



Investigator Guidance: Submission of HUDs to IRB

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Purpose:

To provide guidance for physicians who do not have regulatory or research operations support and are requesting IRB approval for HUDs at AdventHealth facilities.

It is recommended that you contact the AdventHealth IRB prior to starting the below process at 407-200-2677 or email ORL.IRB.General@adventhealth.com.

Initial Submission and Approval:

1. As detailed on this website [Research Credentialing Process \(sharepoint.com\)](#):
 - a. The lead physician must:
 - i. Create a CITI account and affiliate with AdventHealth at www.citiprogram.org.
 1. Complete only the HUD Short course which includes a review of our SOP: [Humanitarian Use Device \(HUD\) v.3 \(navexone.com\)](#).
 - ii. Create an IRBNet account and affiliate with “AdventHealth, Orlando, FL” at www.irbnet.org.
 - iii. Link and verify their CITI & IRBNet accounts.
 - b. All other physicians and personnel listed on the HUD Supplement (details below) must:
 - i. Create a CITI account and affiliate with AdventHealth at www.citiprogram.org.
 1. Complete only the HUD Short course which includes a review of our SOP: [Humanitarian Use Device \(HUD\) v.3 \(navexone.com\)](#).
2. Person responsible for IRB submission must:
 - a. Review HUD SOP: [Humanitarian Use Device \(HUD\) v.3 \(navexone.com\)](#)
 - b. Create a New Project within IRBNet and complete or upload the following as individual documents:
 - i. HRP-200 Initial Application smart form
 - ii. HRP-505 HUD Supplement (must be in Word format)
 - iii. FDA HDE approval letter
 - iv. Device labeling, instructions for use, or manual
 - v. Patient brochure
 - vi. HUD specific consent, when required by the manufacturer or IRB. Note that most HUDs do not require a separate consent beyond the standard hospital treatment/surgery consent.
 - c. Submit the created project to “AdventHealth IRB, Orlando, FL”.
 - d. Provide the lead physician with full access to the project in IRBNet.

Annual Renewal:

Federal regulations require the IRB to renew HUD approval annually. You will receive automated renewal reminders at 90, 60, and 30 days prior to the expiration of IRB approval. IRB recommends submitting the renewal request 6 weeks prior to the expiration date.

1. Under the same IRBNet project number, create a new package.
 2. Complete and upload the HRP-205 Continuing Review Application HUD.
 3. Submit the package to AdventHealth IRB, Orlando, FL.
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Revisions:

Changes to previously submitted documents, including but not limited to updates to device labeling or instructions, revised patient brochures, or additions to physicians and personnel listed in the HUD Supplement, must be submitted for IRB review.

1. Under the same IRBNet project number, create a new package.
2. Complete the HRP-203 Modification Application smart form.
3. Upload the revised documents.
4. Submit the package to AdventHealth IRB, Orlando, FL.

Special Circumstances:

As described in Section F of the HUD SOP, there may be circumstances in which you need to use a HUD but do not have approval and do not have time to seek approval. You may need to submit an emergent use or compassionate use request. Contact the IRB for guidance on how to proceed.

References:

CW AHC SOP 236 – Humanitarian Use Device (HUD)
