

# Kuali Protocols NEW Form Guide – Humanitarian Use Device (HUD)Published 07.01.2023 (version 13)

This form guide is meant as a tool for investigators, HRPP staff, and IRB members and provides information about the Kuali Protocols NEW form. This information is meant as a tool only and should be considered guidance. Please contact the HRPP if you are unsure how to answer a specific question.

| **Question ID** | **Question** | **Options** | **Guidance** |
| --- | --- | --- | --- |
| **General Information** |
| N/A | Principal Investigator | User list | Start typing the value and options will appear. Select desired option. |
| N/A | Lead Unit | Unit list | This is the IU unit under which the research will be conducted. Typically, this is the PI’s division or department. For non-IU PIs, enter “External Organization.” Start typing the value and options will appear. Select desired option. |
| N/A | Study Title |  | Enter Study Title |
| **Protocol Type** |
| 0100 | Select your protocol type. | * Exempt
* Expedited/Full Board
* Request to rely on a non-IU IRB
* Not Human Subjects Research
* **Humanitarian Use Device (HUD)**
* Emergency Use (This is rare. Contact the HRPP at irb@iu.edu before selecting.)
 | If you are unsure of your protocol type, visit the [protocol decision tree](https://research.iu.edu/compliance/human-subjects/review-levels/protocol-decision-tree/index.html) for more information. |
| **Research Personnel** |
| **Personnel List***Select* ***+Add Line*** *to list each person* | List | **This Personnel list is for Research Personnel Only.** For individuals who need access to the protocol but are not research personnel, add them to the Permissions tab.For NEW studies and amendments changing the PI, you must click on the pencil icon to complete all required information in the person record. |
| N/A | Person | User list |  |
| N/A | Email Address | Auto-filled based on person selected |  |
| N/A | Researcher Role | * Principal Investigator (PI)
* Co-PI
* Key Personnel
* Site-specific PI
* Other Research Staff
 |  |
| N/A | *IF Researcher Role = Principal Investigator (PI)*Home Unit | Unit list |  |
| 0144 | IU Faculty/Staff or Student? | * Yes
* No
 |  |
| 0164IU Role | *IF 0144 = Yes AND Researcher Role = PI*Select IU Role | * Tenure Track or Clinical Faculty
* Adjunct, Emeritus or Visiting Faculty
* Staff
* Student/Resident/Fellow
* Other
 | If multiple roles, select the capacity in which the individual will be conducting this research. Adjunct faculty, visiting faculty, students, residents, and fellows generally are not eligible to serve as PI for IU research. Before submitting, review the IU PI eligibility information [embed link] and ensure you have identified an eligible individual to serve as PI.  |
| 0165 | *IF 0164 = Staff OR Other*IU Title/Role | Free text |  |
| 0166Affiliation | Is the researcher affiliated with any of the following? *Select all that apply*. | * IU Health/IU Health Physicians
* Eskenazi Hospital/Health & Hospital Corp of Marion County
* Roudebush VA Medical Center
* Regenstrief Institute
* Rehabilitation Hospital of Indiana
* Purdue University Pharmacy Practice
* None of the Above
 | Affiliation includes employment, having hospital privileges, and in the case of Purdue Pharmacy Practice, being a student.If None of the above is selected and 0144 is No, remove this personnel entry, answer “Yes” to 0195 and list this person in the Non-affiliated Personnel List below. |
| N/A | Permission Type | * Full Access
* Read-Only
 | Select one. |
| 0142 | Training |  | Will display applicable CITI training courses for person and note if active or expired. |
| 0109 | COI Disclosure |  |  |
| N/A | People Attachments*Select* ***+Add Line*** *to list each attachment* |  |  |
| Attachment | Drag & drop a file |  |
| Name | Free text |  |
| Attachment Type | * Curriculum Vitae
* Conflict of Interest
* CITI or Other Training Documentation
* Non-affiliated investigator agreement
* Site Specific Personnel List
* Other
 |  |
| Comments | Free text |  |
| 0259 | Are there any **affiliated** personnel you are unable to add because they were not found in the drop down list? | * Yes
* No
 | Examples of affiliated institutions include: Eskenazi Health, IU Health, Regenstrief Institute, Rehabilitation Hospital of Indiana, and Roudebush VAMC. |
| 0196 | *IF 0259 = Yes*List the first and last name, email address, institution, and Research Role for this person. | Free text |  |
| 0195 | Are you requesting that the IU IRB serve as the IRB of record for any **non-affiliated** research personnel? | * Yes
* No
 |  |
|  | *IF 0195 = Yes***Non-affiliated Personnel List***Select* ***+Add Line*** *to list each person* |  |  |
| 0197 | Name | Free text |  |
| 0198 | Email address | Free text |  |
| 0199 | Researcher Role | * Co-PI
* Key Personnel
* Site-specific PI
* Other Research Staff
 |  |
| 0260 | Choose the research activities which will be conducted by non-affiliated researchers. | * Enrollment of subjects, including obtaining informed consent and/or authorization
* Conducting research interventions or interactions
* Receipt or analysis of identifiable data or identifiable biospecimens
* Other
 |  |
| 0261 | *If 0260 = Other*Describe the Other research activities non-affiliated researchers will conduct. | Free text |  |
| N/A | **Non-affiliated Personnel Attachments***Select* ***+Add Line*** *to list each attachment* |  |  |
| 0262 | **Upload Attachments**For example, documentation of CITI training, Conflict of Interest disclosure, or Non-affiliated Investigator Agreement, as applicable. | Drag & drop a file |  |
|  | Attachment Type | Drop down* Curriculum Vitae
* Conflict of Interest
* CITI or Other Training Documentation
* Non-affiliated investigator agreement
* Site-Specific Personnel List
* Other
 |  |
| **Research Basics** |
| 0102 | Will the study be funded, fully or partly, by any of the following sources (this includes pass through funding)? Select all that apply. | * Federal funding
* Industry/For-profit entity
* Other external source
* No external funding
 | If a funding proposal is pending and you will conduct the research regardless of receipt of funding, select "No external funding" and submit an amendment to update this response if funding is received. If you will only conduct the research if funding is received, select the applicable funding source. |
| 0192 | *IF 0102 = Federal funding*Is your study funded by or through the National Institutes for Health (NIH)? | * Yes
* No
 | If Yes, ensure you list the specific NIH funding institute in addition to any other funding sources. |
| 0103 | *IF 0102 = Federal funding, Industry/For-profit entity, OR Other external source*List Funding Sources*Select* ***+Add Line*** *to list each funding source* | List, Free text | This is a list. You can enter as many funding sources as is necessary. |
| **Research Design** |
| 0960 | Will safety or effectiveness data be collected for purposes of supporting a premarket application (PMA) for the HDE-approved indication? | * Yes
* No
 | If Yes, the proposed use of the HUD is considered a clinical investigation. You will need to change the protocol type to Expedited/Full Board to proceed. |
| *IF 0960 = No* |
| 0961 | Name of Device. | Free text |  |
| 0962 | Name of Device manufacturer. | Free text |  |
| 0963 | Describe (in lay terms) the objective(s) of the proposed use of the HUD. | Free text |  |
| 0964 | Provide a summary of how clinicians will use the device, including a description of any screening procedures, the HUD procedure, and any patient follow-up visits, tests, or procedures. | Free text |  |
| 0965 | Will the HUD be used locally in a manner consistent ONLY with the indications listed in the HDE approval letter? | * Yes
* No
 |  |
| 0966 | *If 0965 = No*List the additional indications and provide justification for use of the device in this way. |  |  |
| **Research Settings** |
| 0117 | Select all of the following hospitals or healthcare facilities involved in the research. | * IU Health
* Eskenazi Health
* Roudebush VA Medical Center
* Rehabilitation Hospital of Indiana
* Other hospital or healthcare facility
 | If you select Eskenazi Health, click on the Permissions tab at the top of the page and add Patricia Noblet (pcnoblet) and Jeanne Lewis (jml14) with a "Read Only" Permission Type.If you select Roudebush VA Medical Center, click on the Permissions tab at the top of the page and add Marta Sears (msears), Angela Harris (anharris), and Bridget Fultz (bafultz) with "Read Only" Permission Types. |
| 0120 | *IF 0117 = Other hospital or healthcare facility* Name the Other hospitals or healthcare facilities. | Free text |  |
| 01180119 | *IF 0117 = IU Health*List the IUH Hospitals*Select* ***+Add Line*** *to list each IUH hospital* | ListDrop down of IUH sites |  |
| **Protocol Attachments** |
| **Protocol Attachments***Select* ***+Add Line*** *to add each attachment**Select* ***Replace*** *to replace an existing document* | List |  |
| N/A | Attachment Type | * Assent Form
* Data Collection Instrument
* HIPAA Authorization Form
* Informed Consent Statement
* Investigator Brochure
* Protocol
* Recruitment Materials
* Reliance Documentation
* Study Information Sheet
* VA – Security/Privacy Checklist
* Other
 |  |
| Attachment | Drag & drop a file |  |
| Description | Free text |  |