**Emory IRB HUD Submission Checklist**

**For Protocols using HUD for Treatment Purposes**

What are Humanitarian Use Device Exemptions? Humanitarian Use Device Exemptions (HDEs) are exemptions provided by the Food and Drug Administration (FDA) to allow the use and marketing of an Investigational Medical Device that is “intended to benefit patients in the treatment and diagnosis of diseases or conditions that affect or are manifested in fewer than 4,000 individuals per year in the United States.” (*IRB P&Ps, Chapter 68, page 262*).

Before the use of a HUD for **treatment** purposes, the PI needs to secure IRB approval. See below the items needed to submit a HUD protocol for treatment purposes:

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| --- | --- | --- |
| Document to submit | Description | Link to Template |
| Protocol | Summary of how the physician proposes to use the device, including a description of any screening procedures, the HUD procedure, and any patient follow-up visits, test, or procedures. Please include a description of the device in this document.  If you have a protocol already, please review our HUD Protocol Guidelines to ensure all information is present. Otherwise please use our guidelines document to create your protocol. | [HUD for Treatment Use](http://irb.emory.edu/documents/HUD-Treatment-Protocol-Outline.docx) |
| Information Packet | Device Labeling: describes device risks/benefits, approved use and other device information | FDA website: <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/HDEApprovals/ucm161827.htm> |
| Information Sheet: sheet containing important information patients should know before agreeing to receive treatment with the HUD device | If not in FDA website, use this [template](http://irb.emory.edu/documents/HUD-Patient-Information-Sheet.docx) in our website. |
| HDE approval order | FDA approval of HUD use | FDA website: <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/HDEApprovals/ucm161827.htm> |

Once these documents are ready, the request can be made via eIRB. Use this [link](http://www.irb.emory.edu/eirb/index.html) for videos or instructions of how to submit this proposed use to the IRB. Because this use is considered treatment and not research, CITI or any other research training is not required for these submissions. Please also consider the following:

* If you are obtaining data for research while using this device under the FDA approved application, please use the [Biomedical Protocol Template](http://www.irb.emory.edu/documents/Protocol%20Guidelines-Biomedical.docx) in our website. Your submission will be considered research, and you will be need to obtain the required research training, as well as any other [requirements](http://www.irb.emory.edu/forms/new.html) for research studies.
* If you are not using the device under the FDA approved application, and you are collecting data for research, you may need an IDE (investigational device exemption). For more information about these, please contact Maria Davila at [maria.davila@emory.edu](mailto:maria.davila@emory.edu).
* If you are not using the device under the FDA approved application, but you want to treat a patient, the use may fall under the compassionate or emergency use categories. For more information about these, please contact Maria Davila at [maria.davila@emory.edu](mailto:maria.davila@emory.edu).