|  |
| --- |
| Adult Authorization Form Template Version 1.1, 11/13/2020  **GENERAL INSTRUCTIONS** – delete this box from the submitted authorization form  This template is ONLY for obtaining HIPAA authorization from adults **when the authorization language is not incorporated into the study consent form**. This form must be signed and dated at the same time as the study consent form.  Use this template as follows:   * Red text represents instructions to you – to be deleted from the final version. For example, when a bullet starts with “[Include if…],” you should read the red bracketed phrase, and either delete the whole bullet if not applicable to your study, or delete just the red bracketed phrase and retain the bullet 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   There are two signature pages at the end of this template, depending on whether or not this form might be signed by a Legally Authorized Representative. Use the one that is applicable (and matches the research consent form) 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 edited version should have no red or blue text (including instruction boxes like this one).  Submit the final authorization form to the IRB along with the consent form that lacks authorization language. You may not use the form until you have received approval from the IRB. |

**AUTHORIZATION TO USE AND SHARE HEALTH INFORMATION THAT IDENTIFIES YOU FOR A RESEARCH PROJECT**

**Basic Information**

Title of Research Project: Title

IRB Number: the local “H number” of the associated research project and any central IRB number

[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

**Use and Sharing of Your Health Information**

You gave consent to participate in the research project named above. The purpose of the research project is brief description of the aims, conduct, and monitoring of the project

To do this research project, the research team has to use and share health information that identifies you. Your signature on this form means that you are giving us your permission to use and share your health information as described below.

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 project.
* Health information from tests, procedures, visits, interviews, or forms filled out as part of the research project.
* [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 in this form.
* 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 in the Informed Consent Form, 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 in the Informed Consent Form, 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 the research project 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 research project or to provide oversight for the research project
  + 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 research project
  + [Include if applicable; otherwise delete bullet] The sponsor(s) of the research project, 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 sign this form that allows us to use and share your health information for research. If you do not sign this form, you cannot be in the research project. This is because we need to use the health information to do the research. 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 health information in this research project. 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 project or to be sure the research is safe and of high quality. If you withdraw your permission, you cannot continue to be in the research project.
* 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).

|  |
| --- |
| Retain the signature page (with or without LARs) matching the consent form and delete the other one  **1. SIGNATURE OF SUBJECT – NO LARs** – delete this box from submitted authorization form |

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

Printed name of subject in research project

By signing this authorization 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 permit the use and sharing of health information that may identify you as described in this form.

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

Signature of subject Date

|  |
| --- |
| Retain the signature page (with or without LARs) matching the consent form and delete the other one  **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 authorization form |

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

Printed name of subject in research project

By signing this authorization 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 permit the use and release of health information that may identify you as described in this form.

[Include if some subjects may sign 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 authorization on behalf of the subject.

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

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

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

Signature of Legally Authorized Representative Date