**TITLE:  *Research – Humanitarian Use Devices (HUD)***

1. **Purpose/Expected Outcome:**
   1. To establish a process to ensure appropriate submission, review, accountability and tracking of devices approved for use by the Food and Drug Administration (FDA) under the Humanitarian Device Exemptions (HDE) regulations. Such devices are referred to as Humanitarian Use Devices or HUD’s.
2. **Definitions:**
   1. Emergency Use – use of a Humanitarian Use Device outside of its FDA-approved labeling (i.e., off-label) in a life-threatening situation in which no comparable device, other than another Humanitarian Use Device or a device being studied under an approved Investigational Device Exemption (IDE), is available to treat or diagnose the condition and in which there is not sufficient time to obtain Institutional Review Board (IRB) approval. The same procedures governing emergency use of unapproved (i.e., investigational) devices apply in an emergency situation involving a Humanitarian Use Device. (See ***Policy: Emergency Use of an Investigational Drug, Biologic or Device or Off-Label Use of a Humanitarian Use Device (HUD)***).
   2. Fact Sheet – a short form consent incorporating information from the product labeling to assist a patient in making an informed decision about the use of the device. Information contained in the Consent consists of a description of the device/procedure, the potential risks and benefits of the device as well as any alternative treatments and estimated costs. It also states that the device is a Humanitarian Use Device for which effectiveness for the labeled indication has not been demonstrated.
   3. Humanitarian Use Device (HUD) – as defined in 21 CFR 814.3(n), a “medical device intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in fewer than 4,000 individuals in the United States per year.”
3. **Policy:**
   1. General.
      1. All use of HUD’s at Banner facilities shall be subject to prior review and approval by the IRB.
         1. As HUD’s are FDA approved devices, so long as the use is within the FDA-approved indication and the other provisions of this policy are met, a Banner Health IRB may approve use of the device however it sees fit. For example, the IRB may approve use of the HUD without any further restrictions, use of the device only under a protocol, use of the device on a case-by-case basis or use of the device limited to a physician(s).
      2. HUD’s are not investigational devices. Therefore, no safety or efficacy data will be collected following their use without disclosure to the IRB of plans for such use of patient information. Any use of a HUD in connection with a research study shall be in accordance with the Banner policies governing research, which shall take precedence over this policy.
      3. Emergency use of a HUD is subject to ***Policy: Emergency Use of an Investigational Drug, Biologic, or Device or Off-Label Use of a Humanitarian Use Device (HUD)***. All procedures outlined in that policy should be followed and reports of emergency use should be submitted to the IRB within the time limitations set forth therein.
      4. For non-emergency use of a HUD in an off-label manner, a physician may request FDA approval through the Sponsor on a case-by-case basis.
   2. Consent.
      1. When a HUD is used for its approved indication, no informed consent form is required by FDA regulations. However, Banner’s IRB requires a separate modified informed consent, along with requiring the patient be given a copy of the product’s patient labeling which discusses potential risks and benefits of the device.
      2. Per the FDA’s Guidance on HDEs, the modified informed consent should include the following:
         1. an explanation that the HUD is designed to diagnose or treat the disease or condition described in the HDE labeling and that no comparable device is available to treat the disease or condition;
         2. a description of any ancilliary procedures associated with the use of the HUD;
         3. a description of the use of the HUD;
         4. all known risks of harm or discomforts;
         5. an explanation of the postulated mechanism of action of the HUD in relation to the disease or condition;
         6. an acknowledgement that the effectiveness of this device for this use has not been demonstrated.
      3. At a minimum, the patient should be informed through the product labeling or other sponsor documentation that the device is a HUD for which effectiveness for the labeled indication has not been demonstrated.
   3. IRB Review.
      1. IRB review of a requested HUD shall be initiated only after the involved facility Department Head, facility finance and facility administration have approved the use of the product.
      2. HUD’s require review and approval by a fully convened Banner IRB prior to use and shall be subject to continuing review.
      3. For continuing review, expedited review procedures may be used unless the Banner IRB determines that full board review should be performed. Per FDA Guidance, expedited review procedures would be appropriate since the initial review was performed by the full board and use of a HUD within its approved labeling does not constitute research.
4. **Procedure/Interventions:**
   1. The applicable Department Head will contact Banner Research to initiate an application to use a humanitarian device.
      1. Banner policy requires prior review and approval by the assigned Research Director, facility administration/finance, facility departments, Medical Staff Services (if credentialing to use the HUD is required) and Supply Chain Services.
      2. Applications not containing the requisite signatures indicating prior facility review and approval will be returned to the Department Head for proper completion.
      3. The facility Department Head will assume responsibility for monitoring and oversight of the HUD (21 CFR 814.124(a)), to include but not limited to, the sponsor training and physician use of the device. Physician training will be required and logged prior to IRB approval and use of any device. Documentation of physician qualifications must also be submitted to the IRB for review.
      4. User facilities must submit reports to FDA, the IRB, and the manufacturer whenever a HUD may have caused or contributed to a death, and must submit reports to the manufacturer whenever a HUD may have caused or contributed to a serious injury per the FDA Guidance (21 CFR 803.30 and 814.125(a)).
      5. Department Head will assure all applicable personnel at designated facilities complete the Collaborative Institutional Training Initiative (CITI) Training for use of a HUD before requesting IRB review and approval.
   2. A Banner Research Regulatory Specialist will process the application and place it on the agenda of the next scheduled meeting for full board review by the applicable IRB panel.
   3. The IRB will communicate its decision regarding use of the HUD in writing to the Department Head within seven (7) days following IRB review. All determinations of the IRB should be clearly set forth in the IRB correspondence including, but not limited to, the following:
      1. any restrictions or additional requirements imposed on the use of the HUD;
      2. approval of informed consent or requested changes;
      3. any special procedure and documentation for obtaining informed consent;
      4. any other directives concerning product access, approved users or physician qualifications; and
      5. the appropriate period of time for continuing review of the use of the HUD, but not more than annually.
   4. If data will be collected and submitted to FDA in support of a Pre-Market Approval (PMA) application, the FDA considers the use research and an IDE is required. Research involving use of a HUD should be submitted in accordance with ***Policy: Institutional Review Board (IRB) Initial Review of Research – Full Board*** and should not be submitted in accordance with III.C. of this policy.
5. **Procedural Documentation:**
   1. N/A
6. **Additional Information:**
   1. N/A
7. **References:**
   1. FDA Guidance on Humanitarian Device Exemption (HDE): Questions and Answers
   2. 21 Code of Federal Regulations (CFR) Part 812
   3. 21 CFR Part 56
   4. 21 CFR Part 814 Subpart H
8. **Other Related Policies/Procedures:**
   1. ***Policy: Emergency Use of an Investigational Drug, Biologic or Device or Off-Label Use of a Humanitarian Use Device (HUD) (#3143)***
   2. ***Policy: Initial IRB Review of Research – Full Board (#3115)***
9. **Keywords and Keyword Phrases:**
   1. HUD
   2. HDE
   3. Humanitarian Device Exemptions
   4. Humanitarian Use
   5. Institutional Review Board
   6. Research
   7. IRB
10. **Appendix:**
    1. Humanitarian Use Device Consent

*[Insert Facility Name]*

**HUMANITARIAN USE DEVICE CONSENT**

|  |  |  |
| --- | --- | --- |
| Name of Device: | | |
| Device Manufacturer: | | |
|  | Telephone No.  (regular office hours) | Telephone No.  (other times) |
| Physician Name: |  |  |
| Department Head: |  | n/a |

A Humanitarian Use Device (HUD) is intended for use in patients with conditions that affect less than 4,000 people in the United States.

Since the number of patients is so small, the Food and Drug Administration (FDA) has approved the use of HUDs for the clinical treatment of patients without the same amount of testing that other products get. The FDA believes that these devices are likely to be safe and will probably benefit patients.

The purpose of this form is to help you understand how *[specify device]* relates to your condition, as well as the risks and benefits of using it.

**DESCRIPTION:** [*Provide information on why the patient is a candidate for the use of the device (medical condition). State name of device and description of use/how used.*]

**INDICATION FOR USE:** This device has been approved by the FDA for use *[insert as stated on the FDA approval letter or sponsor documentation]*. The effectiveness of this device for these uses has not been demonstrated.

**POSSIBLE RISKS:** *[provide information describing the possible risks, side effects and/or adverse events associated with the HUD and its proposed use].*

**POSSIBLE BENEFITS:** *[provide information regarding the benefits associated with the use of the device].*

**ALTERNATIVE TREATMENTS:** *[describe alternative treatments that may be available to patients].*

**FINANCIAL RESPONSIBILITIES:** You or your insurance provider will be responsible for any costs or charges associated with the use of the *[add the name of the device]* and the surgical procedures needed to insert the device. All other costs relating to your normal care will be billed in the usual manner.

**YOU WILL HAVE A COPY OF THIS CONSENT FORM TO KEEP.**

Your signature below certifies the following:

|  |  |  |
| --- | --- | --- |
| • |  | You have read (or been read) the information provided above. |
| • |  | You have received answers to all of your questions. |
| • |  | You have received and read the manufacturer’s Product Information Brochure about this device. |
| • |  | You have freely decided to allow your doctor to use this device in your care. |
|  |  | You understand that you are not giving up any of your legal rights. |

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| --- | --- | --- | --- | --- |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Patient’s Name (printed) | |  |  | |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Patient’s Signature | |  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date/Time: AM-PM | |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Legally Authorized Representative’s Name (printed) | |  |  | |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Legally Authorized Representative’s Signature | |  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date/Time: AM-PM | |
| *Relationship to Patient:*  *Parent*  *Legal Guardian*  *Other:* | | |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Person Witnessing Consent Name(printed) | |  |  | |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Person Witnessing Consent Signature | |  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date/Time: AM-PM | |