KUALI QUICK GUIDE

Humanitarian Use Device

I. GENERAL INSTRUCTIONS

A. Principal Investigator: For purposes of this guide and the Humanitarian Use Device (HUD) protocol, Principal Investigator (PI) refers to the Treating Physician.

B. This Quick Guide applies to: Creation of a new protocol for use of an HUD in clinical practice. It is not applicable to use of an HUD in a clinical investigation (i.e., research).

C. Navigation:

a. In order to move through the smart form, you must complete all sections within the General Information Page, starting with the Study Identification section. Once you have completed all sections, press "**Next**" to continue with the HUD Questionnaire Page.

D. Website Guidance: The use of a HUD must be initially reviewed at a convened IRB meeting and approved before the device can be used. Additional information is available on the IRB website**.**

E. Attachment: Protocols and consent/assent/information sheet documents should initially be provided as Word documents; all other documents should be in PDF format. HUD specific required attachments include FDA HDE approval order, FDA approved product labeling, Consent form, and Patient information brochure.

A. New Protocol Overview: Reference this quick guide found on our Kuali Quickguide webpage for an overview and additional guidance related to each section.

II. GENERAL INFORMATION PAGE

A. Study Identification:

a. **Title:** Enter the title of your study.

b. **Principal Investigator:**

i. Begin typing the first or last name of the PI and candidates will automatically appear from the list of users in Kuali.

ii. Click the PI's name and it will be entered in the field.

c. **Department:** Primary appointment of PI

i. Begin typing the name of the department and candidates will automatically appear from the list of departments stored in Kuali.

ii. Click the department's name and it will be entered in the field.

d. **School:** Select the School from the drop-down list that corresponds to the primary appointment of the PI.

e. **Press "Next"**

B. Protocol Type:

a. **Select the "Protocol Type"** from the drop down menu: **Humanitarian Use Device**

b. **Press "Next"**

C. Performance Site(s):

a. Follow instructions to select the facility where the HUD will be used.
b. If the facility is not listed in the drop-down menu, select "Other" and provide the name of the facility.

D. Study Population

a. Select all population types you intend to treat with the HUD
b. In the count field, enter the total number of patients you expect to treat with this HUD at this facility.

E. Research Personnel

a. The PI's name will automatically be listed in the table.
b. Follow instructions to list all physicians that will use the HUD, adding them as Sub-Investigators; select their level of KR protocol access (view only or full access).
c. **Do NOT attach any research training documents:** Research training certification is not required if the HUD will be used in clinical practice and not in a clinical investigation (*i.e.*, research). CVs of other physicians (i.e., Sub-Investigators) is also not required.
a. **Individual Not a User in KR:** *Reference the Accessing Kuali Quick Guide*

Once all required information has been entered on the General Information Page, press "Next" to begin the HUD specific questionnaire.

III. PROTOCOL TYPE QUESTIONNAIRE PAGE

A. Questionnaire: Humanitarian Use Device

a. The purpose of the first question is to determine if the HUD is being used for clinical treatment or research. You can only complete this protocol if the HUD is being used for clinical treatment.
b. If the HUD is being used in a clinical investigation, you will have to go back and change the protocol type to "Full-Board" and provide information required of that protocol.
c. If the HUD is being used for clinical treatment, answer all protocol questions, which are intended to provide among other information:
    i. A description of the patient's condition;
    ii. A description of the device and its approved indications;
    iii. The procedures involved in the use of the device; and
    iv. The potential risks associated with the use of the device;

IV. SUPPORTING DOCUMENTS

A. Relevant Documents

A complete submission requires attachment of several documents (a-d) while inclusion of other documents is optional (e-f):

a. FDA HDE approval order
b. FDA approved product labeling
c. HUD Use Consent form

d. Patient information brochure
e. Manufacturer's Device Brochure or equivalent document (if available)
f. Any other relevant documents

B. Instructions

a. Click the "+Add Line" button to the right to upload a Supporting Document.
b. In the dialogue box, Drag and Drop a file or Click "+ Choose" and browse for a file:
    i. If browsing, locate the file and click open to attach. Note: all commonly used file types should be compatible except for ".msg" (Outlook messages).
c. Enter a Name that will help you identify the document
d. Select an Attachment Type from the drop-down list.
e. Repeat Steps a-d as many times as necessary to add all necessary documents.

Note: All four required attachments must be loaded into this section.

V. PI CERTIFICATION & SUBMISSION

A. PI IDENTIFICATION

a. **The protocol may only be submitted by the PI.**
a. If you are the PI, you will be asked to provide your statement of assurance. If you do not agree with the statement, you can permanently terminate the submission by clicking the "abandon" button.
b. *Reference the New Protocol Overview Quick Guide for Detailed Guidance*.

VI. SUBMISSION INSTRUCTIONS

A. When the HUD application is ready for submission

a. Click "**Submit**" for it to be sent to the HRPP office.
b. If required fields have no entry, error messages will appear
    i. Complete all required fields and click "**Submit**" again.
c. Submission's status will change from "In Progress" to "Submitted for Review"

VII. DEPARTMENT CERTIFICATION

Once the protocol is submitted for review, the HRPP office will assign the Department Head as an ancillary reviewer. The Protocol will not be "approved" until the ancillary review has been approved by the Department Head (*i.e.*, Department certification provided).

VIII. CHECKING THE STATUS OF A HUD PROTOCOL

Click on "Manage Protocols" to view the submission type and status of your HUD protocol.
Once your HUD Protocol is Approved, the status will be:

A. HUD Status Post Approval:

a. **Submission Type:** Initial
b. **Review Type:** Full Board

c. **Status:** Approved
d. **Continuing Review Date:** Listed

B. Submission Type Definitions:

a. **New:** an initial (new) protocol submission.
b. **Initial:** "New" submission that is approved by the IRB
c. **Amendment:** submission to request modification of an approved protocol.
d. **Renewal:** submission to request renewal/re-approval of a protocol.
e. **Renewed:** "Renewal" submission that is approved by the IRB.
f. **Close Request:** submission to request closure of an approved protocol.

C. Status Type Definitions:

a. **In Progress:** This is the first version of the Protocol and it has not yet been submitted for review.
b. **Submitted for Review:** This submission has been submitted to the compliance office for review for the first time.
c. **Revisions in Progress:** This is the new version of a protocol created when the Revisions Requested action is taken. This version is sent to the researcher so they can make their changes.
d. **Approved:** This version of the protocol has been approved by the compliance office.
e. **Disapproved:** This protocol was disapproved by the compliance office.
f. **{Submission Type: Amendment} In Progress:** An Amendment is being worked on in this version and has not yet been submitted for review.
g. **{Submission Type: Renewal} In Progress:** A Renewal is being worked on and has not yet been submitted for review.
h. **{Submission Type: Close Request} In Progress:** A request to close the protocol is being worked on and has not yet been submitted for review.
i. **Closed:** This protocol has been closed and is no longer active.
j. **Abandoned:** This submission was abandoned by the researcher.

IX. HUD POST APPROVAL REQUIREMENTS

Actions Post Approval:

A. RENEWAL The physician is responsible for fulfilling renewal requirements to the IRB at least annually. At the time of renewal, the physician must submit a renewal report via the "Renew" action in KR to the IRB in summary form for each HUD activity at LSUNO or affiliated sites. This report must include the following:

a. The clinical indications for the use of the HUD in each patient;
b. Clinical outcomes of each participant, if known.

B. REPORTABLE NEW INFORMATION Adverse events and unanticipated problems that result from the use of a humanitarian device are subject to LSUNO IRB requirements for Reportable New Information. Submit RNIs via the "Report an Event" button in KR

C. **AMENDMENTS** to the HUD or the clinical use of the HUD are to be promptly reported to the LSUNO IRB in accordance with the IRB procedures for **Modifications** to approved research. Submit an amendment via the "Amend" action in KR.

D. CLOSURE should be submitted if all research-related interventions or interactions with participants have been completed and collection and analysis of identifiable private data (as described in the IRB-approved protocol) are finished. Close the study via the "Close Request" action in KR.