*(Use your department letterhead)*

*INVESTIGATOR INSTRUCTIONS ARE IN BLUE ITALICS – THE INSTRUCTIONS ARE INCLUDED TO ASSIST IN YOUR SUBMISSION AND MUST BE DELETED PRIOR TO SUBMISSION*

**CONSENT TO TAKE PART IN A RESEARCH STUDY FOR INDIVIDUALS ENROLLED UNDER PRIOR SURROGATE CONSENT**

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

Under certain circumstances, someone can give consent for another person to take part in a research study. This person is providing “surrogate consent.” The surrogate can make choices for the subject, if the subject is not able to make choices for him or herself. In fact, since *(add date),* you have been enrolled in this research study by your surrogate, *(add name).*

Now that you can make your own decision about whether or not to participate in this research study, please carefully review this form, which tells you about the research study. After reading through this form and having the research explained to you by someone conducting this research, you can decide if you wish to remain in the study or to withdraw. *(If appropriate, add: “Your decision to withdraw will not affect the medical treatment you receive at the University.”)*

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

After all of your questions have been answered, you will be asked to sign this informed consent form. You will be given a copy of the signed consent form to keep.

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**A. Who is conducting this research study?**

Dr. *(insert name of PI)* is the Principal Investigator of this research study. A Principal Investigator has the overall responsibility for the conduct of the study. However, there are often other individuals who are part of the research team.

Dr. *(PI)* may be reached at *provide contact phone number and address*.

*(ADD THE NAME OF THE SPONSOR OF THE STUDY HERE-ONLY IF THERE IS ONE)*

SPONSOR OF THE STUDY:

*Use language in this section for a sponsored study or if the investigator or University has a patent interest or other financial interest in the research. Select from the following examples and use the language most appropriate for the situation.*

*EXAMPLE OF SUGGESTED LANGUAGE:*

*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.

*IF APPLICABLE:*

This company has an affiliation with the investigator/Rowan University and .

*EXAMPLE OF SUGGESTED LANGUAGE:*

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.

**B. Why is this study being done?**

*Explain in simple lay language the purpose of the study. Limit sentences to twelve words (or fewer) where possible.*

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

*Explain why the subject was invited to take part in the study.*

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

*Clearly describe inclusion and exclusion criteria in lay language.*

**E. How long will the study take place?**

*Explain in simple lay language how many subjects will participate in this study and how long they will be participating.*

**F. How many subjects will participate?**

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

**What has already been done and what else will you be asked to do as part of this research study?**

*Clearly describe all procedures that take place during the study and then clearly outline which procedures are experimental. Use simple lay language to describe procedures.*

*NOTE: Include a chart or table of the procedures if the study has a number of steps.*

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

*Describe in simple lay language what the risks and discomforts may be for each procedure/intervention; Describe the potential, immediate and long-term discomforts and risks (include physical, psychological, social, and reproductive risks). If the incidence of these risks or discomforts is known, it should be stated in terms of rare, occasion, or common.*

*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 investigator of this fact as soon as possible, since the risks to your unborn child or to yourself are unknown.

*IF APPLICABLE FOR CLINICAL TRIALS:* 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 are asked not to remain in this study and asked not to sign this consent form.

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 investigator and get permission from the investigator 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 investigator about all medicines that other doctors may have prescribed for you to take.

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.

**Are there any benefits for you if you take part in this research study?**

The benefits of taking part in this study may be:

*LIST POSSIBLE BENEFITS*

However, you might receive no direct benefit from taking part in this study.

**What are your alternatives if you don’t want to continue in this study?**

You have the alternative to choose not to continue to participate in this research study. (*This statement is sufficient if there are no alternative for the participant.)*

*If there is an alternative:*

* *Describe any appropriate alternative procedures, drugs or devices that might be advantageous to the subject, and their relative risks and benefits.*

**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 go on 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.

**Is there be any cost to you to take part in this study?**

*Explain what the cost to the participant will be, if any. If the individual’s insurance company will be charge this should be noted.*

**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 records 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.)*

**What will happen if you are injured during this study?** *(Minimal risk studies do not require this section.)*

*USE ONLY THIS Rowan University STANDARD LANGUAGE FOR THIS SECTION.*

If you take part in this study, you may be exposed to certain risks of physical 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 these studies, new adverse effects of (*Fill in the name of the drug, device, procedure, etc.)* that result in physical injury may be discovered. Medical and/or dental treatment will be arranged by Rowan University for subjects who sustain physical injuries or illnesses as a direct consequence of participation in this research. Your insurance carrier or other third party payer will be billed for the cost of this treatment. No additional financial payment to you is available.

**What will happen if you do not wish to continue your participation in the study or if you later decide not to stay in the study?**

You may choose not to be in the study. If you do choose to take part it is voluntary. You may refuse to take part or may change your mind at any time.

If you do not want to remain the study and decide to withdraw from the study, 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.

At any time, the investigator can take you out of this study because it would not be in your best interest to stay in it, even if you are willing to stay in the study.

**Who can you call if you have any questions, concerns, or complaints?**

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:

*EXAMPLE: Name of Study Doctor*, MD, DO OR Name of Principal Investigator

*Department*

856-*Contact Number*

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

 *Office of the Institutional Review Board Rowan University School of Osteopathic Medicine* *(856) 566-2712*

 *Glassboro/CMSRU Institutional Review Board (856) 256-4058*

 *Be sure to only list the IRB above which is reviewing the Cayuse IRB application*

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

You are not giving up any of your legal rights by signing this informed consent form or by taking 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.

**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. If you sign this form, it will provide that authorization. The form is intended to inform 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 form and the informed consent form and as required or allowed by law. Please read it carefully before signing it.

**What is the purpose of this research study and how will your 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.)*

**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 continue my participation in this research study. *(If the study includes any treatment, add the following: “, including receiving any research-related treatment”.)* Signing the form is not a condition for receiving any medical care outside the study.

**If I sign, can I revoke it or withdraw from the research 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 us to continue using your information (e.g., necessary to maintain integrity of research). If you wish to revoke your authorization for the research use or disclosure of your health information in this study, you must contact *(investigator’s name and contact information).*

**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.)

**Who May use or Disclose the Information?**

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

Rowan University Institutional Review Board

Officials at Rowan University who are responsible for research oversight

*(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.*

**Who May Receive/use the Information?**

The parties listed in the preceding paragraph may disclose your health information to the following to 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 by the recipients described above, if they are not required by law to protect the privacy of the information.

**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 you are uncertain, choose a date provides plenty of time for your work to be completed.*

**Will access to my medical 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 decision 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.

\_\_\_\_\_\_\_\_\_ **I** **agree**  **OR** \_\_\_\_\_\_\_ **I** **do not agree** to continue to participate.

 (Initial (Initial)

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 have been accurately answered.

Investigator/Person Obtaining Consent:

Signature: Date: