

# Kuali Protocols NEW Form Guide – Emergency Use Published 07.01.23 (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](mailto: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 |  |
| N/A | IU Faculty/Staff or Student? | | * Yes * No |  |
| 0164 IU 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 |  |
| 0166 Affiliation | 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. |
| 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 |  |
| **Emergency Use** | | | | |
| 0146 | | State the name of the investigational product used. | Free text |  |
| **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 |  |