**Emory IRB Protocol Outline
For Protocols using a HUD for Treatment Purposes**

**Full study title:** Click here to enter text.

**Principal Investigator:** Click here to enter text.

**Department:** Click here to enter text.

**HUD Holder:** Click here to enter text.

1. Summary of use: Click here to enter text.
2. Proposed treatment: Click here to enter text.
3. Patient selection: Click here to enter text.
4. Patient consent to treatment: Click here to enter text.

**NOTE**: The treating physician must document that they have provided this information sheet and taken time to go over it with the patient. This should be documented in the patient medical record or treatment record.

1. Device storage: Click here to enter text.

References

* [Emory P&Ps](http://www.irb.emory.edu/documents/PoliciesandProcedures.pdf), Chapter 68 (Humanitarian Use Devices: Exemptions & Uses)
* FDA [Guidance for HDE Holders, Institutional Review Boards (IRBs), Clinical Investigators, and FDA Staff - Humanitarian Device Exemption (HDE) Regulation: Questions and Answers](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm110194.htm)
* FDA guidance: [Humanitarian Use Device (HUD) Designations](http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM336515.pdf)