

# Kuali Protocols NEW Form Guide – Expedited/Full BoardPublished 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 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 | * Status
* Disposition (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 |  |
| 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
 |  |
| **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. |  |  |
| 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** |
| 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. |
| 0104 | 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
 |  |
| 0128 | *IF 0104 = 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
 |  |
| 0125 | *IF 0104 = 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
 |  |
| 0127 | *IF 0104 = Demonstration project*Confirm the demonstration project is designed to study, evaluate, or otherwise examine one of the following AND the project could not practicably be conducted without a waiver of informed consent:* Public benefit or service programs
* Procedures for obtaining benefits or services under those programs
* Possible changes in or alternatives to those programs or procedures
* Possible changes in methods or levels of payment for benefits or services under those programs.
 | * Yes
* No. Return to question 0104 above and remove selection Demonstration Project.
 |  |
| 0105 | 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
* CTSI SRC: Biomedical, no prior peer review, and does not qualify for expedited review
* 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 0105 = IUSCC SRC, CTSI SRC, Radiation safety, or IBC review*Upload 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
 |  |
| 0126 | *IF 0107 = Children*Will any subjects be 18 or older at time of enrollment? | * Yes
* No
 |  |
| 0108 | Does any research activity in this study present more than minimal risk to human subjects? | * Yes
* No
 | Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. Risks may be psychological, physical, and/or privacy-related.A protocol document is required for greater than minimal risk research. For a sample template, visit the IU HRPP [Forms & Templates](https://research.iu.edu/forms/human-subjects-irb.html) webpage. |
| 0129 | *IF 0108 = No*Does the research involve ANY subject interaction and/or intervention? Select No if the research is limited to use of previously collected data or specimens. | * Yes
* No
 |  |
| 0130 | *IF 0129 = No*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 “Read Only” Permission Type.
* Complete the Eskenazi Health Research Approval Application at <https://redcap.uits.iu.edu/surveys/?s=M8AL8APJLT>.

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 |  |
| 0132 | *IF 0129 = No*How will you identify data, records, and/or specimens to include in the study? | Free text |  |
| **Research Design** |
| 0150 | Provide a brief statement (no more than 2-3 sentences) of the purpose of this study, in lay terms. | Free text |  |
| 0151 | *IF 0108 = No*Is there a separate Protocol document or research plan for this study? | * Yes, and the Protocol is attached.
* No
 | A Protocol is not required for minimal risk research, but should be attached if one is available. |
| 0191 | *IF 0151 = Yes OR 0108 = Yes*Enter Sponsor Protocol # or “N/A” if there is none. | Free text |  |
| 0152 | *IF 0151 = No*Provide the scientific background, justification for conducting the study, and if applicable, results of similar studies or pilot data. | Free text |  |
| 0153 | *IF 0129 = Yes AND 0151 = No*Describe the research interactions or interventions and data collection methods for the study. Include the frequency and duration of each procedure or activity. | Free text | If you will have multiple subject groups, you will need to explain the study procedures for each group of subjects. |
| 0154 | *IF 0108 = Yes* Will ongoing safety review be conducted by an independent group of individuals often called a data safety monitoring board (DSMB) or committee (DSMC/DMC)? | * Yes
* No
 |  |
| 0141 | *IF 0108 = No, 0192 = Yes AND 0104 = Clinical Trial*Will ongoing safety review be conducted by an independent group of individuals often called a data safety monitoring board (DSMB) or committee (DSMC/DMC)? | * Yes
* No
 |  |
| 0155 | *IF 0154 = Yes OR 0141 = Yes*Describe the frequency of DSMB review. | Free text |  |
| 0156 | *IF 0154 = Yes OR 0141 = Yes*Indicate you have attached a charter or describe the expertise of the members of the DSMB. | Free text | For example, physician and specialty, statistician, etc. |
| 0157 | *IF 0154 = No or 0141 = No*Describe the plan for conducting ongoing review of study-wide data to ensure the safety of subjects. Consider the following:* Who will review data
* What data will be reviewed, at minimum adverse event data
* How often data will be reviewed.
 | Free text |  |
| 0158 | *IF 0154 = No or 0141 = No*What documentation will be maintained to demonstrate that safety review was conducted in accordance with this plan? | Free text | This might be accomplished with:* Notes in the study records that each meeting has occurred
* Separate document indicating that safety review was conducted and the results (e.g., no concerns were identified)
* A formal report which includes the results/conclusion of the safety review
 |
| **Research Settings** |
| 0116 | *IF 0108 = Yes OR 0129 = Yes*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 |  |
| 0122 | *IF 0116 = Elementary or secondary school OR Other*Select one of the following as it relates to the other research settings. | * Permission from the location has been or will be obtained prior to conducting research interactions or interventions at the facility. Ensure a copy of this permission is retained in the research record.
* Permission from the location is not required.
 |  |
| 0123 | *IF 0122 = Permission from the location is not required.*Explain why permission from the location is not required. | 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 “Read Only” Permission Type.
* Complete the Eskenazi Health Research Approval Application at <https://redcap.uits.iu.edu/surveys/?s=M8AL8APJLT>.

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 |  |
| 0118 0119 | *IF 0117 = IU Health*List the IUH Hospitals*Select +Add Line to list each IUH hospital* | List Drop down of IUH sites |  |
| **Confidentiality & Privacy** |
| 0133 | 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
* None of the above
 |  |
| 0139 | *IF 0117 = Roudebush VA Medical Center*For VA research only. Will you be collecting self-reported health information ? | * Yes
* No
 |  |
| 0135 | *IF 0133 ≠ Medical records (0133 = Student records OR None of the above)*Will any data generated as part of the research be entered into a subject’s medical record? | * Yes
* No
 |  |
| 0159 | *IF 0135 ≠ Yes AND 0139 ≠ Yes*Describe where identifiable electronic subject data will be stored, and how it will be protected to ensure confidentiality (e.g. all electronic data will be collected and stored on only encrypted devices). | Free text |  |
| 0160 | *IF 0135 = Yes OR 0133 = Medical records OR 0139 = Yes*Select the electronic systems to be used for the collection and/or storage of health information. Choose all that apply | * OnCore
* REDCap
* Microsoft at IU Secure Storage/Google at IU Secure Storage
* Sponsor-provided systems
* Other
* No health information will be collected or stored electronically
 |  |
| 0161 | *IF 0160 = Other*For Other systems, provide additional information regarding the status of certification for storage of electronic protected health information (ePHI). | * Electronic systems used to collect or store health information have previously been approved or certified for electronic protected health information (ePHI).
* The study team will complete the required IU system certification checklist and process for certifying the collection and/or storage locations and systems with their IT professional and data steward prior to the collection of any ePHI.
 | If the study team is not responsible for managing the system(s), check with the [IT professional responsible for managing the system](https://itpeople.apps.iu.edu/) to confirm it is approved or certified for ePHI before proceeding. IU researchers who need additional assistance regarding secure data storage can contact securemyresearch@iu.edu. |
| 0162 | Describe the procedures that will be used to ensure confidentiality of written/paper records that contain subjects’ identifiable data. | Free text |  |
| 0163 | *IF 0108 = Yes OR 0129 = Yes*Describe the setting where research procedures will occur and how that protects subjects’ privacy. Consider recruitment, consent, and study interventions. | Free text |  |
| 0351 | *IF 0133 = Student records*Are the student records from IU and/or another institution? Select all that apply. | * IU
* Another institution
 |  |
| 0352 | *IF 0351 = IU*Is the research intended to study the effectiveness of an instructional technique, curricula, or classroom management method in an IU course? | * Yes
* No, and signed permission will be obtained to access student records.
 |  |
| 0353 | *IF 0352 = Yes*Will only IU faculty and staff who have professional responsibilities to conduct such research have access to the IU student records data? | * Yes
* No, and signed permission will be obtained to access student records.
 |  |
| 0354 | *IF 0351 = Another institution*Has the other institution providing the data determined that the research is eligible for an exception to the FERPA requirement for written release from the students/parents? | * Yes, and documentation confirming this is included with the submission.
* Yes, and documentation confirming this will be provided via an amendment before records are accessed.
* No, and signed permission will be obtained to access student records.
 |  |
| 0355 | *IF 0354 = Yes, and documentation confirming this is included with the submission*Upload documentation from the organization providing the data confirming the exception to the FERPA requirement for written release from the students/parents.*Select* ***+Add Line*** *to list each attachment* | List, File Attachment |  |
| **Multi-site and IU IRB** |
| 0124 | Is this a multi-site study? | * Yes
* No
 | A multi-site study is a study conducted using a single protocol at multiple different sites with individual PIs responsible for the conduct of the research at the various sites. |
| 0136 | *IF 0124 = Yes*Is the PI listed above the lead PI for this multi-site study? | * Yes
* No
 |  |
| 0137 | *IF 0136 = Yes AND 0108 = Yes*Describe the plan for communication from the lead PI to the site PIs, and vice-versa, of information that may be relevant to the protection of participants (e.g., safety information). | Free text |  |
| 0138 | *IF 0124 = Yes*Are you requesting that the IU IRB serve as IRB for other sites (serve as single IRB or sIRB)? | * No
* Yes. Click on “Participating Sites” at the top of the page and add each external site.
 |  |
| 7002 | IF 0138 = YesDescribe the plan for communication of IRB-related information to sites and/or non-affiliated investigators. | Free text | The plan should include, at minimum, (1) how non-affiliated investigators will be informed of applicable IU HRPP policies and procedures, (2) a process for ensuring noncompliance and unanticipated problems occurring at the participating site are reported to the IU IRB, (3) a process for ensuring requests for amendments by the participating site are submitted to the IU IRB, and (4) who will be responsible for communicating IRB decisions and approved documents to the participating site.  |
| ***IF 0138 = Yes*****Participating Sites** *(on a separate tab)* |
| Participating Site | List |  |
| N/A | Organization | Organization drop-down | Begin typing name of site/organization to determine if site is listed in drop-down. If site is not found in drop-down, select “Organization Not Found” and mark the checkbox. |
| 7000 |  | * I cannot find my Organization (Enter \*\*Organization Not Found\*\* in the Organization search)
 |  |
| 7001 | *IF 7000 is checked*List the name of the Site/Organization. | Free text |  |
| N/A | IRB Contact, if known. | Free text | NOTE: If the IRB contact at the Participating Site is not known, enter "Unknown." |
| N/A | Site PI Name |  |  |
| N/A | Reliance Documentation – for HRPP use only | List | This is a list. You can upload as many attachments as is necessary. |
|  | Attachment Description | Free text |  |
|  | Site Attachment | Drag & drop a file |  |
| **Transnational Research** |
| 0475 | Does the research involve any of the following transnational components? *Select all that apply*. | * IU is the prime awardee for a federally-funded international study
* Interacting directly with subjects outside the US
* Targeting subjects outside the US but with no direct interaction (e.g., online surveys)
* Receipt of identifiable data about subjects outside the US
* None of the above but IU is responsible for research being conducted outside the US
* None of the above
 | For more information, see the HRPP guidance on [Transnational Research](https://research.iu.edu/compliance/human-subjects/guidance/transnational.html). |
| 0384 | *IF 0475 = IU is the prime awardee, Interacting directly with subjects, Targeting subjects outside the US, Receipt of identifiable data OR IU is responsible for research being done outside the US*List each country. | Free text |  |
| 0388 | *IF 0475 = IU is the prime awardee, Interacting directly with subjects, Targeting subjects outside the US, Receipt of identifiable data OR IU is responsible for research being done outside the US*Provide a brief overview of the laws and regulations regarding human research protections in the non-US location(s). | Free text |  |
| 0389 | *IF 0475 = IU is the prime awardee, Interacting directly with subjects, Targeting subjects outside the US, Receipt of identifiable data OR IU is responsible for research being done outside the US*Describe any social, cultural, economic, and/or political considerations for the non-US location(s) which may impact the research or risks to subjects. | Free text |  |
| 0390 | *IF 0475 = IU is the prime awardee, Interacting directly with subjects, OR IU is responsible for research being done outside the US*Describe the researchers’ experience with and knowledge of the non-US location(s). | Free text |  |
| 0385 | *IF 0475 = IU is the prime awardee, Interacting directly with subjects, OR IU is responsible for research being done outside the US*Is there an IRB, ethics committee, government agency, or other community group which reviews human subjects research for the non-US location(s)? | * Yes
* No
 | Documentation of committee approval is required before final approval can be granted. |
| 0390 | *IF 0475 = IU is the prime awardee, Interacting directly with subjects, OR IU is responsible for research being done outside the US* | * Yes
* No
 |  |
| 0387 | *IF 0385 = Yes*Upload approval here.*Select +Add Line to list each attachment* | List, file attachment |  |
| **FDA** |
| 0200 | *IF 0125 ≠ Research of a drug/biological product conducted under an IND OR Research of a medical device conducted under an IDE* Does this research involve the study of any of the following products (regardless of FDA approval status)? | * None
* Drug
* Biological product
* Dietary supplement
* Medical device
* Food
* Cosmetic
 | The “study of” means at least one objective of the research is related to obtaining data about the product. This also includes the “use of” a drug/biological product/medical device that has not been approved by the FDA for use in the U.S.  |
| 0201 | *IF 0200 = Drug, Biological product, Dietary supplement, Medical device, Food, OR Cosmetic*Is this an Investigator Initiated Trial (IIT)? | * Yes
* No
 |  |
| 0253 | *IF 0200 = Food*Explain why use of the food in this study does not require an IND application to the FDA.  | Free text | See [FDA Guidance: IND Applications – Determining Whether Human Research Studies Can Be Conducted Without an IND](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/investigational-new-drug-applications-inds-determining-whether-human-research-studies-can-be). If additional assistance is needed, contact the HRPP at [irb@iu.edu](file:///%5C%5Cads.iu.edu%5Cutsfs%5CIU-RCIN%5CGroup%5CHRPP%5CKuali%20Protocols%5CImplementation%5CWorking%20Groups%5CForms%5CAnalysis%5CKP%20Form%20Guide%5Cirb%40iu.edu).  |
| 0254 | *IF 0200 = Cosmetic*Explain why use of the cosmetic in this study does not require an IND application to the FDA. | Free text | See [FDA Guidance: IND Applications – Determining Whether Human Research Studies Can Be Conducted Without an IND](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/investigational-new-drug-applications-inds-determining-whether-human-research-studies-can-be). If additional assistance is needed, contact the HRPP at [irb@iu.edu](file:///%5C%5Cads.iu.edu%5Cutsfs%5CIU-RCIN%5CGroup%5CHRPP%5CKuali%20Protocols%5CImplementation%5CWorking%20Groups%5CForms%5CAnalysis%5CKP%20Form%20Guide%5Cirb%40iu.edu). |
| 0223 | *IF 0200 = Dietary supplement*List all dietary supplements being studied. | Free text |  |
| 0224 | *IF 0200 = Dietary supplement*Is this study intended to evaluate a dietary supplement’s ability to diagnose, cure, mitigate, treat, or prevent a disease? | * Yes
* No. The research is designed to study the relationship between the dietary supplement’s effect on normal structure or function in humans or characterize the mechanism by which a dietary supplement acts to maintain such structure or function.
 |  |
| 0225 | *IF 0224 = No*Explain why the supplement is not being used to diagnose, cure, mitigate, treat, or prevent a disease. | Free text |  |
| 0226 | *IF 0224 = Yes*Does the disease being targeted result from an essential nutrient deficiency (e.g. scurvy, pellagra)? | * Yes
* No
 |  |
| 0227 | *IF 0226 = No*Is the use or administration of the dietary supplement dictated by the protocol (e.g. randomization to determine the dietary supplement(s) administered; protocol dictates the route, dose, timing, etc.)? | * Yes. Use of the dietary supplement is regulated by the FDA as a drug. You must contact the FDA to determine whether an IND is needed.
* No
 |  |
| 0228 | *IF 0227 = Yes*Indicate the result of the IND discussion with the FDA. | * IND has been granted and supporting documentation is included with this submission.
* FDA confirmed an IND is not needed and supporting documentation is included with this submission.
 |  |
| 0229 | *IF 0228 = FDA confirmed an IND is not needed* Upload documentation of the IND discussion with the FDA | List, File Attachment | This is an *optional* list. You upload none or as many attachments as is necessary. |
| 0202 | *IF 0200 = Drug OR Biological Product*Is the study being conducted under an IND (investigational new drug application)? | * Yes
* No
 |  |
| 0203 | *IF 0125 = Research of a drug/biological product OR 0202 = Yes OR 0228 = IND has been granted*IND number | Free text |  |
| 0204 | *IF 0125 = Research of a drug/biological product OR 0202 = Yes OR 0228 = IND has been granted*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. | List, File Attachment |  |
| 0205 | *IF 0125 = Research of a drug/biological product OR 0202 = Yes OR 0228 = IND has been granted*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
 |  |
| 0230 | *IF 0228 = IND has been granted* Describe how you will ensure appropriate labeling, storage, and control of the supplements, including ensuring it is used and distributed only in accordance with the IRB-approved application, and maintain adequate records.  |  | See the IU HRPP Policy on Research Personnel Responsibilities.  |
| 0206 | *IF 0125 = Research of a drug/biological product OR 0202 = Yes*Will Investigational Drug Services (IDS; e.g. IU Health or Eskenazi) be used for drug handling and control for ALL drugs at ALL locations? | * Yes
* No
 |  |
| 0207 | *IF 0206 = No*For any locations not using IDS, describe how you will ensure appropriate labeling, storage, and control of the drugs, including ensuring the drugs are used and distributed only in accordance with the IRB-approved application, and maintain adequate records. |  | See the IU HRPP Policy on Research Personnel Responsibilities. |
| 0208 | *IF 0202 = No*The research includes: Select all of the following that apply. | * The study of one or more lawfully marketed drugs
* IND exemption AND documentation from the FDA confirming this determination is included with the submission
* The study of a drug’s bioavailability or bioequivalence (This is rare)
* Use of radioactive drug(s) for basic science research under RDRC approval (This is rare)
* Use of cold isotope(s) for basic science research (This is rare)
* None of the above
 | For purposes of this question, biological products should be considered "drugs". |
| 0256 | *IF 0208 = IND exemption*Upload IND exemption documentation | File Attachment |  |
| 0209 | *IF 0208 = The study of one or more lawfully marketed drugs*Is the use or administration of all lawfully marketed drugs dictated by the protocol (e.g. randomization to determine the drug(s) administered; protocol dictates the route, dose, timing, etc.)? | * Yes
* No
 |  |
| 0210 | *IF 0209 = No*Will data generated be submitted to the FDA? | * Yes
* No
 |  |
| 0211 | *IF 0209 = Yes*List all lawfully marketed drugs | List | This is a list. You can list as many lawfully marketed drugs as is necessary. |
| 0212 | IF 0209 = YesName of Drug |  |  |
| 0213 | *IF 0209 = Yes*Is the research intended to be:* reported to the FDA as a well-controlled study in support of a new indication or use, OR
* used to support any other significant change in the labeling of the drug, OR
* in support of a significant change in the advertising of the drug?
 | * Yes. An IND or documentation of an IND exemption from the FDA is required.
* No
 |  |
| 0214 | *IF 0213 = No*Is the use of the drug in this study consistent with the drug’s approved indication, route of administration, dose, and patient populations? | * Yes
* No
 |  |
| 0215 | *IF 0214 = Yes***Is there any other factor which would significantly increase the risk (or decrease the acceptability of the risk) associated with the use of the drug in this study?** | * Yes. An IND or documentation of an IND exemption from the FDA is required.
* No. Use of the drug is exempt from the IND regulations. Include the product labeling (e.g. package insert) showing the product’s approved indication, route of administration, dose, and patient population.
 |  |
| 0216 | *IF 0214 = No*Explain how the use of the drug in this study differs from the drug’s approved indication. |  |  |
| 0217 | *IF 0214 = No*Does the use of the drug in this study significantly increase the risk (or decrease the acceptability of the risk) associated with the approved use of the drug, considering the route of administration, dose, patient population, or other factor? | * Yes. An IND or documentation of an IND exemption from the FDA is required.
* No
 |  |
| 0218 | *IF 0217 = No*Explain how the use of the drug in this study does not significantly increase the risk (or decrease the acceptability of the risk) associated with the approved use of the drug, considering the route of administration, dose, patient population, or other factor. | Free text | Include the product labeling (e.g. package insert) showing the product’s approved indication, route of administration, dose, and patient population. |
| 0255 | *IF 0215 = No OR 0217 = No*Upload the product labeling (e.g. package insert) showing the product’s approved indication, route of administration, dose, and patient population. | File Attachment |  |
| 0219 | *IF 0208 = The study of a drug’s bioavailability* Provide justification that this qualifies as a bioavailability or bioequivalence study using unapproved versions of approved drug products without submission of an IND application. | Free text |  |
| 0220 | *IF 0208 = Use of radioactive drug(s)* Provide justification that this qualifies as basic research not intended for immediate therapeutic, diagnostic, or similar purposes, or otherwise to determine the safety and efficacy of the product. | Free text |  |
| 0221 | *IF 0208 = Use of cold isotope(s)* Provide justification that the research is intended to obtain basic information regarding the metabolism (including kinetics, distribution, and localization) of a drug labeled with a cold isotope or regarding human physiology, pathophysiology, or biochemistry. | Free text |  |
| 0222 | *IF 0208 = None of the above*Due to the selection of None of the Above, provide further information as to why the drug does not fit any of the available options listed above. | Free text | An IND or documentation of an IND exemption from the FDA may be required. |
| 0231 | *IF 0200 = Medical device*Is the study being conducted under an IDE? | * Yes
* No
 |  |
| 0232 | *IF 0125 = Research of a medical device OR 0231 = Yes*IDE number | Free text |  |
| 0233 | *IF 0125 = Research with a medical device OR 0231 = Yes*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. | List, File Attachment |  |
| 0234 | *IF 0125 = Research of a medical device OR 0231 = Yes*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
 |  |
| 0235 | *IF 0231 = No*Is the use or administration of the device dictated by the protocol (e.g. randomization to determine the device(s) administered; protocol dictates the route, timing, etc.)? | * Yes
* No
 |  |
| 0236 | *IF 0235 = No*Will data generated be submitted to the FDA? | * Yes
* No
 |  |
| 0237 | *IF 0235 = Yes*The research includes: Select all of the following that apply. | * The study of one or more lawfully marketed medical devices
* The study of one or more non-invasive diagnostic devices
* Exemption from the IDE regulations AND documentation from the FDA confirming this is including with the submission. Note: documentation of 510(K) clearance is not the same as documentation of exemption from an IDE.
* The study of at least one medical device that does not fall into any of the three options above.
 |  |
| 0258 | *IF 0237 = Exemption from the IDE regulations*Upload IDE exemption documentation | File Attachment |  |
| 0238 | *IF 0237 = The study of one or more lawfully marketed medical devices*List all lawfully marketed medical devices*Select +Add Line to list each lawfully marketed medical device* | List |  |
| 0239 | *IF 0237 = The study of one or more lawfully marketed medical devices*Name of lawfully marketed device. | Free text |  |
| 0240 | *IF 0237 = The study of one or more lawfully marketed medical devices*Will the device be used or investigated in accordance with the indications in the FDA approved or cleared labeling? | * Yes
* No
 |  |
| 0257 | *IF 0240 = Yes*Use of the device is exempt from the IDE regulations. Upload the device Instructions for Use describing the device's cleared indications. | File Attachment |  |
| 0241 | *IF 0237 = The study of one or more non-invasive diagnostic devices*List of non-invasive diagnostic devices*Select +Add Line to list each non-invasive diagnostic device* | List |  |
| 0242 | *IF 0237 = The study of one or more non-invasive diagnostic devices*Name of non-invasive diagnostic device. | Free text |  |
| 0243 | *IF 0237 = The study of one or more non-invasive diagnostic devices*Does the device testing require an invasive sampling procedure that presents significant risk? | * Yes
* No
 |  |
| 0244 | *IF 0243 = No*Does the device testing by design or intention introduce energy into a subject? | * Yes
* No
 |  |
| 0245 | *IF 0244 = No*Will the results of the testing be confirmed by another medically established diagnostic product or procedure? | * Yes
* No
 |  |
| 0246 | *IF 0245 = Yes*Confirm the device will be labeled for research or investigational use only, in accordance with FDA requirements (see 21 CFR 809.10). | * Yes. Use of the device is exempt from the IDE regulations.
 |  |
| 0247 | *IF 0237 = The study of at least one medical device OR 0240 = No OR 0243 = Yes OR 0244 = Yes OR 0245 = No*One or more of your devices does not qualify for exemption from the IDE regulations based on your responses above. Complete the information below regarding your device(s).*Select +Add Line to list each device* | List |  |
| 0248 | *IF 0237 = The study of at least one medical device OR 0240 = No OR 0243 = Yes OR 0244 = Yes OR 0245 = No*Name of device. | Free text |  |
| 0249 | *IF 0237 = The study of at least one medical device OR 0240 = No OR 0243 = Yes OR 0244 = Yes OR 0245 = No*Is the device banned in the United States? | * Yes
* No
 |  |
| 0250 | *IF 0249 = No*Does the device present a potential for serious risk to the health, safety, or welfare of a subject? | * Yes
* No
 |  |
| 0251 | *IF 0250 = No*Explain why the use of the device in this study does NOT present a potential for serious risk to the health, safety, or welfare of subjects. | Free text |  |
| 0252 | *IF 0249 = Yes OR 0250 = Yes*Generally, an IDE or a determination of non-significant risk from the FDA is required for devices that do not otherwise qualify as non-significant risk. Justify why an IDE is not required for this study. | Free text |  |
| **Eligibility and Recruitment** |
| 0300 | *IF 0129 = Yes AND 0151 = No*List the criteria that would make people eligible to be included in this study. | Free text | If you will have multiple subject groups with different characteristics, explain the inclusion criteria for each group of subjects. |
| 0301 | *IF 0129 = Yes AND 0151 = No*List the criteria that would exclude people from this study. | Free text | If you will have multiple subject groups with different characteristics, explain the exclusion criteria for each group of subjects. |
| 0302 | *IF 0129 = No*List the criteria that would make data, records, and/or specimens eligible to be included in this study. | Free text |  |
| 0303 | *IF 0129 = No*List the criteria that would exclude data, records, and/or specimens from this study. | Free text |  |
| 0304 | *IF 0129 = Yes OR 0108 = Yes AND 0104 ≠ Demonstration project*Will subjects be offered any of the following for their participation in the study? All of these are forms of payment. Select all that apply. | * Cash, gift card, or check
* Gifts
* Prize drawing
* Course credit
* Direct payment of expenses (e.g., travel)
* Other
* None of the above. No payment.
 | For more information, visit the IU Policy on [Contests, Drawings, Games and Prizes](https://policies.iu.edu/policies/fin-acc-640-contests-drawings-games-prizes/index.html). |
| 0305 | *IF 0304 = Other*Describe the Other form of payment. | Free text |  |
| 0306 | *IF 0304 = Cash, gift card, or check, Gifts, Prize drawing, Course credit, OR Other*Explain why the amount offered is reasonable in relation to the subjects’ involvement in the study. | Free text |  |
| 0307 | *IF 0108 = Yes OR 0129 = Yes*Describe your recruitment process, including how subjects will be identified and contacted. Ensure all recruitment materials are attached below for IRB review and approval. | Free text | If you will have multiple subject groups, explain the recruitment process for each group of subjects. |
| 0308 | *IF 0108 = Yes OR 0129 = Yes*Will any of the following sources be used to recruit subjects? | * Medical records or information provided by a health care provider
* Social media
* Neither of the above
 |  |
| 0313 | *IF 0308 = Social media*Explain how you will engage with potential subjects on social media. | Free text |  |
|  |  | * ~~The study team member will access VA medical records~~.
 |  |
| 1050 – 1056 | *IF 0139 = Yes* HIPAA Waiver – VA Self Report (see questions below) | Free text/checkbox |  |
| 0311 | *IF 0308 = Medical records*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.).
 |  |
| 1060  | *IF 0311 = Authorization will not be obtained* Provide a brief description of the protected health information (PHI), including identifiers, to be used or accessed for recruitment purposes. | Free text |  |
| 1067 | *IF 0311 = Authorization will not be obtained*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 stored securely to prevent improper use and disclosure, as described above in the Confidentiality and Privacy section of the form.
* 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
 |  |
| 0386 | *IF 0308 = Medical records AND 0117 ≠ Roudebush VA*HIPAA authorization or a waiver of authorization may be required for participation. Will health information obtained from the subject’s medical record be recorded in the research record? | * Yes
* No (This is rare.)
 | IF 0386 = No AND 0133 = Medical records, change 0133 to “None of the above”. |
| 0314 | *IF 0108 = Yes OR 0129 = Yes*Will any information be kept about individuals who decline participation or are found to be ineligible? | * Yes
* No
 | Note that once a subject has provided consent to participate, all information about the subject should be retained in the research record, even if they are subsequently found ineligible. Answer Yes only if you plan to keep information provided prior to consent. |
| 0315 | *IF 0314 = Yes*Explain what information will be kept and why, and how the information will be handled to ensure confidentiality. | Free text |  |
| 0316 | *IF 0108 = Yes OR 0129 = Yes*If a subject participates in this study, would it stop or prevent them from participating in another study? | * Yes
* No
 |  |
| 0317 | *IF 0316 = Yes*Is the investigator currently aware of competing studies? | * Yes
* No
 | Click [here](https://research.iu.edu/compliance/human-subjects/guidance/competing-studies.html) for information on IU HRPP guidance on Enrollment into Competing Studies |
| 0318 | *IF 0317 = Yes*Describe the plan to assure the subjects will be informed of all studies for which they qualify and will be supported in making an informed and voluntary choice regarding study participation. | Free text |  |
| 0319 | *IF 0317 = Yes*If such an approach will potentially introduce bias into recruitment, further address these difficulties. | Free text |  |
| 0320 | *IF 0317 = Yes*If the approach suggests that multiple competing studies could exist concurrently, justify the existence of an adequate subject population to meet the recruitment goals of each study. | Free text |  |
| **Prisoners** |
| *IF 0107 = Prisoners*  |
| 0323 | ***IF 0102 = Federal funding*****Identify the appropriate research category. Select all options that apply.** | * A study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects.
* A study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects.
* Research on conditions particularly affecting prisoners as a class. For example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere, or research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults. If the research is federally funded, the study may proceed only after the Secretary has consulted with appropriate experts, including experts in penology medicine and ethics, and published notice, in the Federal Register, of his/her intent to approve such research.
* Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. If the research is federally funded, in cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only after the Secretary has consulted with appropriate experts, including experts in penology medicine and ethics, and published notice, in the Federal Register, of his/her intent to approve such research.
* Epidemiological studies in which the sole purposes are (i) to describe the prevalence or incidence of a disease by identifying all cases, or (ii) to study potential risk factor associations for a disease.
 |  |
| 0324 | ***IF 0102 ≠ Federal funding*****Explain the need for inclusion of prisoners in the research.** | Free text |  |
| 0325 | ***IF 0108 = Yes OR 0129 = Yes*****Provide information on the PI’s experience with prisoners.** | Free text |  |
| 0326 | **Explain how any possible advantages to the prisoner through his or her participation in the research do not provide undue influence when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison.** | Free text | The possibility for undue influence exists when the advantages are of such a magnitude that the subject’s ability to weigh the risks of the research against the value of participation is impaired, given the limited choice environment of the subject. |
| 0327 | **Explain how the risks involved in the research are equivalent to those that would be accepted by non-prisoner participants.** | Free text |  |
| 0328 | **Explain how procedures for the selection of subjects within the prison are fair to all prisoners and not subject to arbitrary intervention by prison authorities or prisoners.** | Free text |  |
| 0329 | **Will prisoners serve as control subjects?** | * Yes
* No
 |  |
| 0330 | ***IF 0329 = Yes*****Will control subjects be selected randomly from the group of available prisoners who meet the characteristics needed for the research?** | * Yes
* No
 |  |
| 0331 | ***IF 0330 = No*****Explain how control subjects will be selected, and provide justification why random selection is not appropriate for this research.** | Free text |  |
| 0332 | **Select to confirm** | * Parole boards will not take into account a prisoner’s participation in the research when making decisions regarding parole.
 |  |
| 0333 | **Explain how each prisoner subject will be clearly informed in advance that participation in the research will have no effect on his or her parole.** | Free text |  |
| 0334 | **Is follow-up examination or care of subjects after the end of their participation in research necessary or appropriate?** | * Yes
* No
 |  |
| 0335 | ***IF 0334 = Yes*****Explain the procedures for ensuring examination or care is conducted, including how subjects will be informed.** | Free text |  |
| 0336 | **Will the research be conducted within a correctional institution?** | * Yes, and a letter of cooperation from all facilities where research will be conducted is attached.
* No
 |  |
| 0337 | ***IF 0336 = Yes*****Select all applicable locations of research.** | * Department of Corrections (Indiana state prisons)
* Bureau of Prisons (federal prisons)
* Other
 |  |
| 0338 | ***IF 0337 = Bureau of Prisons*****Explain how the research contributes to the advancement of knowledge about corrections.** | Free text |  |
| 0339 | ***IF 0337 = Bureau of Prisons*****Select to confirm** | * The PI agrees to abide by the requirements of 28 CFR 512.11.
 | <https://ecfr.io/Title-28/Part-512>  |
| 0340 | ***IF 0337 = Other*****Due to the selection of other, describe further the locations of the research.** | Free text |  |
| 0341 | ***IF 0336 = Yes*****Describe the location(s) of interviews and other interactions with subjects, including privacy features.** | Free text | The investigator must explain how the setting will prevent other prisoners, as well as facility officials, from overhearing or recording the discussion. If this is not possible, the subject must be clearly advised of this fact at the beginning of each interview or interaction. |
| 0342 | ***IF 0129 ≠ Yes OR 0108 = Yes*****Due to prisoners not always having access to a phone (or other methods of contact), explain the plan for communication with subjects.** | Free text |  |
| **Veterans** |
| *IF 0117 = Roudebush VA Medical Center*  |
| 0343 | **Will VA time or resources be used to support the conduct of this study in non-veterans?** | * Yes
* No
 |  |
| 0344 | ***IF 0343 = Yes*****Select all of the following participant types that will be included in the research.** | * Subjects are VA health care providers or employees
* Family members of veterans
* Active duty military personnel
* Other
 |  |
| 0345 | ***IF 0344 = Other*****Due to the selection of other, explain and provide justification for the use of VA time and/or resources for non-veterans.** | Free text |  |
| 0346 | **Explain how this research is relevant to the VA mission and the veteran population it serves.** | Free text |  |
| 0347 | **Is this collaborative research?** | * Yes
* No
 | For example, this study involves both VA and non-VA investigators. |
| 0348 | ***IF 0347 = Yes*****Describe which research procedures, including recruitment, interactions, interventions, data collection, etc., will be conducted by VA investigators on VA time and which procedures will not.** | Free text |  |
| 0349 | **Will any research data be shared or stored outside the VA?** | * Yes
* No
 |  |
| 0350 | ***IF 0349 = Yes*****Describe where data will be shred or stored.** | Free text |  |
| **ILCC** |
| *IF 0107 = Individuals Lacking Consent Capacity*  |
| 0356 | **You indicated you are enrolling individuals lacking consent capacity. Which of the following is applicable?** Choose one. | * The research cannot happen solely with those who have consent capacity and the focus is the disorder which led to the lack of capacity.
* The research is not directly related to the subjects’ lack of consent capacity, but there is a compelling argument for including these subjects.
 |  |
| 0357 | *IF 0356 = The research is not directly related to the subjects’ lack of consent capacity*Explain the need for inclusion of individuals lacking consent capacity in the research. | Free text |  |
| 0358 | *IF 0108 = Yes*The research presents the following to individuals lacking consent capacity: | * No greater than minimal risk to subjects.
* Greater than minimal risk but greater probability of direct benefit than harm to subjects.
* Greater than minimal risk and no prospect of direct benefit to individual subjects, but is likely to yield generalizable knowledge about the subjects’ disorder or condition which is of vital importance for the understanding or amelioration of the disorder or condition.
 |  |
| 0359 | Describe how you will assess a person’s capacity to consent to the research. | Free text | This may include the individuals being assessed, information or tools used to assess an individual’s capacity, and the timing of assessments (including re-assessments). |
| 0360 | Do you require a modification to the defined process for identifying an LAR and/or in determining when an individual that may serve as LAR is reasonably available? If a modification is needed, explain. (This is rare) | Free text | For more information, visit the IU HRPP Policy on [Adult Individuals Lacking Consent Capacity in Research](https://research.iu.edu/policies/human-subjects-irb/adult-individuals-lacking-consent-capacity.html).  |
| 0361 | Explain how you will obtain assent to participate from individuals who cannot consent for themselves. If assent will not be obtained, provide justification. | Free text |  |
| 0362 | *IF 0107 = Individuals admitted for inpatient or residential psychiatric treatment*Provide justification for the enrollment of inpatient psychiatric subjects, including why an alternative subject population is not appropriate for this research, or why participation in the research offers the potential for significant benefit to inpatient psychiatric subjects. | Free text |  |
| 0363 | *IF 0107 = Individuals admitted for inpatient or residential psychiatric treatment*Please describe additional safeguards which will be implemented to protect inpatient psychiatric subjects from potential coercion or undue influence. | Free text |  |
| **Pregnant Women and Fetuses** |
| *IF 0107 = Pregnant women and/or fetuses*  |
| 0364 | **Who may receive direct benefit from the research? Select the appropriate option.** | * Direct benefit to pregnant woman
* Direct benefit to fetus
* Direct benefit to pregnant woman & fetus
* No direct benefit to pregnant woman or fetus
 |  |
| 0365 | ***IF 0364 = Direct benefit to pregnant woman*****Explain how the risk to the fetus is caused solely by the interventions or procedures that hold out the prospect of direct benefit to the pregnant woman.** | Free text |  |
| 0366 | ***IF 0364 = Direct benefit to fetus*****Explain how the risk to the fetus is caused solely by the interventions or procedures that hold out the prospect of direct benefit to the fetus.** | Free text |  |
| 0367 | ***IF 0364 = Direct benefit to fetus*****Select to confirm** | * Consent from the pregnant woman and father of the fetus will be obtained (except consent of the father need not be obtained if the pregnancy resulted from rape or incest).
 |  |
| 0368 | ***IF 0364 = Direct benefit to pregnant woman & fetus***Explain how the risk to the fetus is caused solely by the interventions or procedures that hold out the prospect of direct benefit to the pregnant woman and fetus. | Free text |  |
| 0369 | ***IF 0364 = No direct benefit to pregnant woman or fetus*****Explain how the risk to the fetus is minimal.** | Free text |  |
| 0370 | ***IF 0364 = No direct benefit to pregnant woman or fetus*****Explain how the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means.** | Free text |  |
| 0371 | **Describe any relevant pre-clinical and clinical studies which may help assess potential risks to pregnant women and fetuses.** | Free text |  |
| 0372 | **The PI confirms all of the following:*** **No inducements, monetary or otherwise, will be offered to terminate a pregnancy**
* **Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy**
* **Individuals engaged in the research will have no part in determining the viability of a neonate.**
 | * Yes
* No
 |  |
| 0373 | ***IF 0372 = No*****Explain why No was selected above.** | Free text |  |
| 0374 | ***IF 0117 = Roudebush VA Medical Center*****The Facility Director has certified that the VA medical facility has sufficient expertise in women’s or reproductive health to conduct the proposed research.** | * Yes, and documentation of certification is attached.
* N/A – the research is not interventional and does not involve invasive monitoring.
 |  |
| **Neonates** |
| *IF 0107 = Nonviable neonates or neonates of uncertain viability*  |
| 0391 | Will the research be conducted on: Select all options that apply. | * Neonates of uncertain viability
* Nonviable neonates
 |  |
| 0392 | *IF 0391 = Neonates of uncertain viability***For neonates of uncertain viability, which of the following is applicable? Choose one.** | * The research holds out the prospect of enhancing the probability of survival of the neonate to the point of viability, and any risk is the least possible for achieving that objective
* The purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means and there will be no added risk to the neonate resulting from the research
* Neither of the above
 |  |
| 0393 | *IF 0392 = Neither of the above*Explain why Neither of the above was selected. | Free text |  |
| 0394 | *IF 0391 = Neonates of uncertain viability*The PI confirms all of the following regarding neonates of uncertain viability:* Individuals engaged in the research will have no part in determining the viability of a neonate and
* The legally effective informed consent of either parent of the neonate will be obtained, except consent of the father need not be obtained if the pregnancy resulted from rape or incest.
 | * Yes
* No
 |  |
| 0395 | *IF 0394 = No*Explain why No was selected. | Free text |  |
| 0396 | *IF 0391 = Nonviable neonates*The PI confirms all of the following regarding nonviable neonates:* Vital functions of the neonate will not be artificially maintained
* The research will not terminate the heartbeat or respiration of the neonate
* There will be no added risk to the neonate resulting from the research
* Individuals engaged in the research will have no part in determining the viability of a neonate.
* The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means; and
* The legally effective informed consent of both parents of the neonate will be obtained unless either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, or the consent of the father need not be obtained if the pregnancy resulted from rape or incest.
 | * Yes
* No
 |  |
| 0397 | *IF 0396 = No*Explain why No was selected. | Free text |  |
| 0398 | Describe any relevant pre-clinical and clinical studies which may help assess potential risks to neonates. | Free text |  |
| 0399 | *IF 0117 = Roudebush VA Medical Center*VA investigators must not conduct research interventions that include neonates. Select all options that apply. | * Study interventions are not being performed by VA investigators
* Study procedures are limited to observation, retrospective review, and/or noninvasive monitoring.
 |  |
| **Children** |
| *IF 0107 = Children AND 0108 = Yes* |
| 0376 | Select all that apply. | * This study includes a group of children that will take part in only minimal risk procedures. (404)
* This study includes a group of children that will take part in greater than minimal risk procedures that may directly benefit the child. (405)
* The study includes a group of children who will participate in procedures which are greater than minimal risk and will not directly benefit the child, but which are likely to yield generalizable knowledge about the child’s disorder or condition. (406)
* The study includes a group of children that do not fit within any of the above choices, but the research presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children. If the research is federally funded, a determination from the Secretary of Health and Human Services will be obtained. (407)
 | Some research involves multiple groups of subjects or varying research procedures based on protocol assignment and multiple selections should be made below (e.g., randomized procedures, study includes a control and intervention group, placebo arm). |
| 0377 | *IF 0376 = (405)*Explain why each procedure is at least as favorable as available alternative approaches.  | Free text | Address only procedures that present greater than minimal risk but may directly benefit the child. |
| 0378 | *IF 0376 = (406)*Explain why each procedure presents only a minor increase over minimal risk.  | Free text | Address only procedures that will not directly benefit the child. |
| 0379 | *IF 0376 = (406)*Explain why each procedure presents experiences that are reasonably equivalent to the child’s actual or expected medical, dental, psychological, social, or educational situations.  | Free text | Address only procedures that will not directly benefit the child. |
| 0380 | *IF 0376 = (406)*Explain why each procedure is likely to yield generalizable knowledge about the disorder or condition which is of vital importance for the understanding or improvement of the disorder or condition.  | Free text | Address only procedures that will not directly benefit the child. |
| 0381 | *IF 0376 = (406) OR (407)*Will you enroll children who are wards of the state or foster children? | * Yes
* No
 |  |
| 0382 | *IF 0381 = Yes*The research is | * Related to the child’s status as a ward/foster child
* Conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards/foster children.
 |  |
| 0383 | *IF 0381 = Yes*Explain how you will identify the appropriate person to provide consent and who will serve as an advocate for each child to act in the best interests of the child throughout the research process. | Free text | For more information, visit the IU HRPP Guidance on [Conducting Research with Children](https://research.iu.edu/compliance/human-subjects/guidance/subject-types/children.html). |
| **Exception From Informed Consent** |
| IF 0104 = Planned emergency research |
| 0400 | Explain all of the following:* The human subjects are in a life-threatening situation that necessitates urgent intervention
* Available treatments are unproven or unsatisfactory
* Collection of valid scientific evidence is necessary to determine the safety and effectiveness of the intervention.
 | Free text |  |
| 0401 | Choose which of the following applies: | * Some subjects (or their LAR) may be able to provide informed consent prior to the study intervention(s).
* No subjects (nor their LAR) can provide informed consent prior to the study intervention(s).
 |  |
| 0402 | Explain why subjects will not be able to give their informed consent as a result of their medical condition. | Free text |  |
| 0403 | Explain why the intervention under investigation must be administered before consent from the subject’s LAR is feasible.  | Free text | Consider the length of the potential therapeutic window that has been defined based on scientific evidence and the commitment to attempt to contact and obtain consent from an LAR for each subject within that window of time. |
| 0404 | Explain why there is no reasonable way to identify prospectively the individuals likely to become eligible for participation in the research. | Free text |  |
| 0405 | Explain how the research could not practicably be carried out without the waiver. | Free text |  |
| 0406 | Explain how participation in the research holds out the prospect of direct benefit to the subjects. | Free text |  |
| 0407 | Describe your plan for community consultation. | Free text |  |
| 0408 | Describe your plan for public disclosure, before, during, and after completion of the research. | Free text |  |
| 0409 | Describe your plan to inform each subject and/or their LAR at the earliest feasible opportunity of the following:* That the subject was enrolled in the research
* The details of the research
* Other information contained in the informed consent document
* The subject or LAR may discontinue the subject’s participation at any time without penalty or loss of benefits to which the subject is otherwise entitled
* If an LAR is told about the research and the subject’s condition improves, the subject is also to be informed as soon as feasible
* If the subject dies before an LAR can be contacted, information about the research is to be provided to the subject’s LAR, if feasible.
 | Free text |  |
| **Consent/Assent/Authorization** |
| *0401 ≠ No subjects can provide informed consent AND 0104 ≠ Demonstration project AND 0104 ≠ Planned emergency use* |
| 0410 | *IF 0107 ≠ Children AND 0107 ≠ Adults lacking consent capacity*Will all or some subjects consent to participate in the research? | * All subjects will consent to participate in the research.
* Some subjects will consent to participate in the research, and some subjects will not. A waiver has been requested.
* No subjects will consent to participate in the research. A waiver has been requested.
 |  |
| 0411 | IF 0107 = Adults lacking consent capacity AND 0107 *≠ Children*Will all or some subjects consent to participate in the research? | * All subjects (or their legally authorized representative) will consent to participate in the research.
* Some subjects (or their legally authorized representative) will consent to participate in the research, and some subjects will not. A waiver has been requested.
* No subjects will consent to participate in the research. A waiver has been requested.
 |  |
| 0412 | *IF 0126 = No*Who will provide consent (permission) for their child’s participation in the research? | * All parents/guardians will provide consent to participate in the research.
* Some parents/guardians will provide consent to participate in the research, and some will not. A waiver has been requested.
* No parents/guardians will provide consent to participate in the research. A waiver has been requested.
 |  |
| 0413 | *IF 0126 = Yes*Who will provide consent to participate in the research? | * All adult subjects/parents will provide consent to participate in the research.
* Some adult subjects/parents will provide consent to participate in the research, and some will not. A waiver will be requested.
* No adult subjects/parents will provide consent to participate in the research. A waiver will be requested.
 |  |
| 0414 | *IF 0410 = Some subjects will consent to participate OR 0411 = Some subjects will consent to participate OR 0412 = Some parents/guardians will provide consent OR 0413 = Some adult subjects/parents will provide consent*Explain which subjects will consent and which subjects will not. | Free text |  |
| 0443 | *0410 = All subjects will consent to participate or Some subjects will consent to participate OR 0411 = All subjects will consent to participate or Some subjects will consent to participate OR 0412 = All parents/guardians will provide consent or Some parents/guardians will provide consent OR 0413 = All adult subjects/parents will provide consent or Some adult subjects/parents will provide consent* Does your study require any research procedures to occur prior to discussing study participation with subjects? | * Yes (This is rare)
* No
 |  |
| 0444 | *IF 0443 = Yes*Explain what procedures will be conducted prior to informed consent. | Free text |  |
| 0445 | *IF 0443 = Yes*Explain how the research could not practicably be carried out if informed consent was required prior to these procedures. | Free text |  |
| 0446 | *IF 0443 = Yes*Explain why the research could not practicably be carried out without collecting identifiable information or biospecimens prior to obtaining consent. | Free text |  |
| 0447 | *IF 0443 = Yes*Explain how the waiver of consent will not adversely affect their rights and welfare. | Free text |  |
| 0448 | *IF 0443 = Yes*State whether subjects will be provided with additional information after participation in the study. | Free text |  |
| 0415 | *IF 0401 = Some subjects may be able to provide informed consent OR 0410 = All subjects will consent to participate or Some subjects will consent to participate OR 0411 = All subjects will consent to participate or Some subjects will consent to participate OR 0412 = All parents/guardians will provide consent or Some parents/guardians will provide consent OR 0413 = All adult subjects/parents will provide consent or Some adult subjects/parents will provide consent*Describe your typical consent process for this study. | Free text | This may include how and when subjects will be approached for consent, who will consent subjects, any waiting period between informing the potential subject of the study and conducting the consent process, and what information and materials will be provided to the subject. Note, subject facing consent materials require IRB approval. |
| 0417 | *IF 0376 = (406) OR (407)*This research includes procedures which are greater than minimal risk but present no direct benefit. Parental consent (permission) is required from both parents unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child. Select to confirm. | * When only one parent signature is obtained, I confirm I will document the reason why the second parent did not sign.
 | For more information, visit the IU HRPP Policy on [Children in Research](https://research.iu.edu/policies/human-subjects-irb/children-in-research.html). |
| 0418 | *IF 0401 = Some subjects may be able to provide informed consent OR 0410 = All subjects will consent to participate or Some subjects will consent to participate OR 0411 = All subjects will consent to participate or Some subjects will consent to participate OR 0412 = All parents/guardians will provide consent or Some parents/guardians will provide consent OR 0413 = All adult subjects/parents will provide consent or Some adult subjects/parents will provide consent*Will the study include deception, incomplete disclosure, or withholding information from subjects? | * Yes
* No
 | For more information, see the HSO guidance on [Deception or Incomplete Disclosure in Research](https://research.iu.edu/compliance/human-subjects/guidance/deception.html) |
| 0471 | *IF 0418 = Yes*Describe what information will be omitted. | Free text |  |
| 0419 | *IF 0418 = Yes*Explain how the omission of information will not adversely affect the rights and welfare of the subjects. | Free text |  |
| 0420 | *IF 0418 = Yes*Explain how the research could not practicably be carried out without deception, incomplete disclosure, or withholding information. | Free text |  |
| 0421 | *IF 0418 = Yes*Explain how the research could not practicably be carried out without using identifiable information. | Free text |  |
| 0422 | *IF 0418 = Yes*Will subjects be debriefed or provided additional information after participation in the study? | * Yes
* No
 |  |
| 0423 | *IF 0422 = Yes*Describe how subjects will be debriefed or provided additional information after participation in the study. | Free text |  |
| 0424 | *IF 0422 = No*Justify why subjects will not be debriefed or provided additional information after participation in the study. | Free text |  |
| 0425 | *IF 0401 = Some subjects may be able to provide informed consent OR 0410 = All subjects will consent to participate or Some subjects will consent to participate OR 0411 = All subjects will consent to participate or Some subjects will consent to participate OR 0412 = All parents/guardians will provide consent or Some parents/guardians will provide consent OR 0413 = All adult subjects/parents will provide consent or Some adult subjects/parents will provide consent*Will any member of the research team be in a position of authority (e.g. instructor and his/her students, manager and his/her employees) over the subjects to be consented? | * Yes
* No
 |  |
| 0426 | *IF 0425 = Yes*Explain how the research team will conduct the consent process so that potential subjects do not feel undue influence to join the study or continue participation. | Free text |  |
| 0427 | *IF 0401 = Some subjects may be able to provide informed consent OR 0410 = All subjects will consent to participate or Some subjects will consent to participate OR 0411 = All subjects will consent to participate or Some subjects will consent to participate OR 0412 = All parents/guardians will provide consent or Some parents/guardians will provide consent OR 0413 = All adult subjects/parents will provide consent or Some adult subjects/parents will provide consent*Do you plan to consent subjects who do not speak English? | * Yes
* No
 |  |
| 0428 | *IF 0427 = Yes*List the language(s) that will be used in addition to English. | Free text |  |
| 0429 | *IF 0427 = Yes*Select to affirm | * The PI affirms that all translated documents are accurate, contain all information presented in the English versions, and do not contain information not presented in the English versions.
 |  |
| 0416 | Describe how you will protect against, or minimize, each of the risks listed in the consent document(s). | Free text |  |
|  | *0133 ≠ Medical records AND 0135 = No AND 0139 ≠ Yes* |
| 0430 | *IF 0410 = All subjects will consent or Some subjects will consent OR 0411 = All subjects will consent or Some subjects will consent*For those subjects who will consent to participate, choose whether the consent process will be documented by a signature from subjects. | * All consented subjects will provide a signature as documentation of consent.
* Some consented subjects will provide a signature as documentation of consent, and some consented subjects will not.
* No subjects will provide a signature as documentation of consent.
 |  |
| 0431 | *IF 0412 = All parents/guardians will provide consent or Some parents/guardians will provide consent*For those parents (or guardians) who will consent to allow their child to participate, choose whether the consent process will be documented by a signature from the parents. | * All consented parents will provide a signature as documentation of consent.
* Some parents will provide a signature as documentation of consent, and some parents will not.
* No parents will provide a signature as documentation of consent.
 |  |
| 0432 | *IF 0413 = All adult subjects/parents will provide consent or Some adult subjects/parents will provide consent*For those subjects who will consent to participate, choose whether the consent process will be documented by a signature from the subjects. | * All consented adult subjects/parents will provide a signature as documentation of consent.
* Some adult subjects/parents will provide a signature as documentation of consent, and some will not.
* No adult subjects/parents will provide a signature as documentation of consent.
 |  |
|  | *IF 0133 = Medical records OR 0135 = Yes OR 0139 = Yes* |
| 0433 | *IF 0410 – All subjects will consent or Some subjects will consent OR 0411 = All subjects will consent or Some subjects will consent*For those subjects who will consent to participate, choose whether the consent and authorization process will be documented by a signature from subjects. | * All consented subjects will provide a signature as documentation of consent and, if applicable, authorization.
* Some subjects will provide a signature as documentation of consent and, if applicable, authorization, and some subjects will not.
* No subjects will provide a signature as documentation of consent and authorization.
 |  |
| 0434 | *IF 0412 = All parents/guardians will provide consent or Some parents/guardians will provide consent*For those parents (or guardians) who will consent to allow their child to participate, choose whether the consent and authorization process will be documented by a signature from the parents. | * All consented parents will provide a signature as documentation of consent and, if applicable, authorization.
* Some parents will provide a signature as documentation of consent and, if applicable, authorization, and some parents will not.
* No parents will provide a signature as documentation of consent and authorization.
 |  |
| 0435 | *IF 0413 = All adult subjects/parents will provide consent or Some adult subjects/parents will provide consent*For those subjects who will consent to participate, choose whether the consent and authorization process will be documented by a signature from the subjects. | * All consented adult subjects/parents will provide a signature as documentation of consent and, if applicable, authorization.
* Some adult subjects/parents will provide a signature as documentation of consent and, if applicable, authorization, and some will not.
* No adult subjects/parents will provide a signature as documentation of consent and authorization.
 |  |
| 0436 | *IF 0430 = All consented subjects will provide a signature or Some consented subjects will provide a signature OR 0431 = All consented parents will provide a signature or Some consented parents will provide a signature OR 0432 = All consented adult subjects/parents will provide a signature or Some consented adult subjects/parents will provide a signature OR 0433 = All consented subjects will provide a signature OR Some consented subjects will provide a signature OR 0434 = All consented parents will provide a signature or Some consented parents will provide a signature OR 0435 = All consented adult subjects/parents will provide a signature or Some adult subjects/parents will provide a signature*Will subjects participate in any study activity prior to signing a consent document? | * Yes
* No
 | For example, some studies require subjects to fast, to refrain from drinking or smoking, or to keep a food or exercise journal prior to their first study visit. |
| 0437 | *IF 0436 = Yes*List the activities in which subjects will participate prior to signing the consent document.*Each activity must present no more than minimal risk of harm to subjects AND involve only activities which do not* require *written consent outside of a research study. Please note that subjects must provide verbal consent to these activities*. | Free text |  |
| 0438 | *IF 0430 = some consented subjects will provide a signature OR 0431 = Some parents will provide a signature OR 0432 = Some adult subjects/parents will provide a signature*Explain *which* subjects will provide a signature as documentation of consent and which subjects will not. | Free text |  |
| 0439 | *IF 0433 = Some subjects will provide a signature OR 0434 = Some subjects will provide a signature OR 0435 = Some adult subjects/parents will provide a signature*Explain which subjects will provide a signature as *documentation* of consent and, if applicable, authorization, and which subjects will not. | Free text |  |
| 0440 | *IF 0430 = No subjects will provide a signature or Some consented subjects will provide a signature OR 0431 = No parents will provide a signature or Some parents will provide a signature OR 0432 = No adult subjects/parents will provide a signature or Some consented adult subjects/parents will provide a signature OR 0433 = No subjects will provide a signature OR Some consented subjects will provide a signature OR 0434 = No parents will provide a signature or Some parents will provide a signature OR 0435 = No adult subjects/parents will provide a signature or Some adult subjects/parents will provide a signature*For subjects who will not sign consent, is the research minimal *risk* and involves only procedures which do not require written consent outside of a research study? | * Yes
* No
 |  |
| 0441 | *IF 0440 = No*Since no was selected above, choose the applicable option. | * The only record linking the subject and the research would be the consent document and the principal risk of the study is potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research and the subject’s wishes will govern.
* The subjects or legally authorized representatives are members of a distinct cultural group or community, in which signing forms is not the norm for this group, the research presents no more than minimal risk of harm to subjects, and there is an appropriate alternative mechanism for documenting that informed consent was obtained.
 |  |
| 0451 | *IF 0410 = Some subjects will consent to participate or No subjects will consent to participate OR 0411 = Some subjects will consent to participate or No subjects will consent to participate OR 0412 = Some parents/guardians will provide consent or No parents/guardians will provide consent to participate OR 0413 = Some adult subjects/parents will provide consent or No adult subjects/parents will provide consent to participate OR 0401 = No subjects can provide informed consent* For subjects not consenting, are there any anticipated risks beyond risk of loss of confidentiality? | * Yes
* No
 |  |
| 0452 | *IF 0451 = Yes*Describe those risks. | Free text |  |
| 0453 | *IF 0451 = Yes*Describe how you will protect against, or minimize, each of those risks. | Free text |  |
| 0449 | *IF 0412 = Some parents/guardians will provide consent or No parents/guardians will provide consent*For those parents (or guardians) who will not consent to allow their child to participate, choose from the following options. | * Parental permission cannot be practicably obtained.
* Parental permission is not a reasonable requirement to protect participants, due to their status (such as neglected or abused children). (This is rare.)
 |  |
| 0450 | *IF 0413 = Some adult subjects/parents will provide consent or No adult subjects/parents will provide consent*For adult subjects/parents who will not consent, choose from the following options. | * Consent from adult subjects cannot be practicably obtained.
* Parental permission cannot be practicably obtained.
* Parental permission is not a reasonable requirement to protect participants, due to their status (such as neglected or abused children). (This is rare)
 |  |
| 0473 | *IF 0449 = Parental permission cannot be practicably obtained OR 0450 = Consent from adult subjects cannot be practicably obtained or Parental permission cannot be practicably obtained*Explain how the research could not practicably be carried out without the waiver of informed consent. | Free text |  |
| 0454 | *IF 0410 = No subjects will consent to participate or Some subjects will consent to participate OR 0411 = No subjects will consent to participate or Some subjects will consent to participate*For those subjects who will not consent to participate, explain how the research could not practicably be carried out without the waiver. | Free text |  |
| 0455 | *IF 0449 = Parental permission cannot be practicably obtained OR 0450 = Consent from subjects cannot be practicably obtained or Parental permission cannot be practicably obtained OR 0410 = No or some OR 0411 = No or some*Explain how the research could not practicably be carried out without using identifiable information or biospecimens. | Free text |  |
| 0456 | *IF 0449 = Parental permission cannot be practicably obtained OR 0450 = Consent from subjects cannot be practicably obtained or Parental permission cannot be practicably obtained OR 0410 = No or some OR 0411 = No or some*Explain how the waiver will not adversely affect the rights and welfare of the subjects. | Free text |  |
| 0457 | *IF 0449 = Parental permission cannot be practicably obtained OR 0450 = Consent from subjects cannot be practicably obtained or Parental permission cannot be practicably obtained OR 0410 = No or some OR 0411 = No or some*State whether subjects will be provided with additional information after participation in the study. | Free text |  |
| 0458 | *IF 0449 = Parental permission is not a reasonable requirement OR 0450 = Parental permission is not a reasonable requirement*Explain why parental/guardian permission is not a reasonable requirement to protect the children as subjects. | Free text |  |
| 0459 | *IF 0449 = Parental permission is not a reasonable requirement OR 0450 = Parental permission is not a reasonable requirement*Describe how you will implement an appropriate mechanism for protecting the children as subjects since parental/guardian permission will not be obtained. | Free text | An appropriate mechanism includes consideration of the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research participants, and their age, maturity, status, and condition. |
| *IF 0133 = Medical records OR 0135 = Yes* |
| 0442 | *IF 0433 = Some subjects will provide signature or No subjects will provide a signature OR 0434 = Some or No OR 0435 = Some or No*For subjects who will not sign authorization, choose from the following options. | * A signature is not practicable; a waiver is being requested.
* There are multiple subject groups (e.g. patients and health care providers) and the participation of one or more groups is not subject to HIPAA.
 |  |
| 1080 - 1086 | *IF 0442 = A signature is not practicable OR 0410 = No subjects will consent to participate OR 0411 = No subjects OR 0412 = No parents/guardians OR 0413 = No adult subjects/parents* HIPAA Waiver (see questions below) | Free text/checkbox |  |
| 0461 | *IF 0410 = Some subjects will consent to participate OR 0411 = Some subjects will consent to participate OR 0412 = Some parents/guardians will provide consent OR 0413 = Some adult subjects/parents will provide consent OR 0401 = No subjects can provide informed consent*For those subjects who will not provide authorization, select yes to confirm you are requesting a waiver of authorization. | * Yes
* No. This population is not subject to HIPAA. (This is rare.)
 |  |
| 0460 | *IF 0104 = Demonstration project*Explain how the demonstration project could not practicably be carried out without the waiver. | Free text |  |
| 1090 - 1096 | *IF 0461 = Yes OR 0104 = Demonstration project* HIPAA Waiver (see questions below) | Free text/checkbox |  |
| IF 0107 = Children AND 0104 ≠ Demonstration project |
| 0462 | Will all or some children provide agreement to participate in the research? | * All children will provide agreement to participate in the research.
* Some children will provide agreement to participate in the research, and some children will not.
* No children will provide agreement to participate in the research.
 | For more information, visit the IU HRPP Policy on [Children in Research](https://research.iu.edu/compliance/human-subjects/guidance/subject-types/children.html). |
| 0463 | *IF 0462 = Some children will provide agreement OR No children will provide agreement* For those children who will not provide agreement to participate in the research, select all that apply. | * Children are not capable due to age, maturity, medical condition, or psychological state.
* Children are capable but a waiver of assent is being requested.
 |  |
| 0464 | *IF 0463 = Children are not capable*Explain why children are not capable of providing agreement considering their age, maturity, psychological state, or situations where capability is so limited that they cannot reasonably be consulted. | Free text |  |
| 0465 | *IF 0463 = Children are capable but a waiver of assent is being requested*For those subjects who will not assent to participate, explain how the research could not practicably be carried out without the waiver. | Free text |  |
| 0466 | *IF 0463 = Children are capable but a waiver of assent is being requested*Explain how the research could not practicably be carried out without using identifiable information or biospecimens. | Free text |  |
| 0467 | *IF 0463 = Children are capable but a waiver of assent is being requested*Explain how the waiver will not adversely affect the rights and welfare of the subjects. | Free text |  |
| 0468 | *IF 0463 = Children are capable but a waiver of assent is being requested*State whether subject will be provided with additional information after participation in the study. | Free text |  |
| 0469 | *IF 0462 = All children will provide agreement OR Some children will provide agreement* For those children who will provide agreement to participate, describe your typical assent process for this study. | Free text | This may include how and when child subjects will be approached, who will obtain subjects’ agreement, any waiting period between informing the potential subject of the study and conducting the assent process, and what information and materials will be provided to the subject. Note, subject facing assent/consent materials require IRB approval. |
| 0470 | *IF 0462 = All children will provide agreement OR Some children will provide agreement* Will children indicate their agreement with a signature on an assent or consent document? Select all that apply. | * Assent document
* Consent document with an additional signature line for the child subject
* Children will verbally agree to participate, but will not provide a signature
 |  |
| **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 |  |

|  |
| --- |
| **HIPAA Waiver Questions** |
| 105010801090 | Provide a brief description of the protected health information (PHI), including identifiers, to be used or accessed. | Free text |  |
| 105110811091 | Explain how this research involves no more than minimal risk of loss of confidentiality to the subject. | Free text |  |
| 105210821092 | Describe the plan for protecting identifiers from improper use and disclosure. | Free text |  |
| 105310831093 | 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 |  |
| 105410841094 | 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.
 |  |
| 105510851095 | Explain how the research could not practicably be conducted without the waiver or alteration. | Free text |  |
| 105610861096 | Explain how the research could not practicably be conducted without access to and use of the PHI. | Free text |  |