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| Screening Questions Full Consent Template Version 1.7, 4/14/2023  **GENERAL INSTRUCTIONS** – delete this box from the submitted consent form  This template is used to conduct a consent process for answering screening questions when full consent is required because Protected Health Information (PHI) is being retained and signed authorization is required. If PHI is not being retained or the IRB has granted a waiver or alteration of authorization for retention of PHI for screening, you may instead use the “[Brief Screening Agreement](https://www.bumc.bu.edu/irb/files/2016/12/Brief-Screening-Agreement.docx)” template.  Use this template as follows:   * Blue text represents guidance on suggested content – to be edited and changed to black or replaced with black in the final version. * Black text represents text that should ordinarily be incorporated as-is, if applicable   The submitted version should have no red or blue text (including this instruction box).  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. |

**FULL CONSENT SCRIPT FOR SCREENING**

**Background**

You are being asked to voluntarily answer some questions to see if your child might qualify to be enrolled in a research study. We are doing the research study brief explanation of the purpose of the study. We are asking to see if your child qualifyies to be in this study because a one-sentence summary in lay language of why the subject might be eligible for the study.

If you agree, we will ask you some questions about brief description of screening questions. You may feel some discomfort or embarrassment about answering these personal questions, but please know that you may end the screening at any time.

**Confidentiality**

We will be keeping your answers on file for our records. We will store paper files in locked filing cabinets. We will store electronic files in computer systems with password protection and encryption.

[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 or your child 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. [Include if study information will be placed in medical records; otherwise, delete remainder of paragraph] We will record information from these screening questions study in your child’s medical record, such as information related to your child’s medical care. Please ask us if you have any questions about what information will be included in your child’s medical records. You should know that once information has been put into your child’s medical records, it is not covered by the CoC. However, information in your child’s medical records is protected in other ways.

If you agree to answer our screening questions, we will share your answers with the following groups of people:

* People who do the research or help oversee the research.
* People from Federal and state agencies, 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 child’s medical records. Please ask us if you have any questions about what information will be included in your child’s medical records or how your child’s medical records are protected.
* Any people if you give us separate permission allowing us to give them your answers.

[Include and edit if the screening gathers information that requires mandatory reporting; otherwise, delete bullet] 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 and edit if the screening gathers information on self-harm; otherwise, delete paragraph] If you are in immediate danger of hurting yourself, 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 might share your answers 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.
* 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 child’s health information to do this study. By agreeing to be screened for this study, you are giving us your authorization (permission) to use and share health information that may identify you or your child.

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

* Information that is in your child’s 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 interviews or forms filled out as part of this screening.
* [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 screening for 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 your child. As we explained above, if your child is are in immediate danger of self-harm, it is possible that your child’s 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 child’s 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 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 your child if your child expresses thoughts about self-harm.
  + [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 child’s health information from us to protect the privacy of your child’s information. However, we cannot control how they may use or share your child’s 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 child’s health information for research. If you do not agree, your child cannot be screened for the research. This is because we need to use the health information to do the research. Your decision not to agree 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 child’s health information in this research study. If you want to withdraw your permission, you must write a letter to the Principal Investigator. 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, your child 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 child’s treatment or payment decisions. If you ask for research information that is not in your child’s 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 child’s 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]

**Subject’s Rights**

Saying yes to this screening and the sharing of your child’s health information does not mean you have/your child has to be in the study. Your child’s participation is completely up to you. You can decide to start answering the questions but then stop at any time. Your decision will not affect your child’s ability to get health care or payment for health care. It will not affect your child’s enrollment in any health plan or benefits your child can get. However, if you don’t answer all the questions, your child may not be able to be in the research study.

If you have any questions, please ask them now or at any time you can contact name, email, and phone number of research team member. If you would like more information about your rights as a research subject, you may call 617-358-5372 or email [medirb@bu.edu](mailto:medirb@bu.edu). You will be talking to someone at the Boston Medical Center/Boston University Medical Campus IRB. The IRB is a group that helps monitor research.

**Signatures**

By signing this permission 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 and to have your child participate in this screening
* you permit the use and sharing of information that may identify you or your child as described [include if health information is obtained; otherwise, delete blue phrase] , including your child’s health information.

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Printed name of subject

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Signature of subject Date

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.

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Signature of person conducting consent discussion Date