

# Kuali Protocols NEW Form Guide – Request to Rely on a non-IU IRBPublished 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 | StatusDisposition (IRB Admin only) |  |
| N/A | People Attachments*Select* ***+Add Line*** *to list each attachment* |  | For Expedited/Full Board or Request to rely on non-IU IRB protocol types, attach a CV for the Principal Investigator. |
| 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 Researcher Role for this person. | Free text |  |
| **Conflict of Interest** |
| 0110 | Do any of the research personnel have a significant financial interest which could affect this research? | * Yes
* No
 |  |
| 0112 | *IF 0110 = Yes*List the name(s) of the research personnel. | Free text |  |
| 0113 | *IF 0110 = Yes*Describe the nature of the significant financial interest which could affect this research. | Free text |  |
| 0114 | Are any of the research personnel aware of an institutional conflict of interest which could affect or be affected by this research? | * Yes
* No
 |  |
| 0115 | *IF 0114 = Yes*Explain the institutional conflict of interest. | Free text |  |
| **Research Basics** |
| 0101 | Provide the name of the institution or IRB who will provide review. | Free text |  |
| 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 the list below 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. |
| 0662 | Select all of the following that are applicable to the research. | * Clinical trial. Subjects are prospectively assigned to one or more interventions to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.
* Community-engaged research
* Planned emergency research, which includes exception from informed consent (EFIC) (This is rare)
* Human fetal tissue
* Demonstration project that is conducted by or subject to the approval of state or local government officials (This is rare)
* None of the above
 |  |
| 0663 | *IF 0662 = Clinical trial*Do either of the following apply to your research? | * Research of a drug/biological product conducted under an IND
* Research of a medical device conducted under an IDE
* Neither of the above
 |  |
| 0128 | *IF 0662 = Community-engaged research*How are the community partners involved in the research? Select all that apply. | * Topic development, need identification, or development of research questions
* Research design or selection of appropriate measures and data collection methods
* Contribution to consensus about findings, conclusions, or recommendations for implementing findings
* Dissemination of findings and actions taken based upon results
* Only provided access to study subjects or project sites, and not involved with study design, subject recruitment, data collection, data analysis, or dissemination of results
 |  |
| 0664 | Select all of the following ancillary reviews that are required for this research. | * IUSCCC SRC: Prospective cancer-related research (including research with a cancer focus enrolling healthy subjects) utilizing IU Simon Comprehensive Cancer Center patients or resources
* Radiation safety: radiation/radioactivity in addition to what is used for standard clinical treatment
* IBC review: recombinant DNA or human gene transfer
* None of the above
 |  |
| 0106 | *IF 0664 = IUSCCC SRC, Radiation safety, or IBC review*Upload applicable ancillary review documentation approval, if available.*Select* ***+Add Line*** *to list each attachment* | List, Attachment |  |
| 0107 | Select all of the following participant types that will be included in the research. | * Children
* Adults lacking consent capacity
* Pregnant women and/or fetuses
* Prisoners
* Individuals admitted for inpatient or residential psychiatric treatment
* Nonviable neonates or neonates of uncertain viability
* None of the above
 |  |
| 0650 | This research is: | * Minimal risk
* Greater than minimal risk
* Greater than minimal risk, but IU-affiliated investigators are performing only minimal risk procedures
 |  |
| 0651 | Choose the research activities which will be conducted by IU-affiliated investigators. | * Enrollment of subjects, including obtaining informed consent and/or authorization
* Conducting research interventions or interactions
* Receipt or analysis of identifiable data or identifiable biospecimens
* IU is the prime awardee for a federally-funded study
* Other
 |  |
| 0652 | Describe the research activities IU-affiliated investigators will conduct. | Free text |  |
| **Research Design** |
| 0653 | Select any source of information listed below that will be used for the research, either to identify potential subjects or gather research data. Select all that apply. | * Medical records or information provided by a health care provider
* Student records
* Neither of the above
 |  |
| 0654 | *IF 0653 = Student records OR Neither of the above*Will any data generated as part of the research be entered into a subject’s medical record? | * Yes
* No
 |  |
| 0655 | *IF 0653 = Medical records or information provided by a health care provider OR 0654 = Yes* Will medical records or information provided by a health care provider be used to identify or recruit potential subjects? | * Yes
* No
 |  |
| 0658 | *IF 0655=Yes*HIPAA applies to your study. IU HRPP Policy requires that you obtain authorization or a waiver prior to use of health information for recruitment. | * Authorization will not be obtained prior to use of health information for recruitment.
* An external health care provider will obtain written authorization from individuals prior to sharing health information with the research team for recruitment. (This is rare.).
 |  |
| 0659 | *IF 0658 = Authorization will not be obtained*Has or will the reviewing (external) IRB grant a waiver of authorization for recruitment?  | * Yes
* No (This is rare)
 | If uncertain, contact the HRPP – Reliance Team at irb@iu.edu. |
| 0660 | *IF 0653=Medical records OR 0654 = Yes*For subjects whose participation is subject to HIPAA | * I will obtain signed authorization (either combined with the consent or separate).
* I will obtain authorization, but subjects will not provide a signature.
* I will not obtain authorization from subjects.
 |  |
| 0665 | *IF 0660 = I will obtain signed authorization*What will subjects sign to document they are providing authorization? | * The consent form with Authorization language, which includes a specific expiration date or event and the subject’s address, as required by Indiana state law
* A separate standalone Authorization, using the IU template
 | If separate standalone Authorization, upload the standalone Authorization in the Protocol Attachments section below. |
| 0661 | *IF 0660 = I will obtain authorization, but subjects will not provide a signature OR I will not obtain authorization from subjects*Has or will the reviewing (external) IRB grant a waiver or alteration of authorization? | * Yes
* No (This is rare)
 | If uncertain, contact the HRPP – Reliance Team at irb@iu.edu. |
| *IF 0659 = No – Recruitment HIPAA Waiver* |
| 1030 | Provide a brief description of the protected health information (PHI), including identifiers, to be used or accessed for recruitment purposes. | Free text |  |
| 1032 | Describe the plan for protecting identifiers from improper use and disclosure. | Free text |  |
| 1037 | The PI confirms all of the following:* The use and disclosure of PHI for recruitment involves no more than minimal risk of loss of confidentiality to potential subjects.
* Identifiers used for recruitment will be destroyed at the earliest opportunity consistent with the conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law.
* The PHI will not be re-used or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of protected health information would be permitted by the HIPAA Privacy Rule.
* Recruitment activities cannot practicably be conducted without the waiver as potential subjects must be identified before they can be contacted for authorization.
* Recruitment activities cannot practicably be conducted without access to and use of PHI which is required to screen for eligibility and to contact potential subjects for recruitment purposes.
 | * Yes
 |  |
| *IF 661 = No – HIPAA Waiver* |
| 1040 | Provide a brief description of the protected health information (PHI) to be used or accessed. | Free text |  |
| 1041 | Explain how this research involves no more than minimal risk of loss of confidentiality to the subject.  | Free text |  |
| 1042 | Describe the plan for protecting identifiers from improper use and disclosure. | Free text |  |
| 1043 | Describe the plan to destroy identifiers at the earliest opportunity consistent with the conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law. | Free text |  |
| 1044 | Select to confirm | * The PHI will not be re-used or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of protected health information would be permitted by the HIPAA Privacy Rule
 |  |
| 1045 | Explain how the research could not practicably be conducted without the waiver or alteration. | Free text |  |
| 1046 | Explain how the research could not practicably be conducted without access to and use of the PHI. | Free text |  |
| **Research Settings** |
| 0116 | Select all of the settings where the research interactions or interventions will take place. | * IU campus
* Hospital or other healthcare facility
* Elementary or secondary school
* Subject’s home
* Public setting, like a park, coffee shop, or health fair
* Other
 |  |
| 0121 | *IF 0116 = Elementary or secondary school OR Other* Name or describe the other settings where the research interactions or interventions will take place. | Free text |  |
| 0117 | *IF 0116 = Hospital or other healthcare facility* 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 |  |
| **FDA** |
| *IF 0663 = IND* |
| 0203 | IND number | Free text |  |
| 0204 | If the protocol does not list the IND number, upload documentation of the IND number (e.g. letter from FDA including protocol title and IND number) below.*Select* ***+Add Line*** *to list each attachment* | List, IND Attachment |  |
| 0205 | Does an IU, or IU-affiliated, faculty-staff member hold the IND? | * Yes. The investigator must attend a meeting to discuss the additional responsibilities as a sponsor-investigator. Staff will reach out to the investigator to schedule the meeting.
* No
 |  |
| *IF 0663 = IDE* |
| 0232 | IDE number | Free text |  |
| 0204 | If the protocol does not include the IDE number, upload documentation of the IDE number (e.g. letter from FDA including protocol title and IDE number) below.*Select* ***+Add Line*** *to list each attachment* | List, IND Attachment |  |
| 0234 | Does an IU, or IU-affiliated, faculty/staff member hold the IDE? | * Yes. The investigator must attend a meeting to discuss the additional responsibilities as a sponsor-investigator. Staff will reach out to the investigator to schedule the meeting.
* No
 |  |
| **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 |  |