we can share research information. Because we have a CoC, we cannot give out research information 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 in connection with a legal proceeding, we cannot give it to them. The CoC does not prevent you from sharing your own research information.

If you agree to let us follow up with you and sign this form, we will share follow-up information 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 and edit if identifiable study information 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 from us describe who will get the information and why. These people are expected to protect your information in the same way we protect it.
* Any people who you give us separate permission to share your follow up information.

We will share your follow up information where we have removed anything that we think would show your identity. There still may be a 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 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.

**Use and Sharing of Your Health Information**

The research team has to use and share your health information to do this follow up. By agreeing to allow us to follow up with you and signing this form, 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.
* [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 disorder 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.

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 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 sign this form that allows us to use and share your health information for follow up. If you do not sign this form, you are saying you do not permit us to do the follow up. This is because we need to use the health information to do the follow up. Your decision not to sign the form 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 follow up health information. 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, we will stop following up with you.
* 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 / Boston University at HIPAA@BU.EDU.

[Include **Re-Contact** if you might re-contact the subjects after the study is over (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 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 allow us to follow up with you, you do not waive any of your legal rights. Consenting means that you have been given information about allowing follow up and that you agree to allow us to get follow up information about you. You will be given a copy of this form to keep.

If you do not agree to allow us to follow up or if at any time you withdraw your permission, you will not suffer any penalty or lose any benefits to which you are entitled. Your agreement 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.

**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 main 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. 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.

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| **SIGNATURE PAGES** – delete this box from submitted consent formTwo signature pages follow. Select and edit the one that is applicable to your study, and delete the other page. 1. Signature of subject only
2. Signature of subject/Legally Authorized Representative (LAR)

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. |

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| **1. 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 have us follow up with you
* you permit the use and sharing of information that may identify you as described, 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 agreeing to follow-up and freely gives permission.

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

Signature of person conducting consent discussion Date

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| **2. 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 have us follow up with you
* you permit the use and sharing of information that may identify you as described, 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.

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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 agreeing to follow-up and freely gives permission.

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

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 agreeing to follow-up for the subject and freely gives permission. 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 agreeing to follow up and freely gives permission.

🞏 is not capable of understanding what is involved in agreeing to follow up.

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

Signature of person conducting consent discussion Date