**KEY INFORMATION AND ADULT CONSENT TO TAKE PART IN A RESEARCH STUDY**

*USE YOUR DEPARTMENT LETTERHEAD/ROWAN UNIVERSITY APPROVED LOGO*

DESCRIPTION IN BLACK FONTS are required language to be included on the form.

*INVESTIGATOR INSTRUCTIONS ARE IN ITALICS (in blue) – The instructions are included to assist in your submission. Those instructions must be deleted prior to submission*

*SUGGESTED LANGUAGE (in green) – When a section is optional, suggested language has been included, but suggested language may be altered as appropriate; however, the IRB will have the final say.*

*You can use I or YOU (First or Second Person) language throughout, but, be consistent. Second person is preferred. The entire consent document should be at the 8th grade reading level.*

**TITLE OF STUDY:**(*Add the Title of the study here.)*

**Principal Investigator:** (*Add the PI’s name here.)*

You are being asked to take part in a research study. This consent form is part of an informed consent process for a research study and it will provide key information that will help you decide whether you wish to volunteer for this research study.

Please carefully read the key information provided in questions 1-10 below. The purpose behind those questions are to provide clear key information about the purpose of the study, study specific information about what will happen in the course of the study, what are the anticipated risks and benefits, and what alternatives are available to you if you do not wish to participate in this research study.

The study team will explain the study to you and they will answer any questions you might have before volunteering to take part in this study. It is important that you take your time to make your decision. You may take this consent form with you to ask a family member or anyone else before agreeing to participate in the study.

If you have questions at any time during the research study, you should feel free to ask the study team and should expect to be given answers that you completely understand.

After all of your questions have been answered, if you still wish to take part in the study, you will be asked to sign this informed consent form.

You are not giving up any of your legal rights by volunteering for this research study or by signing this consent form.

The Principal Investigator, (Add the PI’s name here), or another member of the study team will also be asked to sign this informed consent.

1. **Who is the study sponsor? Include this section if your study is sponsored or if the study is conducted by Rowan inventor or if Rowan University is an investor as part of Rowan or Rowan Investigator invention.**

**Study Sponsor**: Add the name of the sponsor of the study here – (only if there is one). If there is no sponsor and the study is internal, remove this question on the consent form.

***Industry Sponsor:*** *An example of suggested language to be used for Industry-sponsored study is provided below.*

*XYZ COMPANY* is the sponsor of this research study. The study doctor is being paid to conduct this study according to a budget that will cover the costs of the study. The costs that are usually covered include things such as: physical examinations, laboratory tests required by the study, and the costs of collecting all of the information required by the study.

***Rowan Inventors proposing a study****: There are circumstances in which Rowan investigator could be the inventor and wants to conduct a research study as part of his/her invention. In such circumstances, use language in this section for a sponsored study if the investigator or University has a patent interest or other financial interest in the research.*

The investigator/ Rowan University is an investor in this company. The investigator(s) and Rowan University are joint owners of the patent for this drug/device and stand to gain financially if the results of this research prove that this drug/device helps the condition being studied.

1. **Why is this study being done (purpose of the study)?**

*Provide key information in full detail and in lay language, regarding the purpose of the study.*

1. **Who may participate in this study? And who may not?**

*Clearly provide the key information in detail about the inclusion and exclusion criteria. Include the following mandatory statement in this section:*

“Participation in this study is voluntary, refusal to participate will involve no penalty or loss of benefits you are entitled. You may discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled to.”

1. **Why have you been asked to take part in this study?**

*Provide key information by explaining in lay language why the subject is being invited to take part in the study.*

1. **What will you be asked to do or what this study involves if you take part in this research study?**

*Clearly provide key information in sufficient detail regarding all procedures that will take place during the study. Details should give better understanding to the subject so that they can make an informed decision whether to participate or not. Clearly identify those that are experimental. Use lay language at or about 8th grade level; avoid scientific terms.*

1. **How long will the study take and how many subjects will participate?**

*Explain in lay language how many subjects will participate in this study (for this site and study-wide if other sites are involved. Describe the duration of the individual’s participation in the study. (Not the length of the study for all subjects). Include the number of subjects that will participate in the study.*

*NOTE: Include a chart or diagram of activities if the study has a number or steps.*

1. **What are the risks and/or discomforts you might experience if you take part in this study?**

*Clearly provide key information in detail in lay language regarding the risks and/or discomforts for each procedure or intervention. Describe those that are: potential, immediate, and/or long-term. Include physical, psychological, social, and reproductive risks. Incidence of these risks should be stated as: rare, occasional, or common; providing examples such as: 1 out of 5 or 20%. Add information on reproductive risks of harm from drugs, devices or procedures. The decision to recruit a participant (male or female) to any study should always be at the discretion of the investigator and should be based upon: (1) the minimum contraceptive requirement in the protocol; the investigator’s knowledge of that potential participant’s medical history and lifestyle; and the risks of harm and or benefits to the participant and any offspring. Please be sure to address reproductive risks of harm for both men and women, as applicable.*

***Describe reproductive Risks of Harm***

*For Women: The study drug in this research may…*

*For Men: The study drug in this research may…*

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

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

*IF APPLICABLE: The drug under study 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 study who is pregnant or who could get pregnant while taking the study drug. If you are a woman of childbearing age and you are sexually active, you are asked to use one of the following methods of contraception while taking the study drug: LIST METHODS:*

*If you are unwilling to use adequate birth control measures, you should not sign up for this study 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 study drug may interact with other medications the subject is already taking:***

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

*You should also tell the study doctor about all medicines that other doctors may have prescribed for you to take.*

1. **Are there any benefits if you choose to take part in this research study?**

The benefits of taking part in this study may be:

*Provide key information by providing a list of possible benefits, if any. Also include the following statement:* “However, it is possible that you might receive no direct personal benefit from taking part in this study.”

1. **What are your alternatives if you don’t want to take part in this study?**

*Provide key information if alternatives are available: The following alternative treatments are available if you choose not to take part in this study: If applicable, list alternative treatments:*

*If there are no alternative treatments available, use the following statement:* “There are no alternative treatments available. Your alternative is not to take part in this study.”

1. **What will happen if you are injured during this study?**

*Include this section for greater than minimal risk studies only; choose the appropriate text from one of the following examples and include text from one of these sections, as-is.*

***1. For research on normal healthy volunteers:***

Subjects in this study will be exposed to certain risks of personal injury, 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 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 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 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.

***2. For research on patients 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 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 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 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.

***3. 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 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.

**11. What will happen if you do not wish to take part in the study or if you later decide not to stay in the study?**

*Participation in this study is voluntary. You may choose not to participate or you may change your mind at any time.*

*If you do not want to enter the study or decide to stop participating, 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.*

*You may also withdraw your consent for the use of data already collected about you, but you must do this in writing to Dr. …………….(provide address.)*

*NOTE: Additional language that may be appropriate:*

*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 treatment even if you are willing to stay in the study.*

*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.*

1. **Will there be any cost to you to take part in this study?**

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

**NOTE TO RESEARCHERS REGARDING INCLUSION OF LANGUAGE IF IDENTIFIABLE PRIVATE INFORMATION OR IDENTIFIABLE BIOSPECIMMEN ARE GOING TO BE COLLECTED.**

**Include on the consent form questions 13 – 16 if you are collecting identifiable private information or my identifiable biospecimen for this research study. If not, skip to Question # 17.**

1. **Am I providing my identifiable private information or my identifiable biospecimen as part of this research study?**

*Include this question only if the study involves the collection of identifiable private information or identifiable biospecimen as part of this research study. If so, include the following statement:*

*“We are collecting identifiable private information of identifiable biospecimen in this research study.” And include any one of the following exemplified language that is appropriate for your study.*

***Example 1:***After collecting your identifiable private information or identifiable biospecimen, we may remove the identifiers and after such removal, we may use your information or biospecimen for future research studies or distributed to another researcher for future studies without additional consent from you.

***Example 2****:* Your identifiable private information or identifiable biospecimen collected as part of this research study will not be used or distributed for future research studies.

1. **If researchers find medically relevant results, will they be informing you about the results obtained using your identifiable private information or identifiable biospecimen?**

*You may disclose in this consent form the possibility of informing medically relevant results to the subject. If so, describe in lay terms, how, what, and when the results will be disclosed to the subject. If you are not disclosing medically relevant information, state:*

We will not be disclosing any medically relevant results to you or to any else.

1. **Will your identifiable biospecimen be used for whole genomic sequencing (a process used to determine my complete DNA in a single test)?**

***If you are not performing whole genomic sequencing, please state:***

Your identifiable biospecimen will not be used for whole genomic sequencing.

*If you are performing whole genomic sequencing, please explain in simple terms the individual’s susceptibility to a broad range of conditions (some of which may be unexpected given personal and family history, risks they carry that are uncertain or unclear, change in interpretation and change in relevance to time, privacy concerns and relevance to family members and reproductive decision making).*

1. **Will you be receiving any financial or nonfinancial benefits from the products, tests, or discoveries resulting from the use of your identifiable private information or identifiable biospecimen?**

You will not be receiving any financial benefit from the products, tests or discoveries resulting from the use of your identifiable private information or identifiable biospecimen.

1. **Where will this study be conducted?**

*Provide the exact location where this study will be conducted*.

1. **How will you know if new information is learned that may affect whether you are willing to stay in this research study?**

*During the course of 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.*

1. **How will information about you 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.

*Insert a description of how record and data/specimens 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.*

*If the**study is a clinical trial, the following must be included.*

A description of this clinical trial will be available on 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.

1. **Will you be paid to take part in this study?**

*Clearly outline how subject will be paid.*

*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 gift cards will be obtained via Rowan University Accounts Payable, include the language below:*

Personal information, such as SSN, ITIN, name, and address, may be collected for tax reporting purposes related to compensation for participation in this study and will not be included as research data. Tax law requires collection of personal information for IRS reporting purposes. You may be required to pay any tax that is due. You may choose to participate in this study and not accept compensation if you do not wish to provide your personal information for tax reporting purposes.

*If subject will not be paid:* You will not be paid for your participation in this research study.

1. **Who can you call if you have any questions?**

If you have any questions about taking part in this study or if you feel you may have suffered a research related injury, you can call the study doctor:

*(Provide investigator’s name)*

*Department*

856-*Contact Number*

If you have any questions about your rights as a research subject, you can call:

*EXAMPLE:* *Office of the Institutional Review Board*

*(856) 566-2712 Stratford*

*Or*

*Office of the Institutional Review Board*

856-256- 4078 Glassboro

1. **What are your rights if you decide to take part in this research study?**

You have the right to ask questions about any part of the study at any time. You should not sign this form unless you have had a chance to ask questions and have been given answers to all of your questions.

***For studies involving the use of Protected Health Information (PHI), include the following HIPAA Authorization Section:***

***(Protected Health Information (PHI) under HIPAA means any information that identifies an individual and relates to at least one of the following:***

* ***The individual’s past, present or future physical or mental health.***
* ***The provision of health care to the individual.***
* ***The past, present or future payment for health care)***

***If the study does not involve health information, you do not need to include the HIPAA Authorization Section. Proceed to “Agreement to Participate section.***

**AUTHORIZATION TO USE YOUR HEALTH INFORMATION FOR RESEARCH PURPOSES**

Because information about you and your health is personal and private, it generally cannot be used in this research study without your written authorization (permission). If you sign this consent form, it will provide that authorization. The next few paragraphs tell you about how your health information will be used or disclosed in the study. Your information will only be used in accordance with this authorization and informed consent form as required or allowed by law. Because we are committed to protecting your health information, some of the paragraphs that follow repeat what we described to you earlier in this consent form about what information we will collect about you, how we will use it, when or if it will be shared with others, and the measures we will take to protect your privacy and the confidentiality of your personal information.

Please read this authorization section and the consent form carefully. Ask questions if anything is not understandable to you.

1. **What is the purpose of this research study and how will my health information be utilized in the study?**

*(Provide a description of the study, such as its purpose, and describe how the individual’s health information will generally be used in the study, including any publication. If this is a clinical trial, also explain that the information in some form will be submitted to the sponsor and the FDA.)*

1. **Do I have to sign this authorization form?**

You do not have to sign this authorization form. But if you do not, you will not be able to participate in this research study and receive any research-related products. However, signing the form is not a condition for receiving any medical care outside the study.

1. **If I sign, can I revoke my authorization or withdraw my information later?**

If you decide to participate, you are free to withdraw your authorization regarding the use and disclosure of your health information (and to discontinue any other participation in the study) at any time. After any revocation, your health information will no longer be used or disclosed in the study, except to the extent that the law allows the researchers to continue using and disclosing your information. Therefore, you should be aware that the researchers may continue to use and disclose the health information that was provided before you withdrew your authorization if necessary to maintain integrity of the research or if the data had already been stripped of all identifiers.

If you wish to revoke your authorization for the research use or disclosure of your health information in this study, you may do so in writing by contacting *(investigator’s name, address, and contact information).*

1. **What personal information will be used or disclosed?**

Your health information related to this study, may be used or disclosed in connection with this research study, including, but not limited to, (*List or describe any and all medical information collected from or about the subject in connection with this study. For example: all information in a medical record, certain information indicating or relating to a particular medical condition, blood and other tissue samples and related records, physical examinations, x-rays, MRI’s, etc.)*

1. **Who may use or disclose the information?**

The following parties are authorized to use and/or disclose your health information in connection with this research study:

* The Rowan University-Institutional Review Board

*(Please list every other class of persons or organization affiliated with Rowan University (for example, the research team, the study coordinators, etc.)* *who might need to use and/or disclose the subject’s information in connection with this study.)*

1. **Who may receive/use the information?**

The parties listed in the preceding paragraph may disclose your health information to the following persons and organizations for their use in connection with this research study:

* The Office for Human Research Protections in the U.S. Department of Health and Human Services.

*(Please list every other class of persons or organization not affiliated with Rowan University (for example, a sponsor, data safety monitoring board, collaborators at other institutions, outside data analysts, the National Institutes of Health, the Food and Drug Administration, etc.) to whom the subject’s information might be disclosed.)*

Your information may be re-disclosed (shared) by the recipients described above, if they are not required by law to protect the privacy of the information.

1. **When will my authorization expire?**

Your authorization for the use and /or disclosure of your health information will expire … *(List a specific date on which the authorization will expire, e.g., “expire on December 31, 2015.” If a participant’s authorization will never expire, state so. If you are uncertain as to when the authorization will expire, you may say “There is no set date at which your authorization will expire. This is because the information used and created during the study may be analyzed for many years, and it is not possible to know when this will be complete.”)*

1. **Will access to my research study record be limited during the study?**

To maintain the integrity of this research study, you may not have access to any health information developed as part of this study until it is completed. At that point, you would have access to such health information if it were used to make medical or billing decisions about you and was included in your official medical record.

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**AGREEMENT TO PARTICIPATE**

I have read this entire 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 or this study have been answered.

Subject Name:

Subject Signature: Date:

**Signature of Investigator/Individual Obtaining Consent:**

To the best of my ability, I have explained and discussed the full contents of the study including all of the information contained in this consent form. All questions of the research subject and those of his/her parent or legal guardian have been accurately answered.

Investigator/Person Obtaining Consent:

Signature: Date:

*FOR NON-ENGLISH SPEAKING SUBJECTS:*

*Translation of the consent document (either verbal or written) must have prior approval by the IRB. Contact your local IRB office for assistance.*

*SURROGATE OR PROXY CONSENT*

*Use of a surrogate or proxy to consent for a research subject must have prior approval by the IRB. Information about the surrogate consent process is available on your local IRB website or contact your local IRB office for assistance.*

*CONSENT ADDENDUM: REQUEST TO STORE TISSUE [AND HEALTH INFORMATION] FOR FUTURE RESEARCH*

*Investigators that wish to develop a consent addendum seeking permission to store tissue for future research secondary to a main study may find recommended consent addendum language on the IRB Guidance Page titled Research Tissue or Data Bank* [*http://www.rowan.edu/som/hsp/guidance/index.html*](http://www.rowan.edu/som/hsp/guidance/index.html)*.*