

# Kuali Protocols NEW Form Guide – Exempt Published 07.01.2023 (version 13)

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

| **Question ID** | **Question** | **Options** | **Guidance** |
| --- | --- | --- | --- |
| **General Information** | | | |
| N/A | Principal Investigator | User list | Start typing the value and options will appear. Select desired option. |
| N/A | Lead Unit | Unit list | This is the IU unit under which the research will be conducted. Typically, this is the PI’s division or department. For non-IU PIs, enter “External Organization.” Start typing the value and options will appear. Select desired option. |
| N/A | Study Title |  | Enter Study Title |
| **Protocol Type** | | | |
| 0100 | Select your protocol type. | * **Exempt** * Expedited/Full Board * Request to rely on a non-IU IRB * Not Human Subjects Research * Humanitarian Use Device (HUD) * Emergency Use (This is rare. Contact the HRPP at [irb@iu.edu](mailto:irb@iu.edu) before selecting.) | If you are unsure of your protocol type, visit the [protocol decision tree](https://research.iu.edu/compliance/human-subjects/review-levels/protocol-decision-tree/index.html) for more information. |
| **Research Personnel** | | | |
| **Personnel List**  *Select* ***+Add Line*** *to list each person* | | List | **This Personnel list is for Research Personnel Only.** For individuals who need access to the protocol but are not research personnel, add them to the Permissions tab.  For NEW studies and amendments changing the PI, you must click on the pencil icon to complete all required information in the person record. |
| N/A | Person | User list |  |
| N/A | Email Address | Auto-filled based on person selected |  |
| N/A | Researcher Role | * Principal Investigator (PI) * Co-PI * Key Personnel * Site-specific PI * Other Research Staff |  |
| N/A | *IF Researcher Role = Principal Investigator (PI)*  Home Unit | Unit list |  |
| 0144 | IU Faculty/Staff or Student? | * Yes * No |  |
| 0164  IU Role | *IF 0144 = Yes AND Researcher Role = PI*  Select IU Role | * Tenure Track or Clinical Faculty * Adjunct, Emeritus or Visiting Faculty * Staff * Student/Resident/Fellow * Other | If multiple roles, select the capacity in which the individual will be conducting this research.  Adjunct faculty, visiting faculty, students, residents, and fellows generally are not eligible to serve as PI for IU research. Before submitting, review the IU PI eligibility information [embed link] and ensure you have identified an eligible individual to serve as PI. |
| 0165 | *IF 0164 = Staff OR Other*  IU Title/Role | Free text |  |
| 0166  Affiliation | Is the researcher affiliated with any of the following? *Select all that apply*. | * IU Health/IU Health Physicians * Eskenazi Hospital/Health & Hospital Corp of Marion County * Roudebush VA Medical Center * Regenstrief Institute * Rehabilitation Hospital of Indiana * Purdue University Pharmacy Practice * None of the Above | Affiliation includes employment, having hospital privileges, and in the case of Purdue Pharmacy Practice, being a student.  If None of the above is selected and 0144 is No, remove this personnel entry, answer “Yes” to 0195 and list this person in the Non-affiliated Personnel List below. |
| N/A | Permission Type | * Full Access * Read-Only |  |
| 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* |  |  |
| 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. |
| 0832 | 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 |  |
| 0800 | The research includes: Select all options that apply. | * Normal educational practices conducted in established or common education settings. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. * Research involving data collection with subject interaction. This includes in person and online surveys, focus groups, interviews, benign behavioral interventions, and public observation when a researcher is participating in the activities being observed * Data collection that does not include interacting with subjects. * Taste and food quality evaluation and consumer acceptance studies. * Research designed to study public benefit or service programs AND supported by a federal department or agency | If Research involving data collection with subject interaction, BUT not normal educational practices AND NOT no interaction, due to the inclusion of children, this research is not eligible for exempt review. Change the protocol type to Expedited/Full Board before proceeding. |
| 0804 | *IF 0800 = Research designed to study public benefit*  Provide a link to the federal website on which the project is listed. | Free text |  |
| 0829 | *IF 0800 = Research involving data collection with subject interaction AND Data collection that does not include interacting with subjects AND 0832 = Children*  Will all subjects researchers are interacting with be age 18 or older, or will you communicate that individuals under age 18 should not participate? | * Yes * No | If No, due to the inclusion of children, this research is not eligible for exempt review. Change the protocol type to Expedited/Full Board before proceeding. |
| 0805 | *IF 0800 = Data collection that does not include interacting with subjects*  For data collection that does not include interacting with subjects, select all options that apply to the research. | * Data subject to HIPAA (including chart reviews) * Observation of public behavior * Data not protected by HIPAA * Secondary use of biospecimens |  |
| 0807 | *IF 0805 = Data not protected by HIPAA OR Secondary use of biospecimens*  Will information be recorded in a de-identified manner (this includes no direct identifiers or identifiers linked to the subject), and researchers will not attempt to re-identify subjects? | * Yes * No * No, but the identifiable information is publicly available. | This may include audio recordings, video recordings, direct subject identifiers linked to research data. Direct identifiers may include name, email address, contact information, and IP address.  IF NO – The research may not be eligible for exempt review. Either revise the question above or change the protocol type to Expedited/Full board before proceeding. |
| 0806 | *IF 0805 = Data not protected by HIPAA OR Secondary use of biospecimens*  Confirm a data collection form is uploaded in the Protocol Attachments section below. | * Yes * No |  |
| 0808 | *IF 0806 = No*  Justify why a data collection form cannot be submitted. | Free text |  |
| 0809 | *IF 0805 = Secondary use of biospecimens*  What sources will be used to identify data, records, or specimens? | * Medical records or information provided by a health care provider * Student records * Other |  |
| 0828 | *IF 0805 = Data not protected by HIPAA AND ≠ Secondary use of biospecimens*  What sources will be used to identify data, records, or specimens? | * Student records * Other |  |
| 0830 | *IF 0828 = Other OR 0809 = Other*  Name the Other sources. | Free text |  |
| 0810 | *IF 0805 = Observation of public behavior*  Describe the setting in which you will be observing subjects and how you are collecting data. | Free text |  |
| 0811 | *IF 0800 = Normal educational practices AND Research involving data collection with subject interaction AND 0832 = Children*  Will all subjects researchers are interacting with be age 18 or older, or will you communicate that individuals under age 18 should not participate? | * Yes * No, but my research is being conducted only on normal educational practices in common education settings * No | If No, the research is not eligible for exempt review. Change the protocol type to Expedited/Full Board before proceeding. |
| 0823 | *IF 0800 = Taste and food quality evaluation*  Does the food that will be consumed contain any additives? | * Yes * No |  |
| 0824 | *IF 0823 = Yes*  Are the level of the additives (i.e. food ingredients, chemical additives, or environmental contaminants) at or below the levels approved by the FDA, EPA, or USDA? | * Yes and supporting documentation is attached. * No | If No, the research is not eligible for exempt review. Change the protocol type to Expedited/Full Board before proceeding. |
| 0130 | *IF 0805 = Data subject to HIPAA OR 0809 = Medical records*  Are you obtaining data, records, and/or specimens from any of the following sources? | * IU Health * Eskenazi Health * Roudebush VA Medical Center * Regenstrief Institute/INPC (Indiana Network for Patient Care) * Other | If you select Eskenazi Health, click on the Permissions tab at the top of the page and add Patricia Noblet (pcnoblet) and Jeanne Lewis (jml14) with a "Read Only" Permission Type.  If you select Roudebush VA Medical Center, click on the Permissions tab at the top of the page and add Marta Sears (msears), Angela Harris (anharris), and Bridget Fultz (bafultz) with "Read Only" Permission Types. |
| 0131 | *IF 0130 = Other*  Name the Other sources. | Free text |  |
| 1010 – 1016 | *IF 0800 = Research involving data collection with subject interaction AND Data collection that does not include interacting with subjects; AND 0805 = Data subject to HIPAA OR 0809 = Medical records*  HIPAA Waiver (see questions below) | Free text/checkbox |  |
| **Research Design** | | | |
| 0150 | Provide a brief statement (no more than 2-3 sentences) of the purpose of this study, in lay terms. | Free text |  |
| 0812 | *IF 0800 = Normal education practices OR Research involving data collection with subject interaction OR Taste and food*  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. |
| 0802 | *IF 0800 = Normal educational practices OR 0828 = Student records*  Explain how these research procedures will be carried out in a way that is not likely to adversely impact students’ ability to learn or the assessment of the educators who provide instruction. | Free text |  |
| 0813 | *IF 0800 = Research involving data collection with subject interaction OR Taste and food OR 0805 = Observation of public behavior*  Will identifiable information be collected? | * Yes * No | This may include audio recordings, video recordings, or direct subject identifiers linked to research data. Direct identifiers include name, email address, contact information, and IP address. |
| 0814 | *IF 0813 = Yes*  If disclosed outside of the research, could subjects’ data place them at risk of any of the following:   * criminal or civil liability * damage to their financial standing, * damage to their employability * damage to their educational advancement * damage to their reputation | * Yes * No |  |
| 0815 | *IF 0814 = Yes AND 0800 = Data collection that does not include interacting with subjects*  Describe the setting where research procedures will occur and how that protects subjects’ privacy. | Free text |  |
| 0825 | *IF 0813 = Yes AND 0805 = Observation of public behavior*  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 |  |
| **Research Settings** | | | |
| *IF 0800 ≠ Data collection that does not include interacting with subjects AND 0800 = Research designed to study public benefit* | | | |
| 0116 | *IF 0800 = Normal educational practices OR Research involving data collection with subject interaction OR Taste and food*  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 a "Read Only" Permission Type.  If you select Roudebush VA Medical Center, click on the Permissions tab at the top of the page and add Marta Sears (msears), Angela Harris (anharris), and Bridget Fultz (bafultz) with "Read Only" Permission Types. |
| 0120 | *IF 0117 = Other hospital or healthcare facility*  Name the Other hospitals or healthcare facilities. | Free text |  |
| 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 | *IF 0800 = Research involving data collection with subject interaction OR Taste and food*  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*  Will any data generated as part of the research be entered into a subject’s medical record? | * Yes * No |  |
| 0159 | IF 0135 ≠ Yes, 0139 ≠ Yes, 0813 ≠ No, 0805 ≠ Data subject to HIPAA, 0809 ≠ Medical records, 0807 ≠ No AND 0807 ≠ 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 0813 ≠ No AND IF 0135 = Yes OR 0133 = Medical records OR 0139 = Yes OR 0805 = Data subject to HIPAA*  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](mailto:securemyresearch@iu.edu). |
| 0162 | *IF 0813 = Yes OR 0805 = Data subject to HIPAA*  Describe the procedures that will be used to ensure confidentiality of written/paper records that contain subjects’ identifiable data. | Free text |  |
| 0803 | *IF 0800 = Normal educational practices OR 0828 = Student records*  Which student records are you accessing for the research? | * IU * Another institution * N/A, not accessing student records |  |
| 0351 | *IF 0133 = student records OR 0809 = Student records OR 0828 = Student records*  Are the student records from IU and/or another institution? Select all that apply. | * IU * Another institution |  |
| 0352 | *IF 0803 = IU OR 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 0803 = Another institution OR 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 |  |
| **Transnational Research** | | | |
| *IF 0800 = Normal educational practice, Research involving data collection with subject interaction, Data collection that does not include interacting with subjects, OR Taste and food quality evaluation* | | | |
| 0474 | Does the research involve any of the following transnational components? *Select all that apply*. | * 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 | For more information, see the HRPP guidance on [Transnational Research](https://research.iu.edu/compliance/human-subjects/guidance/transnational.html). |
| 0384 | *IF 0474 = Interacting directly with subjects OR Targeting subjects outside the US OR Receipt of identifiable data*  List each country. | Free text |  |
| 0388 | *IF 0474 = Interacting directly with subjects OR Targeting subjects outside the US OR Receipt of identifiable data*  Provide a brief overview of the laws and regulations regarding human research protections in the non-US location(s). | Free text |  |
| 0389 | *IF 0474 = Interacting directly with subjects OR Targeting subjects outside the US OR Receipt of identifiable data*  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 0474 = Interacting directly with subjects*  Describe the researchers’ experience with and knowledge of the non-US location(s). | Free text |  |
| 0385 | *IF 0826 = Yes*  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. |
| 0387 | *IF 0385 = Yes*  Upload approval here.  *Select +Add Line to list each attachment* | List, file attachment |  |
| **Eligibility and Recruitment** | | | |
| 0816 | *IF 0800 = Normal educational practice OR Research involving data collection with subject interaction OR Taste and food*  List criteria used to determine that a subject is eligible to participate in this study. | Free text | If you will have multiple subject groups, explain the eligibility criteria for each group of subjects. |
| 0304 | *IF 0800 = Research involving data collection with subject interaction OR Taste and food*  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 |  |
| 0818 | *IF 0304 = Cash, gift card, or check, Gifts, Prize drawing, Course credit, Direct payment OR Other*  Describe the payment arrangement, including amount and timing of disbursement. | Free text |  |
| 0307 | *IF 0800 = Research involving data collection with subject interaction OR Taste and food*  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 0800 = Research involving data collection with subject interaction OR Taste and food*  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 |  |
| 0311 | *IF 0308 = Medical records*HIPAA applies to your study. IU HRPP Policyrequires 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 – 1066 | *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 |  |
| 0831 | *IF 0133 = Medical records OR 0135 = Yes OR 0139 = Yes*  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 |  |
| 0817 | *IF 0831 = Yes OR 0139 = Yes*  HIPAA applies to your study and requires that you obtain authorization or a waiver for participation. | * I will obtain written, signed authorization from subjects prior to their participation. * I will obtain authorization from subjects prior to their participation, but a signature is not practicable, and a waiver is being requested. * I will not obtain authorization for participation, and a waiver is being requested. |  |
| 1070 - 1076 | *IF 0817 = I will obtain authorization from subjects prior to their participation, but a signature is not practicable OR I will not obtain authorization*  HIPAA Waiver (see questions below) | Free text/checkbox |  |
| 0819 | *IF 0800 = Research involving data collection with subject interaction OR Taste and food*  Describe how you will obtain permission from subjects to participate, which includes the following information:   * They are being asked to participate in research, * What they will be asked to do, * Their participation is voluntary, * The risks and benefits of participation, and * Who to contact with any questions about the research. | * This information will be included at the beginning of written materials, such as a survey, that will be completed by subjects. * A separate study information sheet will be given to each potential subject to review. The study information sheet is attached. * Other |  |
| 0820 | *IF 0819 = Other*  Describe further how you will provide subjects with the information listed in 0819 above and obtain permission from subjects to participate. | Free text |  |
| 0821 | *IF 0800 = Research involving data collection with subject interaction OR Taste and food*  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? | * Yes * No |  |
| 0822 | *IF 0821 = Yes*  Explain how the research team will ensure that potential subjects do not feel undue influence to join the study or continue participation. | Free text |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **HIPAA Waiver Questions** | | | |
| 1010  1050  1070 | Provide a brief description of the protected health information (PHI), including identifiers, to be used or accessed. | Free text |  |
| 1011  1051  1071 | Explain how this research involves no more than minimal risk of loss of confidentiality to the subject. | Free text |  |
| 1012  1052  1072 | Describe the plan for protecting identifiers from improper use and disclosure. | Free text |  |
| 1013  1053  1073 | 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 |  |
| 1014  1054  1074 | 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. |  |
| 1015  1055  1075 | Explain how the research could not practicably be conducted without the waiver or alteration. | Free text |  |
| 1016  1056  1076 | Explain how the research could not practicably be conducted without access to and use of the PHI. | Free text |  |