**Dartmouth College**

**COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS**

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**CPHS – DEVICE FORM**

**(Note:** Please review the criteria for determining whether a project should be submitted to the D-HH IRB rather than the CPHS prior to beginning your application. The criteria are posted [here](https://med.dartmouth-hitchcock.org/research/irb-submission.html). )

**Please complete: CPHS# PI:**

 **If you are completing this form on a Mac, indicate your answer to any checkboxes by bolding or highlighting, or by deleting any incorrect options.**

**CPHS Review of Devices**

Use this form for Devices that are

* Significant Risk Devices,
* Nonsignificant Risk Devices or
* Humanitarian Use Devices

Significant Risk Status

A significant risk device (21 C.F.R. 812.66) means an investigational medical device that:

 (a) Is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject; or

 (b) Is purported or represented to be for a use in supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a subject; or

 (c) Is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject; or

 (d) Otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.

Until the study has been approved by both the FDA and CPHS, federal regulations do not permit investigations that involve a significant risk device to enroll participants. The CPHS will not approve human subjects research involving a significant risk device without documentation that the device has received an IDE # or a 510(k) clearance from the FDA. Documentation of device status is either clearance as substantially equivalent under section 510(k) of the Food, Drug, and Cosmetic Act or the assignment of an IDE # to the device. After receipt of such documentation, the CPHS reviews the study, including the consent form, and assesses the risks and benefits of participation by humans using its standard process.

**A.) Significant Risk Device:** [ ]  Check here and respond to items below:

Is this device approved by the FDA for this indication? \_\_\_Yes \_\_\_No

If no or if FDA approval is pending, respond to 1, 2, or 3:

1) If this study is being done under an Investigational Device Exemption from the FDA please provide: IDE#: #\_\_\_\_\_\_\_\_ or ***check here*** if the IDE is pending: \_\_\_

Also ***check*** the FDA Device HCFA Reimbursement Category:

 A\_\_\_\_\_\_ B2\_\_\_\_\_\_ B3\_\_\_\_\_\_

***Please note***: CPHS will not approve a study before an IDE # has been received.

OR

2) If 510(k) notification for the device has been sent to FDA ***check here*** \_\_\_\_and either:

provide a copy of the documentation verifying 510(k) clearance, or

***check here*** if 510(k) clearance is pending \_\_\_.

OR

 3) Do you believe the study is an *exempted investigation* based on 21 C.F.R. 812.2(c 1-4)?

Please indicate the category of device you will use which allows for this exemption (see the longer descriptions in the regulations as they are very specific).

1) pre-1976 as labeled\_\_, 2) equivalent as labeled\_\_, 3) diagnostic\_\_ , 4) preference, modification, combination (no additional risk)\_\_.

***Please note***: The CPHS may approve, disapprove, or require modifications in a protocol that has been approved or cleared by the FDA.

Is the device provided free of charge by the sponsor? Yes\_\_\_\_\_\_ No\_\_\_\_\_\_

**B.) Nonsignificant risk** determination for the device from CPHS. [ ]  Check here and respond to items below:

 [ ]  I am requesting a Nonsignificant Risk Device determination by CPHS.

Device description:

 Please fill out a separate copy of this form for each device for which you are requesting a Nonsignificant Risk Device determination.

Please also respond to items 1 and 2 below with the requested information.

Nonsignificant Risk Status

A nonsignificant risk device does not satisfy any of the above criteria for a significant risk device. Risk level determinations should be based on the nature and seriousness of the harm that could result from the use of the device in the context of the investigational protocol. Significant risk devices have a potential for harm to subjects that could:

 (a) Be life-threatening;

 (b) Result in permanent impairment of a body function;

 (c) Result in permanent damage to body structure; or

(d) Necessitate medical or surgical intervention to preclude permanent impairment of body function or permanent damage to body structure.

Investigations that involve nonsignificant risk devices do not require FDA review, approval, or clearance. The CPHS reviews these studies to assess the risks and benefits of participation by humans and may approve, disapprove, or require modifications in the protocol.

The CPHS may agree or disagree with a sponsor's or investigator’s nonsignificant risk designation. In addition, the CPHS may request further justification of the designation and additional supporting information, e.g., reports of prior investigations using the device or its prototypes. If the FDA or any other IRB (than the CPHS) has made a nonsignificant risk device determination, the CPHS should be promptly notified of these actions. If the CPHS makes the determination that an investigation involves a nonsignificant risk device, the study may begin without FDA review. If the CPHS determines that the study involves a significant risk device, the sponsor or investigator should notify the FDA that this determination has been made whether or not the study is conducted at this institution.

Please note: If your request for nonsignificant risk device determination is rejected by CPHS, the options for conducting the study are either:

* obtain an IDE # or 510(k) clearance for the device; or
* provide additional information for CPHS to reconsider its determination.

To request nonsignificant risk status for a device, answer items 1 and 2:

1. Please respond to each of the following criteria with an explanation for how each of these criteria (a-d below) for significant risk status **does not** apply to the device in question:

(a) The device is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject; or

(b) The device is purported or represented to be for a use in supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a subject; or

(c) The device is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject; or

(d) The device otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.

2. As noted above, risk level determinations should be based on the nature and seriousness of the harm that could result from the use of the device in the context of the investigational protocol. Significant risk devices have a potential for harm to subjects that could:

 (a) Be life-threatening;

 (b) Result in permanent impairment of a body function;

 (c) Result in permanent damage to body structure; or

(d) Necessitate medical or surgical intervention to preclude permanent impairment of body function or permanent damage to body structure.

Please provide information about the seriousness of the harm that could result from the use of the device in the context of the investigational protocol:

**C)** **The device was determined to be a Humanitarian Use Device by the FDA.**

[ ]  Check here and respond to items below:

Definitions:

**Humanitarian Use Device (HUD)**: a medical device intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in not more than 8,000 individuals in the United States per year

**Humanitarian Device Exemption (HDE)**: a marketing application for an HUD (Section 520(m) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)). An HDE is exempt from the effectiveness requirements of Sections 514 and 515 of the FD&C Act and is subject to certain profit and use restrictions.

Please complete the HUD/HDE section below.

1. Is the HUD being used for HDE approved indications only?

Yes\_\_\_\_\_\_ No\_\_\_\_\_\_

(If No, this type of clinical investigation is subject to the IDE regulations at 21 CFR Part 812. Please be sure A(1) for an IDE is filled out above.)

2. If Yes, will data be collected? Please comment on both safety and **effectiveness** data.

3. If Yes, will a consent form be provided for use?

Neither the FD&C Act nor the regulations require informed consent from patients for the use of a HUD for its HDE-approved indication(s). An IRB may, however, choose to require informed consent that is consistent with the approved labeling when the IRB approves use of the HUD in a facility. Most HDE holders develop patient information packets that generally contain a discussion of the potential risks and benefits of the HUD and any procedures associated with its use. The information packets should be provided to the CPHS and the patient should always receive the HDE holder’s patient information packet.

NOTE: **HUD Emergency Use:** If a physician in an emergency situation determines that IRB approval for the use of the HUD at the facility cannot be obtained in time to prevent serious harm or death to a patient, a HUD may be used without prior IRB approval. The physician must, within 5 days after the emergency use of the device, provide written notification of the use to the IRB chair person. The written notification must include the identification of the patient involved, the date of the use, and the reason for the use.

References and links:

Investigational Device Exemptions: 21 C.F.R. Part 812

IRB determination of Nonsignificant risk device: 812.2(b)(1)(ii)

Exempt investigations: 21 C.F.R. 812.2(c 1-7)

FDA Actions: 21 C.F.R. 812.3

IRB determination of significant risk: 21 C.F.R. 812.66.

Electronic Code of Federal Regulations (eCFR).

+Food and Drug Administration, Information Sheets: Guidance for Institutional Review Boards and Clinical Investigators, VIII, General Questions, 60. "Medical Devices," Also, ["Frequently Asked Questions about IRB Review of Medical Devices"](file:///C%3A%5CUsers%5CD27532l%5CDownloads%5CMedical%20Devices%2C%20Frequently%20Asked%20Questions%20About%20-%20Information%20Sheet%20%28PDF%20-%20266KB%29) and ["Significant Risk and Nonsignificant Risk Medical Device Studies”](file:///C%3A%5CUsers%5CD27532l%5CDownloads%5CSignificant%20Risk%20and%20Nonsignificant%20Risk%20Medical%20Device%20Studies%20-%20Information%20Sheet%20%28PDF%20-%20211KB%29)

+R.J. Sherertz and S.A. Streed, Medical Devices: Significant Risk vs Nonsignificant Risk (Special Communication), JAMA 272(12), September 28, 1994, pp 955-956.

+ HUD (Section 3052 of the 21st Century Cures Act (Pub. L. No. 114-255).

+ HUD Emergency Use: See section 520(m)(4) of the FD&C Act; 21 CFR 814.124.

https://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm389154.htm#role