# Surgical Services – Humanitarian Use Device (HUD) Request Form

Office of Research and Education

### Requestor:

**Date of Request:**

### General Information

*(This section to be completed by: Research Development Coordinator)*

Device Name:

Service Line/Specialty Area:

Requesting Physician (serving as lead physician/surgeon for use of this device at Spectrum Health):

Other physicians/surgeons trained and approved to utilize the HUD with oversight by requesting lead Physician:

Spectrum Health IRB #:

Spectrum Health IRB Approval Date:

Number of cases anticipated per year:

Where is the procedure occurring? [ ]  OR [ ]  IR [ ]  Other: \_\_\_\_\_\_\_\_\_\_\_\_

Specific site(s)/location(s) where surgical procedure will occur:

**Main Research Staff Contact Name:**

Email:

Phone:

**Device Contacts:**

Main Device Contact Name:

Email:

Phone:

**Estimated Date of First Procedure (subject to change):** MM/YYYY

Type of Procedure:

### HUD Device / Procedure Information

*(This section to be completed by: Research Development Coordinator)*

Is the product/device FDA approved for the proposed use? [ ]  Yes; [ ]  No

Is this procedure new to SH?

 [ ]  Yes, never been performed here.

 [ ]  No

Is this device new to SH?

 [ ]  Yes

 [ ]  No

What is the method of delivery of the device to the OR?

Are there additional staff or facility needs required for this device use?

[ ]  Yes, explain:

[ ]  No

Will device representatives or other Non-Spectrum Health Staff members need to be present during the cases?

 [ ]  Yes, please list:

 [ ]  No

Please send the IRB Approval letter with the completed request form and any other applicable device information (i.e.. Instructions for Use, Brochures, Manuals, etc.) to:

* ResearchCompliance@spectrumhealth.org
* Carrie Bos and Mindy Dykstra (business operations)
* Daniel Foutch (sourcing)
* Requesting Physician (\*please see follow up communication plan below\*)

### Requesting Physician Communication Plan

Office of Research and Education

As soon as a patient is scheduled to have this device utilized, communication will occur according to the following plan:

Requesting Physician or their designated representative/EMI Coordinator **MUST** send a secure email to: *Carrie Bos, Mindy Dykstra, Daniel Foutch, and Main Research Staff Contact*

Provide the following information:

* Include “[secure] HUD Update” in email subject line, and
* Body of email should include: date of upcoming scheduled procedure, device name, patient name and patient MRN

### Approvals

*(This section to be completed by Main Research Staff Contact after confirmation of receipt of this form and approval is provided by Business Operations, Sourcing and Compliance)*

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[ ]  Reviewed by Business Operations

Date of Review:

Business Operations contact(s):

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[ ]  Reviewed by Sourcing/Procurement Specialist

Date of Review:

Sourcing contact(s):

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[ ]  Reviewed by Clinical Compliance Center of Expertise

Date of Review:

Compliance contact(s):