# 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](mailto: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):