

# Kuali Protocols NEW Form Guide – Not Human Subjects Research 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
 |  |
| 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* |  |  |
| 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 |  |
| 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 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. |
| 0750 | Choose the category of activities which will be conducted by IU-affiliated individuals. Select one. | * Case report
* Quality improvement/quality assurance project not intended to contribute to generalizable knowledge
* Receipt and/or analysis of coded private information or biospecimens
* Receipt and/or analysis of a limited data set
* Receipt and/or analysis of fully deidentified data
* Receipt and/or analysis of only decedent PHI
* Student project not intended to contribute to generalizable knowledge
* Waiver of HIPAA Authorization: IU-affiliated individuals are not engaged in human subjects research but require a waiver of authorization to access or use identifiable information or biospecimens protected by HIPAA
* Other (examples include oral history and public health surveillance)
 | For assistance with determining whether a study is QA/QI, refer to [HSO Guidance on Quality Improvement and Quality Assurance](https://research.iu.edu/compliance/human-subjects/guidance/quality.html), or email irb@iu.edu.  |
| 0130 | Are you obtaining data, records, and/or specimens from any of the following sources? | * IU Health
* Eskenazi Health
* Roudebush VA Medical Center
* Regenstrief Institute/INPC (Indiana Network for Patient Care)
* Other
 | 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. |
| 0131 | *IF 0130 = Other*Name the Other sources. | Free text |  |
| **Research Design** |
| *IF 0750 = Case report* |
| 0751 | Describe the purpose of the project including the activities to be conducted by IU-affiliated individuals. | Free text |  |
| 0761 | Will you obtain HIPAA Authorization from the patient or authorized representative to access and/or use PHI for the case report? | * Yes
* No. A waiver is being requested.
* Not applicable. PHI will not be accessed or used for this case report.
 |  |
| *IF 0750 = Quality improvement/quality assurance project* |
| 0752 | Describe the purpose of the project and whether results may be disseminated outside the institution or published. If the results will be disseminated externally or published, explain why the project is not intended to contribute to generalizable knowledge. | Free text |  |
| 0754 | Explain how data will be collected. | Free text |  |
| *IF 0750 = coded private information, limited data set, deidentified data, decedent PHI, Waiver of HIPAA Authorization* |
| 0753 | Describe the purpose of the project. | Free text |  |
| *IF 0750 = Receipt and/or analysis of coded private information or biospecimens* |
| 0755 | Were the coded data or biospecimens collected specifically for this project through an interaction or intervention with human subjects? | * Yes
* No
 |  |
| 0756 | *IF 0755 = Yes*Was the private information or biospecimens collected at another institution under an appropriate IRB approval? | * Yes
* No
 | If NO, contact the HRPP for assistance prior to proceeding. |
| 0757 | Confirm how you will ensure IU-affiliated individuals will not be able to ascertain the identity of subjects. | * The key to the code will be destroyed before IU-affiliated individuals access private information or biospecimens.
* IU-affiliated individuals and the holder of the code will enter into an agreement prohibiting the release of the code/key to IU-affiliated individuals.
* Other
 |  |
| 0758 | *IF 0757 = Other*Due to the selection of other, explain how you will ensure IU-affiliated individuals will not be able to ascertain the identity of subjects. | Free text |  |
| *IF 0750 = Receipt and/or analysis of a limited data set* |
| 0753 | Describe the purpose of the project. | Free text |  |
| 0759 | Will the IU-affiliated individuals have access to any of the following identifiers?* Names, including initials
* Postal code information other than city, state, or zip code
* Telephone or fax numbers
* Email addresses
* Social security numbers, medical record numbers, health plan beneficiary numbers, or account numbers
* Certificate/license numbers
* Vehicle identifiers or serial numbers, including license plate numbers
* Device identifiers or serial numbers
* Web universal resource locators (URLs)
* Internet protocol (IP) address numbers
* Biometric identifiers, including fingerprints and voice prints
* Full face photographic images or any comparable images.
 | * Yes
* No
 | If Yes, your data is not a limited data set. Review the other options in the form and/or contact the HRPP for assistance.If No, a data use agreement must be established between the entities providing the data and IU-affiliated individual. |
| *IF 0750 = Receipt and/or analysis of fully deidentified data* |
| 0760 | Will IU-affiliated individuals have access to any information (i.e. any unique identifying number, character, or code) which would allow them to identify subjects? Identifiers include the following:* Names, including initials
* Any geographic subdivision smaller than a state, including street address, city, county, precinct, zip codes (except that the first three digits of zip code may be used if the geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people)
* All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, and date of death
* Ages over 89 (unless aggregated in a single category of age 90 or older)
* Telephone or fax numbers
* Email addresses
* Social security numbers, medical record numbers, health plan beneficiary numbers, or account numbers
* Certificate/license numbers
* Vehicle identifiers or serial numbers, including license plate numbers
* Device identifiers or serial numbers
* Web universal resource locators (URLs)
* Internet protocol (IP) address numbers
* Biometric identifiers, including fingerprints and voice prints
* Full face photographic images or any comparable images
 | * Yes
* No
 | If Yes, your project includes identifiers. Review the other options in the form and/or contact the HRPP for assistance. |
| *If 0750 = Student project not intended to contribute to generalizable knowledge OR Other* |
| 0751 | Describe the purpose of the project including the activities conducted by IU-affiliated individuals. | Free text |  |
| *If 0750 = Waiver of HIPAA Authorization* |
| 0762 | List all data points which will be accessed or used by IU-affiliated individuals. This includes data that will be viewed, but not shared with other personnel. | Free text |  |
|  | ***IF 0750 = Waiver of HIPAA Authorization OR 0761 = No*** |
| 1020 | Provide a brief description of the protected health information (PHI), including identifiers, to be used or accessed. | Free text |  |
| 1021 | Explain how this research involves no more than minimal risk of loss of confidentiality to the subject.  | Free text |  |
| 1022 | Describe the plan for protecting identifiers from improper use and disclosure. | Free text |  |
| 1023 | 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 |  |
| 1024 | 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
 |  |
| 1025 | Explain how the research could not practicably be conducted without the waiver or alteration. | Free text |  |
| 1026 | Explain how the research could not practicably be conducted without access to and use of the PHI. | Free text |  |
| *If 0750 = Waiver of HIPAA Authorization* |
| 0763 | Choose the source of the information and/or biospecimens. Select all that apply. | * Medical record
* Biospecimens collected for clinical purposes
* Biospecimens or information originally collected for another research project
* Other
 |  |
| 0765 | *If 0763 = Medical record AND 0130 ≠ Eskenazi, VA, or Other*Select to confirm | * I will abide by the Terms of Use for Researchers Accessing IU Health PHI for Research Purposes.
 | To review the Terms of Use, see [HSO Guidance on HIPAA](https://research.iu.edu/compliance/human-subjects/guidance/hipaa.html). |
| 0767 | *If 0763 = Biospecimens or information originally collected for another research project*Which IRB provided approval for the collection of the information or biospecimens? | * IU IRB
* Other
 |  |
| 0768 | *If 0767 = IU IRB*Provide the IU IRB protocol number(s). | Free text |  |
| 0769 | *If 0767 = Other*Select to confirm | * Documentation of IRB approval and the consent form used for collection of the data or biospecimens are included with this submission.
 |  |
| 0770 | *If 0763 = Other*Describe the other source of the information and/or biospecimens. | Free text |  |
| 0771 | Explain the purpose of the sharing outside of IU and/or its affiliates. | Free text |  |
| 0772 | List the principal investigator(s) and institution(s) with whom you will share information and/or biospecimens. | Free text |  |
| 0773 | What information will be shared? Select all that apply. | * Identifiable data
* Limited data set
* Deidentified data
* Biospecimens
* Images
 |  |
| 0774 | *If 0773 = Identifiable data OR Limited data set*List all of the data points to be shared or confirm a data collection form is attached to this submission. | Free text |  |
| 0775 | If 0773 = Deidentified dataConfirm you will remove the following 18 identifiers prior to sharing any data:* Names, including initials
* Any geographic subdivision smaller than a state, including street address, city, county, precinct, zip codes (except that the first three digits of zip code may be shared if the geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people)
* All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, and date of death
* Ages over 89 (unless aggregated in a single category of age 90 or older)
* Telephone and fax numbers
* Email addresses
* Social security numbers, medical record numbers, health plan beneficiary numbers, and account numbers
* Certificate/license numbers
* Vehicle identifiers or serial numbers, including license plate numbers
* Device identifiers or serial numbers
* Web universal resource locators (URLs)
* Internet protocol (IP) address numbers
* Biometric identifiers, including fingerprints and voice prints
* Full face photographic images or any comparable images
 | * Yes
 |  |
| 0776 | Do you expect the recipient of the information to provide results back to you? | * Yes
* No
 |  |
| 0777 | Indicate additional expectations that should be placed on the recipient of the information, such as return of or destruction of information or specimens, notification of publication, etc., or indicate that there are no additional expectations. | Free text |  |
| 0778 | Is the sharing of information and/or biospecimens being done pursuant to or because of an existing sponsored project, data consortium agreement, or other external collaboration? | * Yes
* No. The HRPP will determine whether an agreement is required for the data sharing.
* Not sure
 |  |
| **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 |  |