

IRB Application for Humanitarian Use Device



Before a **Humanitarian Use Device** under an approved humanitarian device exemption (HDE) can be used at the University of Utah or its affiliates for clinical care, approval by an IRB is required with the exception of emergency use.

Physicians must **submit a New Study Application in ERICA**. The ERICA application will use terms like “research” and “investigator” but for the purposes of an HUD application, those terms should be synonymous with “humanitarian use” and “physician”.

The **tips** provided in these slides are meant to help physicians answer questions in the ERICA application for an HUD.

A **consent document** for humanitarian use should be included in the application. The IRB provides a template here:


<https://irb.utah.edu/forms/index.php>

1. Study Introduction

Question 6: Study purpose and objectives do not need to be outlined. Instead, the physician can state a summary of how the physician will use the device.

6. **Study Purposes and Objectives:**

The objectives should be stated in such a way that the reader can determine the appropriateness of the study design. If appropriate, state the specific hypotheses being tested and/or study aims. Use lay language.




Describe the indication for the HUD here. This section does not need to have purposes and objectives outlined. A summary of how the physician proposes to use the device is sufficient.

Question 8: Physicians can give a summary of the HUD and that the application is being submitted for the humanitarian use of the device. References are not required.

8. **Background and Introduction:**

Identify the research area being studied and provide a review of the literature that provides the basis for understanding the objectives of the study. This review should be written such that scientists outside the investigator's area of expertise can understand the issues involved. Any information about previous research related to this study involving animals and/or humans should be summarized. Include studies on pregnant animals if the research is conducted on pregnant women, fetuses, or neonates.



Give a summary of the HUD here and state that this IRB application is being submitted for humanitarian use of the device because a Humanitarian Device Exemption has been obtained.

A Humanitarian Device Exemption is a medical device meant to benefit patients in the treatment or diagnosis of a disease or condition that is seen in less than 8,000 people in the United States per year. The U.S. Food and Drug Administration (FDA) approves the use of a Humanitarian Use Device based on evidence that it does not pose an unreasonable or significant risk of illness or injury to the patient and that the probable benefits to health outweigh the risk of injury or illness from its use. However, the effectiveness of the device has not been shown.

2. Study Location and Sponsors



On the Study Location and Sponsor page, once a location has been added under question number 1, a page called "Addition of a Site" will open. Answer question 6 and 7 of this page as directed in the graphics. Make sure to click "OK" when finished.

2. Study Location and Sponsors

1. **Add all locations applying for approval of research via the University of Utah IRB or Human Research Protection Program (HRPP).**
If the University of Utah IRB will be the central or single IRB for the study, add all locations that will be covered. If the name of the organization does not appear, contact the IRB.
- If the location is supporting the research, but does not need IRB approval to cover their activities (i.e., the location is not 'engaged in research'), add the name of the site to the Resources and Responsibilities page instead. Click the HELP button for more information about whether a location is engaged in research.*

Click the appropriate button(s) below to add locations:

HELP?

- + University of Utah
- + Primary Children's Hospital (PCH)
- + Veterans Affairs SLC Health Care System (VAMC)
- + Shriners Hospitals for Children Intermountain
- + Add Other Location

Site Name	Investigators Name	Covered Entity	Sub Sites
There are no items to display			

6. **Select HIPAA coverage for this study:**
All administrative units within U of U Health are considered part of the Covered Entity.
Select both options if the study will be conducted in part within a Covered Entity and in part outside a Covered Entity.
- Study procedures will be conducted within a HIPAA Covered Entity at this site (HIPAA Privacy Rule applies)
 - Study procedures will be conducted outside a HIPAA Covered Entity at this site (HIPAA Privacy Rule does not apply)

7. **Select the study procedures that will be conducted at this site:**
Each site may conduct some or all of the study procedures. Ensure that the site's activities are specifically described in the remainder of the application.
- Recruitment
 - Consent/Enrollment
 - Research observation/intervention with participants
 - Data collection
 - Data analysis
 - Other

If Other, describe:

This application is strictly for clinical use of the humanitarian use device and is not research.

2. Study Location and Sponsor (cont.)



If the company is providing the device only a sponsor should still be added. Add the sponsor in question 3. After clicking "Add", the "Sponsor Information" page will open. Select "No" to of whether funds are received through the Office of Sponsored Projects.

Select "Other" and state that only the device is being provided for humanitarian use and no other funds will be received.

3. Indicate the source(s) of funding obtained or applied for to support this study.

+ Add

Sponsor	Sponsor Type	Sponsor Contact Information	Prime Sponsor	Prime Sponsor Type
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Sponsor Information

a. Are you receiving award or contract management for the sponsored funds through the University of Utah Office of Sponsored Projects?

For University of Utah studies, a contract with the Office of Sponsored Projects may be required even if you are not receiving direct funds. Any relationship with an outside entity should be discussed with OSP. Visit <http://osp.utah.edu/>

Yes No

If no, indicate how the funds are being received:

- Funds are being provided by or received directly through a University of Utah department
- Funds are being received entirely through another institution
- Other (specify below)

[Clear](#)

If 'Other', please explain how funds are being received:

The device is being provided by <<company>> for humanitarian use. No other funds are being received.

Sponsor:

[If you cannot find your sponsor click here.](#)

Previously, the following data was entered on your IRB application:

Sponsor Contact Information:

4. Study Information



Question 1: Select "Other" and state that the application is for HUD, not research.

Question 4a: Select "Other" and state that the patient is being treated with an HUD

Question 4b: N/A

4. Study Information

1. Design of Study (select all that apply):

- Non-Experimental and/or Descriptive Research Design:** *collection and assessment of the participant's data and information without prospective manipulation of the participant's body, environment, or treatment.*
 - Secondary/Archival Data Analysis or Retrospective Chart Review
 - Survey/Questionnaire Research
 - Interviews and Focus Groups
 - Oral History
 - Observational Research
- Experimental and/or Interventional Research Design:** *prospectively manipulating the participant's body, environment, treatment, or strategies for receiving information in order to observe a resulting effect or outcome.*
 - Prospective Biomedical Intervention or Experiment
 - Blinded Trial (Single or Double Blinded)
 - Placebo Controlled Trial
 - Randomized Trial
 - Prospective Social/Behavioral Intervention or Experiment
 - Phase I Clinical Trial
 - Phase II Clinical Trial
 - Phase III Clinical Trial
 - Phase IV Clinical Trial
 - Open Label Trial

Development of a research resource (repositories, databases, etc.)

Other

If Other, describe:

Humanitarian Use Device Application

4. How will participants be recruited or identified for inclusion in the study?

The IRB does not allow cold-calling as a method of recruitment. All recruitment materials must be attached to the Documents and Attachments page.

a. Select all methods that will be used:

- In-person contact (e.g., patients, students, etc.)
- Referrals
- Written or electronic record review
- Written advertising (flyers, brochures, website postings, newspaper ads, etc.)
- Audio advertising (radio and television advertisements, etc.)
The ad script and audio/video recording must be attached to the Documents and Attachments page.
- From a database or participant pool for which participants have given prior permission to be contacted for research studies
- Other

This patient is known to the physician and will be treated with an HUD

b. Describe the recruitment/participant identification process in detail (e.g. who will review charts or records, who can refer participants to the study, where will flyers be posted, how often will recruitment letters be sent, when will follow-up phone calls be made, etc.):

Indicate that participants will not be contacted if the study only involves a waiver of informed consent for a retrospective chart/data review.

N/A

4. Study Information (cont.)



5. How will consent be obtained?

If your study uses deception, attach the consent document and debriefing statement to the Documents and Attachments page. Check both Informed Consent Process and Waiver or Alteration of Informed Consent.

Informed Consent Process (with or without a document)
This process may or may not include a consent document. Also check if requesting that documentation of informed consent be waived (e.g. consent process without signature, questionnaire cover letter, web-based consent, etc.)

Waiver or Alteration of Informed Consent
Alteration of consent requests that required element(s) of consent template be removed or altered (e.g. use of deception in consent)

6. Describe all the procedures chronologically, from screening/enrollment through study closeout, which will be completed in the research project.

The investigational activities, treatments, or procedures must be clearly detailed as to how and when they will be performed. For clinical studies, this includes study visits, drug treatments, randomization, and the procedures that are part of standard of care. For clinical studies, a distinction should be made between the procedures for treatment evaluation versus procedures for safety evaluation. Treatment endpoints must be defined as well as interim procedures for dealing with adverse events.

Include a summary of how the physician proposes to use the device, including a description of any screening procedures, the HUD procedure, and any patient follow-up visits, tests or procedures

7. Are all procedures for research purposes only (non-standard or non-standard of care procedures)?

Yes No [Clear](#)

If no, list the procedures that are performed for research purposes only (non-standard or non-standard of care procedures):

If the study is conducted at the VA, you must also indicate who is responsible for research care and who is responsible for non-research care.

This is not applicable. This is not for research. This is for a humanitarian use device.

Question 5: Select "Informed Consent". **University of Utah requires a consent for HUD.**

Question 6: Include a summary of how the physician will use the device, including a description of any screening procedures, the HUD procedure, and any patient follow-up visits, tests or procedures.

Question 7: Select "no". State that this is N/A.

Question 8: Select "no".

Question 9: State that this is N/A.

8. Is there a safety monitoring plan for this study?

All studies determined by the IRB to be more than minimal risk must have a safety monitoring plan. Click Help for more information about risk and safety monitoring plans.

[HELP?](#) Yes No

9. Provide a summary of the statistical methods, data analysis, or data interpretation planned for this study. Factors for determining the proposed sample size (e.g., power) should be stated.

This is not applicable. This is not for research. This is for a humanitarian use device.

5. Data Monitoring Plan



The purpose of a data monitoring plan is to ensure the integrity of the research data, adherence to the approved research plan, and that privacy and confidentiality risks are minimized.

Because the Humanitarian Use Device is not research, the Data Monitoring Plan page can note that the application is not for research. Select “Other or additional details” and add a note. See the sample answers in the graphic.

1. **Privacy Protections:** Privacy refers to persons and to their interest in controlling access of others to themselves. Privacy can be defined in terms of having control over the extent, timing and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others. **What precautions will be used to ensure subject privacy is protected?**

Select all that apply:

Other or additional details (specify):

Other or additional details (specify):

This is a humanitarian use device. Privacy protections will be offered as with clinical care.

2. **Confidentiality Precautions:** Confidentiality is an extension of the concept of privacy; it refers to the subject's understanding of, and agreement to, the ways identifiable information will be stored and shared. Identifiable information can be printed information, electronic information or visual information such as photographs. **What precautions will be used to maintain the confidentiality of identifiable information?**

Select all that apply:

Other or additional details (specify):

Other or additional details (specify):

This application is for a humanitarian use device and research data will not be collected.

3. **Will photos, audio recordings, or video recordings, or medical images of participants be made during the study?**

Select "No" if medical images are made for standard of care purposes.

Yes No

4. **How will study data and documentation be monitored throughout the study?**

Select all that apply:

Other or additional details (specify):

Other additional details (specify):

This application is for a humanitarian use device and research data will not be collected. Data will not be monitored.

5. **Who will be the primary monitor of the study data and documentation?**

Select all that apply:

Other or additional details (specify):

Other or additional details (specify):

This application is for a humanitarian use device and research data will not be collected. Data will not be monitored.

6. **How often is study data and documentation monitoring planned (e.g., monthly, twice a year, annually, after N participants are enrolled, etc.)?**

This application is for a humanitarian use device and research data will not be collected.

7. HIPAA and the Covered Entity

7. HIPAA and the Covered Entity

1. Does this study involve Protected Health Information (PHI) or de-identified health information? [HELP?](#)

Yes No [Clear](#)

a. Select the method(s) of authorization that will be used:

(Consent and) Authorization Document

Waiver or Alteration of Authorization
(If you are using medical records for screening or recruitment, please request a Waiver of Authorization)

Limited data set

De-identified

b. Will PHI be disclosed outside the Covered Entity?

Yes No [Clear](#)

3. The investigational use of a medical device?

Yes No [Clear](#)

6. A Humanitarian Device Exemption (HDE)?

Yes No [Clear](#)

If yes, please attach a copy of the letter from the FDA granting the HDE.

Question 1: Select "Yes".

Question 1a: Select "Consent and Authorization Document".

Question 1b: Select "No".

Question 3: Select "No".

Question 6: Select "Yes".

Investigational Use of a Device



Investigational Use of a Device

1. What is the initial risk determination of the device study according to the investigator and/or sponsor?

[HELP?](#)

- The study is a non-significant risk (NSR) device study.
[Skip parts a and b.](#)
- The study is exempt from IDE requirements.
[Skip parts a and b.](#)
- The study is a significant risk (SR) device study and requires an IDE.
[Complete parts a and b.](#)
[Clear](#)

a. Provide IDE (or HDE) Number(s) for significant risk devices:

[+ Add](#)

IDE #	Device Name	IDE Holder
There are no items to display		

b. Attach verification of the IDE number for significant risk devices to the Documents and attachments page. Please check the method by which you choose to verify the IDE number:

- FDA letter providing the IDE.
- IDE number is printed in protocol
- Letter from the Sponsor
- Other sponsor-generated document

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

This is not an investigational device, it is a Humanitarian Use Device.

Question 1: Although there is not an IDE, select “The study is a significant risk (SR) device study and requires an IDE”.

Question 1a: Click “Add”. A pop up (see below) will open. Complete with the HDE number, device name and HDE holder.

Question 1b: Select “FDA letter providing the IDE” although you will provide the letter with the HDE.

Question 2: Answer “N/A”.

IDE

a. IDE #

b. Device Name:

c. IDE Holder:

8. Resources and Responsibilities



8. Resources and Responsibilities

1. * **State and justify the qualifications of the study staff:**
State and justify the qualifications of the study staff:

The physician has received the required education and training to use the humanitarian use device. A qualified physician should be responsible for all medical-related decisions and care. Only qualified staff personnel.

2. * **Describe the training that study staff and investigators will receive in order to be informed about the protocol and understand their research-related duties and functions:**
Describe the training that study staff and investigators will receive in order to be informed about the protocol and understand their research-related duties and functions:

N/A. There is no research protocol in place. This is a humanitarian use device application.

3. * **Describe the facilities where the research activities will be performed (e.g. hospitals, clinics, laboratories, classrooms/schools, offices, tissue banks, etc.).**
Describe the facilities where the research activities will be performed (e.g. hospitals, clinics, laboratories, classrooms/schools, offices, tissue banks, etc.).

We will consent in the exam room of the clinic. This is not a study.

4. * **Describe the medical or psychological resources available at this site (and other participating sites, if applicable) that participants might require as a consequence of the research. If not applicable, please state.**
Describe the medical or psychological resources available at this site (and other participating sites, if applicable) that participants might require as a consequence of the research. If not applicable, please state.

This is not applicable. This is not for research. This is for a humanitarian use device. This application is strictly for clinical use.

Questions 1-4: This page is intended to outline the research resources and responsibilities of the research staff which does not apply for the humanitarian use device. Sample answers can be seen in the graphic.

Documents and Attachments



Click “Add” under Consent Documents to add the HUD consent. The IRB provides a template here:

<https://irb.utah.edu/forms/index.php>

Physicians should also add a copy of the HDE approval.

If available, product information, product labeling, or patient information packet that may accompany the HUD should be added.

Documents and Attachments

[Go to forms menu](#)

If any of your documents (such as investigational brochures, sponsor protocols, advertisements, etc.) are not available in an electronic format, please scan and save them as PDF files or contact our office for assistance.

Naming Documents: Please use the title field to clearly indicate the content of each form. The name you enter will be listed on your approval letter. Use names that will differentiate from earlier versions.

Examples:

Consent Document Control Group 04/14/05
Consent Document Treatment Group 4/14/05
Sponsor Protocol 04/14/05 Version 2
Assent Document(Highlighted Changes)

[Apple/Macintosh Users:MS Word documents must have a .doc file extension. See ERICA home page for instructions.](#)

Print View: IRB Draft Protocol Summary

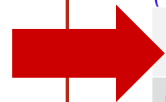
eProtocol Summary:

Name	Version	Date Created	Date Modified	Date Approved
There are no items to display				

Consent Documents, Consent Cover Letters, Consent Information Sheets, Consent Scripts, etc.:
(You must use the current MS Word IRB template to allow watermark approval)

[+ Add](#)

Name	Version	Date Created	Date Modified	Date Approved
There are no items to display				



Questions?



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