

Permission for Use and Disclosure of Your Health Care Information

[Select at least one: Brown University/ Brown University Health/Care New England]

Title of research study: **[insert title of research study here with protocol number, if applicable]**

Investigator: **[insert name of principal investigator]**

Version Number/Date: **[Include the version number and date of this consent]**

Affiliated Hospital Site(s): **[Include the name of the affiliated hospital(s) housing the PHI]**

If you are signing an authorization for a research participant who cannot legally consent to take part, the pronouns “you” and “your” in the consent should be read as referring to the research participant rather than you, (parent, guardian or legally authorized representative) who is signing and dating this form for the participant.

Permission for Use and Disclosure of Your Healthcare Information (if applicable)

What is the purpose of this Authorization?

Federal law requires us to get your permission (Authorization) to use or disclose (release your information to someone outside of **[Brown University / Brown University Health / Care New England]**) your health information for research purposes. This Authorization tells you what information about you may be collected in the study and who might see or use it. If you sign this form you agree to be in this research study and you permit the use and disclosure of your health information for the purpose of conducting the research, providing treatment, collecting payment and running the business of the hospital. Your research records will be treated as private health care records and will be protected according to **[Brown University / Brown University Health / Care New England]** privacy practices and policies that are based on state and federal law.

What health information will be collected, used or shared?

The following protected health information (PHI) will be used or disclosed only for the research outlined in this the form:

[list/identify the information in a specific and meaningful way so that the participant understands what you will be collecting. The next section will address who, besides the research team, may have access].

[If medical records will be accessed, consider the following:]

Your medical records, which may include records from hospital and clinic visits, emergency room visits, immunizations, medical history and physical exams, medications, images and imaging reports, progress notes, psychological tests, EEG/EKG/ECHO reports, lab and pathology reports, dental records and financial records. These records may be used and shared for as long as the research continues.

[If medical records will not be accessed, but health information will be collected in other ways, consider the following:]

Information collected as part of this research study, including research procedures, research visits, and any optional elements of the research you agree to, all as described in the Consent Form. This information might not be part of your medical record, and may include things like responses to surveys

and questionnaires, and information collected during research visits described in the Consent Form.

Who will see, use or share the health information?

The following people or businesses/companies might use, release, or receive such information:

- The researcher(s) and their support staff at **[Brown University / Brown University Health / Care New England]** identified in this form;
- *[If sharing is planned, inform participants here of any potential recipients of their protected health information. If not sharing outside **[Brown University / Brown University Health / Care New England]** and Sponsor, Delete]*
- The study sponsor _____. (Remove if not sponsored)
- *The IRB of record: (Single IRB only)_____. (Remove if the **[Brown University / Brown University Health / Care New England]** does not rely)*
- ***[Brown University / Brown University Health / Care New England]** that rely on the covered IRB for review of this research: _____. (Remove if **[Brown University / Brown University Health / Care New England]** is not the reviewing IRB)*
- Doctors, nurses, laboratories and others who provide services to you or the sponsor in connection with this study;
- The company or section of the U.S. government that is paying for the study and others they hire to oversee, administer, or conduct the research;
- The United States Food and Drug Administration, the Department of Health and Human Services, the Office of Inspector General, the Office of Civil Rights, European Medicines Agency
- People who volunteer to be patient advocates or research volunteer protectors;
- Members of the institution's administrative staff responsible for reviewing, approving and administering clinical trials and other healthcare or research activities (IMembers and staff of the Institutional Review Board (IRB), and staff associated with Human Research Protections Program (HRPP), other staff associated with the Brown University Office of the Vice President for Research (OVPR), Brown University data safety/data security monitoring personnel, other institutional offices as applicable.
- Accrediting Organizations

There are times when the law might require or permit **[Brown University / Brown University Health / Care New England]** to release your health information without your permission. For example, Rhode Island law requires researchers and health care workers to report abuse or neglect of children to the Department of Children, Youth and Families (DCYF) and to report abuse or neglect of people age 60 and older to the Department of Elderly Affairs.

[Insert this paragraph only if applicable to your study:]

If you are in a cancer study that receives federal funding, the National Cancer Institute (NCI) now requires that we report identifiable information (such as zip code) about you to track which groups of people participate in research. You may contact the NCI if you have questions about how this information is used.

All covered entities (researchers and health care providers) are required by law to protect the privacy of your health care information. Other people and businesses/organizations that are not health care providers but who may receive your information as part of the research are not required by Federal Privacy laws to protect your privacy. Thus it is possible they might share your information with others without your permission and that federal and state confidentiality laws may no longer protect it. Brown Health has no control over this.

Federal and state law requires us to review any inadvertent disclosure (release) or inappropriate access of your health information that we become aware of. If we become aware your information has been inadvertently disclosed (released) or inappropriately accessed, Compliance at **[Brown**

University / Brown University Health / Care New England] will complete an investigation to determine if there is a breach of your individual health information that requires us to notify you.

Do you have to sign this Authorization?

You have the right to refuse to sign this form and not participate in the research. Your refusal would have no effect on your treatment, charges billed to you, or benefits at any **[Brown University / Brown University Health / Care New England]** health care site. If you do not sign, you will not be able to enroll in the research study. If you decide to quit the study after signing this form, no new information will be collected about you.

Cancelling and Expiration of Permission

You may change your mind and cancel this Authorization at any time. If you would like to cancel, you must do so in writing. Once your request to cancel permission is received, you will stop taking part in the study and no new information will be collected about you unless you gave us permission to do so. Your cancellation will not affect information already collected in the study, or information that has already been shared with others before you cancelled your authorization. The hospital or the researchers may continue to use information that was collected before you removed yourself from the study to complete analysis and reports of this research. This permission has no expiration date.

To cancel your permission, please write to:

Brown University
Division of Research, Office of Research Integrity
Attention: Human Research Protection Program (HRPP)
350 Eddy Street
Providence, RI 02903

You will not be allowed to see or copy the information about your participation described in this form if the research study is open. You may see and copy the information when the study is completed.

By signing this document, you authorize **[Brown University / Brown University Health / Care New England]** to use and/or disclose (release) your health information for this research.

[There are three signature pages attached to this template consent. Use the signature page or pages appropriate for your study. The IRB recommends that you make separate documents for each signature page to be used.]

Signature Page

- I have read this informed consent and authorization form. ALL OF MY QUESTIONS HAVE BEEN ANSWERED, AND I WANT TO TAKE PART IN THIS RESEARCH STUDY.
- By signing below, I give my permission to participate in this research study and for the use of associated protected health information as described above (HIPAA). *I also confirm that I have been now or previously given a copy of the Brown University Health/ Care New England Privacy Notice.*
- **The Researcher is required to provide a copy of this consent to you.**

Signature Block for Adult who can Consent

Your signature documents your permission to take part in this research.

Signature of participant	Date	Time
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Printed name of participant

Signature of person obtaining consent	Date	Time
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Printed name of person obtaining consent

[Add the following block if a witness will observe the consent process. E.g., short form of consent documentation or illiterate participants.]

My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the participant, and that consent was freely given by the participant.

Signature of witness to consent process	Date	Time
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Printed name of person witnessing consent process

Signature Block for Adult Unable to Consent

Your signature documents your permission for the named participant to take part in this research.

Printed name of participant

Signature of legally authorized representative

Date

Time

Printed name of legally authorized representative

Signature of person obtaining consent

Date

Time

Printed name of person obtaining consent

IRB Approval Date

[Add the following block if you will document assent of the participant.]

Assent

☐ Obtained

☐ Not obtained because the capability of the participant is so limited that the participant cannot reasonably be consulted.

[Add the following block if a witness will observe the consent process. E.g., short form of consent documentation or illiterate participants.]

My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the participant, and that consent was freely given by the participant.

Signature of witness to consent process

Date

Printed name of person witnessing consent process

Signature Block for Children

Your signature documents your permission for the named child to take part in this research.

Printed name of child

Signature of parent or individual legally authorized
to consent to the child's general medical care

Date

Printed name of parent or individual legally authorized
to consent to the child's general medical care

Date

Relationship to Child

☐ Parent

☐ Individual legally authorized to consent to the child's general medical care (See note below)

Note: Investigators are to ensure that individuals who are not parents can demonstrate their legal authority to consent to the child's general medical care. Contact legal counsel if any questions arise.

Signature of parent

Date

Printed name of parent

If signature of second parent not obtained, indicate why: (select one)

- ☐ The IRB determined that the permission of one parent is sufficient. **[Delete if the IRB did not make this determination]**
- ☐ Second parent is deceased
- ☐ Second parent is unknown
- ☐ Second parent is incompetent
- ☐ Second parent is not reasonably available
- ☐ Only one parent has legal responsibility for the care and custody of the child

[Add the following block if you will document assent of children]

Assent

☐ Obtained

- ☐ Not obtained because the capability of the child is so limited that the child cannot reasonably be consulted.

[Add the following block to all consents]

Signature of person obtaining consent and assent

Date

Printed name of person obtaining consent

IRB Approval Date

[Add the following block if a witness will observe the consent process. E.g., short form of consent documentation or illiterate participants.]

My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the participant, and that consent was freely given by the participant.

Signature of witness to consent process

Date

Printed name of person witnessing consent process