**Petition for Approval for Humanitarian Use Device**

Office of Research and Sponsored Programs (RSP)

201J University Hall

Wright State University

Dayton, OH 45435

(937) 775-2425 – Voice / (937) 775- 3781 - Facsimile

The attached petition is to be used when requesting review for approval of a Humanitarian Use Device by the Wright State University Institutional Review Board (IRB). Please **TYPE** and **SIGN** before submitting. Copies should be individually stapled, clipped or banded, with no covers.If you have any questions concerning the petition or meeting dates, please contact the IRB Coordinator at 775-4462.

A Humanitarian Use Device (HUD) is a device that is intended to benefit patients in the treatment and diagnosis of diseases or conditions that affect or are manifested in fewer than 4000 individuals in the United States per year. The sponsor must get a HDE designation from the FDA's Office of Orphan Products Development.  The Federal Food, Drug, and Cosmetic Act and the HDE regulations do not require research informed consent because a HDE provides for marketing approval, and so use of the device does not constitute research or an investigation that would normally require full research informed consent.  The sponsor may provide the patient with patient labeling to assist the patient in making an informed decision about the use of the device.  Even though the device is not considered investigational, the FDA mandates IRB review and approval; the IRB may require an informed consent in addition to any consumer information provided by the manufacturer, and may limit use of the device.

Hospitals may have additional pre-screening requirements for humanitarian use devices. Please consult the hospital research office for further guidance.

**The information requested in this petition is necessary and must be on file for inspection by authorized individuals. Therefore, the appropriate Board/Committee cannot review this petition unless all the questions have been adequately addressed. When submitting your application, follow the INSTRUCTIONS below.**

**The information in this petition may become publicly available either through the Ohio Open Records Act or through open meetings. For additional information, see the signature page.**

**INSTRUCTIONS**

**Submit the following to the Institutional Review Board, c/o RSP:**

* One single-sided typewritten original (petition and supporting documentation) with **original signatures of principal investigator and co-investigator(s)**
* **23 collated copies** of the petition and all supporting documents (**double sided acceptable**).
* Supporting documents:
	+ Copy of the HDE approval order (these can be found at the following web site: <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/HDEApprovals/ucm161827.htm>)
	+ Product information/Product Labeling/Manufacturer brochure (or equivalent documentation) for device
	+ Responses to all questions asked in the Petition for Approval for Humanitarian Use Device
	+ Consent Form or information that will be provided to the patient at the time the device is used. Note: A research consent form is not required by the FDA for use of a Humanitarian Use Device. However, patient information concerning the device is generally available to present to the patient, and this should also be submitted to the IRB. If a patient packet of information is not available, a consent document should be prepared and be submitted. The consent document should address the following:
		- What is a humanitarian use device?
		- What humanitarian use device will be used with this patient?
		- What will be involved with the use of this device?
		- Possible risks, side effects or discomforts associated with the use of the device
		- Possible benefits associated with the use of the device
		- Any alternate treatments or procedures that may be available
		- Who will be charged for the costs of the device and the associated procedures
* 4 copies of the CVs for the physician submitting this application.

**Note: Deadline dates for submission of petitions to RSP may be found on the human subjects web page at:** [**http://www.wright.edu/rsp/subjects.html**](http://www.wright.edu/rsp/subjects.html)

**Petition for Approval of Humanitarian Use Device**

**Wright State University Office of Research and Sponsored Programs**

Date:

For RSP use only

IRB Assignment Number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Title of Humanitarian Use Device:

**PERSONNEL INFORMATION:**

|  |  |  |
| --- | --- | --- |
| Treating Physician | Academic/Professional Title | Phone |
|       |       |       |
|  |  |
| Department | Fax |
|       |       |
|  |  |
| Address | E-mail |
|       |       |

|  |  |
| --- | --- |
| Contact person to receive IRB correspondence. Include name & phone no. | Contact E-mail |
|       |       |

List the names of **all other key personnel** who will be involved in the HUD administration. For every name include each person’s academic/professional title and their role in the use of this device.

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**DEVICE**

1. Device Name:

2. Device Manufacturer:

3. HDE Number:

4. Date of HUD Designation:

5. Site(s) where device will be used:

6. Describe the FDA-approved indication(s) for the use of this device?

7. Is this device going to be used on in accordance with its approved labeling and indications?

 [ ]  Yes [ ]  No

If “No” the use of this device may be subject to the same requirements that apply to all FDA-regulated clinical studies, including 21 CFR Parts 50 (Protection of Human Subjects) and 56 (Institutional Review Boards). Additionally, if the HUD is being studied for a use other than its approved indication(s), the IDE regulations at 21 CFR Part 812 apply. Please complete the IRB Petition entitled “Petition for Approval of Medical Research Involving Human Subjects”.

8. Will this device be use off-label in a non-research capacity, such as for compassionate use?

 [ ]  Yes [ ]  No

If “yes” an informed consent document is required. The HDE holder may have specific requirements for compassionate use. If so, so specify these requirements and submit a plan for meeting these requirements.

**ADDITIONAL DEVICE USE INFORMATION**

|  |  |  |
| --- | --- | --- |
| 1. Do any personnel involved in the design, conduct, or analysis of the treatment protocol have any proprietary interests (royalties, patents, trademarks, copyrights, or licensing agreements) involving any agent, device, or software being evaluated as part of the HUD administration?
 | [ ]  Yes | [ ]  No |
| 1. In addition to the manufacturer (s) of this device, are other companies or business entities involved in or potentially affected in a significant way by the use of the HUD?

If yes, list the names of those companies/business entities. | [ ]  Yes | [ ]  No |

**Submit a treatment protocol or summary that provides the following information regarding the use of the device. The FDA requires the IRB to review the risks to patients that are found in the product labeling, ensure the risks are minimized, and evaluate whether the risks are reasonable in relation to the proposed use of the device. All points must be addressed before IRB approval can be granted. For each item, indicate where the information can be found. It is not necessary to repeat information found in the information provided by the manufacturer, but the location of this information must be specified for the IRB.**

|  |  |
| --- | --- |
| **DEVICE DESCRIPTION**  | Location of Information |
| 9. What is the disease or condition the device is intended to treat or diagnose? |       |
| 10. Provide a description of the device, including the implantation (if applicable) and its use of the device. |       |
| 11. Describe the developmental history of the device, including a summary of existing pre-clinical studies, clinical investigations, and experience with the device. |       |
| 12. Provide an estimation of the number of patients that may receive this device at your institution. |       |

|  |  |
| --- | --- |
| **PATIENT POPULATION, RISKS & BENEFITS TO PATIENTS, SAFETY MONITORING** | Location of Information |
| 14. Describe the target population, provide the specific inclusion/exclusion criteria, and specifically address the following: Are there any restrictions based on age, gender, childbearing potential, race, ethnic origin, or impaired competency? Are there specific contraception requirements? Will pregnant or breast feeding women be excluded? Please provide justification for the target population, enrollment restrictions, and inclusion/exclusion criteria. |       |
| 15. Describe how patients will be identified and contacted.  |       |
| 16. Describe the contraindications, warnings, and precautions for use of the device. |       |
| 17. Describe the potential adverse effects of the device on health. |       |
| 18. Describe the alternatives (practices/procedures) that are available to treat or diagnose the patient’s disease or condition. |       |
| 19. Describe the potential benefits to the patient associated with the use of the device. |       |
| 20. Describe the plan for monitoring patient safety. Include information on how adverse events will be reported to the device manufacturer, the FDA and to the IRB (see below)\* |       |
| 21. Provide the criteria for discontinuation of use of the device. |       |
| 22. What financial obligations (if any) will the patient incur as a result of receiving this device? |       |
| 23. Will safety and effectiveness data be collected? | [ ]  Yes [ ]  No |
| 24. Will individually identifiable health information be collected? If yes, how will the data be stored, secured, and disclosed? | [ ]  Yes [ ]  No      |
| 25. Describe the process to be used for obtaining informed consent from the prospective patient (note – see instruction section of this form for further information on the requirement for informed consent when using a HUD).  |       |

\*User facilities must submit reports to FDA, the IRB of record, and the manufacturer whenever a HUD may have caused or contributed to a death, and must submit reports to the manufacturer (or to FDA and the IRB of record if the manufacturer is unknown) whenever a HUD may have caused or contributed to a serious injury (21 CFR 803.30 and 814.126(a)). Serious injury means an injury or illness that (1) is life-threatening, (2) results in permanent impairment of a body function or permanent damage to a body structure, or (3) necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure (21 CFR 803.3).

**SIGNATURES AND CERTIFICATIONS**

By signing and submitting this application, the Treating Physician agrees that he/she:

1. Is trained in the use of this device and is prepared to provide patient monitoring
2. Is NOT using this HUD as part of a research project or clinical investigation designed to collect data to support an FDA pre-marketing approval application
3. Will use this device only according to its FDA-approved indications.
4. Has provided the IRB with all the information on this device necessary for its complete review.
5. Will submit annual progress reports to the IRB for review in a timely manner in order to obtain appropriate continuing review to maintain the approval status of the HUD.
6. Will report promptly any serious and unexpected adverse event possibly related to the use of the device
7. Will not administer the HUD with any patient until final IRB approval is received.

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Signature of Physician (PI) Submitting Application Date

All other physicians listed on the cover of this petition (if any) must sign to acknowledge their participation in this project:

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Signature of Physician Date Signature of Physician Date

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