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 is affiliates for clinical care, approval by an IRB is required with the exception of emergency use.

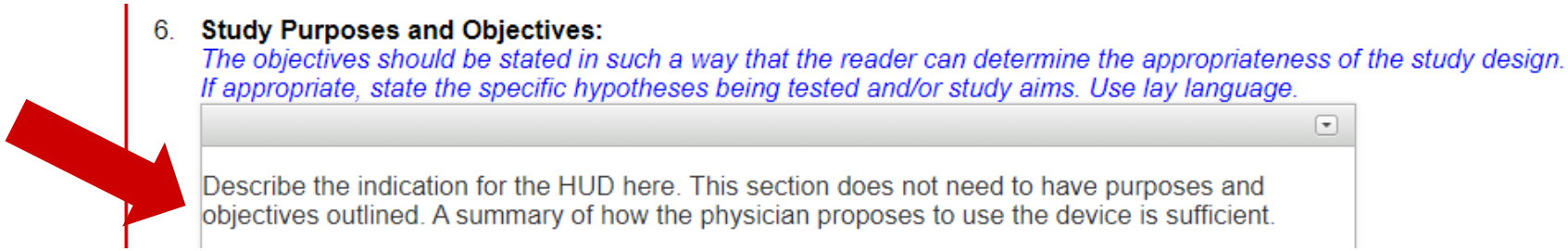
Physicians must **submit a New Study Application in ERICA**. The ERICA application will use terms like “research” and “investigator” but for the purposes of an HUD application, those terms should be synonymous with “humanitarian use” and “physician”.

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

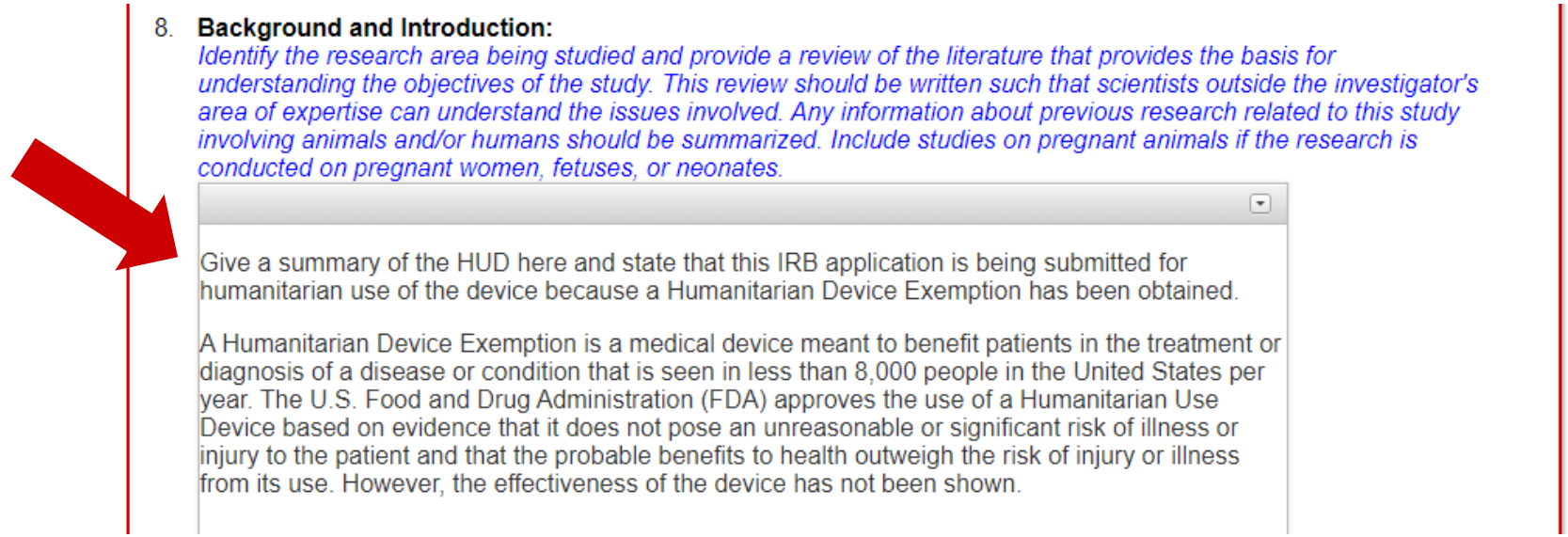
A **consent document** for humanitarian use should be included in the application. The IRB provides a template here: https://irb.utah.edu/forms/index.php

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.

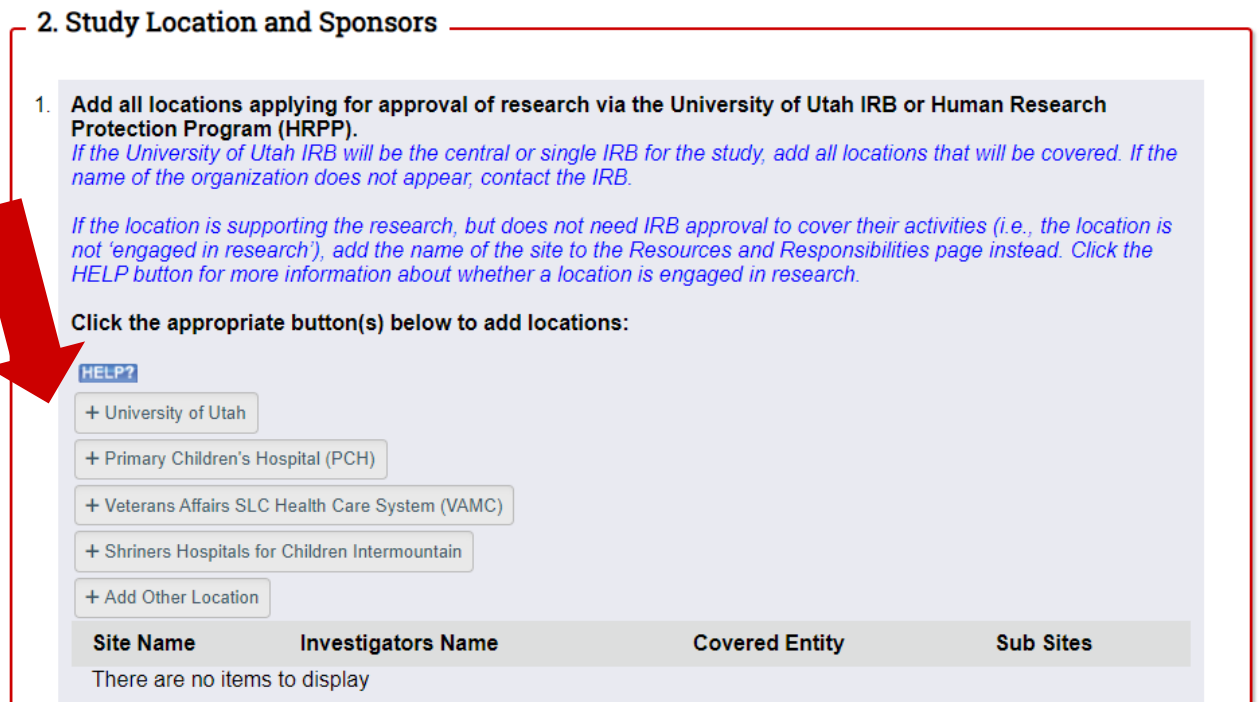


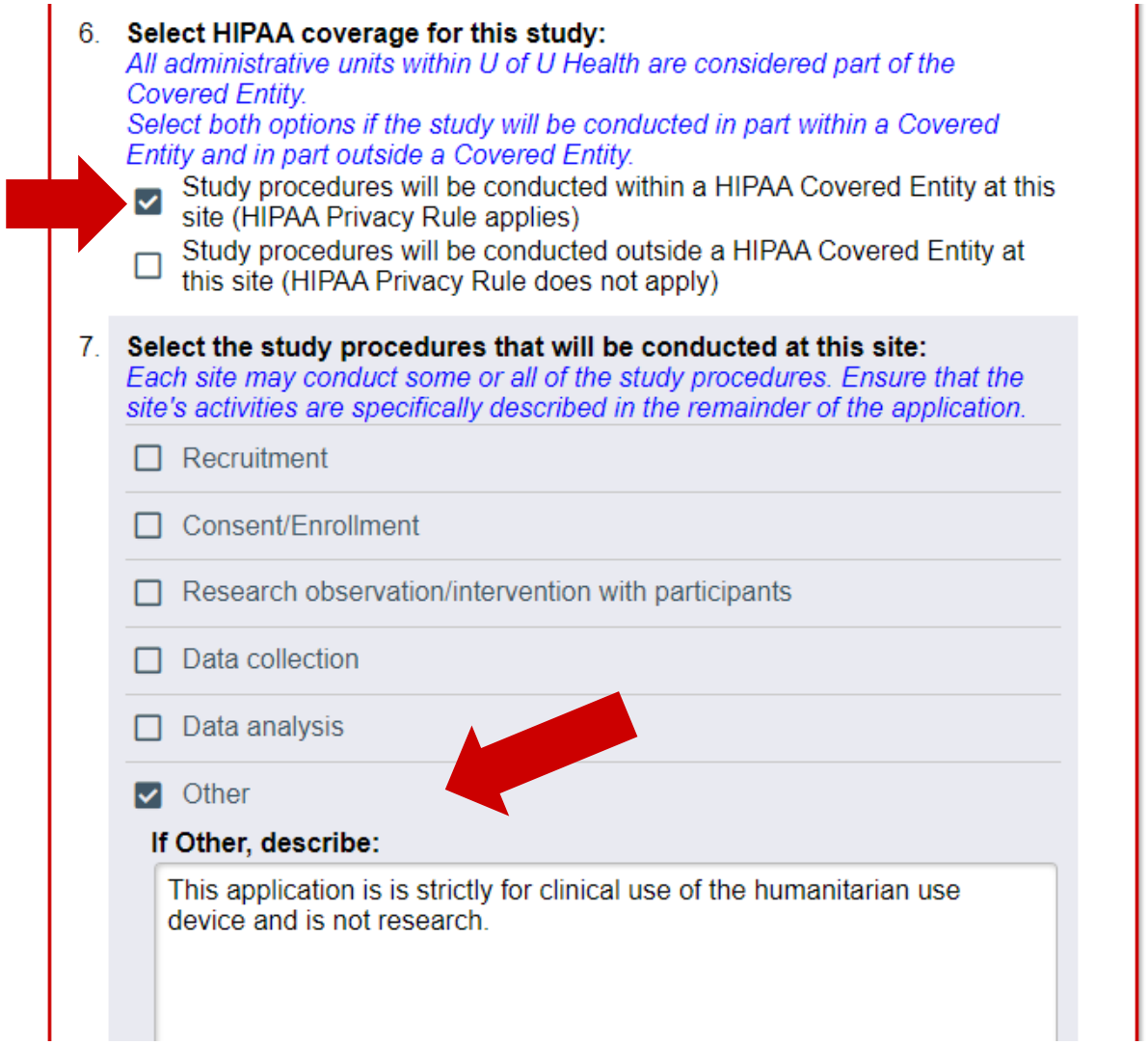
Question 8: Physicians can give a summary of the HUD and that the application is being submitted for the humanitarian use of the device. References are not required.



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.

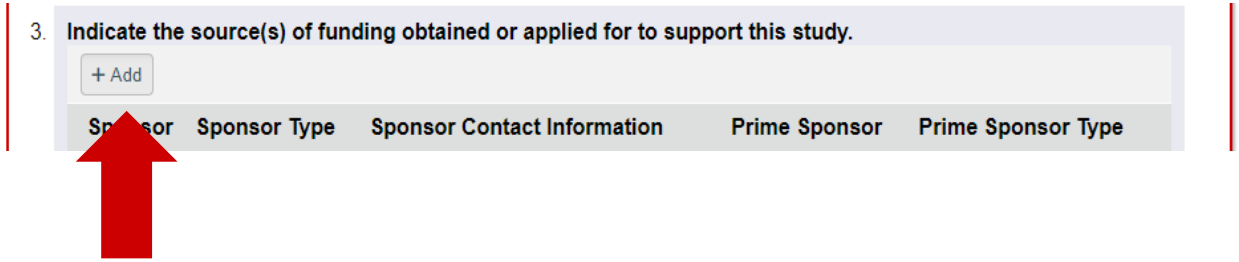


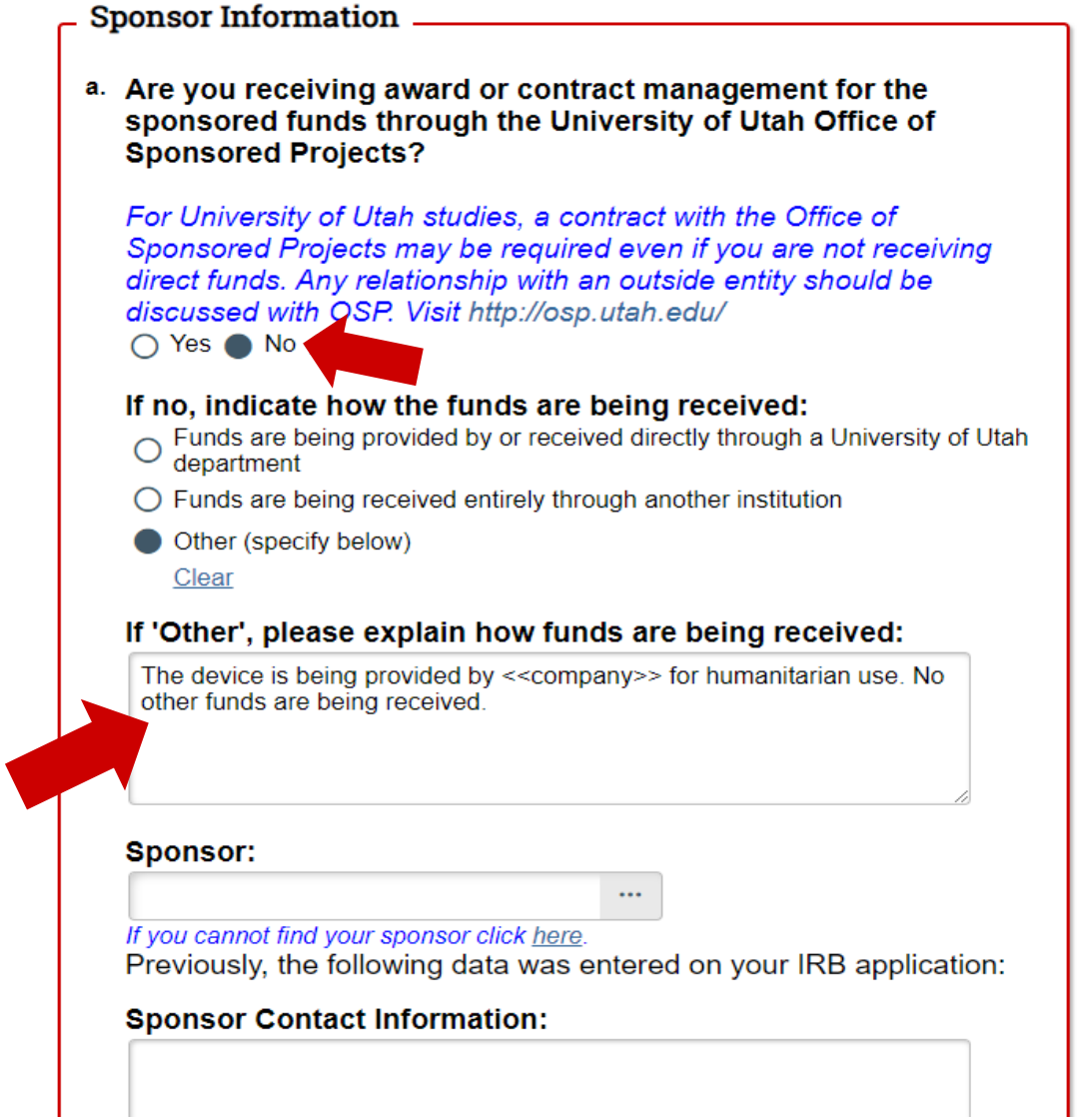


2. Study Location and Sponsor (cont.)

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.

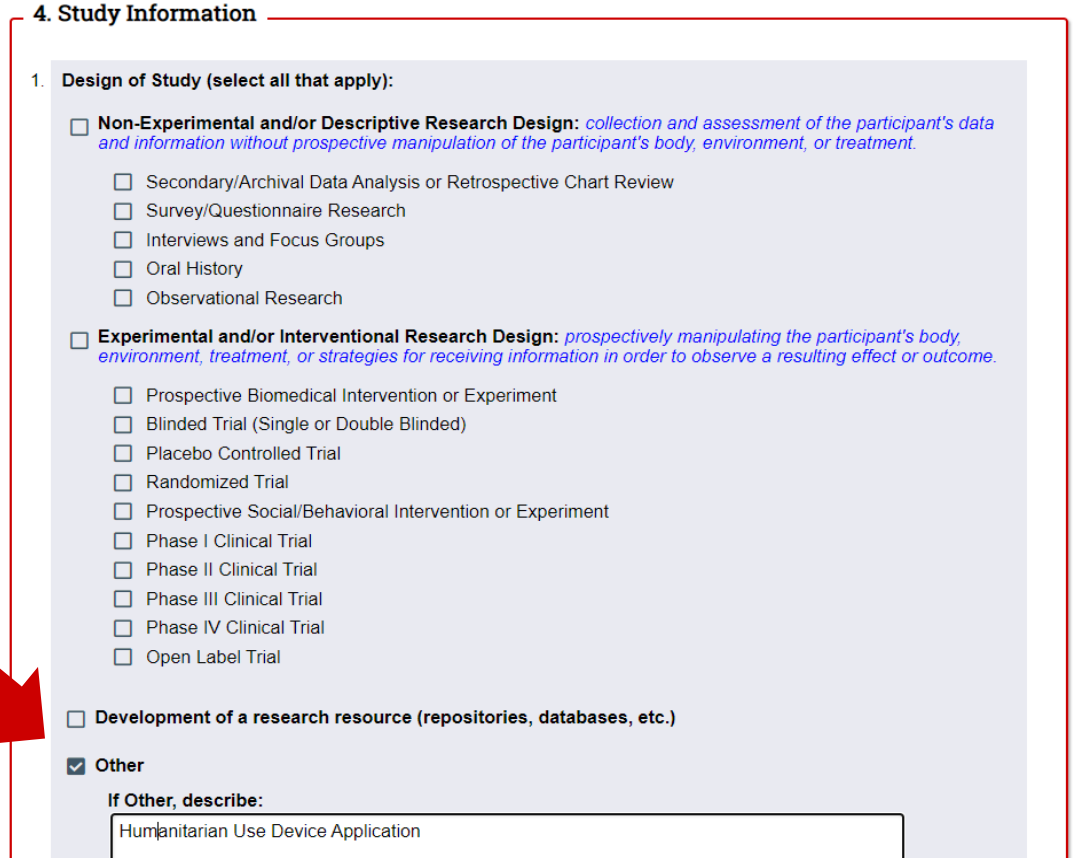
Select “Other” and state that only the device is being provided for humanitarian use and no other funds will be received.





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



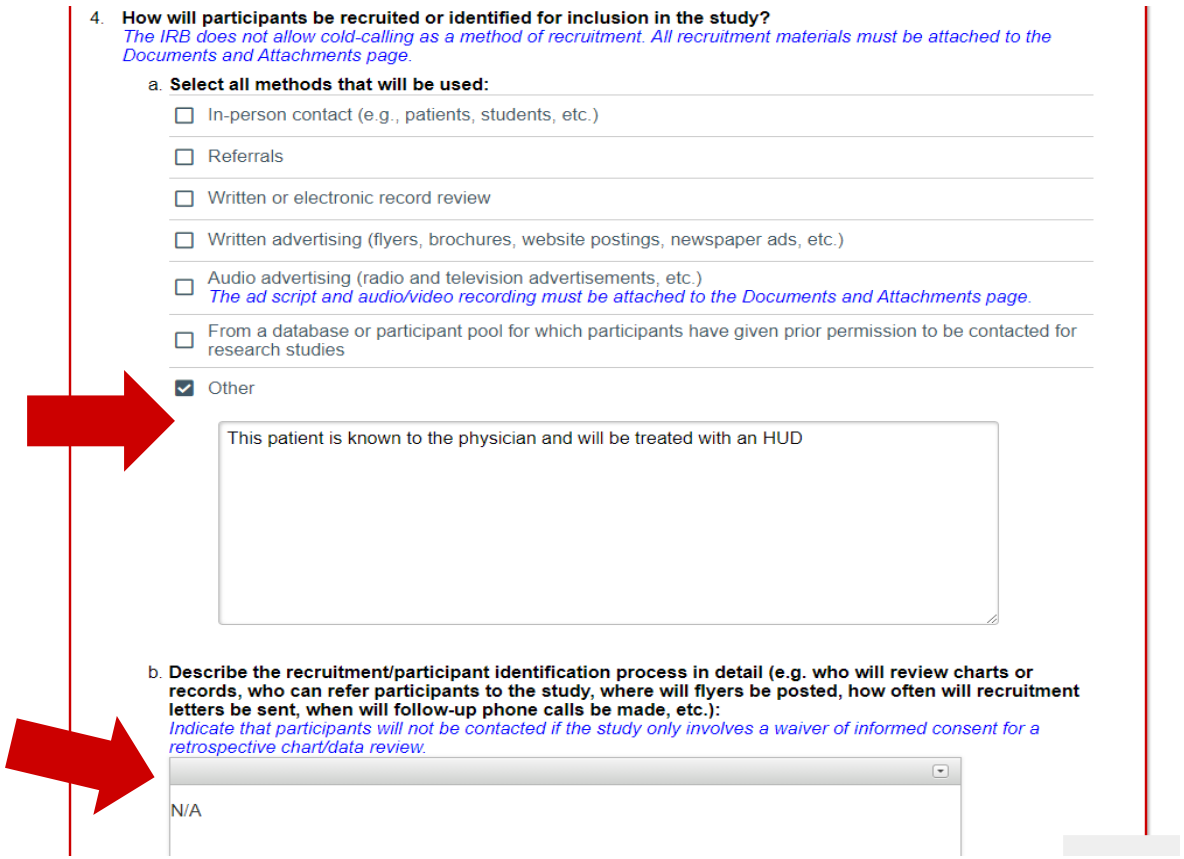
4. Study Information

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:**

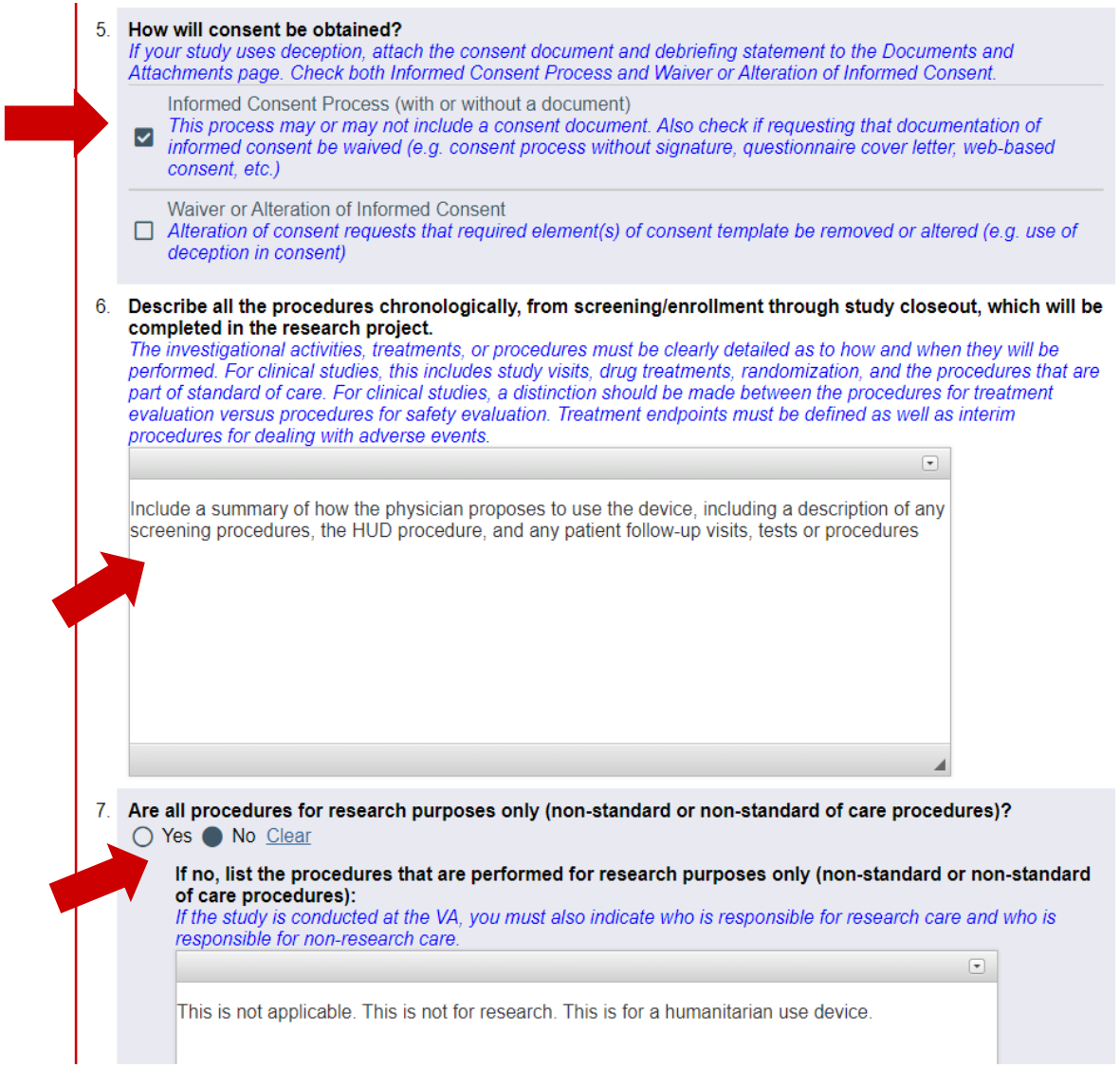
- ☐ In-person contact (e.g., patients, students, etc.)
- ☐ Referrals
- ☐ Written or electronic record review
- ☐ Written advertising (flyers, brochures, website postings, newspaper ads, etc.)
- ☐ Audio advertising (radio and television advertisements, etc.)
  The ad script and audio/video recording must 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

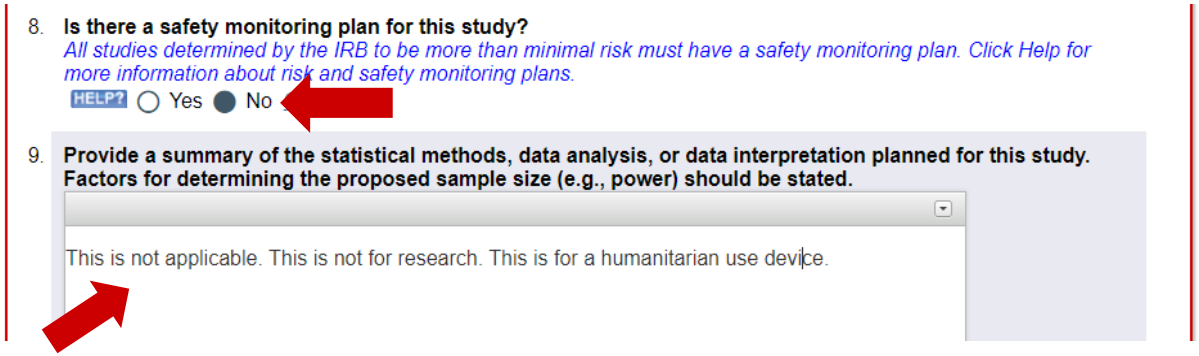
b. **Describe the recruitment/participant identification process in detail (e.g. who will review charts or records, who can refer participants to the study, where will flyers be posted, how often will recruitment letters be sent, when will follow-up phone calls be made, etc.):**
Indicate that participants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



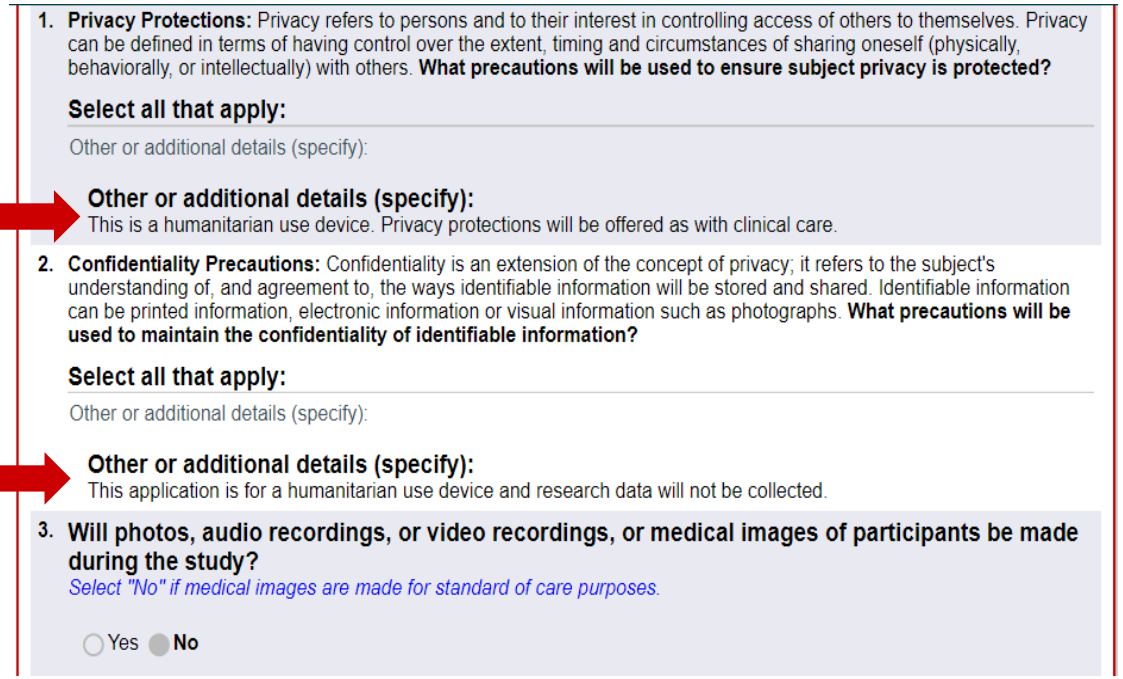
Question 5: Select “Informed Consent”. **University of Utah requires a consent for HUD.**
Question 6: Include a summary of how the physician will use the device, including a description of any screening procedures, the HUD procedure, and any patient follow-up visits, tests or procedures.
Question 7: Select “no”. State that this is N/A.
Question 8: Select “no”.
Question 9: State that this is N/A.



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?**

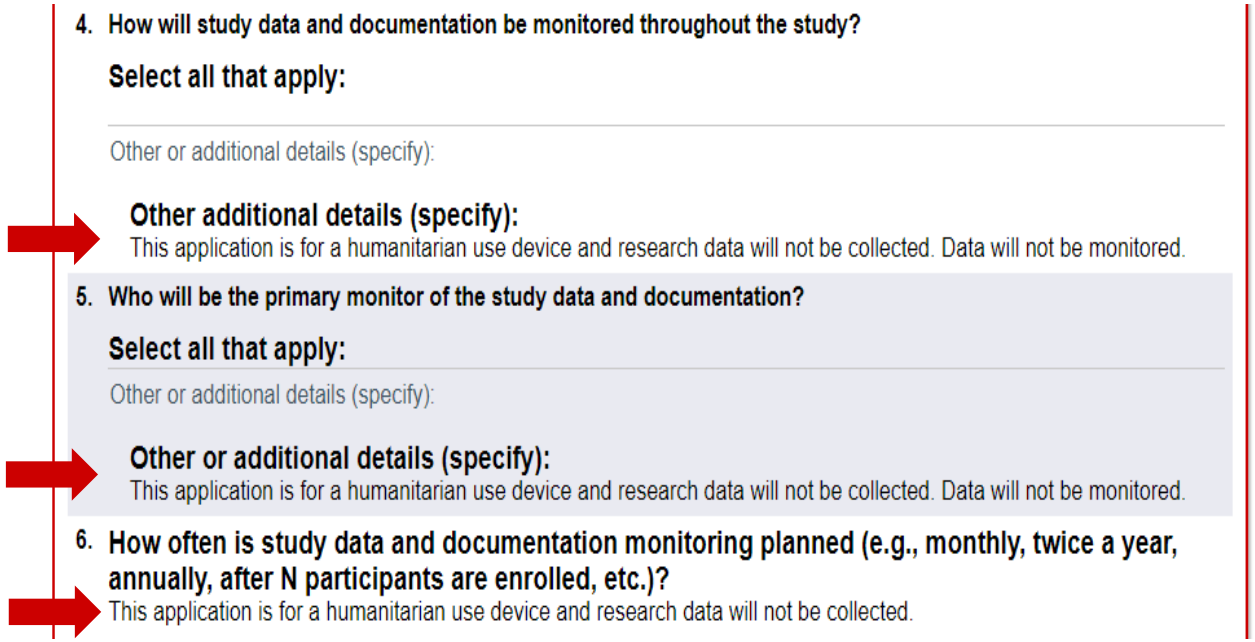
   Select all that apply:

   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.

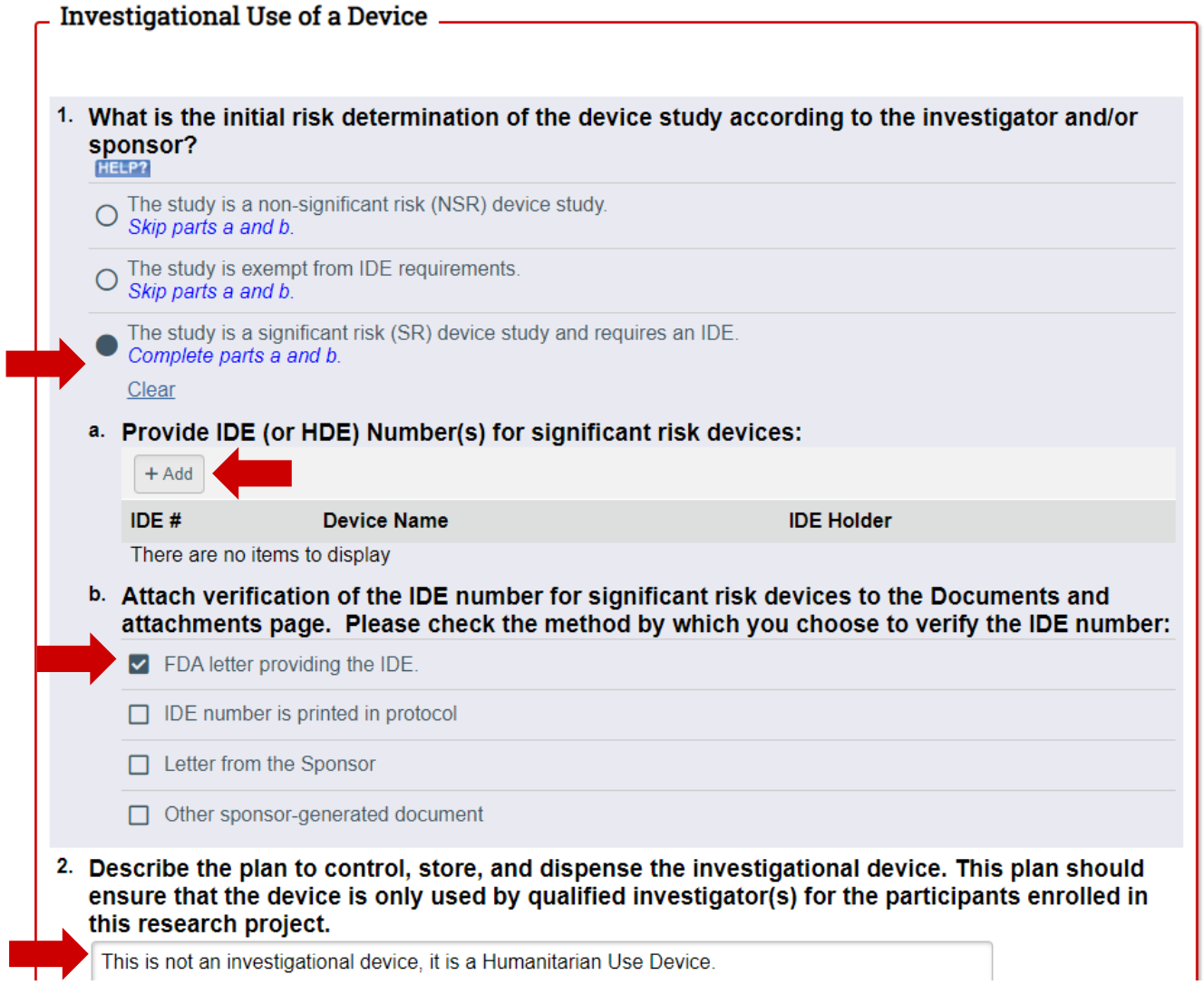
7. HIPAA and the Covered Entity

Question 1: Select “Yes”.
Question1a: Select “Consent and Authorization Document”.
Question 1b: Select “No”.

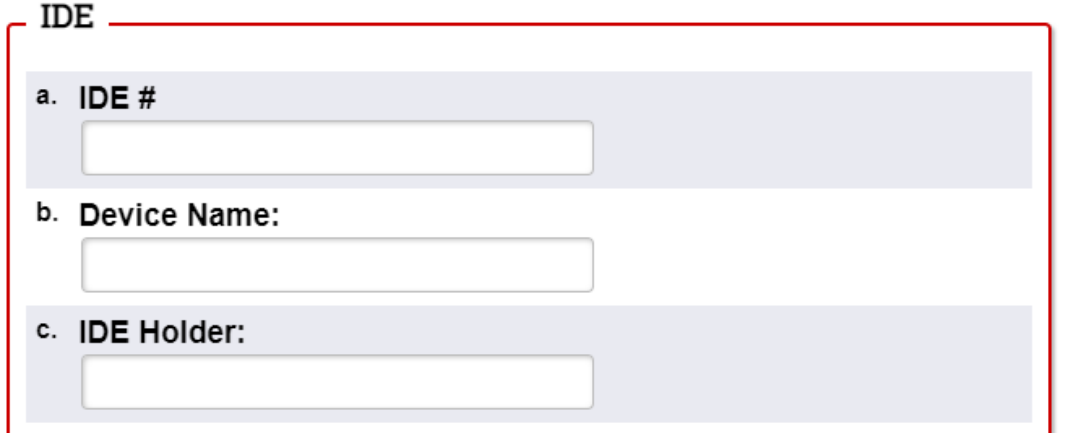
Question 3: Select “No”.

Question 6: Select “Yes”.

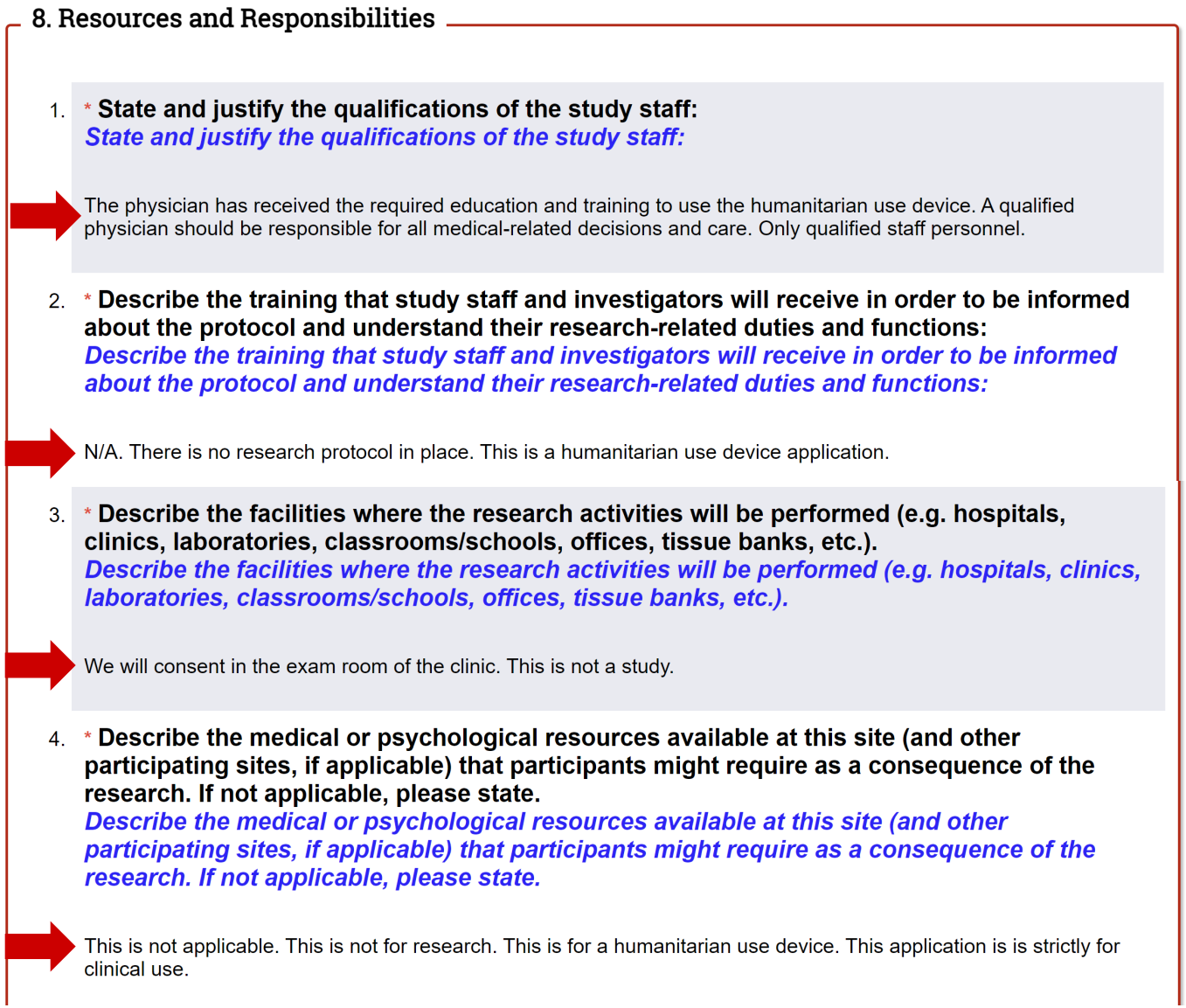
Investigational Use of a Device



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".



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 is strictly for clinical use.

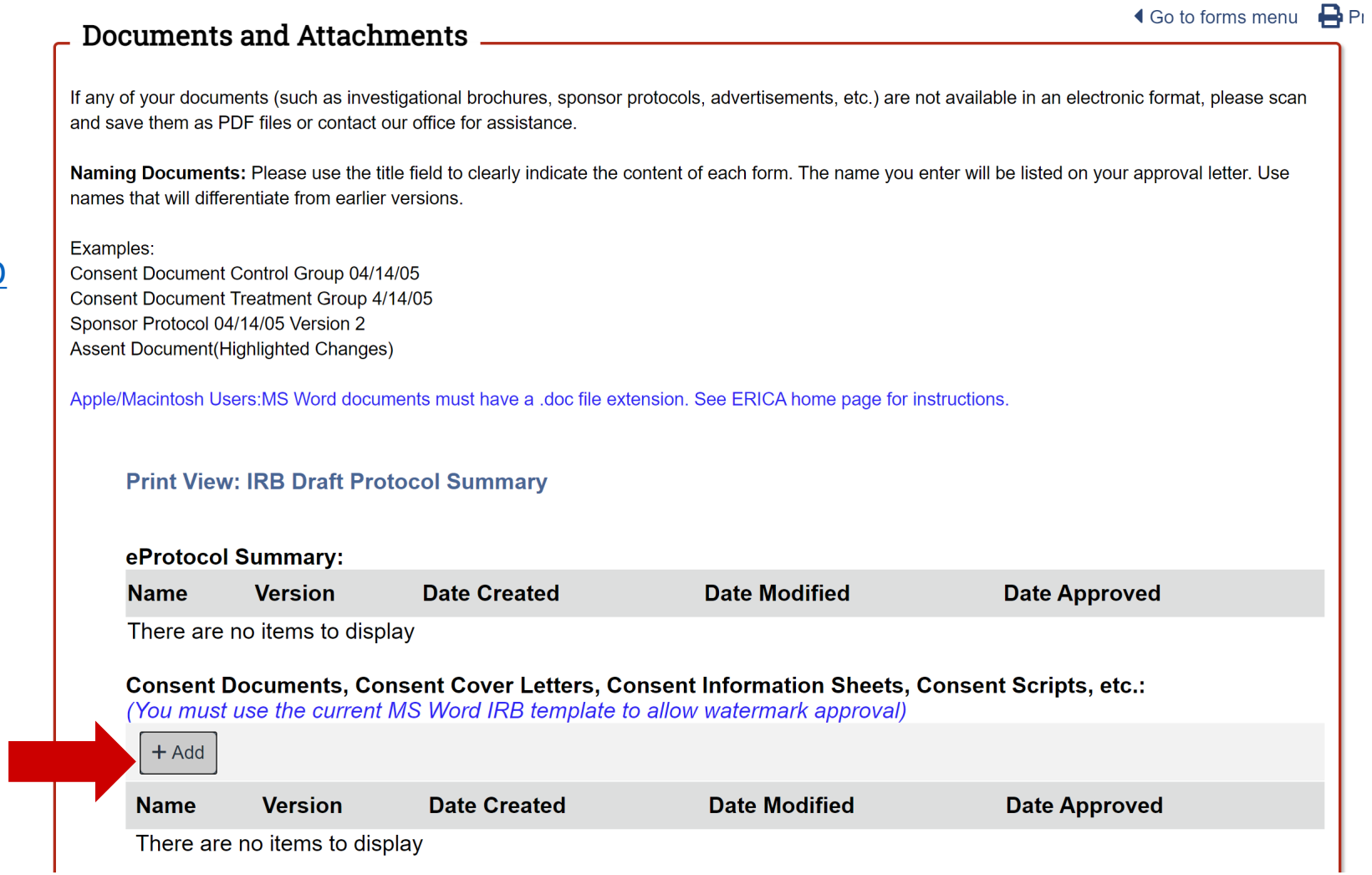
Questions 1-4: This page is intended to outline the research resources and responsibilities of the research staff which does not apply for the humanitarian use device. Sample answers can be seen in the graphic.

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.



Questions?

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