

Submit three collated sets to IRC	<input type="checkbox"/> This form <input type="checkbox"/> Your dated and current <i>curriculum vitae</i> <input type="checkbox"/> Your current professional license, (Copy) <input type="checkbox"/> A facility description or brochure	PLEASE STAPLE YOUR BUSINESS CARD HERE
MAKE A COPY FOR YOUR STUDY BINDER.		

Humanitarian devices are cleared for marketing based on a claim that fewer than 4000 patients per year in the U.S. have this indication. Basic safety information has been gathered but efficacy information may be weak. In order to use a humanitarian device the requesting physician must (unless there is a medical emergency) obtain IRB review before use of the humanitarian device.

IRB review criteria (56.111) apply to research and investigations rather than therapeutic intervention so the usual criteria must be applied differently from usual. The questions in this application seek to learn your qualifications and to obtain enough information to apply the review criteria.

Please complete every box even if it is brief - let the reviewer know you didn't overlook it. Filling in the spaces will alter the pagination.

A. HUMANITARIAN DEVICE A complete description should be in the accompanying submission.

DEVICE NAME _____		
FDA information	HUD Number _____	Version Date _____
	HDE Number _____	Amendment Date _____
COSTS	Amount FDA agreed could be charged for the device _____	

Company	DEVICE COMPANY	Intermediary (distributor? CRO?) , if any
Contact name		
Title		
Phone		
Fax		
e-mail		
Address		

INDICATION: The FDA approved use of the device for what indication?. (50 word max)

IRB HISTORY:

To the best of your knowledge, has any IRB considered this HDE and not granted approval?

No N/A Yes _____

B. THE REQUESTING PHYSICIAN: Consideration of qualifications is one aspect of local review. Our IRB needs more information about you.

CONTACT Physician in Charge _____ Lead Contact Person (can answer questions) _____

Previous IRC number?	Have you ever worked with IRC before? <input type="checkbox"/> No <input type="checkbox"/> Yes PI Number _____	Have you ever worked with IRC before? <input type="checkbox"/> No <input type="checkbox"/> Yes
Name (with degrees)	_____	_____
Mailing address	_____	_____
City, State, Zip	_____	_____
Phone	_____	_____
Fax	_____	_____
Prof. license	Type: _____	Type: _____
	Number: _____	Number: _____
	Expir. Date _____	Expir. Date _____
Board Certification	Board _____	Board _____
	Date: _____	Date: _____

CONFLICT OF INTEREST: Explain any yes response

Do you have any stock or patent position with the device company?	<input type="checkbox"/> No <input type="checkbox"/> Yes – Please describe _____
Did you participate in product design or development or as a company director or consultant?	<input type="checkbox"/> No <input type="checkbox"/> Yes – Please describe: _____

COMMUNITY AND PROFESSIONAL STANDING of PI and key clinical people

Have you ever been convicted of a crime or disciplined by a public or private medical organization or licensing agency?	<input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/> Yes _____
Any medical board sanctions or restrictions or loss or restriction on any hospital privileges?	<input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/> Yes _____

C. PERFORMANCE SITE: An appropriate site for this procedure will be:

Private practice office Outpatient center Hospital: _____ Other: _____

Site specific information will be on the investigator form.

D. PATIENT INFORMATION

FUTURE USE Do you now believe you will use this device only once?. **more than once**

DESCRIPTION: What is YOUR intended use of the device and is this use within or outside the labeled indication?

VULNERABILITY Is the patient (or future patients) in any of the following categories of people for whom consent (comprehending, capable, and voluntary) might be a problem?

<input type="checkbox"/> Fetus/Pregnant	<input type="checkbox"/> Hospitalized	<input type="checkbox"/> Poor/Uninsured
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<input type="checkbox"/> Children 1-7	<input type="checkbox"/> Chronically III	<input type="checkbox"/> Limited English
<input type="checkbox"/> Children 8-18	<input type="checkbox"/> Mentally III	<input type="checkbox"/> Limited literacy
<input type="checkbox"/> Prisoner	<input type="checkbox"/> Terminally III	<input type="checkbox"/> Institutionalized
<input type="checkbox"/> Employee	<input type="checkbox"/> Recent bad diagnosis	<input type="checkbox"/> Unduly deferential

PATIENT ALTERNATIVES IN THE COMMUNITY: Assess how difficult it would be for your patient to obtain a second opinion about the need to use this humanitarian device?
 ____ (1=no problem, 10=major problem)

CONSENT PROCESS/TIMING: The humanitarian device rules do not require the elaborate informed consent forms needed for research but knowledgeable agreement is never a bad idea.

Is any personal consent possible?	
<input type="checkbox"/> YES even if abbreviated	<input type="checkbox"/> No, not at all.
In what format is the consent information presented?	Why not? ____
<input type="checkbox"/> Oral <input type="checkbox"/> Information sheet <input type="checkbox"/> Signed form	
How much time is available for consideration of the information?	Is there a legally authorized person available to consider the information and provide guidance? ____

What assistance or support or situational changes might increase the patient's quality of consent?	

G. CERTIFICATION AND ASSURANCES: HUMANITARIAN DEVICE

As a Principal Physician User, I recognize I am responsible for use of this humanitarian device.

I certify that:

- I have reviewed the information in this document and it is correct and is complete,
- I will follow the device label, the pertinent regulations, state laws, and any additional IRB requirements
- I do allow IRC to check my license and information on my resume and to perform site visits.
- I will notify the IRB of every serious *or* unusual *and* unanticipated adverse event.
- I or my designee will obtain informed consent from each person with whom this device is used
- I will protect the rights and welfare of each patient to the best of my ability and will put their personal rights and welfare first.

Physician User Signature: _____ Date _____

H. RELEASE OF INFORMATION - Physicians: I authorize information sources selected by IRC to release to IRC information about me. I release the selected Board, association or agency from liability for information disseminated from their records except as it is found that it was gathered or disseminated negligently or with malice.

Medical School _____

Year of Graduation _____

Year of birth _____

Any other personal names used? _____

INVESTIGATOR SIGNATURE: _____ **DATE:** _____