Humanitarian Use Devices (HUDs)

Medical University of South Carolina

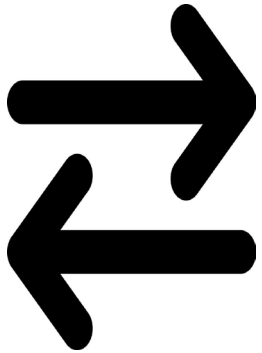
What is a HUD?

A medical device intended to benefit patients in the treatment and diagnosis of a disease or condition that affect or is manifested in fewer than 8,000 individuals in the US per year.

Humanitarian Device Exemption (HDE)

HUD with HDE

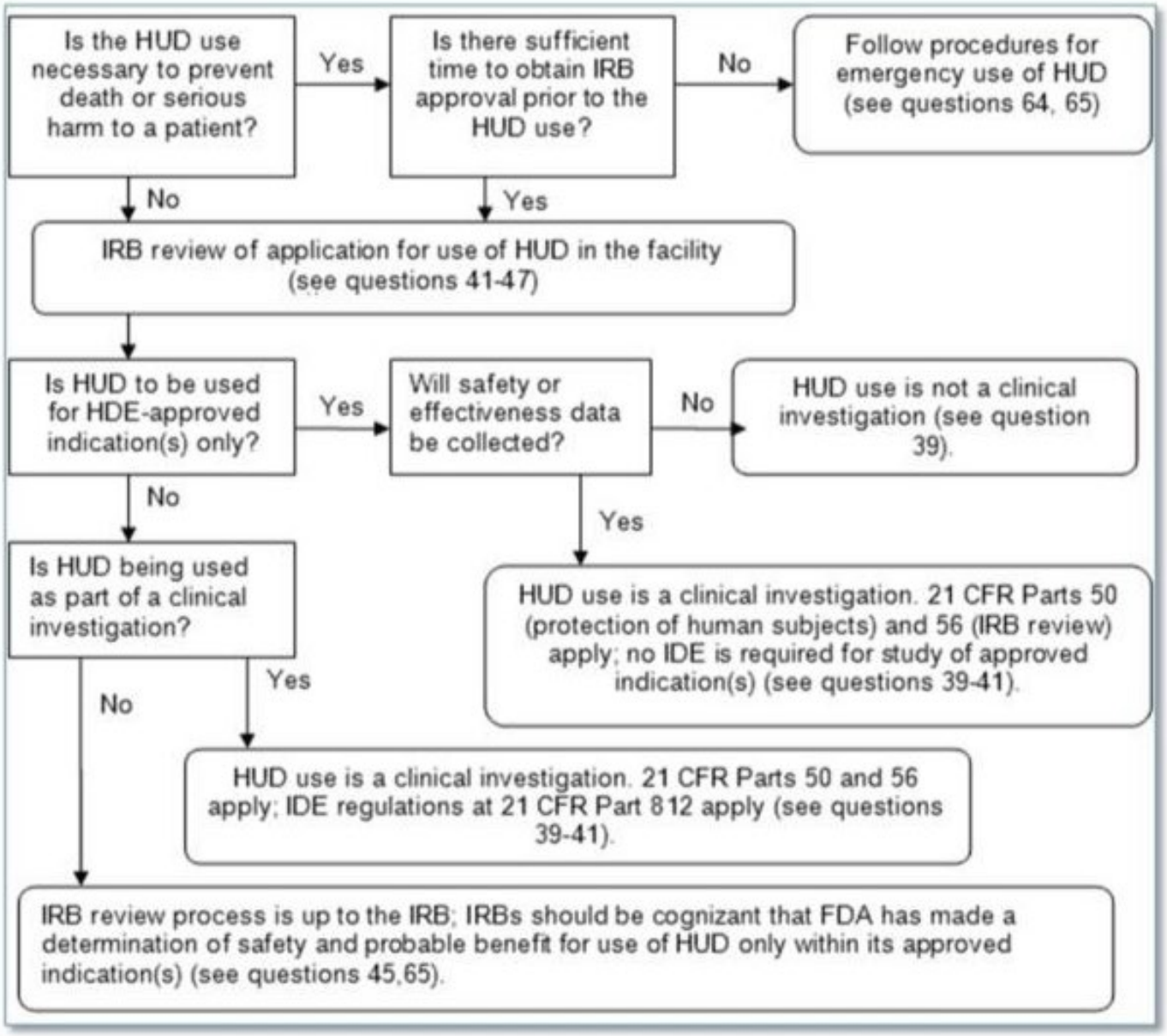
- Treatment *is not* considered research, but the FDA requires IRB approval prior to use
- No SR/NSR determination needed



HUD without HDE

- Clinical investigation of HUD = safety and effectiveness data will be collected on the HUD for the purpose of supporting a premarket approval (PMA) application
- *Is* considered research
- All policies and procedures applicable to human subjects research must be followed

IRB HRPP 4.6



Guidance can also be found on the IRB Website Forms Page: Humanitarian Use Device eIRB Application Guidance Document

Continuing Review/Reportable Events

- Continuing Reviews (CRs)
  - Approved for one year or less
  - Follow procedures and requirements by FDA in its clinical investigation regulations (21 CFR 56)
  - Unless the Board decides otherwise, CRs can be reviewed via expedited procedure
    - A HUD marked under an HDE is a legally marketed device and its use in clinical care does not constitute “research”
- Reportable Events (REs)
  - Unanticipated problems/adverse events/etc.
  - Submitted to the IRB in accordance with policies and procedures involving the use of investigational devices under an IDE application

eIRB Application Review

- **Section 1 - Study Identification Information**
  - 2.0 (Short Title): HUD is included at the end of the short title to easily identify that the study is a HUD
- **Section 2 - Human Subjects Research**
  - 3.0 = YES *(Does this study involve a HUD?)*
  - All other responses (1.0, 2.0, & 4.0) = NO

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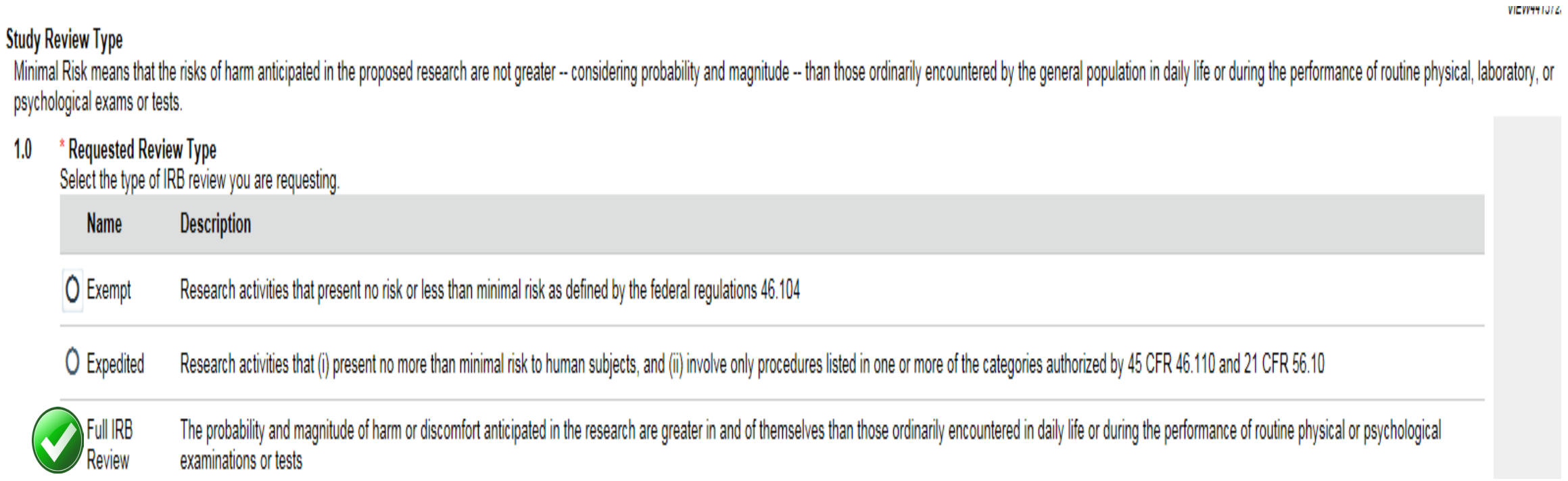
- **Section 4 – Study Review Type**
  - Require Full Board Review



Study Review Type

Minimal Risk means that the risks of harm anticipated in the proposed research are not greater -- considering probability and magnitude -- than those ordinarily encountered by the general population in daily life or during the performance of routine physical, laboratory, or psychological exams or tests.

1.0 * Requested Review Type

Select the type of IRB review you are requesting.

Name	Description
○ Exempt	Research activities that present no risk or less than minimal risk as defined by the federal regulations 46.104
○ Expedited	Research activities that (i) present no more than minimal risk to human subjects, and (ii) involve only procedures listed in one or more of the categories authorized by 45 CFR 46.110 and 21 CFR 56.10
✓ Full IRB Review	The probability and magnitude of harm or discomfort anticipated in the research are greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests

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- **Section 5 – Study Protocol**
  - Device manual and any safety sheets or brochures need to be uploaded
- **Section 6 – Study Populations – Study Subjects**
  - 1.0: Number of patients that the device will be used on
  - 3.0: Include statements:
    1. The project does not involve research
    2. Where the clinical procedure will take place
  - 7.0-9.0: Description of the clinical population that the device will be used on
    - 9.0 (specifically): Indication for the device?
      - Exclusions can be contraindications for the use of the device
- **Section 7 – Funding**
  - Who is paying for the device?

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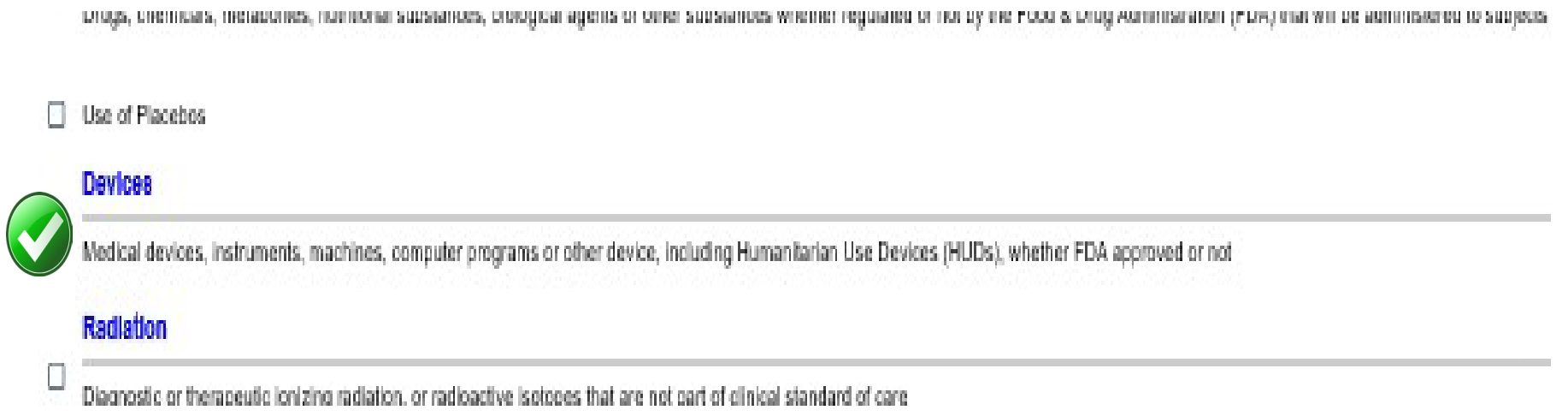
- **Section 8 – Application Checklist**
  - “Devices” should be the only selected item!



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- **Section 9 – Other Study Specifics**
  - Study Procedures
    - Both questions are N/A
      - Use of the HUD is not part of a research study
  - Study Risks and Precautions
    - 1.0: Risks outlined for the device
    - 2.0 & 3.0: Patients need to be followed/monitored after the procedure
      - This is not a research study, so no data or safety monitoring plans need to be utilized
  - Potential Benefits
    - 1.0: What are the clinical benefits?
      - 1.0 would = “YES” if the HUD has been deemed appropriate to be used clinically.
    - 2.0: Statement that it is a HUD

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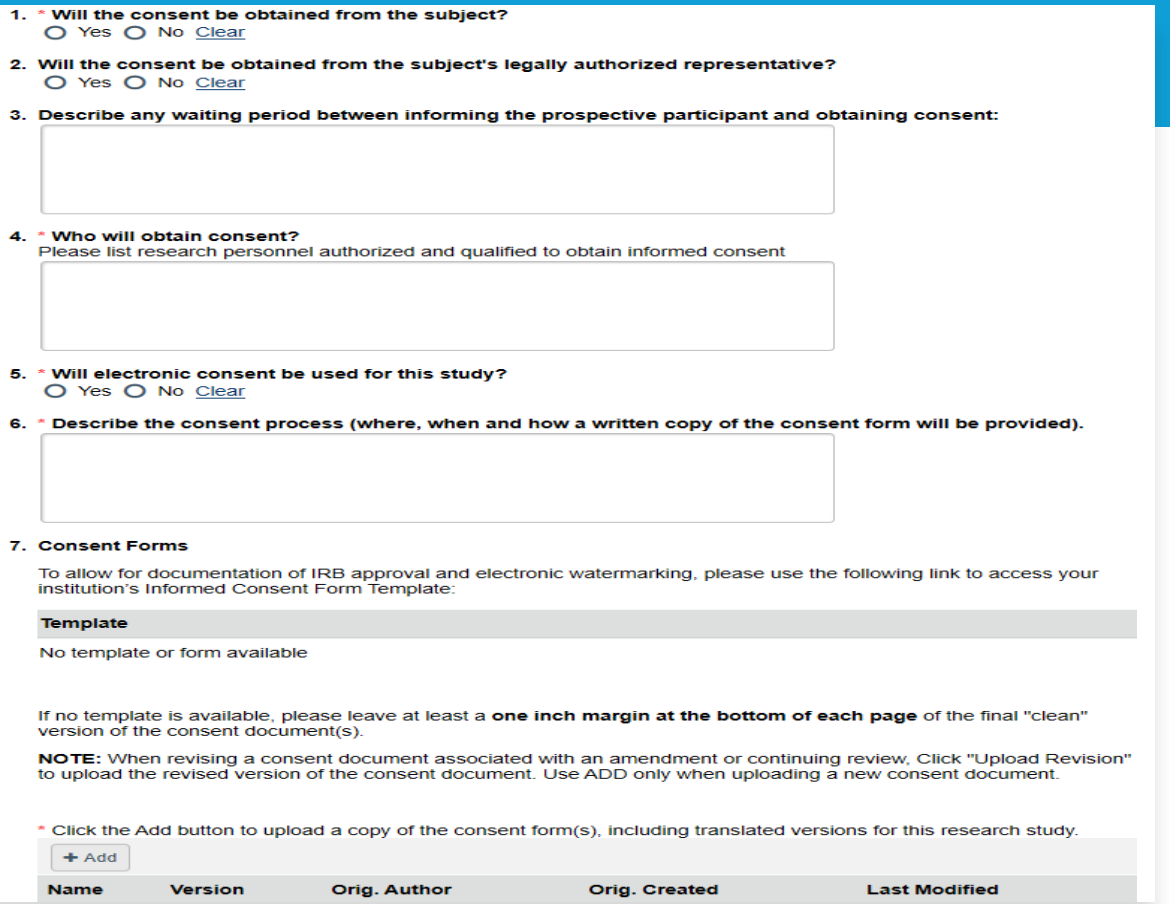
- **Section 11 – Consent Process**
  - 1.0 = YES
    - Needs to be made clear that a research consent will not be obtained but a clinical consent will be provided.
  - 7.0: Clinical Consent uploaded



1. * **Will the consent be obtained from the subject?**
   ○ Yes ○ No Clear
2. **Will the consent be obtained from the subject's legally authorized representative?**
   ○ Yes ○ No Clear
3. **Describe any waiting period between informing the prospective participant and obtaining consent:**
4. * **Who will obtain consent?**
   Please list research personnel authorized and qualified to obtain informed consent
5. * **Will electronic consent be used for this study?**
   ○ Yes ○ No Clear
6. * **Describe the consent process (where, when and how a written copy of the consent form will be provided).**
7. **Consent Forms**

To allow for documentation of IRB approval and electronic watermarking, please use the following link to access your institution's Informed Consent Form Template:

Template
No template or form available

If no template is available, please leave at least a **one inch margin at the bottom of each page** of the final "clean" version of the consent document(s).

NOTE: When revising a consent document associated with an amendment or continuing review, Click "Upload Revision" to upload the revised version of the consent document. Use ADD only when uploading a new consent document.

* Click the Add button to upload a copy of the consent form(s), including translated versions for this research study.

+ Add

Name	Version	Orig. Author	Orig. Created	Last Modified

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- **Section 12 – Privacy**
  - Privacy and Confidentiality
    - 1.0: Looking for the following statements:
      - No research data is being collected because this is not a research study
      - Everything related to the device, and it's associated procedures will be in the patient's EMR
      - Only clinical personnel who already have access to the patient's EMR will have access to the details of the device and procedure
    - 4.0: Participation WILL be documented in EPIC
  - Protected Health Information (PHI) for Research
    - 1.0: None of the above 18 identifiers will be used/disclosed for this research study
  - General Comments
    - FDA letter and any other required documents that haven't already been uploaded are included here!

Example

HUD: A shunt that will be utilized for patients diagnosed with Bladder outlet obstructions/Fetal urinary tract obstructions.

SUMMARY- Bladder shunt
This device will be used to treat …
The procedure will be performed as follows:
…

Patients will follow up weekly/monthly/etc. …

What questions do you have?