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

**ADULT CONSENT FORM FOR SOCIAL AND BEHAVIORAL RESEARCH**

*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 1-9 and 14 below. The purpose behind those questions is to provide clear 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 question 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.

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.

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. W**hat is the purpose of the study?**

*Provide key information about the purpose of the study so subjects may make a decision to participate or not to participate. Explain in lay language the purpose of the study. Where possible, limit length of sentences to twelve words (or fewer). If conducting this study for a thesis or dissertation, it should be mentioned here.*

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

*Provide the key information explaining in lay language why the subject is being invited to take part in the study. Explain and justify why the subject is appropriate for recruitment. Clearly state the requirements for participation.*

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

 *Use lay language to clearly describe all research steps that will take place during the study in chronological order and provide details. If multiple sessions and sites are part of the study, then include building/location name and what will occur at each location and for each multiple visits/sessions. Clearly identify those that are experimental.*

 ***NOTE:*** *Include a chart or diagram of activities if the study has a number or steps. If your study steps and procedures are not complex, do not include more than 3 visits or site locations, and is written in simple, lay terms then you may combine the “Where will the study take place?” and “What will you be asked to do if you take part in this research study?”*

1. **Who may take part in this research study? And who may not?**

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

1. **How long will the study take and where will the research study be conducted?**

 *Clearly describe how long the study may take in terms of hours, days, weeks, months, years. Describe the exact location.*

1. **How many visits may it take to complete the study?**

 Clearly describe the number of visits and location in terms of daily, weekly, monthly visits.

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

Provide key information about the most important risks or reasons for the prospective subject who may NOT wish to volunteer to participate in the research. Risks must include those that are likely to occur or less likely to occur or rare but serious. Include potential, immediate, and/or long-term risks including physical, psychological, social risks. Incidence of these risks should be stated as: rare, occasional, or common; providing examples such as: 1 out of 5 or 20% possibility.

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

 Provide key information about the benefits, including that there may not be any direct benefit to you from participating in this study or benefits to others or society in general. You may also state the study doctor may benefit from the study by learning more about a specific problem or disease that may help him/her in dealing with future treatments of behaviors with conditions like yours.

1. **What are the alternatives if you do not wish to participate in the study?**

Provide key information about alternative treatments/procedures that are key to the participant’s choice. Discuss those that might be advantageous to the subject or indicate if no known alternative exists. State what you will be recommending if no other alternatives are available including “Your alternative is not to participate in the study.”

1. **How many subjects will be enrolled in the study?**

 *Provide the number of subjects to be enrolled in the study.*

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, you will be contacted.

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.

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

 Clearly outline how the subject will be paid.

 *EXAMPLE OF SUGGESTED LANGUAGE:*

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

* $ 5.00 at your first session
* $ 5.00 at your second session
* $ 5.00 at your third session

*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, state “*You will not be paid for your participation in this research study.”

1. **Are you providing any identifiable private information as part of this research study?**

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

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

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

Example 2: Your identifiable information will not be used in any of the future research projects or disclosed to anyone outside of the research team.

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. Your personal information may be given out, if required by law. Presentations and publications to the public and at scientific conferences and meetings will not use your name and other personal information.

 *(Insert a description of how record and data/specimens will be stored and maintained (do not have to include specific locations or addresses of where data is stored) and who will have access to them. Describe any study specific issues that may increase the risk of breach of confidentiality.)*

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

**Delete this question if the study is Minimal Risk and if there is a reasonable possibility an injury may not occur.**

If study is more than minimal risk and there is a reasonable possibility that an injury may occur, describe in lay language, what will happen if a subject is injured during the study, such as sending subjects to a wellness center or calling 911. Include if there is any cost involved or billing the insurance company for the services. However, mention that Rowan University will not responsible for the costs.

 *Not Greater than Minimal Risk studies may use the suggested language below, or develop language based on the example language below:*

*EXAMPLE OF SUGGESTED LANGUAGE:*

If at any time during your participation and conduct in the study you have been injured, you should communicate those injuries to the research staff present at the time of injury. The Principal Investigator’s name and contact information is provided on this consent form.

*Include this section for greater than minimal risk studies only.*

*You may 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 device, procedure, etc*.) *that result in personal injury may be discovered. Rowan 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 Rowan 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 Rowan University and no other type of assistance is available from Rowan University.*

1. **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 *(Input Principal Investigator Name and Address)*

 If you decide to withdraw from the study for any reason, you may be asked to participate in one meeting with the Principal Investigator.

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 Principal Investigator:

 *(Principal Investigator’s Name)*

*Department*

856-*Contact Number*

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

Office of Research Compliance

 (856) 256-4078– Glassboro/CMSRU

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.

**AGREEMENT TO PARTICIPATE**

I have read the entire information about the research study, research risks, benefits and the alternatives, 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 and I agree to volunteer to participate in the study.

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.