**[USE YOUR DEPARTMENT LETTERHEAD]**

**SURROGATE CONSENT TO**

**TAKE PART IN RESEARCH**

This template [16.305 (HRP-502e)] should be used when obtaining consent from a surrogate on behalf of an adult with impaired decision-making capacity to take part in interventional research—research in which participants are assigned to receive one or more interventions and manipulations of the participant or the participant’s environment that are performed for research purposes so that the investigators can evaluate their effects (e.g., clinical trials, CBT, Behavioral Modification studies, or randomized outcome studies).

This form has 3 sections:

1. **PARTICIPANT CONSENT TO TAKE PART IN RESEARCH** – outlines the important details about research for which you seek consent from a surrogate to enroll an adult lacking decisional capacity. The form should be reviewed with both the individual and surrogate who represents them, as practicable.
2. **SURROGATE CONSENT** – to be reviewed and signed by the legally authorized representative (also known as LAR or surrogate) to give consent on behalf of the individual lacking decision-making capacity.
3. **CONSENT FOR INDIVIDUALS ENROLLED UNDER PRIOR SURROGATE CONSENT** – to be completed by the research participant if/when they regain decision-making capacity to give (or decline) consent to continue in the research. This part is not applicable if the participant does not regain decision-making capacity (or never possessed capacity).

**INSTRUCTIONS:**

* **[BLUE]** highlighted text provides instructions to guide you in constructing the consent document.
* **[GREEN]** highlighted text provides different scenarios/options.
* Delete all instructional text and scenarios that are not applicable to your research before uploading the document to e-IRB+.
* The consent document should be written at a 6th to 8th grade reading level.
* For more information about the surrogate consent process, go to [HRPP GUIDANCE Surrogate Consent Process](https://research.rutgers.edu/researcher-support/research-compliance/human-research-protection-program/hrpp-guidance-topics).
* **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 HRPP Toolkit 1.003 (HRP-103a) Standard Operating Procedures to learn more](https://research.rutgers.edu/researcher-support/research-compliance/human-research-protection-program/toolkit#tab=panel-4).]
* Visit the [Human Research Protection Program Toolkit | Rutgers Research](https://research.rutgers.edu/researcher-support/research-compliance/human-research-protection-program/toolkit) to obtain referenced Toolkit Forms & Templates
* Visit the [HRPP Guidance Topics | Rutgers Research](https://research.rutgers.edu/researcher-support/research-compliance/human-research-protection-program/hrpp-guidance-topics) to obtain referenced Guidance documents.
* Contact the IRB Office at [irboffice@research.rutgers.edu](mailto:irboffice@research.rutgers.edu) if you need further assistance.

**TITLE OF RESEARCH:** [Add the Title of the study here.]

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

**SECTION I. PARTICIPANT CONSENT**

A person who takes part in research is called a research or study participant. In this section, “you” always refers to the individual who will be the research participant.

|  |
| --- |
| [Fill in the blanks and, when complete, be sure your customized research summary appears immediately after the Title of the research & PI name/credentials. Keep the black box format. **NOTE:** The purpose of a Research Summary is to provide key information upfront to aid in comprehension when research details are many or complicated. **If the research is uncomplicated and can be described in 5 pages or less, you may delete this Research Summary & box as the need for a summary is no longer necessary.]**  **RESEARCH SUMMARY:** This consent form is part of an informed consent process for research, and it will provide information that will help you decide whether you want to take part in this research. It is your choice whether to take part or not.  **PURPOSE**: 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 research 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 research tasks at the Center; etc.].  **RISKS/BENEFITS: Possible harms or burdens** of taking part in the research 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].  **ALTERNATIVES**: An **alternative to taking part in the research** [state appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the prospective participant]. [If no alternatives exist, state] Your alternative to taking part in the research is not to take part in it. |

The information in this consent form will provide more details about the research and what will be asked of you if you choose to take part in it. If you have any questions now or during the research, if you choose to take part, you should feel free to ask them and should expect to be given answers you completely understand. After all your questions have been answered and you wish to take part in the research, 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 research?**

[Insert name of PI] is the Principal Investigator of this research. 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 research 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 RESEARCH: Add the name of the sponsor of the research here only if there is one. If there is no research sponsor, delete this paragraph.

NAME OF DRUG/DEVICE MANUFACTURER: Add the name of the manufacturer if the research involves a drug or device. If not applicable, delete this paragraph.

**Why is this research being done?**

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

**Who may take part in this research 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 research?**

Explain in lay language why the participant is being invited to take part in the research.

**How long will the research take and how many participants will take part?**

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

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

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

If the research plans to audio- or visually-record or photograph participants and such recordings/images are required to take part in the research, disclose here your plans to record/photograph participants 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/photography in an addendum following the permission to take part in research signature block. Find the 16.328 - Addendum Consent to Record or Photograph Participants in Research template at [HRPP Toolkit Forms & Templates Section Consent Addenda](https://research.rutgers.edu/researcher-support/research-compliance/human-research-protection-program/toolkit" \l "tab=panel-2&chapter=pconsent-addenda-p-17288).

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

Describe in lay language the risks or discomforts for each procedure or intervention.

Describe those that are: potential, immediate, and/or long-term. Include physical, psychological, social, financial, and reproductive risks, if applicable. The incidence of these risks should be stated as: rare, occasional, or common; providing examples such as: 1 out of 5 or 20%.

**Reproductive Risks of Harm**

Add information on reproductive risks of harm from drugs, devices, or procedures, if applicable.

The decision to recruit a participant (all persons of any sex and gender) to any research should always be at the discretion of the investigator and should be based upon: (1) the minimum contraceptive requirement in the protocol; (2) the investigator’s knowledge of that potential participant’s medical history and lifestyle; and (3) the risks of harm and/or benefits to the participant and any offspring. Please be sure to address reproductive risks of harm for all adult persons of any sex and gender as applicable. E.g., f**or those who can become pregnant:** The research drug in this research may…

**Suggested language for drug studies where it is expected that the drug may cause harm to a fetus:**

IF APPLICABLE: If you become pregnant during this research, you should notify the Principal Investigator of this fact as soon as possible, since the risks to your unborn child or to yourself are unknown.

IF APPLICABLE: The drug under research is known to cause birth defects in some animals. It is likely that it may also cause birth defects in people. For this reason, no one can be in this research who is pregnant or who could get pregnant while taking the research drug. If you can become pregnant and are having sexual relationships in which you may become pregnant, you must use birth control [list methods]. If you are unwilling to use adequate birth control measures, you should not sign up for this research and are asked not to sign this consent form.

Suggested language for studies involving a blood draw:

When your blood is drawn, there may be a bruise, or bleeding, or infection, at the place where your blood is drawn. However, infection is rare.

Suggested language if research drug may interact with other medications the participant is already taking:

You should not take any over-the-counter medicines, herbal products, vitamins, or food supplements while taking part in this research, unless you tell the Principal Investigator and get permission from the Principal Investigator to go on taking these medicines. You will follow the instructions of the Principal Investigator about the use of any of these products.

You should also tell the Principal Investigator about all medicines that other doctors may have prescribed for you to take.

Studies that propose to conduct genetic research must disclose risks of harm possible from such research. Required consent language is found at [HRPP Toolkit Forms & Templates - Special Consent Passage GINA](https://research.rutgers.edu/researcher-support/research-compliance/human-research-protection-program/toolkit" \l "tab=panel-2&chapter=pspecial-consent-passages-p-17286) 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 research?**

The benefits of taking part in this research 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 research. If there are no direct benefits, state the following instead: There are no direct benefits to you.].

**What are my alternatives if I do not want to take part in this research?**

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

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

**How will I know if new information is learned that may affect whether I am willing to stay in the research?**

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

**Will I receive the results of the research?**

If you anticipate the research will generate clinically relevant results, including individual research results, state here whether you will disclose the results to participants and, if so, under what conditions that will occur. If this does not apply to your research, omit this section in its entirety. Example:

In general, we will not give you any individual results from the research. 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 research?**

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

**Will I be paid to take part in this research?**

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

You will receive $ 15.00 for taking part in this research 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 participants will not be paid:

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

**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.

**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, Rutgers University would receive a part of the profits from any sales of the product.

**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 research. This means that Rutgers University could gain or lose money depending on the results of this research.

**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 research [or, the person leading this research, 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].

**Investigator Receives Money from the Sponsor Outside of the Research [Consulting, Advisory Boards, Speakers’ Bureau, etc.]:** This research is supported by money from [company].  In addition, [Investigator name], one of the investigators on this research [or, the person leading this research, depending on the situation], receives remunerationfrom [company] for work that is not a part of this research.  These activities may include consulting, advisory boards, giving speeches, or writing reports.

**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 research [or, the person leading this research, 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 research. This means that [investigator name] could gain or lose money depending on the results of this research.

**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 research [or, the person leading this research, 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.

**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 will be stored and maintained and who will have access to them. Describe any research 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 research with the following people and institutions:

* The Rutgers University Institutional Review Board
* The Office for Human Research Protections in the U.S. Dept. of Health and Human Services
* 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 participant’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 theresearch qualifies as a clinical trial or Basic Experimental Research Involving Humans [BESH] that must comply with a requirement for public registration, results reporting, and consent posting at its conclusion the following must be included: A description of this [clinical trial or Basic Experimental Research Involving Humans] will be available on [ClinicalTrials.gov](http://clinicaltrials.gov/), as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

If research data will be protected by a Certificate of Confidentiality (CoC), information about this protection should appear here. To learn more about CoCs and the language that should appear in the consent document about, go to [HRPP Toolkit Forms & Templates Special Consent Passage CoC](https://research.rutgers.edu/researcher-support/research-compliance/human-research-protection-program/toolkit" \l "tab=panel-2&chapter=pspecial-consent-passages-p-17286).

**What will happen to my information—data, recordings and/or images—and biospecimens collected for this research after the research is over?** Delete reference to biospecimens if not applicable to your 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: 16.329 - Addendum Consent to Store Identifiable Biospecimens or Information for Future Research as your guide. It is found at [HRPP Toolkit: Forms & Templates Consent Addenda](https://research.rutgers.edu/researcher-support/research-compliance/human-research-protection-program/toolkit" \l "tab=panel-2&chapter=pconsent-addenda-p-17288). If use of identifiable data or biospecimens in secondary research is required for participants 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.

**NIH funded genetic research:**

One-way researchers learn more is by sharing data and information. The United States National Institutes of Health (NIH) has developed data (information) banks that collect genetic data. The NIH stores this information in these public data banks for other researchers to use in future studies on any topic. This public information will not include your name or other information that could identify you. You will not receive any results from allowing your data to be placed in the NIH databanks. You will not be able to withdraw your information after it has been submitted to the NIH databanks.

We cannot guarantee that you will never be identified if your information is placed in the NIH databanks. The risk of others being able to trace this information back to you or relatives currently is very small but may grow in the future as new technologies are developed. There may be other risks that are not yet known.

**What will happen if I am injured during this research?**

Include this section for greater than minimal risk studies ONLY. (Delete this entire section—including the heading if this is minimal risk research.) Choose the appropriate text from one of the following examples and include text from one of these sections as-is.

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

Participants in this research 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 a direct result of being in this research inform the Principal Investigator as soon as possible. The Institution will make appropriate referrals for treatment. The research Sponsor shall reimburse all the reasonable and necessary costs of diagnosis and treatment of any research participant injury, including hospitalization, if it:

1. Is not a medical condition that you had before you started the research.
2. Is not the result of the natural progression of your disease or condition.
3. Is not caused by your failure to follow the research 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 research **is not industry-sponsored**, choose the appropriate text from one of the following examples and include text from one of these sections as-is:

**For Research on Participants with a Disease or Medical Condition:**

Participants in this research 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 research, new adverse effects of [fill in name of drug, device, procedure, etc.] that result in personal injury may be discovered. The University will make appropriate referrals for medical and/or dental treatment for participants who sustain personal injuries or illnesses as a direct consequence of participation in the research. The participant’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.

**For Patients Seeking Treatment Under a Single-Patient-Treatment, Emergency Use or Compassionate Use (Also Known as Early or Expanded Access) Protocol Involving More Than Minimal Risk Shall Contain the Following Information:**

Patients seeking treatment under [fill in name of the single patient treatment, emergency use or compassionate use protocol] will be exposed to certain risks of personal injury in addition to those associated with standard forms of therapy, 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 treatment, new adverse effects of [fill in name of drug, device, procedure, etc.] that result in personal injury may be discovered. The University will make appropriate referrals for medical and/or dental treatment for patients who sustain personal injuries or illnesses as a direct consequence of the treatment. The patient’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 research or if I later decide not to stay in the research?**

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 research at any time. If you do not want to enter the research or decide to stop taking part, your relationship with the research 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 participant’s decision to withdraw from the research: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.

If FDA-regulated, add: We are required by the Food and Drug Administration to continue to report anything that is related to the safety of the drugs (or devices) used in the research.

**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:** (If FDA applies) Even if you withdraw from taking part in the research, outcome data will continue to be collected about you, such as medical course or lab results obtained through medical chart review. Public records may also be consulted, such as those establishing survival status.

**EXAMPLE:** At any time, the Principal Investigator can take you out of this research because it would not be in your best interest to stay in it. The Principal Investigator can stop treatment even if you are willing to stay in the research.

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

**Who can I call if I have questions?**

If you have questions, concerns, or complaints about the research, wish more information, or if you feel you may have suffered a research related injury, you can contact: (Provide investigator’s name, Rutgers department, address and contact number)

If you have questions, concerns, problems, information or input about the research or would like to know your rights as a research participant, you can contact the Rutgers IRB/Human Research Protection Program via phone at (973) 972-3608 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 research 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 RESEARCH**

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 which is described at the beginning of this form. The purpose of collecting and using your health information for this research 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 research aims and is consistent with what is outlined in the eIRB+ application.)

* 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 research with the following people and institutions:

* Rutgers University Investigators Involved in the Research
* The Rutgers University Institutional Review Board
* 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:
  + he University Hospital (UH)
  + Robert Wood Johnson University Hospital (RWJUH)
  + Robert Wood Johnson Barnabas Health (RWJBH)
* Non-Rutgers Investigators on the Research 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 participant’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 the research participant’s 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 research is over. To ask for this information, please contact the Principal Investigator, the person in charge of this research.

**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 research. (Saying no does not stop you from getting medical care or other benefits you are eligible for outside of this research.)

**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 research) at any time. If you take away permission, your information will no longer be used or shared in the research, 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 participant’s permission for their health records will expire, e.g., “December 31, 2023” or “end of the research”. If a participant’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.”

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**SECTION II. SURROGATE CONSENT PROCESS**

Under certain circumstances, an individual can give consent for another person to take part as a Participant in this Research (hereinafter “Research”) because the Participant is unable to consent to this Research and the Participant has not expressed opposition either to this Research or to the determination of incapacity. This individual is called the Legally Authorized Representative, or Surrogate, and is providing Surrogate consent.

You are being asked to serve as the Surrogate for \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, who is called the Participant in this document. You are being asked to give permission for the Participant to participate in this Research. Your decision should be based on the Participant’s individual health care instructions and other wishes, if known, or on your best estimation of what you believe are the Participant’s personal values and what the Participant would choose for themself.

Would the person for whom you are signing consent want to take part in this Research?

This form tells you about this research. After reading this entire form and having this research explained to you by someone conducting this research, you can decide if you think the person for whom you are authorizing consent would want to take part in this research. It is important to note that the person for whom you are signing the consent for does not have to take part in this research in order to receive medical care outside this Research.

**What will happen if you, as the Surrogate, do not enroll the Participant in this Research, or if the**

**Participant, or you as the Surrogate, later does not want the individual to participate in this Research.**

The Surrogate can decide not to enroll the Participant. The Participant or the Surrogate can decide.

to discontinue participation in this Research at any time. Any decision by the Surrogate not to enroll the Participant or by the Participant or the Surrogate to discontinue the participation shall not affect the Participant including the Participant’s receipt of medical care outside the Research. The Participant may withdraw without penalty and without loss of any benefits to which they are entitled.

**Regardless of the Surrogate’s consent, the Investigator can take the Participant out of this Research at any time because it would not be in the Participant’s best interest to stay in it.**

|  |
| --- |
| **Surrogate Consent to Take Part in Research**  **Surrogate Consent**  I am the surrogate of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (print name of the participant), and I consent for him/her to take part in this research.  Name of Surrogate (Print): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **If documentation of assent of the adult represented by a surrogate (the participant of the research) is by having the participant sign the Surrogate Consent form, add the following Participant Assent Section:**  **Participant Assent**  Participant Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_ Investigator or Person Obtaining Assent initial here if Assent will not be obtained because the participant’s capacity to understand is so limited that they cannot be reasonably consulted.  **Investigator or Person Obtaining Consent**  I have explained and discussed the full contents of the Research including the information contained in this consent form. All questions of the research participant and those of their legally authorized representative have been accurately answered.  Person Obtaining Consent Name (Print): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Witness to Consent Process**  I have observed the consent process which included a description of the purposes and procedures of this Research and an opportunity for questions and answers about this Research. I attest that I am not a person involved in the design, conduct or reporting of the research or the participant, their guardian or authorized representative and that the requirements for informed consent to the research have been satisfied.  Name of Witness (Print): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_ |

**FOR NON-ENGLISH-SPEAKING PARTICIPANTS:**

Translation of the consent form (verbal or written) must have prior approval by the IRB. For more information, go to [HRPP GUIDANCE Non-English-Speaking Participants](https://research.rutgers.edu/researcher-support/research-compliance/human-research-protection-program/hrpp-guidance-topics). See also [HRPP Toolkit Non-English Considerations](https://research.rutgers.edu/researcher-support/research-compliance/human-research-protection-program/toolkit#tab=panel-2&chapter=pnon-english-short-forms-p-17290).

**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/research documents (Braille). For more information, go to [HRPP Toolkit Forms & Templates Special Consent Considerations](https://research.rutgers.edu/researcher-support/research-compliance/human-research-protection-program/toolkit#tab=panel-2&chapter=pspecial-consent-passages-p-17286).

**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 research will find consent addenda language at [HRPP Toolkit Forms & Templates Consent Addenda](https://research.rutgers.edu/researcher-support/research-compliance/human-research-protection-program/toolkit#tab=panel-2&chapter=pconsent-addenda-p-17288).

**SECTION III. CONSENT TO TAKE PART IN RESEARCH FOR INDIVIDUALS ENROLLED UNDER PRIOR SURROGATE CONSENT**

Under certain circumstances, someone can give consent for another person to take part in research. This person is providing “Surrogate Consent.” The Surrogate can make choices for the Participant, if the Participant is not able to make choices for themself. In fact, since (add date), you have been enrolled in this research by your Participant, (add name). If you wish to continue to take part in the research, please consent by signing the agreement to participate.

|  |
| --- |
| **AGREEMENT TO CONTINUE PARTICIPATION**  **Participant 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. My questions about this form and this Research have been answered. I agree to continue to take part in this Research.  Participant Name (Print): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Participant Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:  **Investigator or Individual Obtaining Consent**  To the best of my ability, I have explained and discussed all the important details about the Research including the information contained in this consent form.  Investigator/Person Obtaining Consent Name (Printed): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: |