



IRB
190 E. Bannock
Boise, ID 83712

Institutional Review Board Application for Humanitarian Use Device

All items on the application form must be completed. The contents of this application and attachments will be kept confidential within the limit of the law. For information and assistance, visit the Institutional Review Board website: <http://www.stlukesonline.org/research/index.php> or call (208) 381-1406.

***All initial HUD applications require a full board review.**

Submit the following:

Submitted	On File	Required Item
		Three copies of this application-completed.
		Three copies of the HUD designation letter.
		Three copies of the FDA HDE Approval letter.
		Three copies of manufacturer's product labeling, clinical brochure, and/or other pertinent information.
		Three copies of the summary of safety and probable benefit.
		IRB review fee; \$2,000.00 (Unless other arrangements have been made, or a waiver has been granted.)
		Three copies of the training certificate from the sponsor on the use of the device for each physician listed in the application.
		Three copies of the patient information pamphlet (if applicable)
		Three copies of the consent form and HIPAA (If applicable)
		One copy of CITI completion certificates for all physicians and key personnel involved in the project. CITI on-line human subjects protection course (www.citiprogram.org)
		One signed copy of the conflict of interest questionnaire for all physicians listed in the application.
		One copy of the primary physician's curriculum vitae if submitting for the first time.

PROJECT TITLE

I. Primary Physician (physician applicant) and Contact Information

Name	Practice Group	Mailing Address	Phone/Fax	E-mail

II. Authorized (Secondary) Physicians - List ALL secondary physicians authorized to use this device

Name	Practice Group	Mailing Address	Phone/Fax	Email

III. Primary Contact Person: The person who will be responsible for correspondence with the IRB regarding this project.

Name	Title	Mailing Address	Phone/Fax	E-mail

IV. Manufacturer and Contact Information

Manufacturer	Contact Name	Mailing Address	Phone/Fax	E-mail

V. Device Information

Name of Humanitarian Use Device	Humanitarian Use Exemption Number

VI. Project Sites: Check only sites where project will be conducted:

- St. Luke's Boise
 St. Luke's Meridian
 St. Luke's Magic Valley RMC
 St. Luke's Wood River
 St. Luke's MSTI
 Boise
 Meridian
 Nampa
 Twin Falls
 Fruitland
 Physician Office Clinic
 Other - please list

Important Note for Physicians: While this Humanitarian Use Device may have received a Humanitarian Device Exemption (HDE#) from the FDA, the Office of Research Administration additionally requires a Medicare Coverage Analysis prior to IRB review.

Have you submitted this project to St. Luke's Office of Research Administration (ORA)? Yes No
 If no, please contact Chelsea Cameron at 381-1486.

VII. Physician and Project Information:

- Has the primary physician (and all other physicians listed in this application) received training on the device?
 Yes No If yes, attach training documentation. If no, please provide an explanation.
- Who will conduct informed consent with the patients?
 Primary physician Other (specify): _____
- How many patients per year are expected to receive this device at this site?

VIII. Primary Physician's Assurance of Compliance for Use of a Humanitarian Use Device (HUD)

- ✓ The information provided in this application is correct.
- ✓ I will not initiate this project until final written approval is granted by the St. Luke's IRB.
- ✓ I agree that the use of the HUD will be limited to the FDA approved labeling.
- ✓ I and those listed on this application are qualified by training, education and licensure to perform this procedure using the HUD.
- ✓ I will notify St. Luke's IRB of any manufacturer notices of changes regarding the HUD, any reports of device failures, manufacturing or device modification.
- ✓ I will report progress on the use of the HUD to the IRB as required, at least annually.
- ✓ I will seek and obtain prior written approval from the IRB for any modification in the use of the HUD; including changes in procedures, the project staff, etc.
- ✓ I will promptly report to the IRB any unexpected or otherwise significant adverse events, unanticipated problems or patient injuries that occur during the course of this study.
- ✓ I will comply with all IRB requests on the status of this project.
- ✓ I will make arrangements regarding payment of the IRB review fee (\$2000.00) unless a waiver is granted or other arrangements have been made.
- ✓ I agree to conduct the use of the HUD in accordance with applicable federal regulations, manufacturer and St. Luke's institutional requirements.
- ✓ I, and those listed in this application, currently have no corrective actions pending.

Signature of Primary Physician

Date