**ADD LOGO**

**SCREENING CONSENT AND HIPAA AUTHORIZATION TO TAKE PART IN A RESEARCH STUDY**

Study Title:

Principal Investigator: Telephone Number:

This screening consent form describes information on procedures that you will undergo in the screening part of the study that will help you and the study doctor to decide whether you will be eligible to take part in the main study or not.

If you have questions at any time during the screening process or about the main study, you should feel free to ask the study team and you 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 screening part of the study, you will be asked to sign this informed consent form and HIPAA authorization for Screening.

1. **Why have you been asked to take part in the screening process for the main study?**

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

1. **What is the purpose behind screening?**

The purpose behind the screening part of the study is to determine whether individuals like you who are interested are eligible to participate in the main study.

Describe here the purpose of the main study in a language that is understandable to the lay person (about 8th grade level). Provide information that a reasonable person would understand before they agree (or give permission for their child) to participate in the study. If the study involves a drug, device or diagnostic procedure, provide a short description whether or not such research article or item is approved by the FDA. If the study involves children requiring parental screening consent, describe on the consent form whether such article or item is approved for use in children.

According to federal guidelines, it is appropriate to limit the scope of the screening consent to description of the screening tests and to the reasons for performing tests including a brief but not too detailed description of the study in which they may be asked to participate. If the screening indicates that the prospective study subject is eligible, the informed consent procedures for the main part of the study, as approved by the IRB must be followed.

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

Clearly describe in sufficient detail all procedures that will take place during the screening. Details should be given to provide a 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. **Who may participate in the screening process?**

Clearly describe the inclusion and exclusion criteria. Include the following mandatory statement in this section: Participation in the screening and main part of the 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. **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.

**Example1:** 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 inform me of the results obtained using my 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 will the results be disclosed to the subject. If you are not disclosing medically relevant information, state:

The study staff will not be disclosing any medically relevant results to you or to anyone else.

1. **Will I be receiving any financial or nonfinancial benefits from the products, tests, or discoveries resulting from the use of my 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. **What are the risks and/or discomforts you might experience if you take part in this study?**

Describe in lay language 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. Describe the risks of potential breech of confidential information. State that:

The study team will take every precaution to secure your personal information to ensure confidentiality.

1. **Are there any benefits to taking part in this study?**

There may not be any direct benefit in participating in this part of the study. However, the possible potentials benefits are: Describe the potential benefit including the potential of participating in the main study.

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

Describe if alternatives are available:The following alternatives are available if you choose not to take part in this study:

1. **What happens if you decide not to participate 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.)

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, -Contact Number

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

Provide IRB contact information.

1. **What are my rights if I 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.

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

(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.)

**2. 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.

**3. 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).

**4. 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.)

**5. 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.)

**6. 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.

**7. 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.”)

**8. 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.