**[USE YOUR DEPARTMENT LETTERHEAD]**

**CONSENT TO TAKE PART IN A RESEARCH STUDY**

This template [HRP-502b] should be used when obtaining consent from adults to take part in non-interventional research—research involving various types of interactional or observational methodologies, such as observations, interviews, focus groups, surveys, quality of life, or interactional research, or research involving Biospecimen collection. [Use with Protocol Template HRP-503b]

If the research plans to conduct only anonymous research or employ only one non-interventional methodology, such as only survey research or only interview research, consider using instead a consent template dedicated to single methodologies found at Toolkit Forms and Templates.

**INSTRUCTIONS:**

* **[BLUE]** highlighted text provide instructions to guide you in constructing the consent document.
* **[GREEN]** highlighted text provide different scenarios/options.
* **Delete all instructional text and scenarios that are not applicable** to your study.
* The consent document should be written at a 6th to 8th grade reading level.
* **NOTE:** If the research is conducted, supported, or otherwise subject to regulation by any Federal Department or agency, such as Dept of Defense, Dept of Energy, Dept of Justice, Dept of Education or Environmental Protection Agency, additional protocol plans may be required. [Go to HSPP Toolkit HRP-103a Appendices to learn more.]

Visit the Human Subjects Protection Program (HSPP) website <https://go.rutgers.edu/HSPP-Toolkit> to obtain referenced Toolkit Forms & Templates and <https://go.rutgers.edu/HSPP-Guidance> to obtain referenced Guidance documents. Contact your IRB Office at <https://go.rutgers.edu/ContactUs> if you need further assistance.

**Title of Study:** [Add the Title of the study here.]

**Principal Investigator:** [Add the PI’s name and credentials here (i.e. M.D., Ph.D., etc.).]

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| [Fill in the blanks and, when complete, be sure your customized Study Summary appears immediately after the Title of the Study & PI name/credentials. Keep the black box format. **NOTE:** The purpose of a Study Summary is to provide key information upfront to aid in comprehension when study details are many or complicated. If the study is uncomplicated and can be described in 5 pages or less, you may delete this Study Summary & box as the need for a summary is no longer necessary.]  **STUDY SUMMARY:** This consent form is part of an informed consent process for a research study and it will provide information that will help you decide whether you want to take part in this study. It is your choice to take part or not.  The **purpose of the research** is to: [state the purpose]. If you take part in the research, you will be asked to [describe what they will be asked to do. Be sure to note anything that is experimental.]. Your time in the study will take [state how long you anticipate they will actively be engaged in the research, e.g. 20 minutes to complete a survey; 2 days to complete study tasks at the Center; etc.].  **Possible harms or burdens** of taking part in the study may be [list key risks or harm or burdens that may result from participation] and possible benefits of taking part may be [list key direct benefits they may reasonably expect from participation].  **An alternative to taking part in the research study** [state appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the prospective subject]. [If no alternatives exist, state] Your alternative to taking part in the research study is not to take part in it. |

The information in this consent form will provide more details about the research study and what will be asked of you if you choose to take part in it. If you have any questions now or during the study, if you choose to take part, you should feel free to ask them and should expect to be given answers you completely understand. After your questions have been answered and you wish to take part in the research study, you will be asked to sign this consent form. You are not giving up any of your legal rights by agreeing to take part in this research or by signing this consent form.

**Who is conducting this study?**

[Insert name of PI] is the Principal Investigator of this research study. A Principal Investigator has the overall responsibility for the conduct of the research. However, there are often other individuals who are part of the research team. [PI name] may be reached at [provide PI’s contact phone number and address].

The Principal investigator or another member of the study team will also be asked to sign this informed consent. You will be given a copy of the signed consent form to keep.

**Sponsor of the Study**: Add the name of the sponsor of the study here only if there is one. If there is no study sponsor, delete this paragraph.

**Why is this study being done?**

Explain the purpose of the study in lay language; avoid scientific terms.

**Who may take part in this study and who may not?**

Clearly describe inclusion and exclusion criteria. Use lay language; avoid scientific terms.

**Why have I been asked to take part in this study?**

Explain in lay language why the individual is being invited to take part in the study.

**How long will the study take and how many subjects will take part?**

Explain in lay language how many subjects will participate in this study (for this site and study-wide) and the duration of the individual’s participation in the study. Also state the length of time the study will last overall.

**What will I be asked to do if I take part in this study?**

Describe the procedures that will take place during the study. Clearly identify those that are experimental. Use lay language and provide details. **NOTE**: Include a chart or diagram of activities if the study has a number or steps.

[If the research plans to audio- or visually-record or photograph subjects and such recordings/images are required to take part in the research, disclose here your plans to record/photograph subjects and reason for use in the research. Consider the following text: [Specify audiotaping (sound), photography (picture), videography (movie) or some combination of sound, pictures or videography] will be made to record you (specify: during interview sessions, exercise tasks, etc.). The recordings will be used for (state purpose, such as, for data analysis by the research team, for use as a teaching tool for students who are not members of the research staff, or for commercial purposes).]

If recording or photographing is not required to take part in the main study, instead disclose the optional recording/photos in an addendum following the permission to take part in research signature block. Find the “Addendum Consent to Record or Photograph Subjects in Research” template at HSPP Toolkit Forms & Templates Section Consent Addenda.

**What are the risks of harm or discomforts I might experience if I take part in this study?**

Describe in lay language the risks or discomforts for each interaction or observation. Include physical, psychological, social, and financial risks, if applicable. Suggested language for studies involving a blood draw: When blood is drawn, there may be a bruise, or bleeding, or infection, at the place where the blood is drawn. However, infection is rare.

Studies that propose to conduct genetic research must disclose risks of harm possible from such research. Required consent language is found at HSPP Toolkit Forms & Templates Special Passages GINA as is the definition of what types of genetic research must comply with the Genetic Information Non-Discrimination Act disclosure requirement.

**Are There Any Benefits To Me If I Choose To Take Part In This Study?**

The benefits of taking part in this study may be [List possible direct benefits of participation, if any]. However, it is possible that you may not receive any direct benefit from taking part in this study.

**What Are My Alternatives If I Do Not Want To Take Part In This Study?**

If alternative(s) are available, list them here: The following alternative(s) are available if you choose not to take part in this study:

If there are **no** alternatives available: Your alternative is not to take part in this study.

**How Will I Know If New Information Is Learned That May Affect Whether I Am Willing To Stay In The Study?**

During the study, you will be updated about any new information that may affect whether you are willing to continue taking part in the study. If new information is learned that may affect you after the study or your follow-up is completed, you will be contacted.

**Will I Receive The Results Of The Research?**

If returning research results does not apply to your research, delete this section and heading in its entirety. If you anticipate the research will generate clinically relevant results, including individual research results, state here whether you will disclose the results to subjects and, if so, under what conditions that will occur. In general, we will not give you any individual results from the study. If we find something of urgent medical importance to you, we will inform you, although we expect that this will be a very rare occurrence. [Then add details about what kinds of information you will return, such as, ‘unusual findings on an MRI report that we think you should discuss with your doctor’. Also add details about how you will notify them, such as ‘we will notify you by first class mail after analysis of research data are concluded, which may take up to six months’.]

**Will There Be Any Cost To Me To Take Part In This Study?**

Explain in lay language what the cost to participate will be, if any.

**Will I Be Paid To Take Part In This Study?**

Clearly outline the amount and schedule of all payments to subjects. **EXAMPLE:**

You will receive $ 15.00 for taking part in this study according to the following schedule:

* $ 5.00 at your first visit
* $ 5.00 at your second visit (2-year visit)
* $ 5.00 at your third visit (4-year visit)

If subjects will not be paid:

You will not be paid to take part in this study.

**Who Might Benefit Financially From This Research?**

Delete this entire section and section heading if there is nothing to disclose

Insert **Conflict of Interest (COI) disclosure language** here. Examples appear below.

The examples do not cover every possible situation but begin here and contact the IRB for assistance with refining the disclosure language to accurately reflect your circumstances.

1. **University Holds Patent on a Product [Test, Drug, Device, Treatment, Computer Application, etc.]:** Research studies like this one are designed to determine whether the product is safe and effective. Rutgers University owns a patent on some of the technology used in the product being studied. If research shows the product is safe and effective, the Rutgers University would receive a part of the profits from any sales of the product.
2. **University Holds Equity in the Company Making a Product [Test, Drug, Device, Treatment, Computer Application, etc.]:** This research is designed to test a product made by [company]. Rutgers University has an investment in [company], such as stock. The financial value of this investment might be affected by the results of this study. This means that Rutgers University could gain or lose money depending on the results of this study.

1. **Investigator Is an Inventor/Could Receive Royalties on a Product [Test, Drug, Device, Treatment, Computer Application, etc.]:** Research studies like this one are designed to determine whether the [test, drug, treatment, or device] is safe and effective. [Investigator name], one of the investigators in this study [or, the person leading this study, depending on the situation], is an inventor of the [test, drug, treatment, device] being studied. If research shows the [test, drug, treatment, device] is safe and effective, [Investigator name] would receive a part of the profits from any sales of the [test, drug, treatment, device].
2. **Investigator Receives Money from the Sponsor Outside of the Study [Consulting, Advisory Boards, Speakers’ Bureau, etc.]:** This research study is supported by money from [company].  In addition, [Investigator name], one of the investigators on this study [or, the person leading this study, depending on the situation], receives remunerationfrom [company] for work that is not a part of this study.  These activities may include consulting, advisory boards, giving speeches, or writing reports.
3. **Investigator Holds Equity in the Company Making the Product [Test, Drug, Device, Treatment, Computer Application, etc.]:** This research is designed to test a product made by [company]. [Investigator name], one of the investigators on this study [or, the person leading this study, depending on the situation], has an investment in [company], such as stock. The financial value of this investment might be affected by the results of this study. This means that [Investigator name] could gain or lose money depending on the results of this study.
4. **Investigator Is Employee of Company Which Has Patent/Has or Will Manufacture the Product (but will not receive any royalties and does not expect other incentive income based on sales of the product):** This research is designed to test a product made by [company]. The product is manufactured and sold by [company]. [Investigator name], one of the investigators on this study [or, the person leading this study, depending on the situation], is an employee of [company]. If research shows the product is safe and effective, [Investigator name] would not receive any direct benefit, but [company] would receive profits from any sales of the product.
5. **Biospecimens Collected For The Research May Lead To The Development Of Commercial Products And The Investigator May Realize Commercial Profit From Its Development.** It is possible that research using your biospecimens may lead to the development of new medical tests and techniques, drugs or other commercial products. Should this occur [state **either** “there is no plan to share any profit from products developed from this research with you” **OR** “there is a plan to share profit from products developed from this research with you [and then explain what, when and how it will be shared].

**How Will Information About Me Be Kept Private Or Confidential?**

All efforts will be made to keep your personal information in your research record confidential, but total confidentiality cannot be guaranteed. Provide a description of how data, specimens, recordings and/or images, if applicable, will be stored and maintained and who will have access to them. Describe any study specific issues that may increase the risk of breach of confidentiality.

The research team may use or share your information collected or created for this study with the following people and institutions:

* The Rutgers University Institutional Review Board and Compliance Boards
* The Office for Human Research Protections in the U.S. Dept. of Health and Human Services
* **List every other class of persons or organizations not affiliated with Rutgers University** towhom the subject’s information might be disclosed (for example, a sponsor of the research, a data safety monitoring board, outside data analysis companies, the National Institutes of Health, etc.)

If study data will be protected by a Certificate of Confidentiality (CoC), information about this protection should appear here. To learn about CoCs and the language that should appear in the consent document, go to HSPP Toolkit Forms & Templates Special Passage CoC.

**What Will Happen To My Information—data, recordings and/or images—And Biospecimens Collected For This Research After The Study Is Over?** Delete reference to biospecimens if not applicable to your research.

* If you do not plan to use or distribute subjects’ information or biospecimens—with or without identifiers removed—for secondary research: The information (add or replace with biospecimens, if applicable) collected about you (or from you) for this research will not be used by or distributed to investigators for other research.
* If you plan, or think you may at some future time, use de-identified data or biospecimens for secondary research: After information that could identify you has been removed, de-identified information (add or replace with biospecimens, if applicable) collected for this research may be used for other research we conduct without obtaining additional informed consent from you.
* If you plan to use or distribute identifiable information or biospecimens for secondary research use the Addendum Consent Template titled: “Addendum Consent to Store Identifiable Biospecimens or Information for Future Research” as your guide. It is found at HSPP Toolkit: Forms & Templates Consent Addenda. If use of identifiable data or biospecimens in secondary research is required for subjects to take part in the main study, the relevant information you abstract from the Addendum must appear in this section of the main consent. If participation in secondary research is optional, you may simply revise the Addendum and append it to the main consent.
* If you anticipate that secondary research will or may 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 collected biospecimens) contact the IRB for further guidance.

**What Will Happen If I Am Injured During This Study?**

Include this section for greater than minimal risk studies ONLY. (Delete this entire section—including the heading if this is a minimal risk study.) Select the appropriate text as follows:

If the study **is industry-sponsored** use the following text ONLY:

Subjects in this study may be exposed to certain risks of personal injury in addition to those associated with standard forms of treatment. In addition, it is possible that during the course of this study, new adverse effects that result in personal injury may be discovered.

If you get ill or are injured as the direct result of being in this study inform the Principal Investigator as soon as possible. The Institution will make appropriate referrals for treatment. The Study Sponsor shall reimburse all the reasonable and necessary costs of diagnosis and treatment of any Study subject injury, including hospitalization, if it:

1. Is not a medical condition that you had before you started the study;
2. Is not the result of the natural progression of your disease or condition;
3. Is not caused by your failure to follow the study plan; and
4. Is not proved to be directly caused by the Institution’s negligence or misconduct.

There are no other plans for the University to provide other forms of compensation (such as lost wages) to you for research related illnesses or injuries. However, by signing this form, you are not giving up any legal rights to seek further compensation.

If the study **is not industry-sponsored**, choose the following text ONLY:

**For Research on Subjects With A Disease Or Medical Condition:** Subjects in this study will be exposed to certain risks of personal injury in addition to those associated with standard forms of treatment, which include: [provide a complete description if not provided elsewhere in the consent form, or refer reader to appropriate section of form]. In addition, it is possible that during the course of this study, new adverse effects of [fill in name of test, device, procedure, etc.] that result in personal injury may be discovered. The University will make appropriate referrals for medical and/or dental treatment for subjects who sustain personal injuries or illnesses as a direct consequence of participation in the research. The subject’s health insurance carrier or other third-party payer will be billed for the cost of this treatment; provided that the University shall not submit to federally funded programs, e.g., Medicare, Medicaid or TRICARE/CHAMPUS, for reimbursement first if submission to such programs is prohibited by law. No financial compensation will be provided by the University and no other type of assistance is available from the University. However, by signing this form, you are not giving up any legal rights to seek further compensation.

**What Will Happen If I Do Not Wish To Take Part In The Study Or If I Later Decide Not To Stay In The Study?**

It is your choice whether to take part in the research. You may choose to take part, not to take part or you may change your mind and withdraw from the study at any time. If you do not want to enter the study or decide to stop taking part, your relationship with the study staff will not change, and you may do so without penalty and without loss of benefits to which you are otherwise entitled.

Choose the appropriate text on how you will handle data collected prior to a subject’s decision to withdraw from the study:You may also withdraw your consent for the use of data already collected about you, but you must do this in writing to [PI name and address] . **OR** Any data that has already been collected cannot be withdrawn because there may not be any identifiers to link the data with you.

**NOTE**: Additional language that may be appropriate in this section, such as:

**EXAMPLE:** Any data that has already been sent to (Sponsor Name) or to the Data Coordinating Center cannot be withdrawn because there may not be any identifiers with the data.

**EXAMPLE:** At any time, the study doctor can take you out of this study because it would not be in your best interest to stay in it. Your study doctor can stop your continued participation even if you are willing to stay in the study.

**EXAMPLE:** If you decide to withdraw from the study for any reason, you may be asked to return for at least one additional visit for safety reasons.

**Who Can I Contact If I Have Questions?**

If you have questions, concerns or complaints about the research, wish more information [*Add if applicable*: or if you feel you may have suffered a research related injury], you can contact the Principal Investigator: *[Provide investigator’s name, Department and Rutgers contact number or email address.][For students only:* You can also contact my faculty advisor *[provide name and Rutgers contact info.]*

If you have questions, concerns, problems, information or input about the research or would like to know your rights as a research subject, you can contact the Rutgers IRB or the Rutgers Human Subjects Protection Program via phone at (973) 972-3608 or (732) 235-2866 or (732) 235-9806 OR via email [irboffice@research.rutgers.edu](mailto:irboffice@research.rutgers.edu), or you can write us at 335 George Street, Liberty Plaza Suite 3200, New Brunswick, NJ 08901.

**For studies involving the use of Protected Health Information (PHI)\* stored in medical records, add the following HIPAA Authorization (Permission) Section. If the study does not propose to use PHI, this HIPAA Authorization Section is not needed and must be deleted.**

**PERMISSION (AUTHORIZATION) TO USE OR SHARE HEALTH INFORMATION THAT IDENTIFIES YOU FOR A RESEARCH STUDY**

The next few paragraphs tell you about how investigators want to use and share identifiable health information from your medical record in this research. Your information will only be used as described here or as allowed or required by law. If you sign this consent form, you agree to let the investigators use your identifiable health information in the research and share it with others as described below. Ask questions if there is something you do not understand.

**What Is The Purpose Of The Research And How Will My Information Be Used?**

You are being invited to take part in this research study which is described at the beginning of this form. The purpose of collecting and using your health information for this study is to help investigators answer the questions that are being asked in the research.

**What Information About Me Will Be Used?**

(Tailor the list to reflect only what your study will collect. Collect only what is needed to satisfy study aims and is consistent with what is outlined in the protocol to be collected.)

* All information in your medical record
* Hospital discharge summaries
* Radiology records or images (MRI, CT, PET scans)
* Medical history or treatment
* Medications
* Consultations
* Laboratory/diagnostic tests or imaging
* EKG and/or EEG reports
* Psychological testing, surveys or questionnaires
* Pathology reports, specimen(s) or slide(s)
* Operative reports (about a surgery)
* Dental records
* Emergency Medicine reports
* Other (specify)

**Who May Use, Share or Receive My Information?**

**(Required Text)**

The research team may use or share your information collected or created for this study with the following people and institutions:

* Rutgers University Investigators Involved In The Study
* The Rutgers University Institutional Review Board and Compliance Boards
* The Office for Human Research Protections in the U.S. Dept. of Health and Human Services

**(Additional Items as Applicable)**

* Hospital Personnel as Necessary For Clinical Care: (list only hospitals that apply):
  + University Hospital
  + Robert Wood Johnson University Hospital
  + Barnabas Health
* Non-Rutgers Investigators On the Study Team: (Insert the affiliation and location of investigators at other institutions or organizations)
* The Food and Drug Administration— (For studies involving drugs or biologics, etc.)
* **List every other class of persons or organizations not affiliated with Rutgers University** towhom the subject’s information might be disclosed (for example, a sponsor of the research, a data safety monitoring board, researchers at other institutions, outside data analysis companies, the National Institutes of Health, etc.)

Those persons or organizations that receive your information may not be required by Federal privacy laws to protect it and may share your information with others without your permission, if permitted by the laws governing them.

**Will I Be Able To Review My Research Record While The Research Is Ongoing?**

No. We are not able to share information in the research records with you until the study is over. To ask for this information, please contact the Principal Investigator, the person in charge of this research study.

**Do I Have To Give My Permission?**

No. You do not have to permit use of your information. But, if you do not give permission, you cannot take part in this study. (Saying no does not stop you from getting medical care or other benefits you are eligible for outside of this study.)

**If I Say Yes Now, Can I Change My Mind And Take Away My Permission Later?**

Yes. You may change your mind and not allow the continued use of your information (and to stop taking part in the study) at any time. If you take away permission, your information will no longer be used or shared in the study, but we will not be able to take back information that has already been used or shared with others. If you say yes now but change your mind later for use of your information in the research, you must write to the researcher and tell them of your decision: (insert the investigator’s name and address here).

**How Long Will My Permission Last?**

Your permission for the use and sharing of your health information will last until (List a specific date or event on which the subject’s permission for their health records will expire, e.g., “December 31, 2023” or “end of the research study”. If a subject’s permission will never end, or you don’t know an end-date, say so. Consider using the following sentence: “There is no set date when your permission will end. Your health information may be studied for many years.”

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| **AGREEMENT TO PARTICIPATE**  **Subject Consent:**  I have read this entire consent form, or it has been read to me, and I believe that I understand what has been discussed. All of my questions about this form and this study have been answered. I agree to take part in this study.  Subject Name (Print):  Subject Signature: Date:  **Signature of Investigator/Individual Obtaining Consent:**  To the best of my ability, I have explained and discussed all the important details about the study including all of the information contained in this consent form.  Investigator/Person Obtaining Consent Name (Print):  Signature: Date: |

**FOR NON-ENGLISH-SPEAKING SUBJECTS:**

Translation of the consent form (verbal or written) must have prior approval by the IRB. For more information, go to HSPP GUIDANCE Non-English-Speaking Subjects. See also HSPP Toolkit Forms & Templates Special Consent Considerations.

**SURROGATE OR LEGALLY AUTHORIZED REPRESENTATIVE CONSENT:**

Use of a surrogate or legally authorized representative to consent for an adult research subject must have prior approval by the IRB. For more information, go to HSPP GUIDANCE Surrogate Consent Process.

**SPECIAL CONSENT CONSIDERATIONS**

When research plans to enroll individuals’, who cannot read or write (illiterate or low literacy), who cannot see (blindness or vision-impairment), or who cannot hear (deafness or hearing-impaired), special protections apply, such as the need for an impartial witness to observe the consent conversation, interpretation of the consent conversation (American Sign Language) or translation of the consent/study documents (Braille). For more information, go to HSPP Toolkit Forms & Templates Special Consent Considerations.

**CONSENT ADDENDA:**

Investigators seeking consent to audio or visually record aspects of the research, take photographs, or store information or biospecimens for future research secondary to a main study will find consent addenda language at HSPP Toolkit Forms & Templates Consent Addenda.