



BROWN

Permission to Take Part in a Human Research Study

IRB Approval Date

Title of research study¹: *[insert title of research study here with protocol number, if applicable]*

Investigator: *[insert name of principal investigator]*

Key Information: The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

Why am I being invited to take part in a research study?

We invite you to take part in a research study because _____. *[Fill in the circumstance or condition that makes subjects eligible for the research.]*

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?

[Tell the subject the purpose of the research. Explain the background of the research problem. Explain any potential benefits to others.]

How long will the research last and what will I need to do?

We expect that you will be in this research study for _____ *[hours/days/months/weeks/years, until a certain event].*

You will be asked to _____ *[include a high level summary of the procedures that will be done. For example: You will be given an investigational drug and asked to be asked to come for 3 study visits. You will give a total of 3 blood samples and fill out questionnaires asking about how you feel.]*

More detailed information about the study procedures can be found under “**What happens if I say yes, I want to be in this research?**”

Is there any way being in this study could be bad for me?

[This beginning section of the consent form should identify the most important risks, e.g., emotional distress resulting from a series of questions in a social-behavioral research project or similar to the information that a physician might deliver in the clinical context in telling a

¹ This template satisfies AAHRPP elements I.1.G, I.4.A, I-9, II.3.C-II.3.C.1, II.3.E, II.3.F, II.4.B, III.1.F, III.1.G

patient how sick, e.g., the chemotherapy drugs will make them, but with a particular emphasis on how those risks are changed by participating in the study]

More detailed information about the risks of this study can be found under ***“Is there any way being in this study could be bad for me? (Detailed Risks)”***

Will being in this study help me in any way?

[This beginning section of the consent form should identify one or more likely benefits resulting from participation in the study; in doing so, you should not overemphasize the benefits. If you need to discuss benefits in additional detail, add an additional section later in the consent document]

[Include if there are benefits to participation. Otherwise delete.] We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include _____. ***[First describe any direct benefits to the subject, then any benefits to others. If benefits from participation may not continue after the research has ended, describe them here. Monetary reimbursement for participation is not a benefit.]***

[Include for a study with no benefits to participation. Otherwise delete.] There are no benefits to you from your taking part in this research. We cannot promise any benefits to others from your taking part in this research. However, possible benefits to others include _____. ***[Describe any benefits to others. Monetary reimbursement for participation is not a benefit.]***

[Include for research involving prisoners] Taking part in this research study will not improve your housing or correctional program assignments. Your taking part in this research study will not improve your chance of parole or release.

What happens if I do not want to be in this research?

Participation in research is completely voluntary. You can decide to participate, not participate, or discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled.

[Include if there are alternatives other than participating.] Instead of being in this research study, your choices may include: ***[List alternatives procedures. For student subject pools describe alternatives for course credit. For clinical trials describe the options that you would normally offer patient. If applicable, include supportive care as an option.]***

[Include if there are no alternatives other than participating.] Your alternative to participating in this research study is to not participate.

Detailed Information: The following is more detailed information about this study in addition to the information listed above.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at ***[Insert contact information for the research team]***

This research has been reviewed and approved by the Brown University Institutional Review Board (“IRB”). You may talk to them at (401) 863-3050 or IRB@brown.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

How many people will be studied?

We expect about _____ people here will be in this research study out of _____ people in the entire study nationally ***[or internationally]***.

What happens if I say yes, I want to be in this research?

[Tell the subject what to expect using lay language and simple terms. Whenever appropriate include the following items:]

- ***A time-line description of the procedures that will be performed. If practical, prepare a time-line chart or schematic to accompany descriptions of procedures and tests for research that require more than 1 or 2 steps/visits***
- ***The drugs or biologics that will be given to the subject***
- ***All devices that will be used***
- ***All hospitalizations, outpatient visits and telephone or written follow-up***
- ***The length and duration of visits and procedures***
- ***If blood will be drawn, indicate the amount [in English units] and frequency***
- ***With whom will the subject interact***
- ***Where the research will be done***
- ***When the research will be done***
- ***List experimental procedures and therapies and identify them as such***
- ***How often procedures will be performed***
- ***What is being performed as part of the research study***
- ***What is being performed as part of standard care***
- ***What procedures are part of regular medical care that will be done even if the subject does not take part in the research***
- ***Whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen***
- ***When applicable indicate that the subject will be contacted for future research.***

[Include for a clinical trial that involves randomization. Otherwise delete.] The treatment you get will be chosen by chance, like flipping a coin. Neither you nor the study doctor will choose what treatment you get. You will have an _____ ***[equal/one in three/etc.]*** chance of being

given each treatment. **[For double-blinded research add]** Neither you nor the study doctor will know which treatment you are getting. **[For single blinded research add]** You will not be told which treatment you are getting, however your study doctor will know.

What are my responsibilities if I take part in this research?

[Delete this section if the research is not a clinical trial.]

If you take part in this research, you will be responsible to: **[Describe any responsibilities of the subject.]**

What happens if I say yes, but I change my mind later?

You can leave the research at any time; it will not be held against you.

[Include if there are potential adverse consequences to withdrawing from the research. Otherwise delete]

If you decide to leave the research, **[Describe the adverse consequences.]** If you decide to leave the research, contact the investigator so that the investigator can **[Describe the procedures for orderly termination by the subject, if any.]**

[Include for FDA-regulated research. Otherwise delete.] If you stop being in the research, already collected data may not be removed from the study database. You may be asked whether the investigator can collect data from your routine medical care. **[Note: The consent document cannot give the subject the option of having data removed.]** If you agree, this data will be handled the same as research data. **[Note: If a subject withdraws from the interventional portion of a study and does not consent to continued follow-up of associated clinical outcome information, the investigator must not access for purposes related to the study the subject's medical record or other confidential records requiring the subject's consent. However, an investigator may review study data related to the subject collected prior to the subject's withdrawal from the study, and may consult public records, such as those establishing survival status.]**

[For research that is not FDA-regulated, describe what will happen to data collected to the point of withdrawal. Describe whether subjects will be asked to explain the extent of their withdrawal and whether they will be asked for permission to collect data through interaction or collection of private identifiable information. For example, a subject may wish to withdraw from the experimental procedure because of unacceptable side effects but may agree to undergo follow-up procedures and data collection.]

Is there any way being in this study could be bad for me? (Detailed Risks)

[Delete this section if there are no risks or discomforts.]

[The risks of procedures may be presented in a table form.]

[Describe each of the following risks, if appropriate. If known, describe the probability and magnitude of the risk.]

- **[Physical risks]**
- **[Psychological risks]**
- **[Privacy risks]**
- **[Legal risks]**
- **[Social risks]**
- **[Economic risks]**

[Include for research that involves procedures whose risk profile is not well known, including all research involving an investigational product. Otherwise delete.] In addition to these risks,

this research may hurt you in ways that are unknown. These may be a minor inconvenience or may be so severe as to cause death.

[Include for research that involves pregnant women or women of child-bearing potential and procedures that involve risks to an embryo or fetus or whose risk profile in pregnancy is not well known. Otherwise delete.] The procedures in this research are known to hurt a pregnancy or fetus in the following ways: _____. **[Omit the previous sentence if there are no known risks.]** The research may also hurt a pregnancy or fetus in ways that are unknown. These may be a minor inconvenience or may be so severe as to cause death. **[Omit the previous two sentences for research whose risk profile in pregnancy is well known.]** You should not be or become pregnant **[include as applicable “or father a baby”]** while on this research study.

[Include for research where the sponsor provides study-related agents/procedures at no cost to ALL subjects. Otherwise delete. Note: Detailed coverage analysis information is not required in this section.] The sponsor will provide the following study-related items/procedures for you at no cost during participation in the study: **[Describe what is provided e.g. investigational drug/device.]**

[Include for research that may result in additional costs for all subjects. Otherwise delete.] Taking part in this research study may lead to added costs to you. **[Describe what these costs are. Detailed coverage analysis information is not required in this section.]**

[Include for a clinical trial. Otherwise delete.] You and your insurance company will be charged for the health care services that you would ordinarily be responsible to pay. You remain responsible for all deductibles, co-pays, and balances under your insurance. In some cases, insurance will not pay for services ordinarily covered because these services were performed in a research study. You should check with your insurance to see what services will be covered by your insurance and what you will be responsible to pay. A member of the study team can talk to you about what procedures would be considered standard care and the coverage of those costs.

[Include for research that will collect/store data and samples for future research. Otherwise delete.]

We will do our best to protect your data and samples during storage and when they are shared. However, there remains a possibility that someone could identify you. There is also the possibility that people who are not supposed to might access your data and samples. In either case, we cannot reduce the risk to zero.

[Include for Department of Defense (DoD) research where DoD-affiliated personnel are subjects and if the HSR includes a risk to their fitness for duty (e.g. health, availability to perform job, data breach).] This research project may impact your fitness for duty. Please seek command or Component guidance before participating.

[Include for Department of Defense (DoD) research, if applicable.] This research includes the potential risk of the loss of clearance, credentials, or other privileged access or duty.

[Include for Department of Defense (DoD) research that is greater than minimal risk.] For the duration of the study, you may be eligible for health care services for research-related injuries at a military treatment facility, and this eligibility for health care services extends beyond your participation in the study to such time after the study has ended. **[Add additional information about how this organization will care for participants with research-related injuries, including injuries that are the direct result of activities performed by DoD-affiliated personnel]**

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization. ***[Add to this list other organizations that may have access to the subject's records such as the Food and Drug Administration, when the research is FDA-regulated, the Department of Health and Human Services, when the research is conducted or funded by DHHS, the sponsor, contract research organization, sponsor's agent and other collaborating institutions. Include for Department of Defense (DoD) research that representatives of the DoD are authorized to review research records.]***

[Describe any limitations on confidentiality based on possible legal issues. For example, if the research team is likely to uncover abuse, neglect, or reportable diseases, explain that this information may be disclosed to appropriate authorities.]

[Include for NIH-funded studies or those receiving a CoC by request from NIH.] This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

[If data or specimens will be retained after the study for future research, explain where the data or specimens will be stored, who will have access to the data or specimens, and how long the data or specimens will be retained.]

[If identifiable private information or identifiable specimens will be collected during the research, add one of the following statements:

If identifiers are removed from your identifiable private information or identifiable samples that are collected during this research, that information or those samples could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent. ***_See the information*** found under ***"Will my data or samples be used for future research?"***

OR

Your information or samples that are collected as part of this research will not be used or distributed for future research studies, even if all of your identifiers are removed.

[Include for research where the sponsor may pay for medical expenses of the subject.] If the sponsor pays any of your medical expenses, we may be required to give the sponsor your name, date of birth, and Medicare ID or social security number.

[Include for a clinical trial. Otherwise delete.] The sponsor, monitors, auditors, the IRB, the Food and Drug Administration will be granted direct access to your medical records to conduct and oversee the research. By signing this document you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

[Include for FDA-regulated controlled drug and device trials (except Phase I drug trials) and FDA-regulated pediatric post-market surveillance trials of devices. Otherwise delete.] 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.

[Include if a HIPAA authorization is required. Otherwise delete.] Federal law provides additional protections of your medical records and related health information. These are described in an attached document.

[Include for research involving prisoners. Otherwise delete.] If you are a prisoner, your medical records may also be given to officials and agencies within the criminal justice system when necessary and permitted by law.

Will my data or samples be used for future research?

[Include this section if data or specimens will be retained after the study for future research, add/modify the following text to explain where the data or specimens will be stored, who will have access to the data or specimens, and how long the data or specimens will be retained.]

This study is collecting data and samples from you. We would like to make your data and samples available for other research studies that may be done in the future. The research may be about similar diseases or conditions to this study. However, research could also be about unrelated diseases, conditions, or other types of research. These studies may be done by researchers at this institution or other institutions, including commercial entities. Your data and samples may be shared with researchers around the world. Our goal is to make more research possible. We plan to keep your data and samples for ***[Insert time frame as indicated in the study protocol]***. To get your data or samples, future researchers must seek approval from this institution and review by an IRB may be required.

[If the data and biospecimens are coded and can be linked back to the identity of the participant enter the following text.]

We will protect the confidentiality of your information to the extent possible. Your data and samples will be coded to protect your identity before they are shared with other researchers. Only the study team ***[or indicate who has the code key]*** will have a code key that can be used to link to your identifying information. The code key will be securely stored.

[If the data and biospecimens cannot be easily linked back to the identity of the participant enter the following text.]

Your name and identifying information will be removed from any data and samples you provide before they are shared with other researchers. Researchers cannot easily link your identifying information to the data and samples.

[Include when sharing of data and specimens will NOT be optional (e.g., where sharing is integral to the purpose of the study).]

Participating in this study means you agree to share your data and samples. You can change your mind later, but researchers might still use your data and samples if they have already been shared. If you do not want your data and samples used for other research studies, you should not participate in this study.

Can I be removed from the research without my OK?

[Delete this section if not applicable.]

[Include for research where this is a possibility. Otherwise delete.] The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include **[describe reasons why the subject may be withdrawn, if appropriate.]**

[Include for research where this is a possibility. Otherwise delete.] We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

What else do I need to know?

[Include for sponsored research. Otherwise delete.] This research is being funded by **[Insert name of sponsor]**. **[Include for Department of Defense (DoD) research that the DoD or a DoD organization is funding the study.]**

[Include for research involving more than minimal risk. Otherwise delete.] If you need medical care because of taking part in this research study, contact the investigator and medical care will be made available. Generally, this care will be billed to you, your insurance, or other third party. **[Insert the name of the institution]** has no program to pay for medical care for research-related injury. **[Describe any compensation available for research related injury.]**

[Include for research studies using a drug, biological product, device, or vaccine designed to treat, diagnose, cure or prevent COVID-19. Otherwise delete.] Due to the coronavirus public health emergency, the federal government has issued an order that may limit your right to sue if you are injured or harmed while participating in this COVID-19 study. If the order applies, it limits your right to sue researchers, healthcare providers, any study sponsor, manufacturer, distributor or any other official involved with the study. However, the federal government has a program that may provide compensation to you or your family if you experience serious physical injuries or death. To find out more about this "Countermeasures Injury Compensation Program" please go to <https://www.hrsa.gov/cicp/about/index.html> or call 855-266-2427.

[Include if subjects will be paid. Otherwise delete.] If you agree to take part in this research study, we will pay you **[indicate amount]** for your time and effort. **[Indicate if the amount is pro-rated for research visit completion.]**

[Include for Department of Defense (DOD) research that targets military personnel where subjects will be paid. Otherwise delete.] Military personnel should check with their supervisor before accepting payment for participation in this research.

[Include for research involving prisoners where there may be a need for follow-up examination or care after the end of participation. Otherwise delete.] If you are released from jail before you finish this research study, you should take steps to get insurance or Medicaid coverage. Regular office visits and standard treatment will be billed to you or your health insurance. You may continue in the research study after your release from prison. If you move out of the area, we will help you make arrangements to be followed by a physician.

[Include for a clinical trial.] Instead of being in this research study, your choices may include: **[include alternatives.]** The important risks and possible benefits of these alternatives include: **[Describe the important risks and potential benefits of the alternative procedures and courses of treatment.]**

[Include when applicable.] Your information and samples (both identifiable and de-identified) may be used to create products or to deliver services, including some that may be sold and/or make

money for others. If this happens, there are no plans **[or replace with plans when using identifiable information/samples]** to tell you, or to pay you, or to give any compensation to you or your family.

[When applicable, include whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and for research involving biospecimens.] Most tests done on samples in research studies are only for research and have no clear meaning for health care. If the research with your identifiable information or samples gives results that do have meaning for your health, the researchers **will/will not** contact you to let you know what they have found. If the researchers return genetic test results to you, it may be because they think you could have a health risk and want to recommend that the test should be re-done by a certified clinical laboratory to check the results. If this happens, then you may want to get a second test from a certified clinical laboratory, consult your own doctor, or get professional genetic counseling. You may have to pay for those additional services yourself.

[When the research involves genetic testing or the collection of genetic information.] This research study involves genetic testing. The Genetic Information Nondiscrimination Act (GINA) prohibits health insurers or health plan administrators from requesting or requiring genetic information of you or your family members, or using such information for decisions regarding your eligibility for insurance or your premiums. However, this law does not provide the same protection for disability, life insurance, or long-term care insurance. GINA also prohibits most employers (with 15 employees or more) from using genetic information when making decisions on your employment, including decisions related to hiring, firing, promotion, pay, and job assignments. Information obtained through genetic testing may be susceptible to re-identification. The following safeguards will be used to help protect your information from re-identification: **[indicate safeguards]**. Please contact your study doctor if you would like more information about GINA and how it protects you from genetic discrimination.

[Include this section when sharing of data and specimens will be optional (e.g., for studies that have potential benefit)]

Optional Procedures for the Study

It is your choice whether or not to let researchers share your data and samples for research in the future. If you say “yes,” you can change your mind later. If you say “no,” you can still fully participate in this study. If you change your mind and no longer wish to have us store or share your data and samples, you should contact the investigator. We will do our best to honor your request and to get back any data and samples that have been shared with other researchers. However, there may be times we cannot. For example, if we do not have a way to identify your data and samples, we will not be able to get them back. In addition, if the data and samples have already been used for new research, the information from that research may still be used. We will destroy any samples we have or are able to get back.

Please initial **[or sign depending on institutional practice]** next to your choice:

_____ YES, my data and samples may be used in other research studies

_____ NO, my data and samples MAY NOT be used in other research studies

[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 consent documents for each signature page to be used.]

[Omit the signature page if there is no written documentation of consent.]

Signature Block for Capable Adult

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

Signature of subjectDate

Printed name of subjectDate

Signature of person obtaining consentDate

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 subjects.]

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 subject, and that consent was freely given by the subject.

Signature of witness to consent processDate

Printed name of person witnessing consent processDate

Signature Block for Adult Unable to Consent

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

Printed name of subject

Signature of legally authorized representative

Date

Printed name of legally authorized representative

Signature of person obtaining consent

Date

Printed name of person obtaining consent

IRB Approval Date

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

Assent

- ☐ Obtained
- ☐ Not obtained because the capability of the subject is so limited that the subject 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 subjects.]

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 subject, and that consent was freely given by the subject.

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

☐ 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 subjects.]

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 subject, and that consent was freely given by the subject.

Signature of witness to consent process Date

Printed name of person witnessing consent process