Principal Investigator:	Date:
Study Title:	

Study Device Form

For studies:

- designed to determine the **safety or effectiveness of a medical device;** or
- **protocols using a Humanitarian Use Device (HUD);** or
- conducted under a **Treatment Investigational Device Exemption (IDE),**

please complete and attach this form under the Study Device Information section of your E-IRB application.
If your study involves multiple devices, complete applicable sections (and attach additional forms if needed) for each device being investigated.

Where instructions in this form indicate to attach additional materials, please use the "Protocol/Products Attachments" button under the *Additional Information/Materials* section of your E-IRB application to attach them.

SECTION A: Complete for EACH medical device tested in this study.

Include HUDs if applicable. Do not include devices used solely for medical care or to elicit a physiologic response where NO safety or effectiveness data will be collected on or about the device.

NAME OF DEVICE (*include generic and trade name if applicable*):	* **MANUFACTURER(S)** *(Indicate If device was developed by the investigator or other non-commercial entity):*	**ROUTE OF ADMINISTRATION:**	**DEVICE(S) APPROVAL STATUS:**
		☐ Check if combination drug/device product	☐ FDA Approved/Cleared for Marketing ☐ FDA Approved Humanitarian Use Device (HUD)** ☐ FDA Approved but testing unapproved use ☐ Not FDA Approved/Cleared ☐ Unsure

***Attach two copies of sponsor/manufacturer information (e.g., labeling, indications for use, prior investigations, contraindications, warnings, precautions, instructions, patient information packets, etc).**

**For Humanitarian Use Devices (HUD) attach manufacturer labeling or patient information packet (available from FDA HUD Listing). Unless data is being collected on an indication outside of the HUD labeling, *skip to Section C*.

Principal Investigator:	Date:
Study Title:	

SECTION B: Applicability of Investigational Device Exemption (IDE) Regulatory Requirements.

Complete this section for research involving devices. Do not complete for HUDs used solely for clinical purposes.

Research testing the safety or effectiveness of a medical device must fit in ONE of the following three categories:

CATEGORY 1: STUDIES EXEMPT FROM IDE REQUIREMENTS - To be exempt from IDE requirements the study would need to meet one of the exemptions in the device regulations [21 CFR 812.2].
CATEGORY 2: NONSIGNIFICANT RISK (NSR) DEVICE STUDY - Conducted only under the purview of the IRB as an Abbreviated IDE. A formal IDE submission to FDA is NOT required [21 CFR 812].
CATEGORY 3: SIGNIFICANT RISK (SR) DEVICE STUDY - Conducted under a formal IDE submitted to and approved by FDA [21 CFR 812].

NOTE: If the device study does not meet one of the Category 1 exemptions, the convened IRB must review the sponsor or sponsor-investigator's SR or NSR determination and modify the determination if the IRB disagrees with the sponsor. Consultation with the FDA may be required at the discretion of the IRB. If FDA has already made an Exempt, SR, or NSR determination for the study, the agency's determination is final.

Definitions are included at the end of this form for reference. FDA contact information is available below.

Section B - CATEGORY 1: Study is Exempt from IDE Requirements

If you consider the study to be exempt from IDE requirements, indicate the applicable IDE exemption, (I, II, or III), and attach any supporting documentation from the FDA or the Sponsor.
Before checking an exemption, ensure the device meets all required criteria or conditions of the exemption.
If unsure, consult FDA regulations (21 CFR 812.2), links to additional guidance, or consult the FDA.

I. ☐ Study is exclusively collection of clinical outcomes (i.e., real world data) on an approved/cleared device used in clinical care. In order to meet this exemption, study must not affect treatment decisions or how the device is administered. Treatment must be based on medical practitioner's clinical judgment, (e.g., case-control study, clinical outcomes registry). This exemption would not apply if gathering data would influence treatment decisions.

II. Study is EXEMPT because it meets all of the following criteria as an Approved Devices used in accord with Approved Labeling. In order to meet this exemption category, ALL of the following questions must be "true". If ANY of the following statements are "false", the study does not meet this exemption.

Pro-Tip: Use Adobe's "Undo" tool, or Ctrl-Z, to clear a radio button selection.

1. Device is FDA approved for marketing in the United States.
   ○ True ○ False
2. The results of the investigation are NOT intended to be reported to FDA as a well-controlled study in support of a new indication for use or intended to be used to support any other significant change device labeling.
   ○ True ○ False
3. The investigation is being used in accordance with the indications in the approved labeling and does NOT involve a new device indication such as a new population, condition, area of the body, or significant design change.
   ○ True ○ False

Principal Investigator:	Date:
Study Title:	

Section B - CATEGORY 1 (*continued*): Study is Exempt from IDE Requirements

III. Study is EXEMPT because it meets all applicable criteria for ONE of the following IDE Exemption Categories:

Each of the following exemption categories has specific conditions or criteria that must be met in order to qualify for exemption from IDE requirements. If the study meets ANY of the following categories, you are responsible for consulting FDA guidance and/or checking with FDA to confirm the study/device meets all specific criteria in order to be exempt from IDE requirements.

- ☐ Testing of an In Vitro Diagnostic device that is NON-invasive; does NOT require invasive procedure that presents risk; does NOT introduce energy into a subject; will NOT be used as a diagnostic without confirmation by another medically established procedure or product; and results from study device will NOT be used to make clinical decisions;
- ☐ Consumer preference testing of a device if the testing is NOT for the purpose of determining safety or effectiveness and does not put subjects at risk.
- ☐ Testing of a modification, or testing of a combination of two or more devices in commercial distribution, if the testing is NOT for the purpose of determining safety or effectiveness and does not put subjects at risk.
- ☐ Custom device intended for use by an individual patient and NOT for the purpose of determining safety or effectiveness (specific criteria must be met to qualify for exemption).
- ☐ Testing distinct categories of software or digital health products which are excluded from FDA regulations based on the 21st Century Cures Act. Check the FDA Digital Health Guidance webpage and provide link to the applicable guidance that designates the study device as exempt.

IV. ☐ **Study is EXEMPT because the FDA or commercial sponsor has provided documentation indicating that IDE is not required.** Attach applicable documentation.

If study met one of the IDE exemption categories above (I, II, or III), skip to Section C of this form (pg 4).

If the study does NOT meet one of the exemptions under Category 1, indicate if device(s) as used in this study meets:

Section B - **CATEGORY 2: Nonsignificant Risk (NSR) Device Study** (conducted under the purview of the IRB only; abbreviated IDE requirements apply)

OR

Section B - **CATEGORY 3: Significant Risk (SR) Device Study** (conducted under a formal IDE submitted to and approved by FDA; full IDE requirements apply)

Click links to view definitions at end of this document and/or consult FDA SR/NSR guidance for examples. Unless documentation of an SR/NSR determination by FDA is provided, the convened IRB will review and make their own SR/NSR determination. Consultation with the FDA may be required at the discretion of the IRB. FDA is the final arbitrator and their determination is final.

Principal Investigator:	Date:
Study Title:	

☐ **Section B - CATEGORY 2: Nonsignificant Risk (NSR) Device Study** **REQUIRES FULL BOARD REVIEW**

While NSR device studies do NOT require an IDE submission to FDA, they are subject to "*abbreviated*" FDA regulatory requirements and sponsor responsibilities★★. Describe or attach documentation to justify NSR designation.

☐ **Section B - CATEGORY 3: Significant Risk Device (SR) Device Study with an Investigational Device Exemption**

☐ Check if IDE has been submitted and is pending FDA review or 30-day clearance period

☐ Check if IDE is part of FDA's Expanded Access Program as a Compassionate or Treatment IDE

For FDA Approved IDE, record IDE number and IDE holder on Study Device Section of E-IRB

Application and attach one of the following to validate the IDE Number*:*

- Written communication from commercial sponsor printed with number
- Commercial sponsor protocol printed with number
- Written communication from FDA (required for investigator holding the IDE)

☐ **Section B - Unsure**

If unsure category that best fits the device(s) you propose to use in your research, consult the guidance links at the end of this form or contact the FDA for an Exempt, SR, or NSR determination.

★★**Sponsor-Investigator Training**: IRB policy requires completion of Sponsor-Investigator Good Clinical Practice Training for investigators who initiate a NSR device trial or hold an IDE (see the Research Description Section of the IRB Application).

FDA CONTACTS:

If you have questions, you can contact:

- Office of Product Evaluation and Quality (OPEQ)
- the division of Industry and Consumer Education at 800-638-2041 or DICE@fda.hhs.gov

To obtain a written study risk determination from the FDA, follow the procedures laid out in their Q-Submission Program Guidance and eCopy Program Information.

Principal Investigator:	Date:
Study Title:	

Section C: Device Management, Accountability, Registration, Training, and Qualifications to Administer

(***MUST COMPLETE*** *– attach additional pages if contents exceed space provided in below text fields)*

NOTE: The IRB requires periodic quality improvement reviews (QIR) for investigational device accountability. If your protocol is selected for a device accountability QIR, you should expect an on-site evaluation of policies and procedure for storage, control, dispensing, accountability, and monitoring.

1. Describe how dispensing of the investigational device(s) will be controlled including policies and procedures for, control, dispensing, and accountability:

*The ORI QI Resources website provides a Device Accountability SOP template and sample study logs (See Investigational Device Accountability Log)

2. Indicate where the devices will be stored and how access to the device(s) will be limited to prevent unauthorized access (e.g., *secure, locked storage; signage designating device as HUD or investigational*):

3. Indicate if specific qualifications or training are required for study personnel to use or administer the device, (The CITI Humanitarian Use Device Course* may be required at the discretion of the IRB for new HUD users):

*For information/access to the required HUD training, see the ORI HUD training page.

Principal Investigator:	Date:
Study Title:	

4. If the Principal Investigator (PI) or sub-investigator does NOT have training or experience related to the proposed study with this device, indicate plans to obtain or augment applicable qualifications or expertise:

5. For "applicable clinical trials" initiated after March 7, 2012, FDA regulations require the informed consent document to include a specific statement informing subjects about trial registration and availability of trial data on clinicaltrials.gov.

   If study is registered on clinicaltrials.gov, do all informed consent documents associated with the study include the specific statement?
   ◯ **Yes** ◯ **No** ◯ **N/A** (e.g., not an "applicable clinical trial")

Definitions

Medical Device is an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them, intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body and which is not dependent upon being metabolized for the achievement of its primary intended purposes (*Federal Food, Drug, and Cosmetic Act).*

Nonsignificant Risk device investigation is one that does not meet the definition for a significant risk study.

Significant Risk device study is defined [21 CFR 812.3(m)] as a study of a device that presents a potential for serious risk to the health, safety, or welfare of a subject and (1) is intended as an implant; or (2) is used in supporting or sustaining human life; or (3) is of substantial importance in diagnosing, curing, mitigating or treating disease, or otherwise prevents impairment of human health; or (4) otherwise presents a potential for serious risk to the health, safety, or welfare of a subject. *Note: A significant risk device study requires an Investigational Device Exemption (IDE) be approved by FDA.*

Humanitarian Use Device (HUD) [21 CFR 814] is a device that is intended to benefit patients in the treatment and diagnosis of diseases or conditions that affect or is manifested in fewer than 4,000 individuals in the United States per year. The statute and the implementing regulation (see 21 CFR 814.124(a)) require IRB review and approval before a HUD is used in a facility. For use of a HUD in *emergency, off-label/compassionate, and investigation situations* refer to the UK "Humanitarian Use Device SOP" [PDF] and the "IRB Summary Medical Devices: Humanitarian Use Devices" [PDF]. For more information on HUDs and Humanitarian Device Exemptions (HDE) Regulations see the FDA HDE Regulation Question and Answers guidance.

Treatment IDE [21 CFR 812.36] is a device that is not approved for marketing may be under clinical investigation for a serious or immediately life-threatening disease or condition in patients for whom no comparable or satisfactory alternative device or other therapy is available. During the clinical trial or prior to final action on the marketing application, it may be appropriate to use the device in the treatment of patients not in the trial under the provisions of the FDA Expanded Access program as a Treatment or Compassionate Use. See the UK Medical Device SOP [PDF] for guidance.

ADDITIONAL GUIDANCE MATERIALS:

FDA Frequently Asked Questions about Medical Devices (2006)

Significant Risk and Nonsignificant Risk Medical Device Studies (2006)

IDE Responsibilities for Sponsors and Investigators of SR and NSR Risk Device Studies

FDA Decisions for Investigational Device Exemption (IDE) Clinical Investigations (draft 2013)

CDRH Learn Online Presentations –Clinical Studies/IDE (under "How to Study and Market Your Device")

Additional FDA resources including In-Vitro Devices & Mobile Medical Applications, etc.