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Maxim Mokin, MD, University of South Florida

The efforts in developing this agreement will prove to be instrumental in advancing early feasibility work and may provide US patients' earlier access to potentially helpful medical technologies.

IMPORTANT NOTE: This Informed Consent Form Template is based on FDA Guidance "Investigational Device Exemptions (IDEs) for Early Feasibility Medical Device Clinical studies, Including Certain First in Human (FIH) Studies", Appendix 3*. It is provided as a courtesy to Study Sponsors. Certain paragraphs and sections in this template may not apply based on investigational device and study requirements. The informed consent form should be adapted toreflect the device/procedure and prior experience with the device for the medical condition treated so the patient can make a well-informed decision. The informed consent form should reflect the study needs, regulatory and institutional review board requirements

*https://www.fda.gov/regulatory-information/search-fda-guidance-documents/investigational-device-exemptions-ides-early-feasibility-medical-device-clinical-studies-

INFORMED CONSENT TO PARTICIPATE IN AN EARLY FEASIBILITY STUDY

Title of Study: EARLY FEASIBILITY STUDY OF THE [INSERT DEVICE NAME]

Principal Investigator: [INSERT INVESTIGATOR NAME]

Sponsor: [INSERT SPONSOR NAME]

Emergency Telephone: [INSERT INVESTIGATOR PHONE]

INTRODUCTION

You have been invited to join an Early Feasibility Study to evaluate the **[INSERT GOAL OF STUDY]** of **[INSERT NAME OF THE DEVICE]**. The device is investigational and not approved by the FDA for your medical condition. A description of this study will be available at http://www.clinicaltrials.gov (reference study number), as required by law.

- This study is sponsored by [INSERT SPONSOR NAME]. Before you decide if you want to be involved in the study, it is important that you read and understand this information. Be sure to ask questions about anything that is unclear. Your Physician will answer your questions about the study, the device or any of the information being presented.
- The FDA or regulatory body has approved the clinical use of this device in an early feasibility study.

No study-related tests or procedures will be done before you sign this consent form.

PURPOSE AND BACKGROUND

The reason we are doing this research study is to look at the **[INSERT STUDY DEVICE]** to see if it can help treat **[INSERT MEDICAL CONDITION]**. This type of research study is called a “early feasibility study”. Early feasibility studies typically evaluate innovative devices or innovative uses of approved devices. These studies enroll a small number of patients and provide initial information on the basic safety and performance of the study device when used to treat **[INSERT**

BRIEF DESCRIPTION OF MEDICAL CONDITION]. There is often only limited data and experience treating this condition with the study device. Since, this is an early feasibility study, some risks are unknown, and there is no guarantee that the device will help you or improve your condition. It is possible, however, that the device may help improve your condition, and the information obtained during the study may help others with your condition.

Every research Site must get approval to conduct this study from an Institutional Review Board (IRB) [or an Ethics Committee (EC)]. This group of people reviews the study Protocol and the informed consent form to make sure the research study is ethical, and your safety and welfare rights are protected.

The device **[INSERT DEVICE NAME]** is a **[INSERT BRIEF DESCRIPTION OF DEVICE CHARACTERISTICS, FUNCTION, MODE OF OPERATION, INNOVATIVE FEATURES, AND A DECRIPTION OF WHAT THE DEVICE IS INTENDED TO AND HOW IT IS DIFFERENT FROM CURRENTLY AVAILABLE THERAPY USING SIMPLE LANGUAGE]**.

This study is taking place in approximately **X** hospitals and up to **X** patients will be enrolled.

PRIOR INFORMATION AVAILABLE ON THE DEVICE

[NOTE IF THIS IS A FIRST IN MAN STUDY OR INSERT PRIOR CLINICAL EXPERIENCE WITH THE DEVICE IN THE SAME OR DIFFERENT MEDICAL CONDITION]. *Examples: This early feasibility study is the first time the Study Device will be used to treat humans, or the device has been used in [Europe and Canada in X patients with the same or different medical condition. Add details on the clinical experience, so the patient can make a well-informed decision].*

WHO CAN PARTICIPATE IN THE STUDY

To find out if you meet all the requirements for this early feasibility study, your Physician will ask you questions and check your medical records. Before you decide to be in the study, be sure you understand all the information given and ask your Physician any questions you may have about your participation in this study.

If you decide to participate in this study, you can sign this form which will allow your Physician to perform additional study-related tests to see if you are a good candidate for this study. Please understand that your consent is required in order for your Physician to evaluate you further as a potential candidate for the study. You will not be actually enrolled into the study until your Physician confirms that you meet all the criteria for inclusion in the study. Should you choose not to participate in this study your Physician will continue to provide you with the appropriate medical care for your condition.

You may be considered for this study only if you:

1. Agree in writing to participate in this study (by signing this consent form).

2. Are at least 18 years of age.

3. Meet all eligibility criteria as assessed by your Physician

STUDY PROCEDURE

Once your Physician determines you are a good candidate for this study, your Physician will conduct study-related assessments to determine if you are eligible for the study. These assessments include:

- ❑ Physical examinations
- ❑ Medical and surgical history
- ❑ [LIST PROCEDURES, LAB TESTS, AND EXAMS TO BE PERFORMED FOR STUDY SCREENING AND INDICATE WHICH, IF ANY, ARE EXPERIEMENTAL AND HOW THEY DIFFFER FROM THE STANDARD OF CARE]

GENERAL STUDY PROCEDURES

[DESCRIBE STUDY PROCEDURES AND INDICATE WHICH, IF ANY, ARE EXPERIMENTAL AND HOW THEY DIFFER FROM THE STANDARD OF CARE]

Your health will be monitored, and data will be collected for the study during your hospital stay. Following the study procedure, you will be required to have periodic health assessments [DESCRIBE FOLLOW-UP REQUIREMENTS INCLUDING VISITS, INTERVALS AND TESTING PERFORMED] *[OPTIONAL you will be contacted and asked questions over the phone regarding any changes to your health].*

Should you agree to participate in this study you are responsible to adhere to all clinical testing schedules.

STUDY DURATION

Your participation in the study will end after [INSERT STUDY DURATION].

Your study doctor or (Sponsor) may stop the research study or may stop your participation at any time and this does not require your agreement. This may be done for any reason such as if you have an unrelated illness or complication, if you do not follow the study instructions, if your medical condition changes and he/she feels it is in your best interest to stop the study or for administrative reasons.

If you choose to discontinue or are withdrawn from the study, or your study doctor decides that you should discontinue the study, the study staff will discuss the options with you.

PARTICIPANT RESPONSIBILITIES

If you decide to participate in this study, you must follow the instructions given by your study doctor and return to the hospital for all study follow-up visits. Completing all study visits and following the study doctor's instructions is important to make sure that the study results are complete and accurate. If you have not followed the instructions, it is important that you tell the study doctor.

RISKS AND DISCOMFORTS

There might be unexpected risks from being in this type of early feasibility research study. This is because there may be limited experience with the Study Device. New information from this research study may give the Sponsor useful information to improve the device and procedure to treat your medical condition. This may help support future research studies with the Study Device. Since this device is in its early phase of development, there may not be information to fully predict the severity of the risks associated with the device and how often medical problems might occur. There may be other risks that are unforeseen at this time. Precautions will be taken to avoid harmful side effects as a result of participation in this study. Your physician will closely monitor your health status throughout the study.

Some risks and discomforts in this study are similar to those associated with currently available devices used to treat [INSERT HERE MEDICAL CONDITION] including, but not limited to [LIST REASONABLY FORSEEABLE POTENTIAL RISKS AND DISCOMFORTS HERE]:

If you are female and pregnant, this procedure and/or treatments during the study may involve unforeseeable risks to an embryo or fetus. If you are of childbearing age, please consult your Physician prior to consenting to this study.

RISK MITIGATION STRATEGIES:

[Bullets may be added or deleted as required.]

The Sponsor has done the following things to reduce the risks to subjects.

- Your Study Doctor was chosen to do this research study because he / she knows about your illness. Your Study Doctor has experience in treating [Insert medical condition or therapy].

- Your Study Doctor has been trained to use the Study Device in [Insert medical condition]. The Study Doctor's training includes using a laboratory model and / or other hands-on training.

- Your Study Doctor and any responsible clinical research Site personnel have been trained to follow the research study Protocol. This training includes the design and proper use of the Study Device. It includes all Subject follow-up requirements.

- [Include examples as described in the Risk Mitigation section of the guidance and Appendix 3. (ability to revert to standard of care, additional imaging to assist with device placement…)]

POSSIBLE BENEFITS IF YOU JOIN THIS STUDY

There might be potential benefits to you, but there is limited information to predict how likely you will experience benefit. Potential benefits of the [INSERT DEVICE NAME] may include [INSERT POTENTIAL IMPROVEMENT OF PATIENT CONDITION OR DISEASE without overstating them].

It is possible that there may be no direct benefit to you as a result of your participation in this study. However, your participation in the study may help the investigator collect information to optimize the design and function of the [INSERT DEVICE NAME] or procedure associated with device use, which may help other patients in the future.

OTHER TREATMENTS AVAILABLE

Alternative therapies for your medical condition may include [INSERT POTENTIAL ALTERNATIVE THERAPIES AND THE BENEFITS, RISK AND LIMITS]. Your Physician will discuss your situation with you and will recommend the best treatment for you, including how the experimental therapy would differ from the standard of care.

YOUR PARTICIPATION IS VOLUNTARY

Your participation is entirely voluntary. If you wish to participate in this early feasibility study, you will be asked to sign this form. Please take time to read this information carefully and to discuss it with your family, friends, and Physician before you decide.

You have the right to refuse to participate in this study. If you decide to participate, you can change your mind and choose to withdraw from the study at any time without any negative consequences to the medical care, education, or other services you may receive from this clinic or hospital.

If you decide to stop taking part in this study, you must tell your study Physician. You do not need to specify the reason for your withdrawal. Your study Physician will discuss with you whether any testing or follow-up may need to be done for your safety. [INSERT IF APPLIABLE; If you withdraw from the study before completion, the following may occur: [INSERT LIST OF ANY POSSIBLE ADVERSE EFFECTS THAT MAY OCCUR RELATED TO THE STUDY DEVICE, ANY

ADDITIONAL PROCEDURES RECOMMENDED TO ENSURE PATIENT SAFETY, OR NEED FOR CONTINUED FOLLOW-UP].

Your Physician or the sponsor can remove you from the study at any time without your approval. If your study participation is stopped, you may be asked to undergo a routine medical exam and/or medical testing for safety reasons.

CONFIDENTIALITY OF STUDY RECORDS AND MEDICAL RECORDS

Information collected for this study is confidential. Access to your personal medical information will be limited to the purposes of collection and processing information necessary for the completion of this study.

Your privacy is important. You will only be identified in the study by a code. This number is not derived from any of your personal information. Should results of this study be published (in a medical journal), you will not be identified through your name or other personal information. Data collected and reported to the sponsor for this study are the property of the sponsor. Your study records are just like hospital records. They may be subpoenaed by court order or may be inspected by federal regulatory authorities, including the Food and Drug Administration.

[If study is creating a combined consent form and Authorization, copy language from Appendix A below and paste here.]

STUDY RELATED INJURY

If physical injury happens to you because of your involvement in this early feasibility study, medical treatment will be available, if appropriate, at the hospital. This may include [INSERT LIST OF TREATMENTS OR REFER TO SOURCE OF FURTHER INFORMATION]. Contact your Physician if you experience a study related injury.

NEW STUDY FINDINGS

During the course of this study, you will be provided with any significant new findings that may affect your willingness to continue participating in this study.

RIGHTS AND COMPENSATION

You will not be paid to participate in this study. Your hospitalization and procedures will be considered part of your routine medical care. By signing this form, you do not give up any of your legal rights and you do not release the study Physician or other participating institutions from their legal and professional duties. There will be no costs to you for participation in this study. You will not be charged for any study procedures. If you become ill or physically injured as a result of participation in this study, medical treatment will be provided to you.

[INSERT SPONSOR NAME], as the Sponsor of the study, agrees to reimburse the reasonable medical expenses necessary to diagnose and treat an injury caused by the proper administration of the study device or the proper performance of a procedure required only for the study's research purposes. The Sponsor will not pay the costs to diagnose or treat a condition or injury that is not a result of the study device or procedure, or for expenses related to the normal progression of a preexisting medical condition or an underlying disease. For those costs that are Sponsor's obligation, you or your health insurance won't be billed. In no event will Sponsor pay for coinsurance, co-payments, or deductibles.

It is very important to follow all study directions.

[IF APPLICABLE, INSERT THIS SECTION] PHYSICIAN CONFLICT OF INTEREST

[INSERT STATEMENT] Example: Your physician has a financial interest in the Study Device. If you have any questions about this, call [INSERT NAME] at [INSERT PHONE].

WHO TO CONTACT IF YOU HAVE QUESTIONS?

If you have any questions about taking part in this study, or if you think you may have been injured because of your participation in the study, call [INSERT INVESTIGATOR NAME] at [INSERT INVESTIGATOR PHONE]. If you have any questions about your rights as a study patient, you can call the [NAME OF INSTITUTIONAL REVIEW BOARD] at [IRB PHONE]. You should also inform your study Physician if you have been injured or hospitalized for any reason during the study.

PATIENT'S STATEMENT

I have been given a chance to ask questions about this study. These questions have been answered to my satisfaction. If I have any more questions about taking part in this study, I may contact **[INVESTIGATOR NAME]** at **[INVESTIGATOR PHONE]**.

I understand that my participation in this early feasibility study is voluntary. I know that I may quit the study at any time without harming my future medical care or losing any benefits to which I might be otherwise entitled. I understand that there might be other treatment alternatives for me. I also understand that the investigator in charge of this study may decide at any time that I should no longer participate in this study. If I have any questions about my rights as a patient in this study I may contact:

[IRB Chairperson Name, Address, Telephone Number]

By signing this consent form, I have not waived any of my legal rights or released the parties involved in this study from liability for negligence.

I have read and understand the above information. I agree to participate in this study. I have been given a copy of this form for my own records.

SIGNATURE OF CAPABLE ADULT [ADJUST AS NECESSARY]

Subject name: _____

_____

Subject Signature **Date** **Time**

APPENDIX A:
[Copy and paste language below in accordance with instructions above if creating a combined consent form and HIPAA Authorization. Delete this Appendix A before finalizing document.]

PROTECTED HEALTH INFORMATION
Information about Confidentiality and HIPAA Authorization
AUTHORIZATION TO USE AND DISCLOSE HEALTH INFORMATION

I agree to permit [hospital and/or clinic—include both if study procedures will be conducted in both places] and their staff[s], my doctors, and my other health care providers (together "Providers"), and [investigator(s)] and [his/her/their/its] staff (together "Researchers"), to use and disclose health information about me, including health information in my medical records, as described below.

Note: In this authorization document, "you", "I", "your data" and/or "my data" refer to the subject. If you are a parent or guardian, please remember that "you" refers to the study subject.

1. **The health information that may be used and disclosed includes:**
   - all information collected during the research described in this consent form. ("the Research"); and
   - health information in my medical records that is relevant to the Research.

2. **The Providers may disclose health information in my medical records:**
   - to the Researchers and to the sponsor of the Research, <Enter Sponsor>. and its agents and contractors (together "<Enter Sponsor>"); and
   - as required by law and to representatives of government organizations, review boards, and other persons who are required to watch over the safety and effectiveness of medical products and therapies and the conduct of research.

3. **The Researchers may:**
   - use and share my health information among themselves and with other participating researchers to conduct the Research;
   - disclose my health information to <Enter Sponsor>; and
   - disclose my health information as required by law and to representatives of government organizations, review boards, and other persons who are required to watch over the safety and effectiveness of medical products and therapies and the conduct of research.

4. **<Enter Sponsor> may:**
   - use and share my health information as described in this consent form**.**

5. **Once my health information has been disclosed to a third party:**
   - it may be subject to further disclosure by recipients, and federal privacy laws may no longer protect it from further disclosure.

6. **Please note that:**
   - You do not have to sign this Authorization, but if you do not, you will not be allowed to participate in the Research.
   - You may change your mind and revoke this authorization at any time. To revoke this Authorization, you must write to *[name and contact information]*. However, if you revoke this Authorization, you will no longer be allowed to participate in the Research. Also, even if you revoke this Authorization, the information already obtained by the Researchers and <Enter Sponsor> may be used and disclosed as permitted by this Authorization and this consent form.
   - *[Use/adapt as appropriate]* While the research is in progress, you will not be allowed to see your health information that is created or collected in the course of the research. After the research is finished, however, you may see this information as described in [hospital/clinical trial sites] Notice of Information practices.

7. **This Authorization does not have an expiration (ending) date.**

8. **You will be given a copy of this Authorization after you have signed it.**

Subject name: _____

_____

Subject Signature **Date** **Time**