



Continuing Review Form Humanitarian Device

Independent Review Consulting, Inc.

Phone: 415-485-0717

www.irb-irc.com

Fax: 415-485-0328

Form 4-42C 2/4/02)

IRBs must review studies at regular intervals to determine if – in light of any changes in the study or the world around it – it remains approvable. As humanitarian devices must be IRB reviewed using the same rules, updated information is required.

A. IDENTIFICATION of DEVICE AND PEOPLE

DATES

IRC Approval Number	IRB Expiration Date	Date - Last Possible Submission
---------------------------	---------------------------	---------------------------------------

DESIRES Regardless of what is checked here, please complete the rest of the form.

<input type="checkbox"/>	Final Report, I have no desire to ever again use this device
<input type="checkbox"/>	Continuing Review. I would like continued access to this humanitarian device.
<input type="checkbox"/>	Other

THE DEVICE

Device name
Device company
Contact person
Phone
Is it still a humanitarian device?

PHYSICIAN USER

Contact person (coordinator?)

Name		
Title		
Phone		
Fax		
e-mail		
Address		
City/St/Zip		

B. ACTIVITY – UPDATES AND INFORMATION

CHANGES – Since your original application have you made or had any changes affecting:

stock or patent position with the device company?	<input type="checkbox"/> No	<input type="checkbox"/> Yes – Please describe
your license or privileges, or legal problems affecting your practice	<input type="checkbox"/> No	<input type="checkbox"/> Yes – Please describe:
status of the device as an HDE	<input type="checkbox"/> No	<input type="checkbox"/> Yes – Please describe:
your performance site	<input type="checkbox"/> No	<input type="checkbox"/> Yes – Please describe:

INTERVENTION

With how many patients did you use this device?	<input type="checkbox"/> None	or	<input type="checkbox"/> One	<input type="checkbox"/> Two or more
Did anything unexpected or unanticipated occur with its use?	<input type="checkbox"/> None	or		

C. STUDY EVALUATION

EXTERNAL EVENTS Describe changes or new information since the last IRB review.

FDA regulatory status	<input type="checkbox"/> None	or	
New information about safety	<input type="checkbox"/> None	or	
New information about efficacy	<input type="checkbox"/> None	or	

SIGNATURES

Person who prepared the response

Person responsible for it.

Signature		
Printed name		
Date		