

**Navicent Health IRB
Humanitarian Use Device Submission Packet
Required Documents**

NOTE:

- Humanitarian Devices require a Full Board Review except in an emergent situation
- **ALL** items must be received before a Humanitarian Device will be evaluated
- All forms must be filled out completely. No missing information.
- Application has been **signed in writing** by the Principal Investigator

Required Documents:

- Copy of the Humanitarian Device Exemption (HDE) approval
- HUD product labelling
- Patient Information booklets/leaflets to be issued to educate patients
- Summary of how the physician proposes to use the device, including
 - A description of any screening procedures to be used
 - The HUD procedure
 - Any patient follow-up visits, tests, and/or procedures
- Investigator Information
 - CV for each investigator
 - Documentation of any training completed related to the use of the specific HUD
- Conflict of Interest Disclosure for requesting physician
- Copy of Informed Consent
 - A Certificate of Translation Accuracy for consents/assents used in different languages

List any Additional Documents Submitted.