

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.

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.

DEVICE NAME:		
FDA information	HUD Number ----- HDE Number -----	Version Date ----- 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)

Are you using it for this indication?	<input type="checkbox"/> Yes <input type="checkbox"/> No, it will be used for: -----
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B. THE REQUESTING PHYSICIAN: Consideration of qualifications is one aspect of local review. Our IRB needs more information about you.

CONTACT Physician in Charge

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

COMMUNITY AND PROFESSIONAL STANDING of PI and key clinical people

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

C. PERFORMANCE SITE: Where will you use this device?

Site type	<input type="checkbox"/> Private practice office <input type="checkbox"/> Outpatient center <input type="checkbox"/> Hospital <input type="checkbox"/> Other:
Site Name	
Director's Name	
Address	
Phone	
Fax	
e-mail	
Website	

SITE NOTIFICATION One reason IRBs are involved is to assure that the institution is aware of the use of such a product within its facility. Who should be informed at this site?

Name Address Phone Fax e-mail Website	<input type="checkbox"/> IRB at the site <input type="checkbox"/> Ranking investigational official <input type="checkbox"/> Chief of staff <input type="checkbox"/> Other
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D. PATIENT INFORMATION

How difficult would be it for your patient to obtain a second opinion about the need to use this humanitarian device?	_ (1=no problem, 10=major problem)
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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
<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

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 although possibly abbreviated In what format is the consent information presented? <input type="checkbox"/> Oral <input type="checkbox"/> Information sheet <input type="checkbox"/> Signed form How much time is available for consideration of the information? What assistance or support or situational changes might increase the patient's quality of consent?	<input type="checkbox"/> No, not at all. Why not? Is there a legally authorized person available to consider the information and provide guidance?
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E. Is there anything else we should know about you or your site or your patient base?

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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 _____