



UNIVERSITY HEALTH SYSTEM
All protocol forms submitted to UT IRB must accompany this proposal form.

AUTHORIZATION FOR HUMANITARIAN DEVICE USE

All boxes on the proposal must be filled out. Place N/A on sections that do not apply.

			Date	
Physician (Name, Degree, Department, Provider Number)		Phone Number		Fax Number
E-mail Address Alternate contact				
Alternate contact (Name, Degree, Department, Provider Number)		Phone Number		Fax Number
Department Contact:		Phone Number		Fax Number
E-mail Address				
DEVICE NAME and HDE #				
DEVICE Purpose * Please limit to 95 characters				
IRB Number	IRB Expiration Date	Projected Start Date In UHS Facilities	Projected End Date In UHS Facilities	Approx. #

SUBMIT COPY of IRB Humanitarian device forms and approval IRB letter and FDA approval letter.

I. Requested Institutional Support:

Project Site(s):

- University Hospital
- Site if other than the Hospital _____

A. List the contact person from your research team who will be responsible for submitting the Progress report on number of devices and any adverse events.

Name _____ Phone Number _____ E-Mail _____

V. Funding Source for HDE: Any device requiring UHS purchase, Requires Submission to Product Evaluation Committee approval if not eligible for third party reimbursement.