**KEY INFORMATION AND PARENTAL/LEGAL GUARDIAN 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 in the form.

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

*SUGGESTED LANGUAGE (in green) – When a section is optional, suggested language has been included, but may be altered as appropriate.*

*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 a 6th to 8th grade reading level.*

**Key Information: Key information in questions 1- 10 should be in such detail so the subjects make informed decision whether to participate in the study or not).**

**(Start on a new page with Department Letterhead/Rowan Logo)**

**PARENTAL/LEGAL GUARDIAN CONSENT TO TAKE PART**

**IN A RESEARCH STUDY**

*When conducting studies involving minors, a Parent or Legal Guardian is required to provide permission to the minors’ participation in the study. Children who are capable of providing assent or have attained the developmental level to understand the study are to provide assent to their participation in the study. The assent form should clearly describe what children need to know, who you are, why you are asking them to be in your study, and what you will be doing to them or what you want them to do. The assent form may be based on the maturity of the children in the study. IRB makes a final decision on whether a child’s assent is needed for a particular study, and you can find a Parental/Guardian Consent Form template on the IRB webpage.*

**TITLE OF RESEARCH STUDY:** ***(Add the title of the research study here.)***

**PRINCIPAL INVESTIGATOR:** ***(Add the PI’s name here.)***

You are being asked to serve as the Parent/Legal Guardian for [this is where you will write the child’s name]\_\_\_\_\_\_\_\_\_\_\_, who is called the “Child” in this document. This parental/legal guardian consent form is part of an informed consent process for a research study. This form will provide information that will help you to decide whether you wish to volunteer your Child for this research study. It will help you to understand what the research study is about and what will happen over the course of the research study.

Please carefully read the key information provided in questions 1-10 below. The purpose behind these questions is to provide specific information about the purpose of the research study, specific information about what will happen over the course of the research study, what the anticipated risks and benefits to participating in the research study are, and what alternatives are available to you if you do not give consent for your Child to participate in this research study.

The research study team will explain the research study to you and they will answer any question you might have before volunteering your Child to take part in this research 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 research study.

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

After all of your questions have been answered, if you want your Child to be screened for eligibility to participate in the research study, you will be asked to sign this consent form.

By signing this form, you are not giving up any of your legal rights by allowing your Child to participate in this research study.

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

1. **Who is the research study sponsor?**

***(Add the name of the sponsor of the study here – only if there is one. If a sponsor does not exist, then delete).***

**Sponsor/s of this research study:**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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***Use language in this section for a sponsored research study or if the investigator or University has a patent interest or other financial interest in the research.***

***Select from the following examples***

***EXAMPLE OF SUGGESTED LANGUAGE FOR AN INDUSTRY SPONSOR:***

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

*IF APPLICABLE:* This company has an affiliation with the Principal Investigator and Rowan University and ***(Input company, agency or entity name here).*** ***State what the relationship is.***

***SUGGESTED LANGUAGE IF ROWAN INVENTOR(S) PROPOSING THE RESEARCH 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 research study if the investigator or University has a patent interest or other financial interest in the research study.*

1. **Why is your Child being asked to take part in this research study?**

Explain in lay language why the Child is being invited to take part in the research study. Explain and justify why the Child is appropriate for recruitment. Clearly state the requirements for participation.

1. **What will your Child be asked to do if they take part in this research study?**

Clearly provide key information in sufficient detail regarding all procedures that will take place during the research study.

Use lay language at or about 6th-8th grade level; avoid scientific terms.

Clearly describe all research steps that will take place during the research study in chronological

order and provide details. If multiple sessions and sites, then include building/location name and

what will occur at each location and for each multiple visit/session.

Clearly identify those steps that are experimental. Details should be such that the parent or legal guardian can make an informed decision whether to participate or not.

NOTE: Include a chart or diagram of activities if the research study has a number of steps. If your research study steps and procedures are not complex, do not include more than three visits or site locations, and is written in simple, lay terms then you may combine the “Where will the research study take place” and “What will the Minor be asked to do if the Minor/Child takes part in this research study”

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

Explain in lay language the key information about the purpose of the research study. If conducting this research study for a thesis or dissertation, it should be mentioned here.

**5. Who may take part in this research 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 research study is voluntary. Refusal to participate will involve no penalty or loss of benefits to which you are entitled. You may discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled.”

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

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

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

***EXAMPLE OF SUGGESTED LANGUAGE:***

The research study will take place over a period of *(Input number of years here, if applicable)*. As a parent or legal guardian of the Child, we ask you to spend *(Input number of days here)* days a month for *(Input number of months)* months participating in this research study. Each session will last approximately *(Input number of hours here)* hours. Explain in lay language how many Children will participate in this research study (for this site and study-wide).

1. **What are the risks and/or discomforts your Child may experience if you permit them to take part in this research 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 risks of harm from drugs, devices or procedures. Please be sure to address reproductive risks of harm for both men and women, as applicable.*

***Suggested language for studies involving a blood draw:***

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

***Suggested language if study drug may interact with other medications the Child is already taking:***

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

*You should also tell the study doctor about all medicines that other doctors have prescribed for your Child.*

1. **Will your child receive any benefits for participating in this research study?**

The benefits of taking part in this research 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 your Child might receive no direct personal benefit from taking part in this research study.”

1. **What are your alternatives if you don’t want your Child to take part in this research 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 or other alternatives available. The alternative is your Child not to take part in this research study.”

1. **What will happen if your Child is injured during the research 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. Research on normal, healthy Children:*

Children in this research 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 research study, new adverse effects of (fill in name of drug, device, procedure, etc.) may be discovered and may result in personal injury. The Rowan University Principal Investigator 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 study. Your Child’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. Research on Children with a disease or medical condition:*

Children in this research 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 research study, new adverse effects of (fill in name of drug, device, procedure, etc.) that result in personal injury may be discovered and may result in personal injury. The Rowan University Principal Investigator 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 study. Your Child’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. Children 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:*

Your Child 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 research study, new adverse effects of (fill in name of drug, device, procedure, etc.) may be discovered and may result in personal injury. The Rowan University Principal Investigator 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. Your Child’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 want your Child to take part in the research study or if you later decide you do not want them to stay in the research study?**

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

If you do not want your Child to enter the research study or decide to stop participating, your relationship with the research 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 your Child, 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 Principal Investigator/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 if your Child takes part in this research study?**

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

IF YOU ARE COLLECTING IDENTIFIABLE PRIVATE INFORMATION OR IDENTIFABLE BIOSPEMIENS YOU MUST INCLUDE QUESTIONS 13-16, AS APPROPRIATE.

1. **Are you providing identifiable private information about your Child or identifiable biospecimen of your Child as part of this research study?**

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

*“*We are collecting identifiable private information or 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 Child’s 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 distribute to another researcher for future studies without additional consent from you.

***Example 2****:* Your Child’s 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 you of the results obtained using your Child’s identifiable private information or identifiable biospecimen?**

*You may disclose in this permission consent form the possibility of informing medically relevant or other results to the subject. If so, describe in lay terms, how, what, and when the results will be disclosed to the subject. If not, state:* We will not disclose any medically relevant or other results to you or to anyone else.

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

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

Your Child’s 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, relevance to family members, and reproductive decision making).*

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

You or your Child will not be receiving any financial benefit for discoveries resulting from this research study.

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

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

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

During the course of the research study, you will be updated about any new information that may affect whether you are willing for your Child to continue to participate in the study. If new information is learned that may affect your Child after the study or your Child’s follow-up is completed, you will be contacted.

1. **How will information about your Child be kept private or confidential?**

All efforts will be made to keep your Child’s personal information in your Child’s 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 or your Child 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 parent/legal guardian or Child will not be paid:* You or your Child will not be paid for your Child’s 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 research study or if you feel you may have experienced a research related injury, you can call the *Principal Investigator/study doctor*

*(Provide investigator’s name)*

*Department*

856-*Contact Number*

If you have any questions about your or your Child’s rights as a research study participant, you can call:

*EXAMPLE:*

*Office of the Institutional Review Board, RowanSOM, Stratford Campus*

*856-566-2712*

*Or*

*Office of the Institutional Review Board, Glassboro Campus*

856-256- 4078

1. **What are your and your Child’s rights if you provide consent for your Child to take part in this research study?**

You have the right to ask questions about any part of the research 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 THE SUBJECT’S HEALTH INFORMATION FOR RESEARCH PURPOSES**

Information about the Subject’s health is personal and private and generally cannot be used without written authorization. This authorization form is intended to inform the Parent/Guardian about how the Subject’s health information will be used or disclosed in the Study. The Subject’s information will only be used in accordance with both this authorization form and the informed consent form, and as allowed by law. Parents/Guardians should read this form carefully before signing it.

**What is the purpose of this research study and how will the Subject’s health information be utilized in this Study?**

*(Provide a description of this Study, such as its purpose, and describe how the Subject's health information will generally be used in this 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.)*

**Does the Parent/Guardian have to sign this authorization form?**

The Parent/Guardian does not have to sign this authorization form. But if the Parents/Guardian does not, the Subject will not be able to participate in this Study. *(If this Study includes any treatment, add the following: “, including receiving any research-related treatment.”)*  **Signing the form is not a condition for the Subject to receive medical care outside this Study.**

**If the Parent/Guardian signs, can the Parent/Guardian revoke it or withdraw from the research later?**

If, on behalf of the Subject, the Parent/Guardian decides to participate, the Subject or Parent/Guardian is free to revoke the authorization regarding the use and disclosure of the Subject’s health information at any time. If the Subject or the Parent/Guardian wishes to revoke this Authorization, the Subject or the Parent/Guardian must contact *(Insert Principal Investigator’s name and contact information)*. Such a revocation of the authorization will terminate Subject’s participation in the Study. After any revocation, the Subject’s health information will no longer be used or disclosed in this Study, except to the extent allowed by law. Any such revocation of this authorization will not prejudice Subject’s receipt of medical care outside the Study.

**What health information will be used or disclosed?**

The Subject’s health information related to this Study may be used or disclosed in connection with this 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.)*

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

The following parties are authorized to use and/or disclose the Subject’s health information in connection with this Study:

* The RowanSOM-Institutional Review Board

*(Please list every other class of persons or organization affiliated with RowanSOM, 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.)*

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

The parties listed in the preceding paragraph may disclose the Subject’s health information to the following persons and organizations for use in connection with this 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 RowanSOM, 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.)*

The Subject’s information may be re-disclosed by the recipients described above. RowanSOM is not in a position to control the re-disclosure if they are not required by law to protect the privacy of the information.

**When will authorization expire?**

Authorization for the use and/or disclosure of the Subject’s health information will expire … *(List a specific date on which the authorization will expire, e.g., “expire on December 31, 2015.” If you are uncertain, choose a date that will provide ample time for this Study to be completed.)*

**Will the Subject or the Parent/Guardian have access to the Study file during the Study?**

To maintain the integrity of this Study, neither the Subject nor the Parent/Guardian has access to the health information contained in the Study file until this Study is completed. At the completion of this Study, the Subject and the Parent/Guardian has access to such health information if it is used to make medical or billing decisions about the Subject and was included in the Subject’s official medical record.

**AGREEMENT TO PARTICIPATE**

**Parent/Legal Guardian Consent**

The purpose and procedures for this research study have been described to me verbally and in writing. My questions about this research study have been answered and I have been provided with information about who to contact with additional questions.

**As a Parent/Legal Guardian, I freely give my consent to have *\_\_\_[insert Child’s name here]\_\_* take part in this research study and authorize that their information as described above, be collected/disclosed in this research study.** I understand that by signing this form I am agreeing for the Child named above to take part in this research study. I understand that I have a right to make a copy or receive a copy of this form upon request.

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Signature of Parent/Legal Guardian Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed Name of Parent/Legal Guardian

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

To the best of my ability, I have explained and discussed the purposes and procedures of this research study including all of the information contained in this consent form. All questions of the Child and those of their parent/legal guardian have been accurately answered.

Signature: Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Investigator/Person Obtaining Consent

PLEASE NOTE: IF THIS IS A COLLABORATIVE STUDY WITH ROWAN SOM IN WHICH YOU PLAN TO COLLECT PROTECTED HEALTH INFORMATION, THE IRB MAY ASK YOU TO INCLUDE THE SECTION ON “HIPAA AUTHORIZATION” OR REQUEST FOR WAIVER OF AUTHROATION. IF YOU NEED ADDIIONAL INFORMATION, PLEASE CONTACT THE IRB OFFICE.