**PLEASE USE YOUR DEPARTMENT LETTERHEAD**

**CONSENT FOR THE USE OF** *(Name of HUD)*

**INVESTIGATOR INSTRUCTIONS ARE IN ITALICS- THE INSTRUCTIONS ARE INCLUDED TO ASSIST IN YOUR SUBMISSIN, PLEASE DELETE ALL ITALICIZED TEXT PRIOR TO SUBMISSION**

This form is designed to provide you with information about the humanitarian use device that will be used in the procedure that you will have performed. Please take your time reviewing this information before you consent to its use.

**What is a Humanitarian Use Device?**

A Humanitarian Use Device is a device used to diagnose or treat a disease or condition that affects fewer than 4,000 individuals in the United States per year and for which no comparable device is available.

**Why is this procedure being done?**

You are being asked to consent to the use of the (name of device) because your doctor has determined that (provide rationale for use).

**What will be involved with the use of this device?**

*This section should include a brief description of the device and the procedures involved in its use.*

**What are the Risks From this Procedure?**

*Specify anticipated side effects and indicate possible remedial actions*.

**What are the Benefits of this Procedure?**

*Note anticipated benefits to patient.*

**What are Alternative Treatment Options?**

Instead of consenting to the use of (name of device) for have the following options for treatment:

**What if an Injury Occurs During the Procedure?**

You or your insurance carrier will be responsible for the cost of your hospitalization and all procedures you have during your hospitalization. The (name of device) is not an experimental device. However, because this is a new device, it is possible that your insurance carrier will refuse to pay for the device. If your insurance carrier refuses to pay, you will be responsible for the cost of the device and your treatment.

In the event you believe you have suffered a procedure-related injury or illness, you should contact *Dr. Name at (phone).* A procedure-related injury is an injury caused by the procedure(s) rather than an injury attributable to your underlying disease or condition.

If physical injury resulting from your participation in this procedure should occur, medical treatment will be available to you, including first aid, emergency treatment and follow-up care as needed.  You or your insurance carrier may be billed for the cost of any such medical treatment in the ordinary manner.

**What Are The Costs of Participating?**

The use of the *(name of device)* may lead to added costs to you and/or your insurance company.  Please ask about any expected added cost or insurance problems.  The cost of the *(name of device)* will be billed to your insurance company, but if they deny payment, you will be responsible for the cost of this device.

**Who Can You Call if You Have Questions or Problems?**

You have talked to Dr. *(name of PI)* or one of his colleagues about this procedure and he/she has answered your questions. Dr. *(name of PI)* can be reached at *(phone number)*. They will be available to answer any questions or concerns that you may have.

Information on the availability of treatment for any physical injury resulting from participation in this project may be obtained from(*name of PI*, project Principal Investigator, telephone number ( ) \_\_\_\_\_\_.

If you wish further information regarding your rights as a patient receiving a humanitarian use device, you may contact the Office of Research Compliance at 856-256-4078.

**How Will Information Be Kept Private (Confidential) And Authorization to Use Private Health Information?**

While your doctor will make every effort to maintain confidentiality of information obtained about you, it cannot be absolutely guaranteed, in part because other people may need to look at the information.

 The federal Health Insurance Portability and Accountability Act (HIPAA) require that the healthcare provider get your permission to use health information about you that is either created by or used in connection with this procedure.  This permission is called an Authorization. The information used includes your medical records, including HIV/AIDS related information (if any), and both clinical and research observations made during your participation in this procedure.

In this project, your health information will be collected and used to monitor your health status, to measure effects of drugs/devices/procedures, to determine results, and possibly to develop new tests, procedures, and commercial products.  Health information is used to report results of the procedure to sponsors and federal regulators and may be reviewed when projects are audited for compliance with protocol plans, regulations and policies.

The results of this project may be presented at scientific meetings or published in the medical literature. Any such use will not contain information that will identify you by name.  Identifiers such as photographs, audio or videotapes will only be used with your special written permission.  You may see the photographs and videotapes and hear the audiotapes before giving this permission.

The project investigator may share this consent form and records that identify you to meet regulatory requirements or for purposes related to this project to: 

    The manufacturer of the device, *(provide name),* or its agents

   Federal and state agencies that have authority over the use of a humanitarian use

device, Rowan University School of Osteopathic Medicine (RowanSOM) , or patients (for example: the Department of Health and Human Services, the Food and Drug Administration, the National Institutes of Health, the Office of Human Research Protection, or other governmental offices as required by law)

 Hospital or other accrediting agencies

Officials of the RowanSOM

    Clinical staff who may become involved in your care, if it is potentially relevant to treatment

    Your health insurer, or payer, if necessary, in order to secure their payment

Once Rowan University RowanSOM discloses information in your medical records, RowanSOM cannot guarantee that the recipient of the information will not redisclose your information and it may no longer be protected by federal law.

Your data may be used in scientific publications. If the findings from the study are published, you will not be identified by name. Your identity will be kept confidential. The exception to this rule will be when there is a court order or when a law exists requiring the study doctor to report communicable diseases. In this case, you will be informed of the intent to disclose this information to the state agency. Such a law exists in New Jersey for diseases such as cancer, infectious diseases such as hepatitis, HIV, viruses and many others.

 (*Sponsor)* will be allowed to examine the data in order to analyze the information obtained from the use of this device.

In applications for marketing authorization your data may be submitted to domestic and foreign regulatory agencies.

Your data may also be sent to domestic and foreign drug regulatory agencies if you should suffer an adverse event related to the device.

If you do not sign this approval form, you will not be able to take part in this research study.

You can change your mind and revoke this approval for the use of your data at any time. If you change your mind, you must revoke your approval in writing by contacting \_\_\_\_\_\_*insert doctor’s name*. Beginning on the date you revoke your approval, no new personal health information will be used for research. However, the doctor may continue to use the health information that was provided before you withdrew your approval.

You have the right to look at your health data at your doctor’s office and to ask for corrections of any kind to any of your data that is wrong.

You can change your mind and revoke this approval for the use of your data at any time. If you change your mind, you must revoke your approval in writing by contacting *insert doctor’s name*. Beginning on the date you revoke your approval, no new personal health information will be used. However, the doctor may continue to use the health information that was provided before you withdrew your approval.

You have the right to refuse to sign this consent form. By signing this consent form, you authorize the use and/or sharing of your protected health information.

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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, the procedure, and the Humanitarian Use Device have been answered.

I agree to participate.

Subject Name:

Subject Signature: Date:

**If Appropriate and Approved for this Procedure:**

Legally Authorized Representative:

Relationship: Date:

**Signature of Reader/Translator If the Subject Does Not Read English Well:**

The person who has signed above, , does not read English well. I read English well and am fluent in (*name of the language)*, a language that the subject (his/her parent(s)/legal guardian) understands well. I understand the content of this consent form and I have translated for the patient (his/her parent(s)/legal guardian) the entire content of this form. To the best of my knowledge, the patient (his/her parent(s)/legal guardian) understands the content of this form and has had an opportunity to ask questions regarding the consent form and the procedures/device, and these questions have been answered (his/her parent(s)/legal guardian).

Reader/Translator Name:

Reader/Translator Signature: Date:

Witness Name:

Witness Signature: Date:

**Signature of Individual Conducting Consent Process:**

To the best of my ability, I have explained and discussed the procedure and use of the device, including all of the information contained in this consent form. All questions of the patient and those of his/her parent(s) or legal guardian have been accurately answered.

Person Obtaining Consent:

Signature: Date: