Section 1: About the Device Form

If the human subjects study involves the use of any devices, the study is subject to the Food and Drug Administration (FDA) regulations. Researchers planning to use devices in human subjects research must complete this form and include it with their protocol submission.

Section 2: When to Use This Form

If you answered yes to Section 12.1.9 (Studying the safety, effectiveness, or outcomes of any type of device, algorithm, or mobile application - medical or non-medical) in the New Study Application, you need to complete this form.

If you will be using devices in human subjects research for this study, and if you did not yet select yes in Section 12.1.9 of the New Study Application, please update the appropriate New Study Application section and then complete this form.

Section 3: Protocol Information:

Please complete the information below.

1) Principal Investigator:

Please enter the names of the PI’s.

2) Protocol Number:

Please enter the Protocol number. (If this is a new study application, the protocol number will be assigned and completed by OPRS once the application is submitted.)

3) Project Title:

Please enter the Project Title.

Section 4: Devices in Human Subjects Research - Questions:

1) Please describe the device, algorithm, or mobile application that is being used:

Detail below:

Click or tap here to enter text.

Note: Attach supporting information, if applicable. For example, a drawing of a device, a protocol for an MRI sequence, etc.

2) If applicable, please select each item below that applies to the device, algorithm, or mobile application as it is used in this study.

Select all that apply:

Intended for use in diagnosing a disease or condition

Intended for use in the cure, treatment, or prevention of disease in man or other animals

Intended to affect the structure or any function of the body of man or other animal which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals, and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

Recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them

3) Device, algorithm, or mobile application – is it a type of software function?

3.1) Is the device, algorithm, or mobile application a type of software function?

Select Yes or No.

Yes  No

3.2) If you answered yes to 3.1 above (that the device, algorithm, or mobile application is a type of software function), please select any items below that are true for the software function.

Check those that apply.

Not intended to acquire, process, or analyze a medical image or a signal from an invitro diagnostic device or a patter or signal from a signal acquisition system

Intended for the purpose of displaying, analyzing, or printing medical information about a patient or other medical information (such as clinical practice guidelines)

Intended for the purpose of supporting or providing recommendations to a health care professional about prevention, diagnosis, or treatment of a disease or condition

Intended for the purpose of enabling such health care professional to independently review the basis for such recommendations that the software presents so that it is not the intent that the health care professional rely primarily on any of the recommendations to make a clinical diagnosis or treatment decisions regarding an individual patient

4) Describe the plan to control, store, and dispense the device.   
This plan should ensure that the device is only used by qualified investigator(s) for the participants enrolled in this research project.

Detail below:

Click or tap here to enter text.

5) FDA issued IDE or Humanitarian Use Exemption (HDE) information.

(Please only answer this question if you previously checked any of the items in either question 2 or question 3.2. You may skip all of section 5, if no items were checked in 2 or 3.2.)

5.1) Has FDA issued an IDE or Humanitarian Use Exemption (HDE) for the use of the product?

Please select Yes or No.

Yes (if checked, please also answer 5.2 below.)

No (if checked, please also answer 5.3 below.)

5.2) If you selected “Yes” above in 5.1, please complete the following IDE/HDE information and attach the documentation of the IDE/HDE number(s).

Please list the IDE/HDE number(s):

Click or tap here to enter text.

Who is listed as the IDE/HDE holder (or person/entity that applied for the IDE)?

Click or tap here to enter text.

5.3) If you selected “No” above in 5.1, what is the initial risk determination of the device in the study according to the investigator and/or sponsor?

Select one option only:

As used in this study, the device is a non-significant risk (NSR) device. (If checked, please also answer question 5.4.)

As used in this study, the device is exempt from IDE requirements. (If checked, please also answer question 5.5.)

As used in this study, the device is a significant risk (SR) device study and requires an IDE.

5.4) If you selected “non-significant risk (NSR) device” above in 5.3, please confirm the following as per the definition of a non-significant risk (NSR) device (check all that apply):

The medical device is NOT intended as an implant that presents a potential for serious risk to the health safety, or welfare of a subject.

The medical device is NOT purported or represented to be for use in supporting or sustaining human life that presents a potential for serious risk to the health, safety, or welfare of a subject.

The medical device is NOT for a use of substantial important in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health that presents a potential for serious risk to the health, safety, or welfare of a subject.

The medical device does NOT otherwise present a potential for serious risk to the health, safety, or welfare of a subject.

The medical device is not banned.

5.5) If you selected “non-significant risk (NSR) device” above in 5.3, provide justification of why the medical device being investigated in this study meets the definition of an NSR device.

Note: The investigational device sponsor is responsible for providing this information. If this is an investigator-initiated study, the PI is responsible for this information. Attach any supporting documentation to the application.

Detail below:

Click or tap here to enter text.

5.6) If you selected “exempt from IDE requirements” above in 5.3, provide justification of why the medical device being investigated in this study is exempt from IDE requirements..

Select one choice from the list of exemptions below.

Exemption 1 - **Device approved prior to 1976, if used in accordance with approved labeling:** The medical device was in commercial distribution immediately before May 28, 1976 and the medical device is being used or investigated in accordance with the indications in labeling in effect at that time of commercial distribution. The FDA did not consider the medical device to be a new drug or an antibiotic drug before May 28, 1976.

Exemption 2 - **FDA approved or cleared (PMA or 510(k) devices), if used in accordance with approved labeling:** The medical device was introduced into commercial distribution after May 28, 1976 and the medical device is being used in accordance with the indications in the labeling FDA reviewed under subpart E of part 807 in determining substantial equivalence. The FDA has determined the medical device to be substantially equivalent to a medical device in commercial distribution immediately before May 28, 1976. The FDA did not consider the medical device to be a new drug or an antibiotic drug before May 28, 1976.

Exemption 3 - **In vitro diagnostic devices, as described:** The medical device is a diagnostic device; and the sponsor will comply with applicable requirements in §809.10(c); and the testing is noninvasive; and the testing does not require an invasive sampling procedure that presents significant risk; and the testing does not by design or intention introduce energy into a subject; and the testing is not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic product or procedure.

Exemption 4 - A medical device undergoing one of the following: consumer preference testing, testing of a modification, or testing of a combination of two or more medical devices in commercial distribution; and the testing is not for the purpose of determining safety or effectiveness and does not put subjects at risk.

Exemption 5 - Device intended solely for veterinarian use.

Exemption 6 - The medical device is shipped solely for research on or with laboratory animals and labeled in accordance with §812.5(c).

Exemption 7 - **The medical device is a custom device** meaning all of the following are true: the medical device necessarily deviates from devices generally available or from an applicable performance standard or premarket approval requirement in order to comply with the order of an individual physician or dentist and the medical device is not generally available to, or generally used by, other physicians or dentists and the medical device is not generally available in finished form for purchase or for dispensing upon prescription and the medical device is not offered for commercial distribution through labeling or advertising and the medical device is intended for use by an individual patient named in the order of a physician or dentist. One of the following is true: 1) the medical device is to be made in a specific form for that patient or the medical device is intended to meet the special needs of the physician or dentist in the course of professional practice. 2) The medical device is NOT being used to determine safety or effectiveness for commercial distribution.

Post-Approval Device Studies - The FDA required a post-approval study as a condition of premarket approval (PMA):The medical device has received marketing approval from the FDA; however, the FDA has requested additional testing. The post-approval letter specifying this testing must be provided.