|  |
| --- |
| Exempt Information Sheet Template Version 1.7, 4/14/2023  **GENERAL INSTRUCTIONS** – delete this box from the submitted information sheet  Use this template for exempt research where you will have contact with the subjects. No signature is required, unless you are collecting Protected Health Information (PHI).   * Red text represents instructions to you – to be deleted from the final version. * 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   You may combine sections shown as separate paragraphs into a single paragraph if you believe the information would be clearer that way (except for the Use and Disclosure of Your Health Information section – this authorization language must be a separate section).  Please contact the IRB ([medirb@bu.edu](mailto:medirb@bu.edu), 617-358-5373) for additional instructions if your study involves (1) gathering information that requires mandatory reporting or (2) deception.  Options for conveying the required information:   * Complete and print out this template. * Incorporate the completed language into the first page of your printed survey. * Provide the completed language electronically (as an email, electronic survey, etc.). Obtain electronic signature if collecting PHI. * Provide the completed language orally – this option is acceptable if the subject is given written contact information such as on a business card. If collecting PHI, and it is not practicable to obtain subject signature, request a waiver of HIPAA authorization in the INSPIR application.   Be sure there is no red or blue text (including this instruction box) in your submitted version. |

RESEARCH INFORMATION SHEET

You are being asked to voluntarily participate in a research study. We are doing this study brief explanation 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, we will ask you to brief explanation of what the subjects will do and how long their participation will take.

[Include if subjects will be audio- or video-recorded at any point in the research; otherwise, delete paragraph] We will make an audio OR a video recording of specify what will be recorded. [Include if subjects can refuse to be recorded and still be in the study; otherwise, omit sentence] If you ask us not to, we won’t record you.

[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 the following paragraph if the 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.

[Include the following paragraph if the study DOES record information that would identify subjects; otherwise, delete paragraph] 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. However, we cannot guarantee complete confidentiality.

[Include if the study records identifiable information AND 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 or overseeing 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 or asking us to share your information.

[Include if the study records identifiable information AND has a Certificate of Confidentiality (edit if the CoC is from an agency other than NIH); otherwise, delete paragraph] 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 **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 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.
* 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 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. 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 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).

If you have any questions, please contact name, email, and phone number of research team member.

|  |
| --- |
| **SPECIAL DIRECTIONS** – delete this box from submitted Exempt Information Sheet  You are ready to select and edit the signature page, unless your study involves retention of samples or data for extra use, in which case, copy the required language to the indicated sections. Delete this entire text box from the submitted version.   1. Retention of Samples or Data for Extra Use    * Please 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 discussion of confidentiality protections:   + Add: The repository has standard operating procedures to protect your confidentiality. A description of how specimens and/or data are stored and shared. |

[Include the following signature line sectionif HIPAA authorization is required; otherwise, delete this signature line section]

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

Printed name of subject

By signing this research information sheet, you are indicating that you permit the use and sharing of information that may identify you as described, including your health information.

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

Signature of subject Date