A USER'S GUIDE TO THE RASCAL IRB MODULE
Version 1.1: January, 2025

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***Please note: This User's Guide includes multiple hyperlinks that will direct you to referenced policies and other resources with additional information. These are only accessible through the electronic version of this document.**

INTRODUCTION

Any researcher at Columbia University (**Columbia** or the **University)** who is planning to engage in human subjects research must first submit a protocol and related materials, including an informed consent form, if applicable, to the University's Institutional Review Board (**IRB).** Descriptions of the underlying regulatory requirements, the IRB review processes and the steps involved in obtaining IRB approval, as well as the requirements for informed consent, are described at length in the University's Clinical Research Handbook (CRH). Although the CRH focuses on clinical research, much of the information is applicable to all human subjects research. See Clinical Research Handbook: Preparing for a Study: IRB Approval and Working with Study Subjects: Informed Consent. Such descriptions will not be repeated in this Guide, but will be referred to as applicable throughout the text. Much of the information in the Clinical Research Handbook about IRB procedures is also applicable to human subjects research that is not clinical in nature.

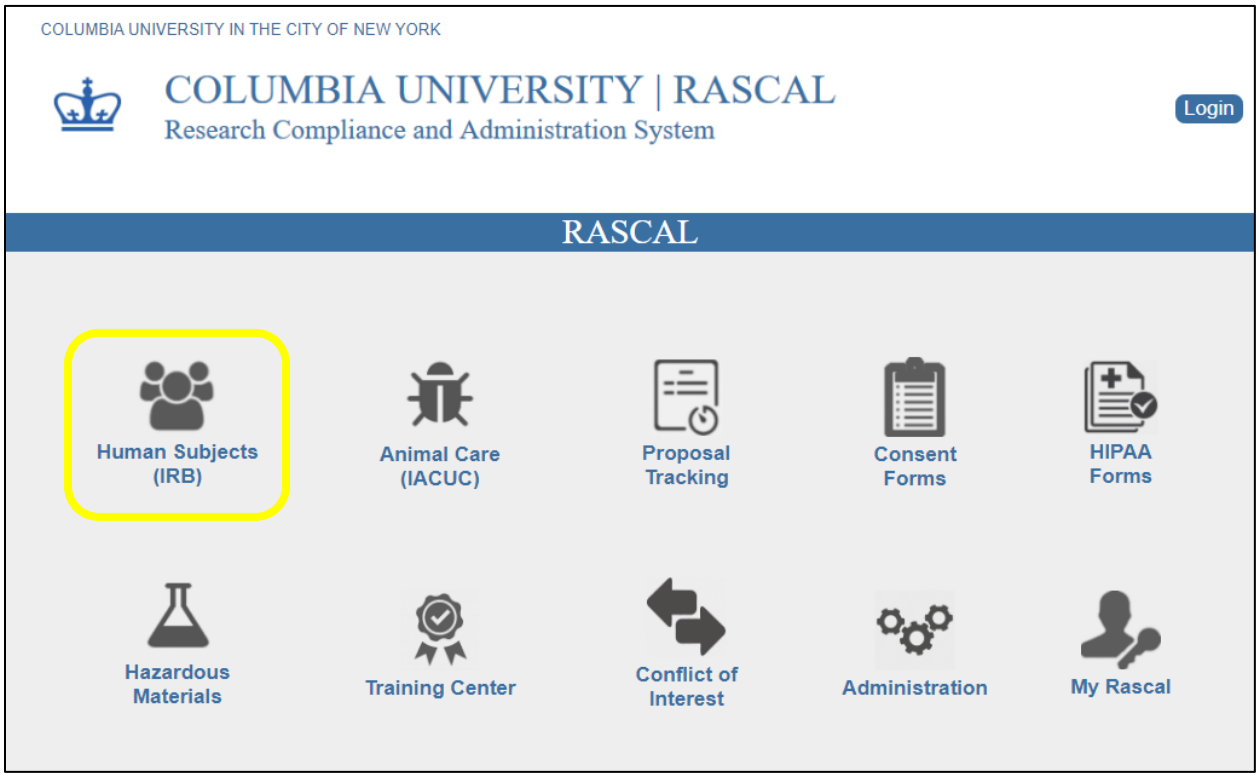
Key to obtaining timely IRB approval is the preparation and submission of a well-written and complete IRB Protocol (**Protocol)** . This Guide has been created to provide Columbia researchers with general guidance and a better understanding of how to create a Protocol in Rascal, the University's research administration and compliance IT system. The intent of the Guide is to help researchers avoid common mistakes that the staff of the Human Research Protection Office (**HRPO**) encounter when reviewing Protocols, particularly from researchers who are not familiar with Rascal and/or new to submitting a research study to the IRB for review and approval. Until one's familiarity with Rascal increases, this Guide will be most helpful if it is used as a step-by-step guide rather than an explanation of particular sections, as returns of Protocol submissions often occur due to inconsistencies or contradictions between sections of the Protocol.

Each section of this Guide includes screen shots of the relevant Rascal pages, followed by explanatory text for the screen shots, to give you detailed directions as to how to fill out the form in Rascal.

If you have questions on this Guide, contact the general IRB mailboxes: irboffice@columbia.edu for the Columbia University Irving Medical Center (**CUIMC**) campus and askirb@columbia.edu for the Morningside (**MS**) and Lamont Dougherty Earth Observatory (**LDEO)** campuses.

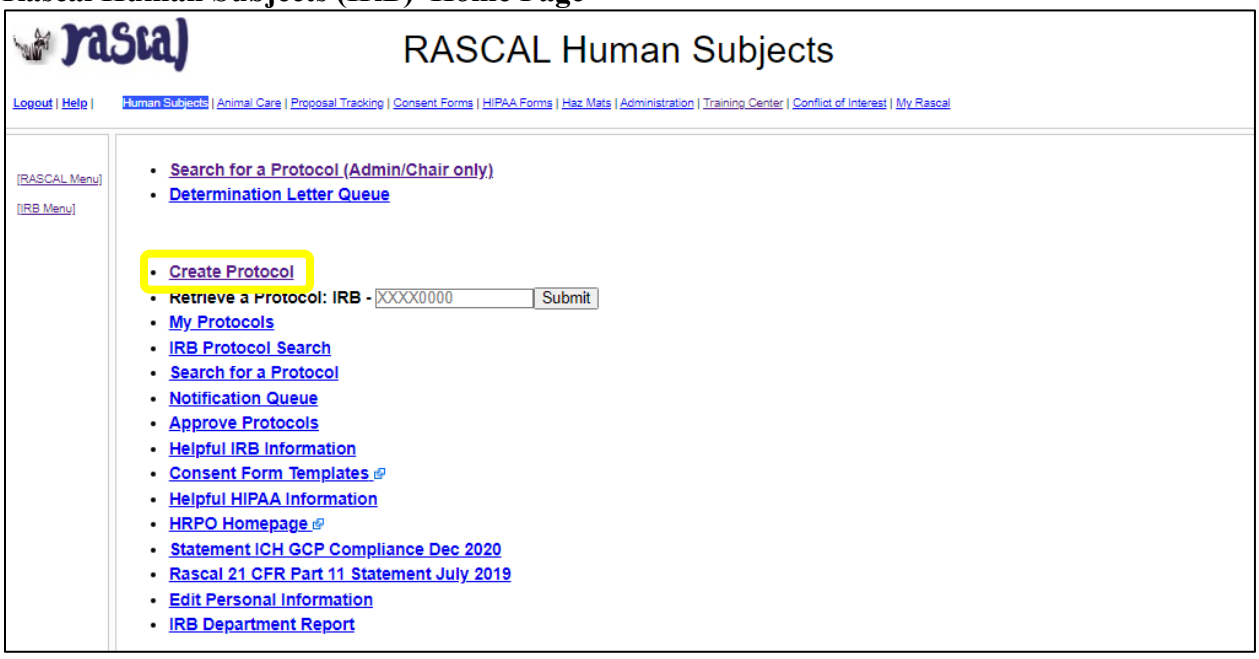
RASCAL HUMAN SUBJECTS

Rascal Home Page



Once you log in to Rascal, the general home page will come up. To go to the Rascal Human Subjects home page, simply click on the Human Subjects (IRB) icon, which will bring you to the following page:

Rascal Human Subjects (IRB) Home Page



In order to *create a protocol for a new research project*, click on Create Protocol. This will bring you to the General Information page. Be sure to read the General Instructions, which provide helpful explanatory notes as you go from page to page.

Important:

1. Text that is copied and pasted from a standalone protocol, grant application, or any pdf document can result in distorted text, e.g., special characters, odd spacing, or varied font sizes. Before submitting the Protocol, go to **View Datasheet** to ensure that the text is clean to avoid an automatic return of the submission for edits.
2. Please select 

at the bottom left of each Rascal page prior to continuing through or exiting the Rascal application.

SECTION 1: GENERAL INFORMATION

Field 1: Originating Department Code
The **Originating Department** is the same as the home department of the Principal Investigator **(PI).** Type at least three letters of the department name and a drop-down list of the department names and codes will appear. Select the appropriate Originating Department. If the PI has appointments in more than one department, select the department to which the research will be attributed.

Field 2: From what Columbia campus does this research originate?
Click on the drop-down menu and select the campus of the Originating Department, which may or may not be the location where the research will be conducted. *There is a Locations Section later in the form to enter that information.*

Field 3: Title (maximum 500 characters)
Enter the full title of the research study. *This should match a related study document, such as a standalone study protocol or an informed consent form, or the grant application, if available.* This is the title that will be included in the official IRB correspondence, such as the IRB determination letter.

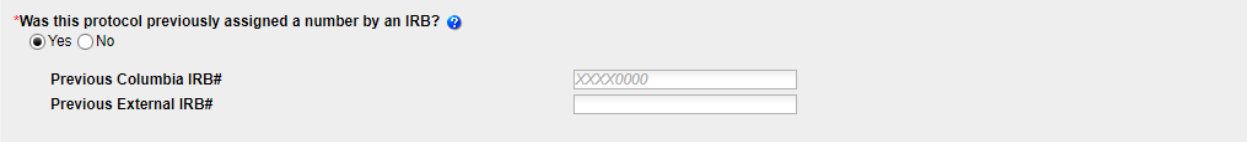
Field 4: Protocol Version #
If you have developed or received a standalone protocol from a lead site or study sponsor, you will need to attach it in Rascal before submitting the Protocol. All clinical trials should have a standalone protocol. Enter in the Protocol Version # field the version number or date of the standalone protocol you have attached to your submission. *You may find this information on the cover page or header/footer of an externally prepared standalone study protocol (e.g., Version 1.0, Amendment 4 or Version Date: December 31, 2020).*

The Protocol version number or version date should be updated for each revised standalone protocol submission.

> **Tip:** Do not use a Rascal Event reference (Ex. Y01M00) as the Protocol version number or version date. The Year component identifies when the Protocol is initially submitted (Y01). This identifier will update (Y02 and beyond) each time the protocol is renewed or the annual report is submitted. The Modification component (M01) identifies the chronological sequence of each modification that is submitted.

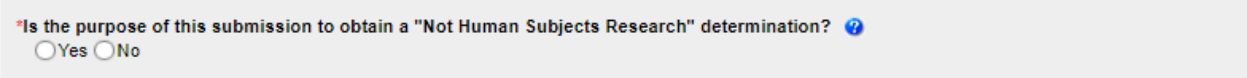
Field 5: Abbreviated Title (maximum 60 characters)
Enter a short title that is meaningful and distinguishes the Protocol from other protocols conducted by the research team. This title will be used in certain reports and should be different from the full title. *For example, you may simply include the study intervention name and study population/condition (e.g., vaccine long-term effect in children) or the acronym for the study.*

Field 6: Was this protocol previously assigned a number by an IRB?



- **Select NO** if this is the first time the IRB is reviewing this research study.
- Select **YES** and enter the IRB Number in the appropriate field, if the research study was:
    - Previously submitted in Rascal, received a Columbia IRB # (i.e., AAAX1234) but was withdrawn prior to or closed after initial approval; or
    - Previously reviewed by a non-Columbia IRB (e.g., under an IRB reliance agreement) and received an External IRB #.

Field 7: Is the purpose of this submission to obtain a "Not Human Subjects Research" determination?



An IRB is only required to review **research** with **human subjects** (as defined in the applicable federal regulations (45 CFR 46)).

- Select **NO** if you would like to move forward with creating an application for IRB review, proceed to **SECTION 2: ATTRIBUTES.**
- Select **YES** to be guided through a series of questions to determine whether the proposed study constitutes human subjects research. When the outcome - based solely on your responses - is presented, you can choose to rely on the outcome or to submit the Protocol for a formal determination by the IRB as to whether it constitutes human subjects research. Responsibility for the determination is solely yours if it is not submitted for a formal determination, as are any consequences that may arise later if the self-determintion is not correct.

Additional Notes:

1. Please note that the final regulatory determination of whether or not the study constitutes human subjects research will be made by the IRB, if the Protocol is submitted for formal review. Therefore, it is strongly recommended that you select **NO** and proceed with the IRB submission, if there is any ambiguity.
2. Some funding agencies, journals or collaborators may require a formal determination of Not Human Subjects Research (**NHSR)** from the HRPO, or a researcher may want a definitive determination to ensure compliance with applicable regulations.

If you selected YES, you will see the following federal definition of **research** and a list of four activities that are deemed **not** to be research, as shown below:

Per 45 CFR 46.102, Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

Activities that meet this definition constitute research, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. The following activities are deemed not to be research:

1. Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.
2. Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).
3. Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.
4. Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

Field 8: Does this project meet the definition of research as defined in 45 CFR 46?

***Does this project meet the definition of research as defined in 45 CFR 46?**
(●) Yes ( ) No

Definition: Research is defined in 45 CFR 46 as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

- **Systematic investigation**: An activity that involves a prospective study plan that incorporates data collection and analysis, either quantitative or qualitative, to answer a study question.
- **Generalizable knowledge**: Investigations to develop or contribute to generalizable knowledge are those designed to draw general conclusions (i.e., knowledge gained from a study may be applied to populations outside of the specific study population or situation).

Definition: The following activities are deemed **not** to be research.

1. Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.
2. Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).
3. Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.
4. Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

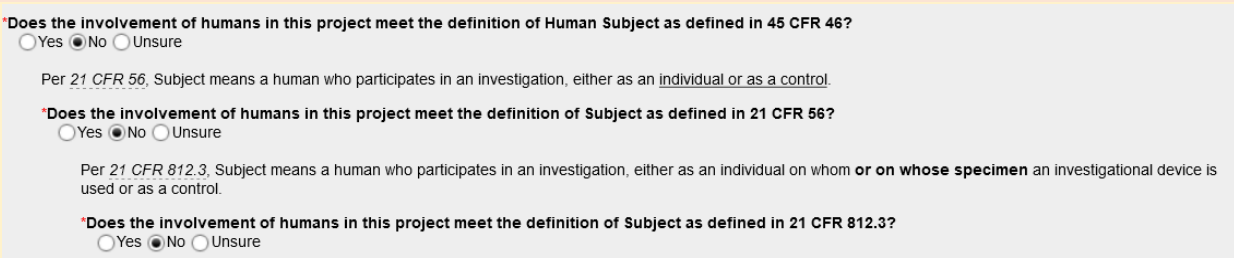
Note: University policy requires that some student projects that do not meet the federal definition of research be submitted for IRB review. See the Columbia University Policy on Students as Researchers.

- Select **NO** if your proposed project **does not** meet the definition of research; and if the overall project solely involves one of the four activities described above.
- Select **YES** if your project **does** meet the federal definition of research; and if it **does not** involve *only* one or more of the four activities described above.

Tip: Research vs. Quality Improvement (QI)

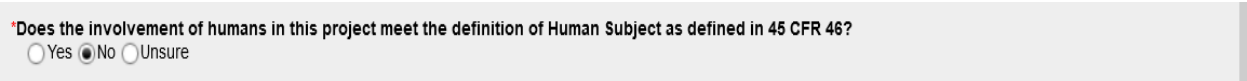
Differentiating between a research study and a QI project can be difficult, as both often involve defining a problem, developing and implementing an intervention or change to address the problem and then analyzing the effect of that change on the problem of interest. QI projects do not need IRB approval. See the Columbia University & Weill Cornell Institutional Review Boards & The Quality & Patient Safety Department at New York-Presbyterian Guidance for the Classification of Quality Improvement Activities versus Research with Human Subjectsfor further information. If you are uncertain as to whether your study constitutes research or QI, you should email irboffice@columbia.edu for guidance.

Note: When considering whether an acitivity is human subjects research, the IRB must consider various federal regulations and their respective definitons of a "human subject" or "subject". The IRB primarily focuses on the following federal regulations that define **Human Subject** or **Subject**:
(1) 45 CFR 46, promulgated by the US Department of Health and Human Services (**DHHS**) and applicable to all federally funded research;
(2) 21 CFR 56, promulgated by the US Food and Drug Administration (**FDA**) and applicable to clinical investigations regulated by the FDA; and
(3) 21 CFR 812, promulgated by the FDA and applicable to clinical investigations with investigational devices. Therefore, there are three different questions in Rascal that will populate if you seek a NHSR determination:



*If you select **NO** to all three questions listed above, an additional question will be generated regarding the New York State Genetic Privacy Act. Further information is provided below (Field 12).

Field 9: Does the involvement of humans in this project meet the definition of Human Subject as defined in 45 CFR 46?



Carefully read the definitions shown below and pay particular attention to the definition of private information for assistance in making this determination.

Definition: Human Subject is defined in 45 CFR 46 as a living individual about whom an investigator (whether professional or student) conducting research:

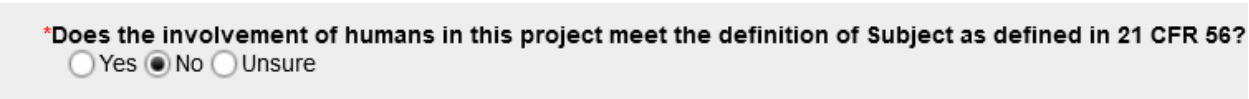
- Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
- Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. Intervention includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

Tip: Private information includes information that is sourced from a place in which an individual can reasonably expect not to be observed or recorded or the information has been provided for specific purposes and which the individual can reasonably expect will not be made public. This expectation would apply to researchers directly accessing medical records or having medical information shared with another researcher.

- Select **NO** if the involvement of humans in your project **does not** result in your obtaining information or biospecimens through intervention or interaction with individuals or include obtaining, studying, or analyzing identifiable private information or biospecimens.
- Select **YES** if the involvement of humans in your project **does** include interaction with individuals to obtain, study and analyze identifiable private information and biospecimens.

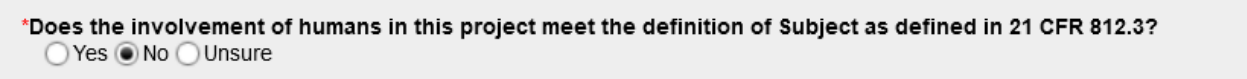
The next few questions provide definitions of "Subject" found in DHHS and FDS regulations, and solicit responses to identify whether the researcher involves human subjects. All human subjects research require a submission for either IRB or HRPO review.

Field 10: Does the involvement of humans in this project meet the definition of Subject as defined in 212 CFR 56?



Per 21 CFR 56, **Subject** means a human who participates in an investigation, either as an individual or as a control.

Field 11: Does the involvement of humans in this project meet the definition of Subject as defined in 21 CFR 812.3?



Per 21 CFR 812.3, **Subject** means a human who participates in an investigation, either as an individual on whom or on whose specimen an investigational device is used or as a control.

Field 12: Does this research involve genetic testing, as defined in the New York Genetic Privacy Act, of deidentified biological samples?

The New York Genetic Privacy Act (NYS 79-L) defines a genetic test as, "any laboratory test of human DNA, chromosomes, genes, or gene products to diagnose the presence of a genetic variation linked to a predisposition to a genetic disease or disability in the individual or the individual's offspring, such term shall also include DNA profile analysis. "Genetic test" shall not be deemed to include any test of blood or other medically prescribed test in routine use that has been or may be hereafter found to be associated with a genetic variation, unless conducted purposely to identify such genetic variation."

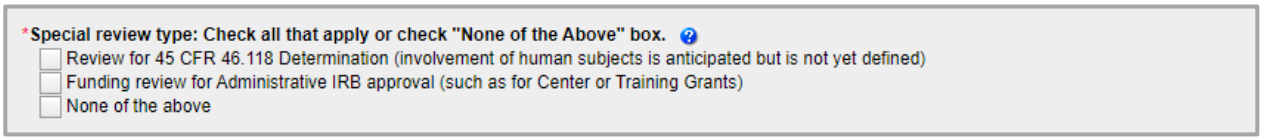
If the proposed research proposes genetic testing as defined above, submission to the IRB for confirmation that consent requirements are met or certification of deidentification, the latter of which will result in a "Not Human Subjects Research" determination, is required. If deidentification is not possible, the research must be reviewed as human subjects research.

Important: If you selected **YES** to meeting the definition of Research **AND YES** or **UNSURE** to meeting the definition of Human Subject, go back to the question "**Field 7: Is the purpose of this submission to obtain a Not Human Subjects Research determination?"** and select **NO** to proceed with the submission of your Protocol for review.

Tip: For additional guidance on determining whether the proposed activity is considered research, involves human subjects, etc., please refer to the OHRP Decision Charts.

SECTION 2: ATTRIBUTES

Field 1: Special review type: Check all boxes that apply or check the "None of the Above" box.



A **Special Review Type** is either a review for a CFR 46.118 determination (a **118 Review)** or a funding review for administrative IRB approval (an **Administrative Review);** these reviews apply only to **federal awards**.

- Select **REVIEW FOR 45 CFR 46.118 DETERMINATION (INVOLVEMENT OF HUMAN SUBJECTS IS ANTICIPATED BUT IS NOT YET DEFINED** if your study requires a 118 Review.
  The regulations at 45 CFR 46.118 provide a mechanism by which an IRB review is not required when research applications submitted for federal funding lack definite plans for the involvement of human subjects and cannot be fully described in the grant. The IRB will conduct a 118 Review and approve the Protocol to allow investigators access to funding that is required to develop preliminary aspects of the research that do not involve human subjects (e.g., pre-clinical pilot testing, establishment of a committee to evaluate the feasibility of the research, development of a protocol, etc.). This determination will be reflected in Rascal, but will require a subsequent modification describing all procedures, etc. when they are known, and approval of such modification before procedures involving human subjects can commence.

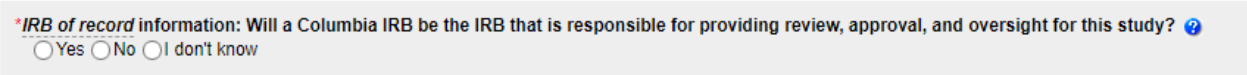
Tip: If the research activities have been defined to such a degree that a consent form has been created and will be attached to the protocol when submitted for the IRB review, the 118 designation would generally not be applicable as the criterion of lacking definite plans for the involvement of human subjects cannot be met.

- Select **FUNDING REVIEW FOR ADMINISTRATIVE IRB APPROVAL (SUCH AS FOR CENTER OR TRAINING GRANTS)** if your study requires an Administrative Review.
  An Administrative Review generally applies to federally funded grants such as Program Project/Center (P series) or Training (T series) grants, when specific projects have not been identified before the award is made. Each project that involves human subjects will require its own Rascal submission. If it is not clear if this Section applies to a particular federal award, check with your Project Officer in Sponsored Projects Administration (**SPA**).

- Select **NONE OF THE ABOVE** if neither Option One or Option Two applies.

Important: Be careful to select the appropriate option because the information solicited by Rascal in the remainder of the submission will vary based on that selection. For 118 and Administrative Reviews, Rascal will only present the following pages: Funding, Personnel, and Research Aims and Abstracts. If you select "None of the above", all pages in Rascal will be presented.

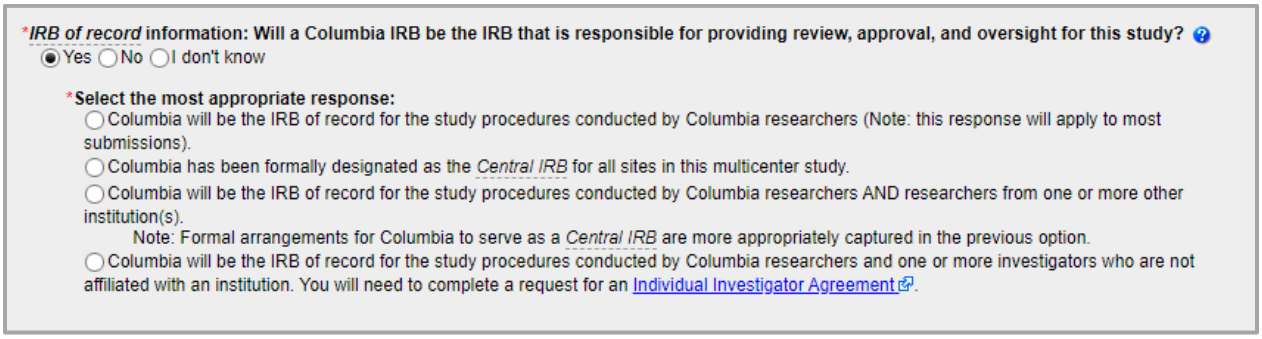
Field 2: IRB of record information: Will a Columbia IRB be the IRB that is responsible for providing review, approval, and oversight for this study?



- Select **YES** if the Columbia IRB will provide review, approval and oversight for the study.
- Select **NO** if the Columbia IRB has agreed to cede review to an external IRB and therefore "rely" on that IRB, and the reliance agreement has been fully executed.
- See below for further guidance before selecting the **I DON'T KNOW** option.

Important: If you are inclined to select **I DON'T KNOW,** it is an indication that you do not have all of the information that is needed for IRB review. Consult with the HRPO (at irboffice@columbia.edu) before submitting the Protocol. Selecting **I DON'T KNOW** will result in a **return of the submission** or **delay in reviewing the submission until it is determined whether a Columbia IRB will conduct the review**.

If you selected **YES** for **Field 2: IRB of record information**, you will see the following four responses; you must check one of them.



- Select **COLUMBIA WILL BE THE IRB OF RECORD….** if Columbia will be the IRB of record and is reviewing for Columbia affiliates only and has not agreed to review for non-Columbia affiliates from relying sites.
- Select **COLUMBIA HAS BEEN FORMALLY DESIGNATED…** if Columbia has agreed to serve as the Central IRB for all studies activated by a network or consortium, e.g., North American Mitochondrial Disease Consortium (**NAMDC**) or Perinatal Research Consortium (**PRC**).

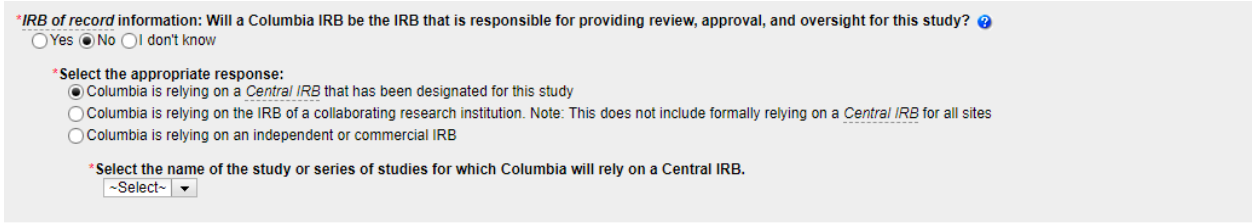
Definition: A **Central IRB** is one that serves as the IRB of record for all studies conducted at all sites through an established network or consortium.

Tip: Do not select the Central IRB option if Columbia has agreed to serve as the IRB of record for a single study that involves multiple sites. Please refer to the option, **COLUMBIA WILL BE THE IRB OF RECORD FOR THE STUDY PROCEDURES CONDUCTED BY COLUMBIA RESEARCHERS AND RESEARCHERS FROM ONE OR MORE INSTITUTIONS.**

- Select **COLUMBIA WILL BE THE IRB OF RECORD FOR THE STUDY PROCEDURES CONDUCTED BY COLUMBIA RESEARCHERS AND RESEARCHERS FROM ONE OR MORE INSTITUTIONS (S)…** if the Columbia HRPO has agreed to serve as the IRB of record for one or more of the collaborating sites for the single study being submitted. List all of the sites that will be relying on the Columbia IRB. The IRB Authorization Agreement (**IAA**) checklist is needed if the sites that are relying on Columbia do not have an IRB at their affiliated institution.
- Select **COLUMBIA WILL BE THE IRB OF RECORD FOR THE STUDY PROCEDURES CONDUCTED BY COLUMBIA RESEARCHERS AND ONE OR MORE INVESTIGATORS WHO ARE NOT AFFILIATED WITH AN INSTITUTION…** if Columbia will be the IRB of record for the study procedures conducted by Columbia researchers and one or more investigators who are not affiliated with an institution. *For example, if you plan to work with a physician in private practice, that individual would need IRB approval for human subject activities. For an individual or individuals conducting human subject activities on behalf of an organization without an IRB, an IAA is required (RESPONSE 3).*

Note: If you selected RESPONSE 2 or 3, and the situation represents a new reliance relationship, please be sure to submit a **reliance request** to confirm the University's willingness to act as the IRB of record for collaborating sites. Submission of the request form is not required for established reliance situations for which Columbia serves as the IRB of Record for other institutions, e.g. NAMDC, PRC, or Weill Cornell Medicine. For any questions related to reliance, please email irbreliance@cumc.columbia.edu.

If you selected **NO** for **Field 2: IRB of record information**, you will see the following three responses; you must check one of them.

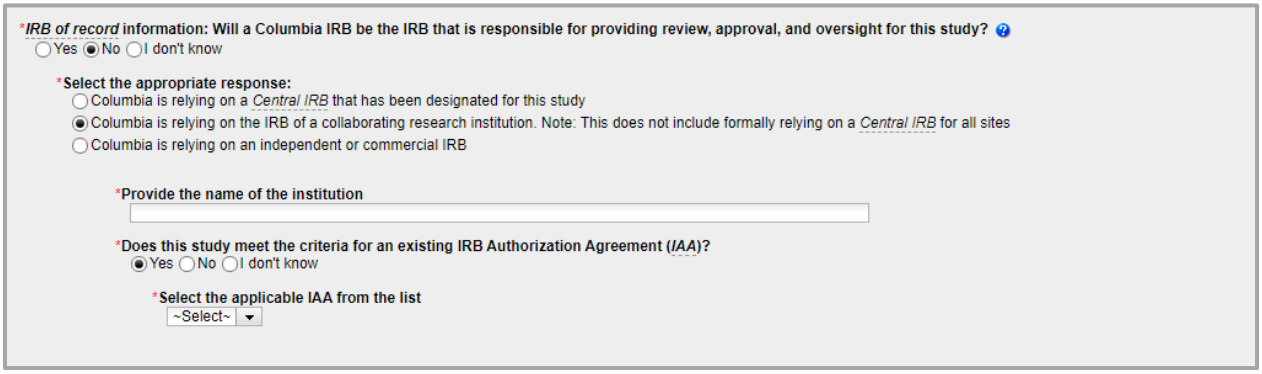


Note: Columbia has existing reliance agreements with many institutions including Bassett Healthcare for certain research involving Columbia students, and Weill Cornell Medicine for bi-campus or other collaborative research.

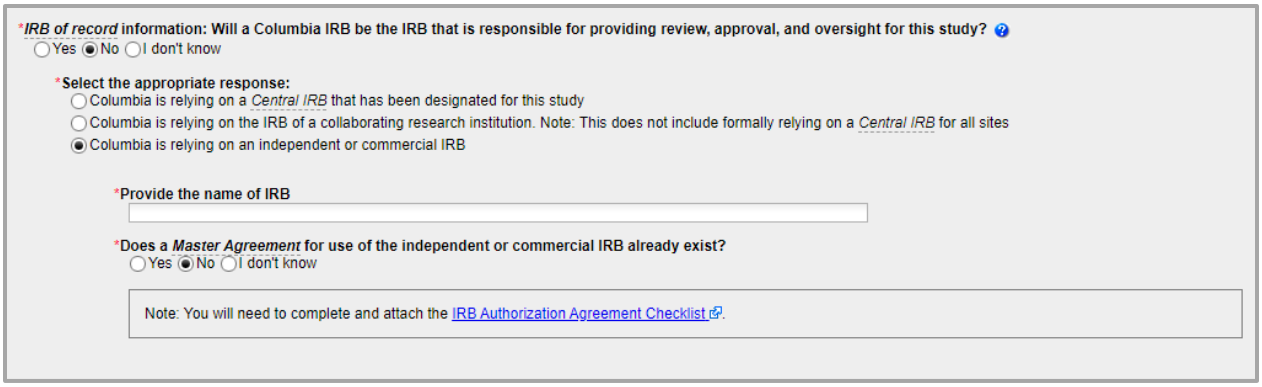
The SMART IRB is not an IRB; it is a platform and agreement that is used as the basis for reliance on an institution's IRB.

For most submissions, the answer will be **NO** to the above question.

- Select **COLUMBIA IS RELYING ON A CENTRAL IRB THAT HAS BEEN DESIGNATED FOR THIS STUDY** if Columbia has agreed to cede review to an external IRB for more than one study being conducted by the applicable network or consortium. If you select this response, a drop-down menu will appear. Select the network or consortium from the list. If the network or consortium is not on the list, select **Other** and type in the name of the network or consortium.



- Select **COLUMBIA IS RELYING ON THE IRB OF A COLLABOATING RESEARCH INSTITUTION** if Columbia has agreed to rely on a collaborating research institution's IRB for one specific study, and enter the name of that institution.



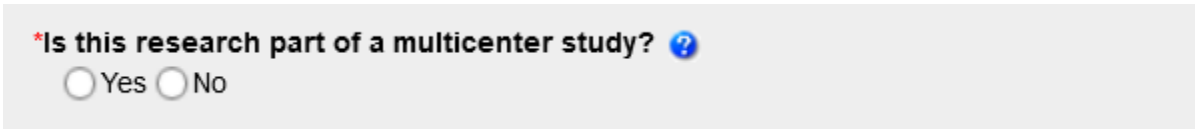
- Select **COLUMBIA IS RELYING ON AN INDEPENDENT OR COMMERCIAL IRB** if Columbia is relying on an independent or commercial IRB. Examples of such IRBs are Advarra or WIRB Copernicus Group (**WCG**). If you select this response, enter the name of the IRB in the box that appears.

If you select **YES** to this question, you must then answer the question: **Does a Master Agreement for use of the independent or commercial IRB already exist?**

- Select **YES** if WCG is being used as the IRB, as Columbia has a master agreement with WCG, or if it is known that there is a master agreement with another independent or commercial IRB for the study.
- Select **NO** if it is known, through consultation with HRPO staff, that another independent or commercial IRB is being used and Columbia will need to execute a study specific reliance agreement.
- If you are inclined to select **I DON'T KNOW** it is an indicaton that you do not have all of the information that is needed for IRB review. Consult with the HRPO at irbreliance@columbia.edu before submitting the Protocol.

Note: If the situation represents a new reliance relationship, and a request to cede review to the external IRB has not been submitted, please complete our reliance survey before proceeding with the submission.

Field 3: Is this research part of a multicenter study?

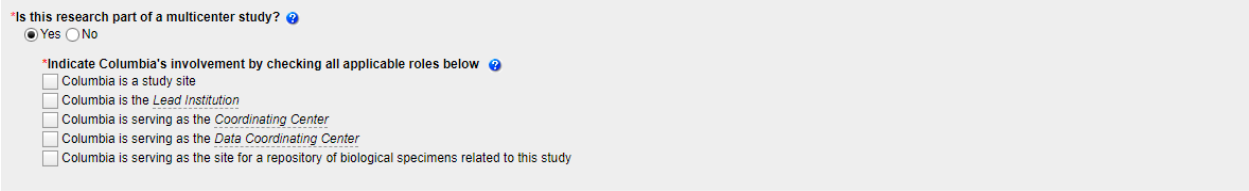


- Select **NO** if Columbia is the only institution conducting this study.
- Select **YES** if Columbia is not the only institution conducting research-related activities.

Tip: A study is considered to be a multicenter study for the purposes of IRB review even if all sites are not "engaged" in human subjects research, i.e,. are not interacting or intervening with subjects and do not have access to identifiable data about or biospecimens from the human subjects. For instance, if one site is interacting with subjects and another site is only receiving identifiable data or speciemns for analysis, both sites are engaged in human

subjects research and the research should be considered multicenter. Another multicenter scenario, for purposes of IRB review, is an MPI federally funded study for which engagement occurs at only one of the sites; each MPI's institution is considered to be engaged in HSR.

If you selected **YES**, you will see the following five responses from which you must check one or more of the roles that Columbia will assume. Hover over **Lead institution**, **Coordinating Center** and **Data Coordinating Center** for a description of each such role.

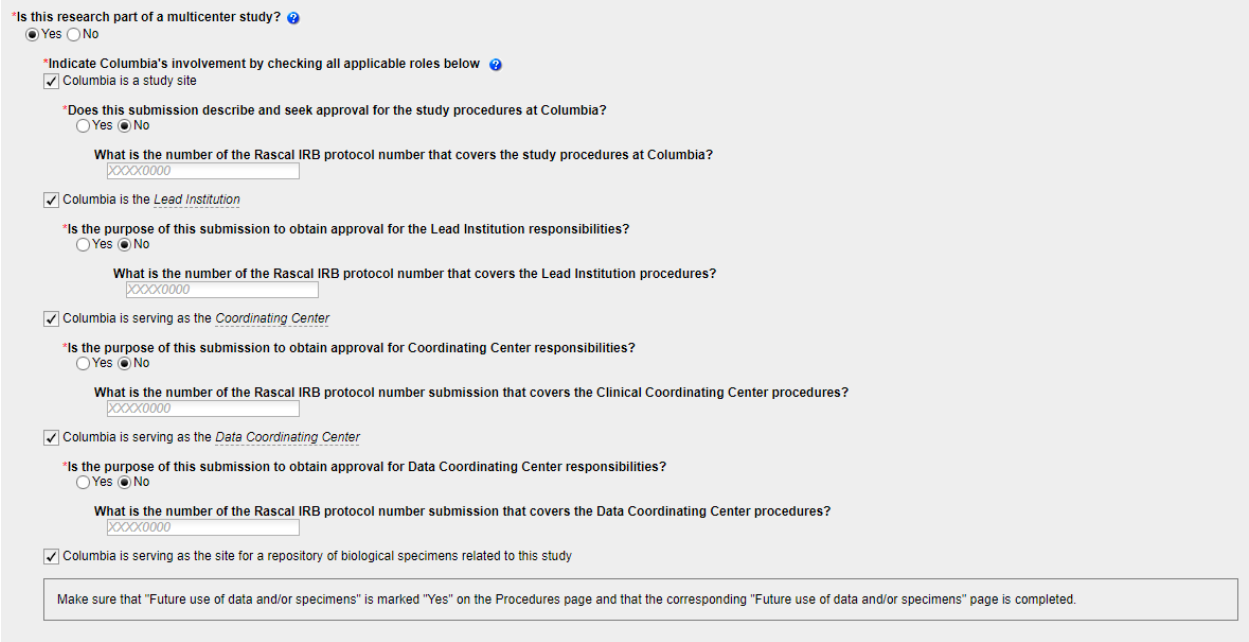


Note: In general, if Columbia is serving in more than one role in a federally funded multicenter study, separate Rascal submissions should be prepared for each role. The exception is when Columbia is serving as the lead institution. In that case, the procedures relating to either its role as a clinical coordinating center or data coordinating center may be included in the lead site submission. Please note that the response selected here will appear on the Subjects page and affect the questions there on target enrollment and accrual numbers.

Even if separate submissions will be prepared for each of Columbia's roles, all applicable roles should be checked here. For example, if Columbia is a study site and the Data Coordinating Center, but the current submission will only cover the Data Coordinating Center, both **Study site** and **Data Coordinating Center** should be selected. This will alert the HRPO and IRB reviewers to the structure of the study and the fact that there will be a related but separate Rascal protocol for subject recruitment and the study procedures that will be conducted.

- Select **COLUMBIA IS A STUDY SITE** if Columbia is a study site and participating in research-related activities such as recruitment, enrollment, study procedures, assessments or follow-up procedures with subjects.
- Select **COLUMBIA IS THE LEAD INSTITUTION** if Columbia is the Lead Institution, and the Columbia PI is leading the collaborative research with the PIs at other sites, performing such activities as initiating monthly meetings with site PIs and providing meeting minutes, etc.
- Select **COLUMBIA IS SERVING AS THE COORDINATING CENTER** if Columbia is serving as the Coordinating Center and managing the conduct of research and administrative procedures for all sites.
- Select **COLUMBIA IS SERVING AS THE DATA COORDINATING CENTER** if Columbia is serving as the Data Coordinating Center and storing collected data from all sites.
- Select **COLUMBIA IS SERVING AS THE SITE FOR A REPOSITORY OF BIOLOGICAL SPECIMENS RELATED TO THIS STUDY** if Columbia is serving as the site for a repository of biological specimens.

If you select any of the roles in RESPONSES 1-4, you will be asked "**Is the purpose of this submission to obtain approval for said responsibilities?**" If you select **NO** to this question, fill in the number of the Rascal IRB Protocol submission that covers such responsibilities. See below screenshot for examples.



Field 4: Please indicate if any of the following University resources are utilized:

Selection of a resource provides the selected resource with the opportunity to receive reports of the protocols that have made that seletion. It does not route the entire protocol to the resource for review or approval.

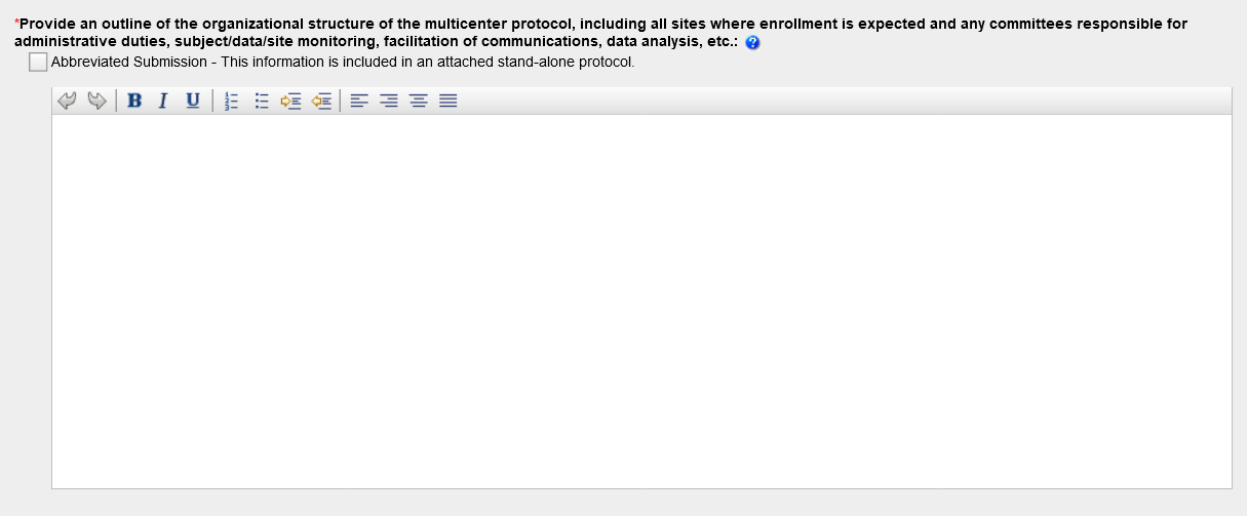
Links to listed resources:

1. CRR: https://www.irvinginstitute.columbia.edu/about-us/resources-and-cores/clinical-research-resource-crr
2. CCPH: https://www.irvinginstitute.columbia.edu/services/campus-activity-space-washington-heights
3. CPDM: https://www.cancer.columbia.edu/research/researchers/clinical-protocol-and-data-management
4. CUB: https://www.vagelos.columbia.edu/research/researchers/core-and-shared-facilities/new-instruments-and-facilities/bridge-biobanking-facility/columbia-university-biobank

SECTION 2A: LEAD INSTITUTION/COORDINATING CENTER

This page will populate if you have selected Lead Institution, Coordinating Center, and/or Data Coordinating Center role on the **ATTRIBUTES** page and selected **YES** to "**Is the purpose of this submission to obtain approval for said responsibilities?**"

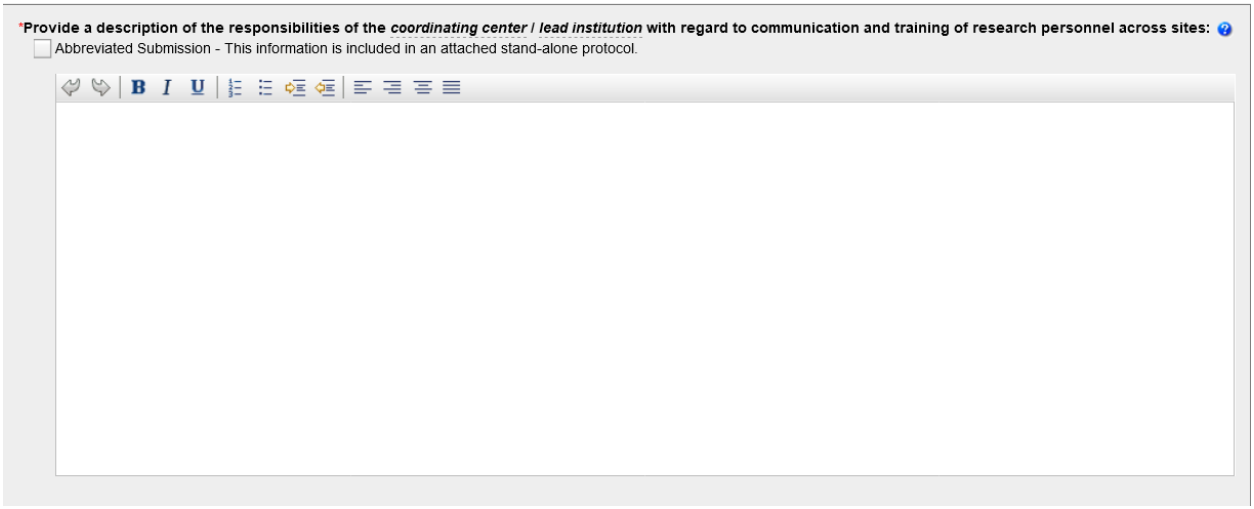
Field 1: Provide an outline of the organizational structure of the multicenter protocol, including all sites where enrollment is expected and any committees responsible for administrative duties, subject/data/site monitoring, facilitation of communications, data analysis, etc.



Tip: Include the name, responsibilities and qualifications of the individual designated as being responsible for the conduct of the research study at each site.

If the research study is funded by a federal agency (e.g., NIH) specify the Federal Wide Assurance number assigned to each site by the Office for Human Research Protection (**OHRP**) for each non-local site.

Field 2: Provide a description of the responsibilities of the coordinating center/lead institution with regard to communication and training of research personnel across sites.

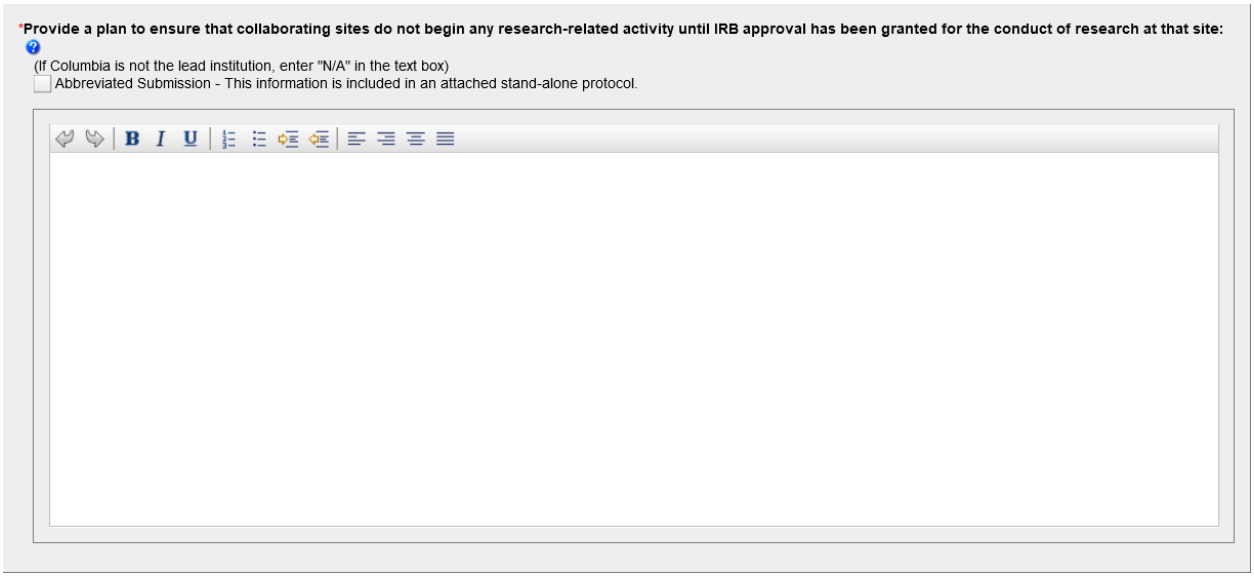


Tip: This section should include efforts to ensure training for all sites, including how data are managed and if applicable, accurate, consistent instrument training. Specific details of any special equipment needed (e.g., scanners, computers, software) for study procedures or data transfer should be included.

Defintions:

1. **Lead Institution:** The overall Principal Investigator, who is responsible for the oversight of research procedures for the multicenter study, is based at Columbia
2. **Coordinating Center:** The site managing the conduct of research and administrative procedures for all sites involved in a multicenter research project.

Field 3: Provide a plan to ensure that collaborating sites do not begin any research-related activity until IRB approval has been granted for the conduct of research at that site.

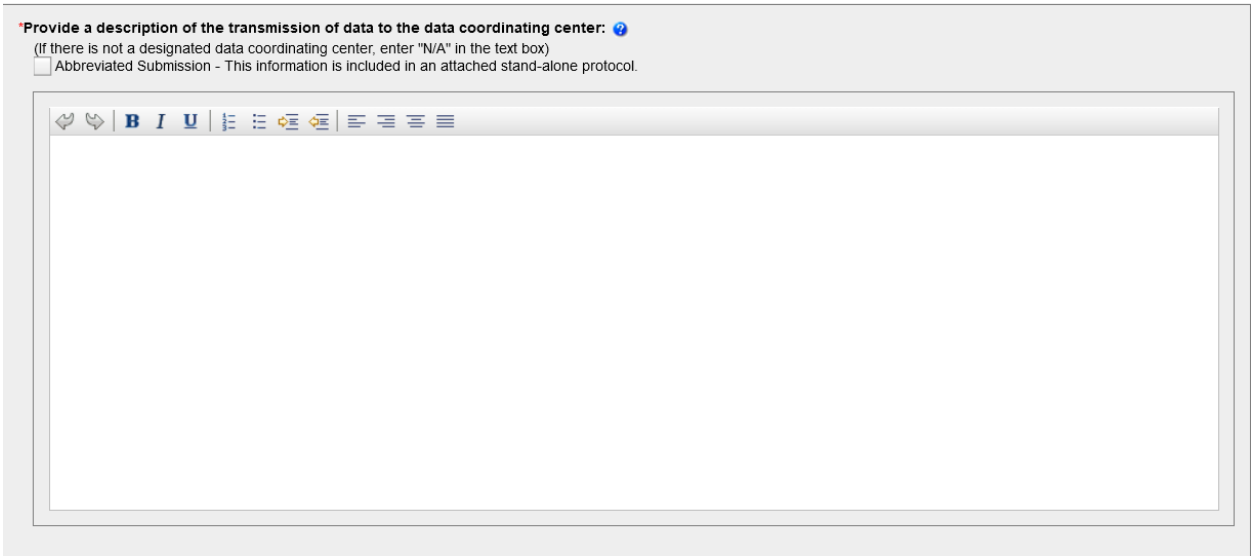


If Columbia is the lead institution, include a plan to ensure that collaborating sites do not begin any research-related activity until IRB approval has been granted for the conduct of research at that site. If Columbia is not the lead institution, describe the requirements for Columbia to provide documentation of IRB approval to the lead institution.

Tip: Specify the local IRB or other human subject protections entity responsible for the review and approval of research conducted for each non-local study site. If there are 3 or fewer study sites, attach the approval letters from each site in Rascal when obtained. If more than 3 sites, maintaining approval letters with other research records is acceptable.

This section should include a plan to maintain records of IRB/ethics committee review and approval of all protocols and consent forms for all collaborating sites throughout the duration of the study. Renewal for each site does not need to be submitted to the Columbia IRB; however, the PI is responsible for ensuring that all modifications and renewals are reviewed and approved appropriately; i.e., modifications are approved prior to their implementation and protocols and consent forms are renewed in a timely manner with no lapse in the renewal.

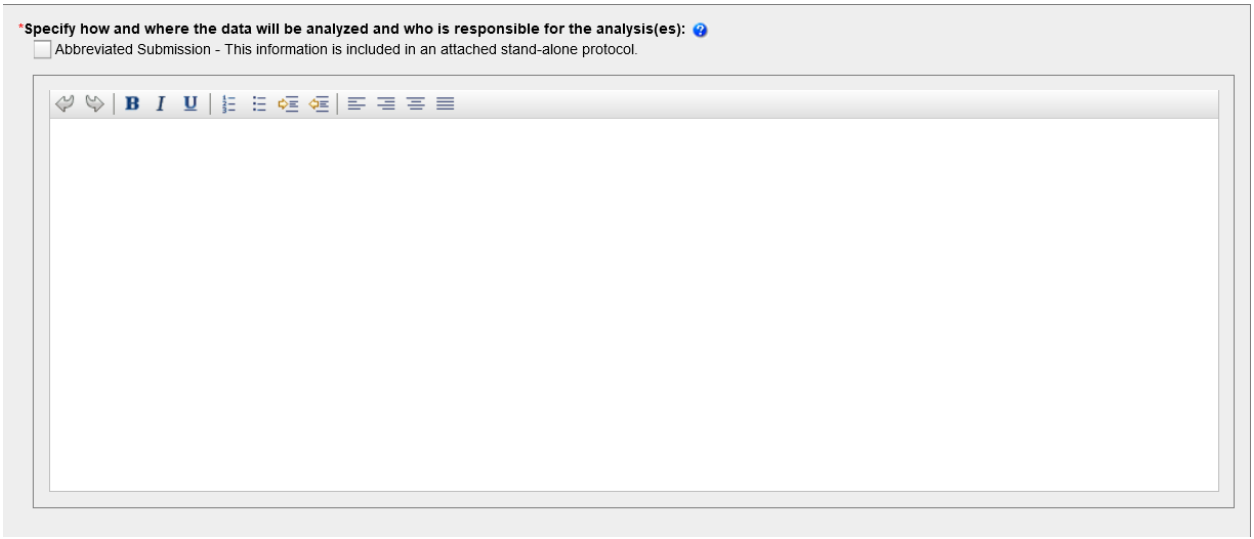
Field 4: Provide a description of the transmission of data to the data coordinating center.



If there is a designated data coordinating center, include a description of the transmission of data to the data coordinating center.

Tip: This section should include information on how data will be sent and how data will be labeled to protect the privacy of the subjects and the confidentiality of the data. If records or files are to be transmitted via the internet or shipped to another site, describe how the subjects' confidentiality will be protected, e.g., through use of a unique study identifier assigned to each subject, and whether the key linking the study identifier and subject names will be shared. Indicate the specific department/office that will receive the data. Indicate who will review all data for completeness, and indicate who is responsible for obtaining missing data or correcting errors. Note that details about future use of data and data security during storage and transmission will be requested on a separate page.

Field 5: Specify how and where the data will be analyzed and who is responsible for the analysis(es).



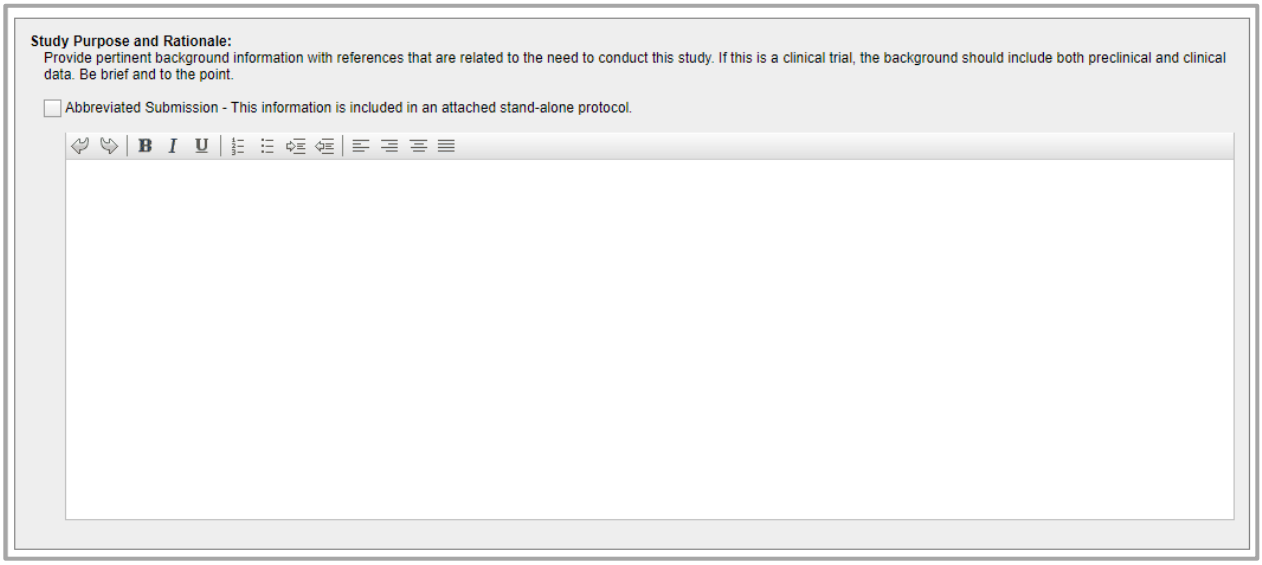
Include a description of how and where the data will be analyzed and who is responsible for the analysis. Describe whether data analysis will occur at the Lead Institution, Coordinating Center, Data Coordinating Center, study sites, or elsewhere. This will inform the IRB of when it is appropriate for individual study sites to close out IRB oversight at that location.

SECTION 3: BACKGROUND

Note: If the study team has developed or received a standalone protocol document from the lead site or the Sponsor of the study, and all of the information that is being requested is in such document, the "Abbreviated Submsision" check box in each of the text fields on this page should be checked (see below). This will remove text fields from the page and direct the HRPO Staff to the standalone document that should be attached in the Documents section.

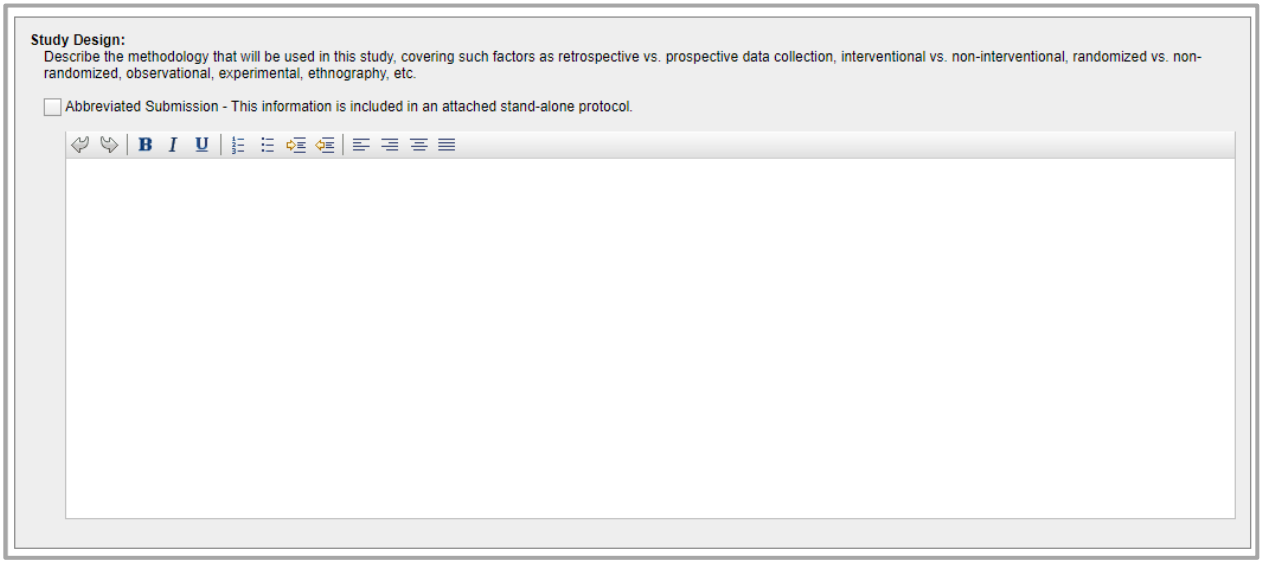
*Grant proposal pages are not appropriate alternatives to a standalone submission.

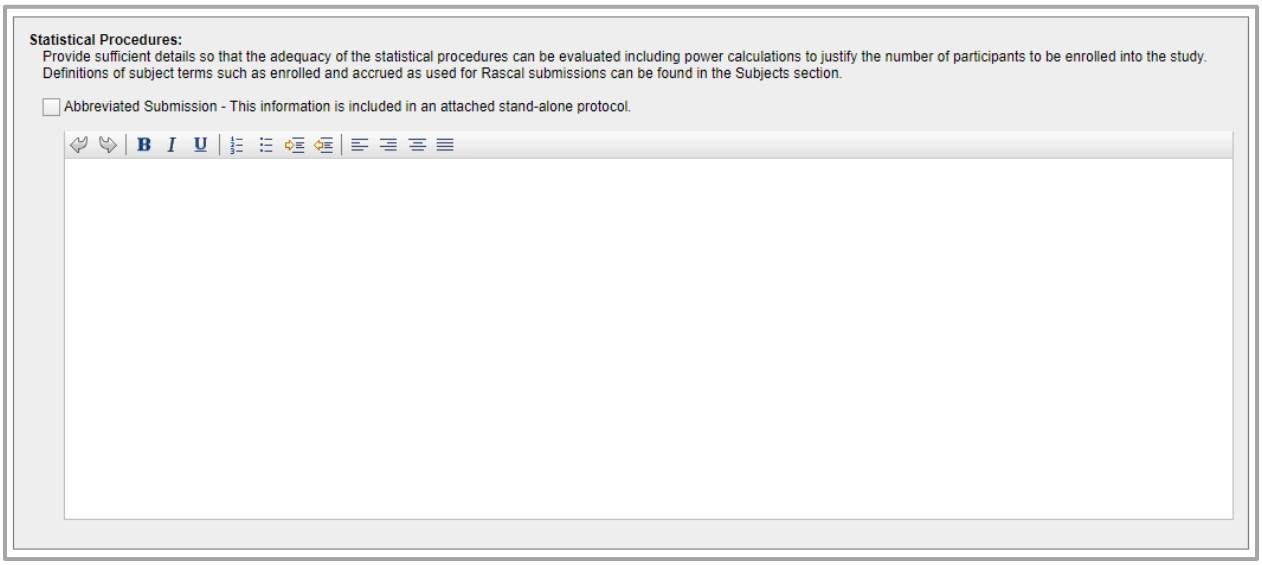
Field 1: Study Purpose and Rationale



Enter pertinent study background information in the provided text box.

The same request for background information is present in **Field 2: Study Design** and **Field 3: Statistical Procedures.**



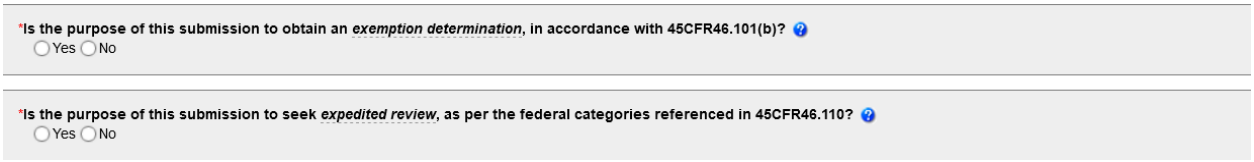


Important:

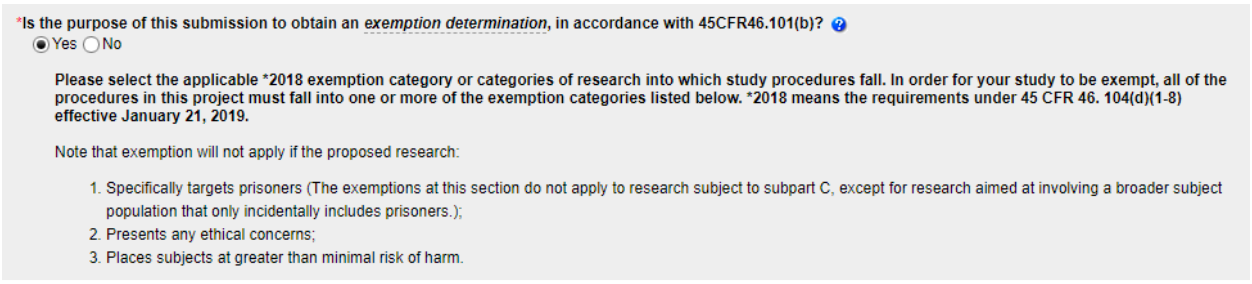
1. Each of the questions on this page require a response. You must either respond to the questions within the fields, or indicate that this is an Abbreviated Submission and attach your standalone protocol in the **Documents** section.
2. Text that is copied and pasted from a standalone protocol, grant application, or any pdf document can result in distorted text, e.g., special characters, odd spacing, or varied font sizes, which may not be apparent until the page is saved. Before submitting the Protocol, go to **Review Datasheet** and review all entries to ensure that the text is clean and to avoid an automatic return of the submission for edits.

SECTION 4: EXEMPT AND EXPEDITED

The purpose of the two questions below is to help researchers and the IRB determine whether the study qualifies as **exempt** or **expedited** and to facilitate understanding of the applicable categories. The IRB will make the final determination. Researchers may opt to simply select "No" to each of these questions and rely entirely on the IRB's assessment.



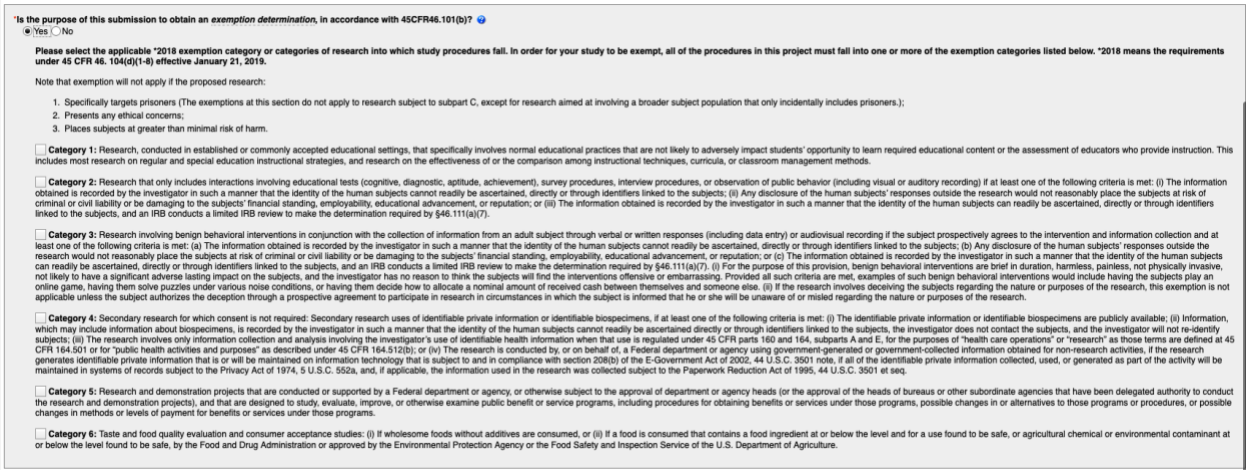
Field 1: Is the purpose of this submission to obtain an exemption determination, in accordance with 45 CFR 46.101(b)?



Definition: Exempt Research means research that presents no more than minimal risk, with all procedures falling into one or more of the six federally defined categories described below. Such studies are exempt from some of the requirements of 45 CFR 46 (e.g., informed consent and data/safety monitoring). Although some exempt research does not require IRB review under the federal regulations, Columbia requires that all categories of exempt research be submitted in Rascal for prospective review and approval by staff of Columbia's Human Research Protection Office.

- Select **NO** if your proposed project does **not** meet the definition of Exempt; and if the overall project does **not** fit into one or more of the six defined categories.
- Select **YES** if your project **does** meet the federal definition of Exempt; and if **it does** involve only procedures that fit into one or more of the six defined categories.

The following are summary descriptions of the six federal categories of Exempt research:



*Is the purpose of this submission to obtain an *exemption determination*, in accordance with 45CFR46.101(b)?
(•) Yes ( ) No

Please select the applicable *2018 exemption category or categories of research into which study procedures fall. In order for your study to be exempt, all of the procedures in this project must fall into one or more of the exemption categories listed below. *2018 means the requirements under 45 CFR 46. 104(d)(1-8) effective January 21, 2019.

Note that exemption will not apply if the proposed research:

1. Specifically targets prisoners (The exemptions at this section do not apply to research subject to subpart C, except for research aimed at involving a broader subject population that only incidentally includes prisoners.);
2. Presents any ethical concerns;
3. Places subjects at greater than minimal risk of harm.

☐ **Category 1:** Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. 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.

☐ **Category 2:** Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met: (i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; (ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or (iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).

☐ **Category 3:** Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met: (a) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; (b) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or (c) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7). (i) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else. (ii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

☐ **Category 4:** Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met: (i) The identifiable private information or identifiable biospecimens are publicly available; (ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects; (iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or (iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

☐ **Category 5:** Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs.

☐ **Category 6:** Taste and food quality evaluation and consumer acceptance studies: (i) If wholesome foods without additives are consumed, or (ii) If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Notes:

1. **Exempt Category 2**
    a. Research involving educational tests, survey procedures, and/or interview procedures with minors is not eligible for exemption.
    b. If the research involves the observation of public behavior and some or all participants are children, the exemption is available only if the investigator does not participate in the activities being observed, i.e., observes but does not control or manipulate the situation.
2. **Exempt Category 3**
    a. If the research involves deceiving the subjects regarding the nature or purpose of the research, the exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that they will be unaware of or misled regarding the nature or purpose of the research. Documentation of such agreement such as with the subject's signature on an agreement or research notes that describe verbal agreement should be maintained.
3. **Exempt Category 4**
    a. If the research involves the collection of patient data accessed directly through Epic, the Electronic Health Record used by Columbia, WCM and NYP, or via the Tripartite Request Assessment Committee of Columbia, WCM and NYP (TRAC), it is not eligible for exemption. If the research involves only retrospective medical chart review that does not involve interaction with subjects, the HRPO has created further instructions showing how to fill out the form in Rascal.

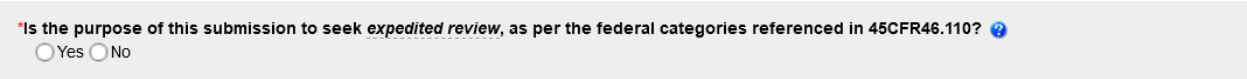
Additional Notes:

1. Research specifically targeting prisoners is **not** eligible for an exemption.

2. **Exempt Categories 7 and 8** relate to broad consent, which is not currently used at Columbia.

Tip: For additional guidance on determining whether the proposed study is eligible for exemption under categories 1-6, see the OHRP Decision Charts.

Field 2: Is the purpose of this submission to seek expedited review, as per the federal categories referenced in 45 CFR 46.110?



Definition: Research Eligible for Expedited Review (Expedited) means minimal risk research with all procedures falling into one or more of the federally defined categories that can be reviewed by an experienced member of the IRB, rather than a convened Board.

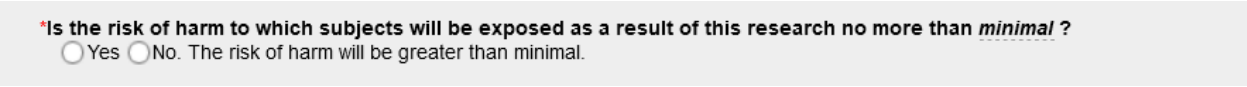
Minimal Risk as defined in DHHS 45 CFR 45 and FDA 21 CFR 56 means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

OHRP provides additional definitions and guidance on Minimal Risk research that can be found here.

- Select **NO** if your proposed project **does not** meet the definition of Minimal Risk; or if the overall project **does not** fit entirely into one or more of the seven defined categories.
- Select **YES** if your project **does** meet the federal definition of Minimal Risk; and if all procedures fit into one or more of the seven defined categories.

If you selected **YES**, the following question will be seen on the screen:

Field 3: Is the risk of harm to which subjects will be exposed as a result of this research no more than minimal?

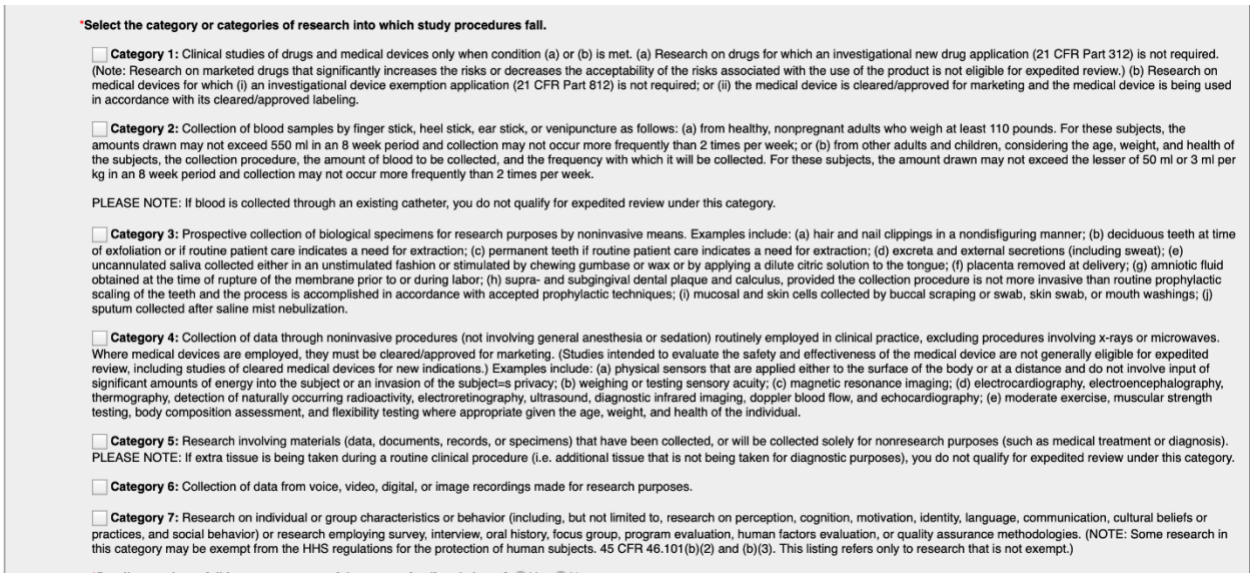


- Select **NO** if subjects enrolled in the proposed project will be exposed greater than minimal risks.

Additional Tips:

1. OHRP provides additional definitions and guidance on Minimal Risk research that can be found here.
2. For research involving prisoners, DHHS defines Minimal Risk as "the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental or psychological examination of healthy persons."

- Select **YES** if your project does meet the federal definition of Minimal Risk; and if all procedures fit into one or more of the seven defined categories:



*Select the category or categories of research into which study procedures fall.

☐ **Category 1:** Clinical studies of drugs and medical devices only when condition (a) or (b) is met. (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.) (b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

☐ **Category 2:** Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows: (a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or (b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

PLEASE NOTE: If blood is collected through an existing catheter, you do not qualify for expedited review under this category.

☐ **Category 3:** Prospective collection of biological specimens for research purposes by noninvasive means. Examples include: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

☐ **Category 4:** Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples include: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject=s privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

☐ **Category 5:** Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). PLEASE NOTE: If extra tissue is being taken during a routine clinical procedure (i.e. additional tissue that is not being taken for diagnostic purposes), you do not qualify for expedited review under this category.

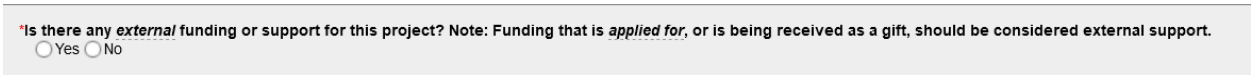
☐ **Category 6:** Collection of data from voice, video, digital, or image recordings made for research purposes.

☐ **Category 7:** Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

Important: DO NOT select YES to both questions asking if you are seeking an Exempt Determination or an Expedited Review (i.e., if a proposed project is "exempt" then if would not need an "expedited review"). If there is one component of the research that does not meet an exempt or expedited criterion, then select **NO** to both questions. The research will need to be reviewed by a convened Board.

SECTION 5: FUNDING

Field 1: Is there any external funding or support for this project?

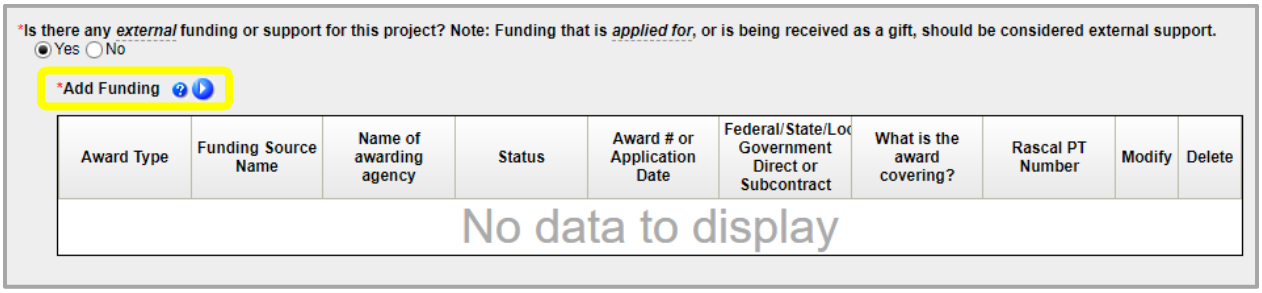


- **Select NO** if your proposed project is "unfunded", i.e., conducted through effort covered solely by salary or discretionary funds.

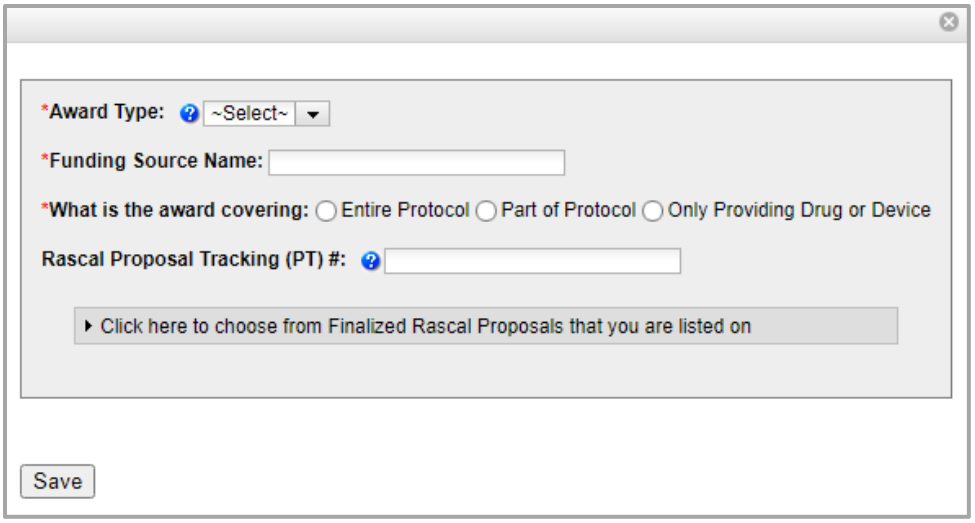
- **Select YES** if your study is receiving funding either externally or internally from the following sources:

    - **Federal/State/Local Government:** Funding provided by a government agency (e.g., NIH, NSF, NYC DOMH).
    - **Industry:** A specific award granted to provide funding from a corporate or other for-profit business entity (e.g., a pharmaceutical company such as Pfizer or Merck).
    - **Foundation/Private:** A specific award granted to provide funding from a foundation or other non-profit entity (e.g., Gates Foundation), or an individual if the funding is not a gift.
    - **Internal Sponsored Project:** Funding from an external source that is being distributed internally within Columbia (e.g., a training grant or funding provided by the Irving Institute) OR funding from a department or other internal funding source.
    - **Gift/Endowment:** A voluntary transfer of funds from a private entity or individual to support Columbia's programs or activities.

Click on the blue arrow icon  to enter funding information.



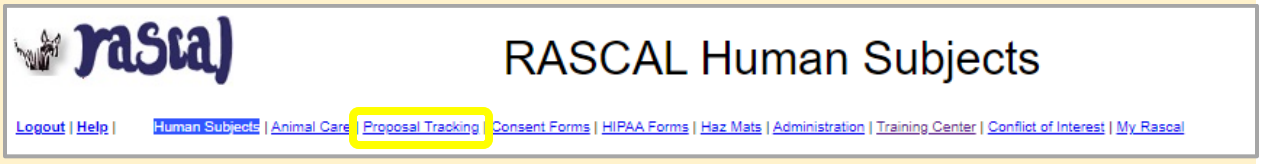
A pop-up window (see below image) will then display additional required fields, such as **Award Type**, **Funding Source Name**, **What is the award covering**, and **Rascal Proposal Tracking (PT) #**.



Note: Both funds that are *awarded* and funds that are *applied* for must be listed in the funding section.

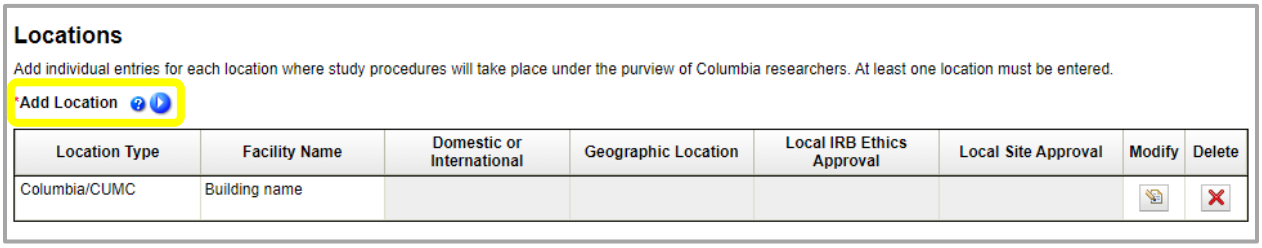
Important: If a funding agency is providing financial support, type in the full name of the agency; some abbreviations will return an error message.

Note: Funding from **federal/state/local government** agencies and **foundation/private entities** requires a Proposal Tracking (**PT)** number. The PT number is generated by creating a proposal in the Proposal Tracking module in Rascal. See Sponsored Projects Handbook: Review and Submission of a Sponsored Project Proposal: Review Process.

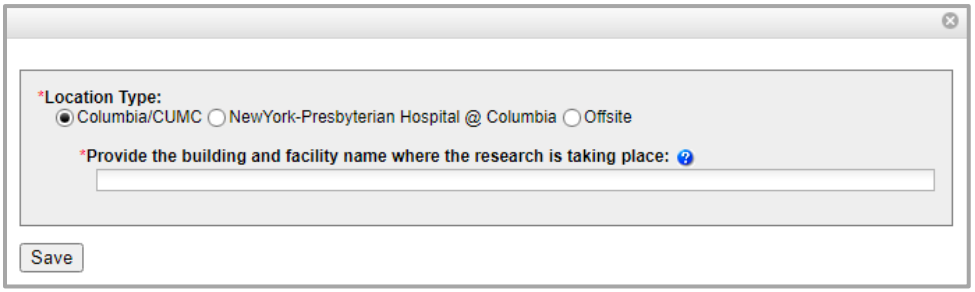


SECTION 6: LOCATIONS

Click on the blue arrow icon to enter location information.



A pop-up window (see below image) will display additional required fields, such as **Location Type** and **Provide the building and facility name where the research is taking place**.



List **all** sites/institutions where research procedures are taking place, including data analysis. **At least one Columbia location must be entered.** Each CU-MS, CUIMC and NYP facility should have its own listing. Additional entries may be appropriate if procedures are taking place in multiple buildings or in different offices (e.g., in the MRI suite, in an office in Black Building and in Milstein Hospital Building).

Local site approval may be required for a location such as a school where study procedures will occur, but individuals affiliated with the site will not be involved in the conduct of the study; a letter of support to conduct study procedures at the site is appropriate documentation of approval.

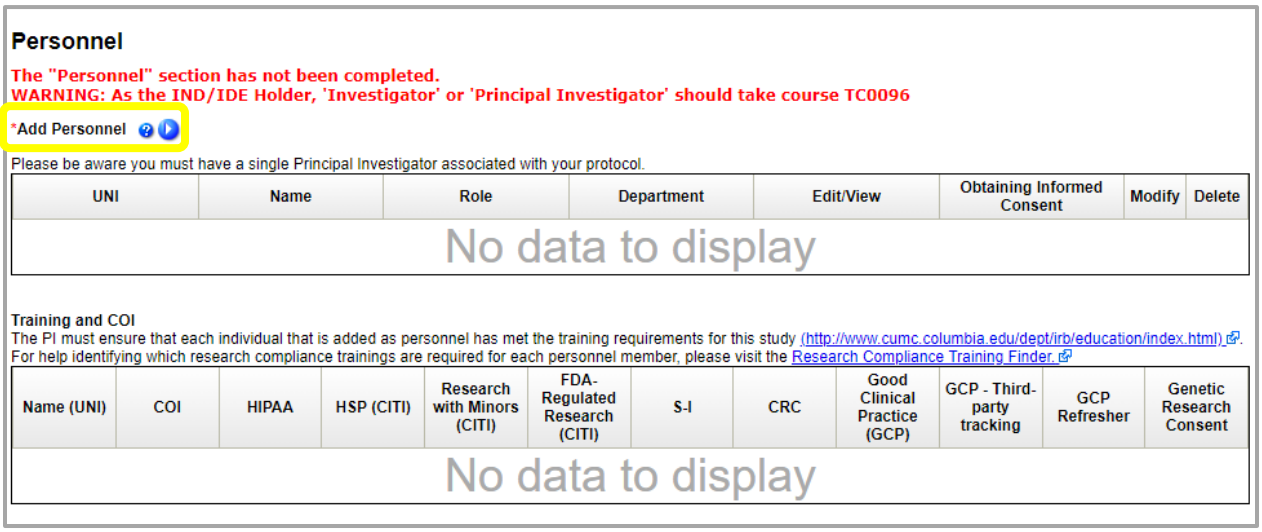
Important: Research that occurs in NYC schools requires the approval of the NYC Department of Education IRB in addition to the Columbia IRB or other IRB of Record, if Columbia has ceded review to a non-Columbia IRB.

SECTION 7: PERSONNEL

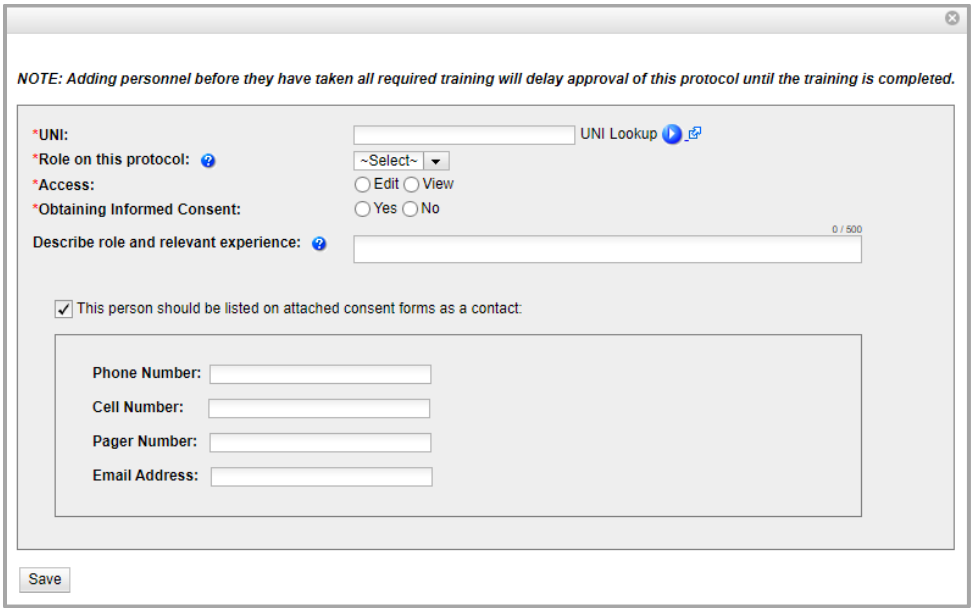
Add Personnel

The following screenshot displays the information that must be provided for each Columbia affiliate who will be engaged in the research or responsible for the regulatory management of the study. Only Columbia affiliated research personnel should be named on the Rascal protocol.

Click on the blue arrow icon to enter personnel information.



A pop-up window (see below image) will display additional required fields with respect to each individual who will be listed as Personnel, such as **UNI**, **Role on this protocol**, **Access**, **Obtaining Informed Consent**, and **Describe role and relevant experience**. By checking the box next to "This person should be listed on attached consent forms as a contact", you will be asked to enter additional information, such as phone number and email address.



Field 1: UNI
Individuals listed under **Personnel** must be Columbia affiliates who have UNIs. Although many Barnard, TC and NYSPI affiliates have UNIs, they should only be added if they are a member of the Columbia "workforce" or a Columbia student. Non-Columbia affiliates should not be listed in the Rascal Personnel section. The TC, Barnard and NYSPI affiliates' conduct of the research must be approved by their respective IRB or by the Columbia IRB under a reliance agreement.

NYP staff with appropriate research roles who do not have Columbia appointments may be added to Rascal protocols but in general may not serve as the Principal Investigator. The exception is for minimal risk research that will be conducted at NYP by a NYP affiliate with an advanced degree in their professional area and does not involve patient care. Such exceptions must be approved by the signatories of the CUIMC and NYP-CUIMC Federalwide Assurances or their designees.

> **Note:** The HRPO does not issue UNIs; rather, they are obtained through the individual's department or school. UNIs should not be requested for non-Columbia affiliates for the sole purpose of adding them as Personnel on a research project.

Field 2: Role on this protocol
Each person must be assigned a **Role.** There are five Roles in Rascal: **Principal Investigator, Investigator, Coordinator, Other Engaged Personnel and Non-Engaged Personnel**.

For each research study, one investigator is designated as the PI. The PI bears ultimate responsibility for academic decisions as well as for the project's financial, administrative and compliance matters. You must list a PI of the study. There can only be one Columbia PI. When the research is funded by a federal award for which there are MPIs, the contact PI is generally named as the PI on the IRB protocol.

The University limits the eligibility of persons who may serve as PIs. A Columbia Officer of Instruction, with a full-time appointment at the rank of instructor or higher, may serve as a PI. An Officer of Research with a full-time appointment at the rank of Research Scientist/Scholar or higher may also serve as a PI. All ranks of Lamont Research Professors are eligible to serve as PIs.

Those individuals who do not hold appointments in one of the above ranks may act as a co-investigator on a project, but may not serve as a sole PI unless they receive approval from the Chair of their department and/or the Dean (or equivalent officer) of their School, as well as approval from the applicable Institutional Official. The University's procedures for obtaining a waiver are described in the Sponsored Projects Handbook at https://research.columbia.edu/pi-eligibility-sponsored-projects.

The five Roles of Personnel on the Protocol are defined as follows:

Principal Investigator:
The individual who has the primary responsibility to direct the project. In addition to their academic and scholarly duties, the PI has managerial and oversight responsibilities for the administrative aspects of a project.

Investigator:
An individual involved with the scientific development, execution and/or reporting of a project or a part of a project. An Investigator typically devotes a specified percentage of time to the project and is considered part of the project leadership team.

Coordinator:
An individual who works closely with the PI to organize and manage the conduct of a study. They may be involved in preparing study materials, screening subjects, managing proposal submissions, preparing reports, and/or managing IRB protocol approvals, etc. Note that because study coordinators are frequently responsible for obtaining informed consent and supervising other conduct of research, they are presumed to be investigators on projects funded by the U.S. Public Health Service.

Other Engaged Personnel:
Study personnel who are not investigators or coordinators, and who are responsible for the design, conduct, or reporting of the research (i.e., who are sufficiently independent to be in a position to influence the design, conduct, or results of the research). Examples: some biostatisticians, technicians who interact with subjects or have access to identifiable data, or, rarely,consultants. .

Non-Engaged Personnel:
Study personnel other than investigators or coordinators, e.g., individuals who act in a purely advisory, technical, or advisory role, or who are not sufficiently independent to be in a position to influence the design, conduct or results of the research, and are not engaged in the research, i.e., do not interact with human subjects, do not have contact with identifiable private subject data, and do not obtain informed consent. Examples: some technicians, some statisticians, Departmental Administrators.

Note: Individuals who are not part of the study team and are providing a service that would also be performed outside of the research context, e.g., phlebotomists or x-ray technicians, would not be considered to be engaged in the research and would not have to be listed.

Guidance issued in 2008 by OHRP (**Engagement of Institutions in Human Subject Research**) states in part, that, in general, an institution is considered **engaged in** a particular non-exempt human subjects research project when its employees or agents for the purposes of the research project obtain:

- Data about the subjects of the research through intervention or interaction with them;
- Identifiable private information about the subjects of the research; or
- The informed consent of the subjects of the research.

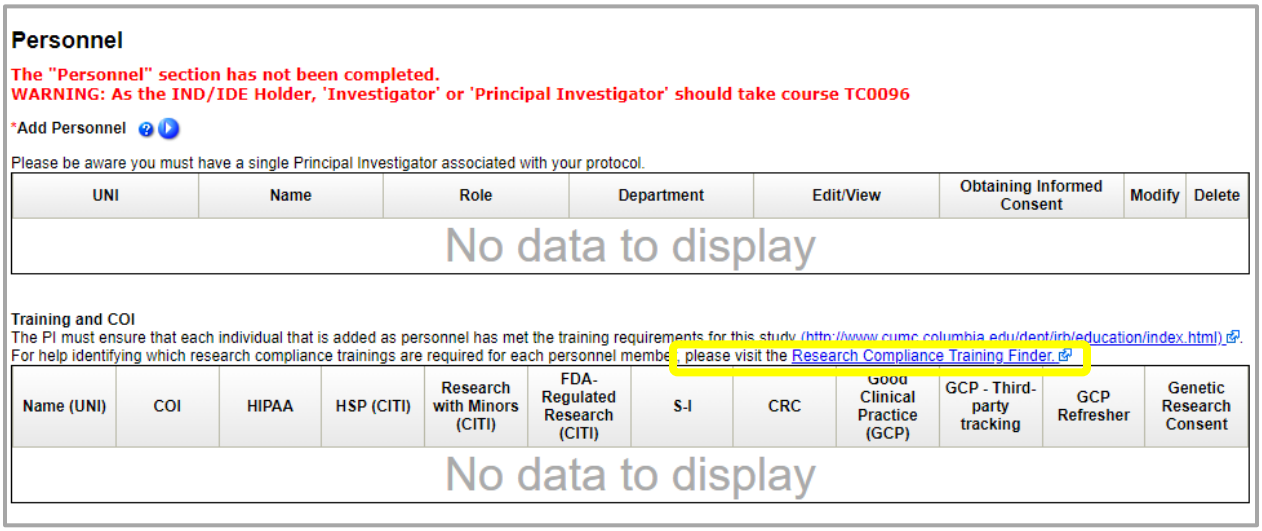
Accordingly, individuals who are involved as described above are considered to be engaged in research. The 2008 OHRP Guidance includes examples of activities by individuals or institutions that would constitute engagement in research.

Important: Individuals who are not affiliated with Columbia and do not hold UNIs should not be listed in the Personnel section. Note that Teachers College and Barnard College personnel are not considered to be affiliates of Columbia for IRB purposes. Individuals that are engaged in human subjects research and are affiliated with an insititution or organization that has an IRB or local ethics board should receive approval for their conduct of research from their respective IRB. Unique situations may require consultation with the HRPO prior to submission.

Training and Conflicts of Interest (COI)

When an individual is added in the **Add Personnel** section, the same individual will automatically appear under the **Training and COI** section of the Rascal application with their completed training courses.

Any individual participating in a human subjects research study must take the training courses that are appropriate for their Role on the project. The PI must ensure that each individual has met the required training requirements for the study. For help identifying which research trainings each personnel may be required to complete, go to the Research Compliance Training Finder.



The following Rascal online courses are mandatory for Personnel conducting human subjects research, based on the Role or job title of the person, and are listed at the top of the **Training and COI** box:

- Human Subjects Protection: **Rascal Course TC0087** for all human subjects researchers, including staff, students and postdocs.
    - Research with Minors and FDA-regulated Research are elective courses within TC0087, which should be completed, respectively, if the study will involve minors as subjects or their data and/or specimens, or involves FDA-regulated products (i.e., drug, device, biologic).

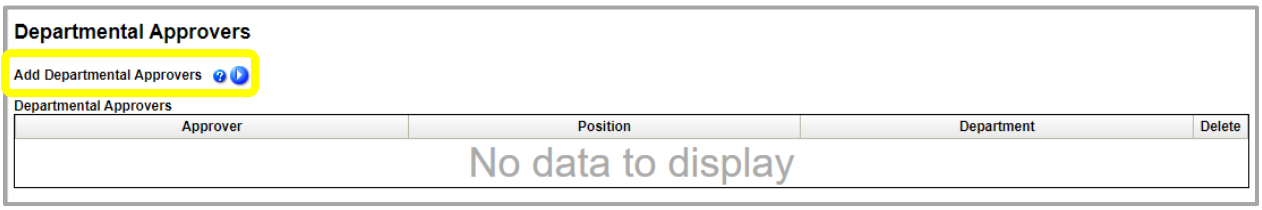
- Privacy and Security (HIPAA): **Rascal Course TC0019** for all engaged personnel listed on Protocols originating from the CUIMC campus.
- FDA Sponsor Investigator: **Rascal Course TC0096** for all Columbia faculty members who hold an IND or an IDE.
- Clinical Research: **Rascal Course TC0098** for all research personnel who are involved in work with human subjects or collection and maintenance of study data. This training is mandatory for individuals who participate in clinical human subjects research that involves more than minimal risk.
- Genetic Research: **Rascal Course TC3700** for coordinators who are involved in obtaining informed consent from research subjects who will undergo genetic testing (as defined by NYS Civil Rights Law Section 79-l,) when the results of the testing will be returned to subjects.
- Good Clinical Practice Training: **Rascal Course TC3450** for all investigators and clinical research staff who are involved in NIH-funded clinical trials.
    - A refresher course, **Rascal Course TC3452**, must be taken every three years.
- Financial Conflicts of Interest: **Rascal Course TC1450** for all investigators funded by the Public Health Service.

All study personnel must submit an annual COI report by logging into Rascal and clicking the link **Conflict of Interest** and recording any disclosures. As personnel are added, the Training section will highlight in red the Personnel who have not completed the annual COI disclosure. The PI is responsible for ensuring that such COI disclosure is completed.

The IRB cannot approve the participation in research of personnel who have not satisfied training requirements.

Departmental Approvers

Click on the blue arrow icon  to enter approvers' information.

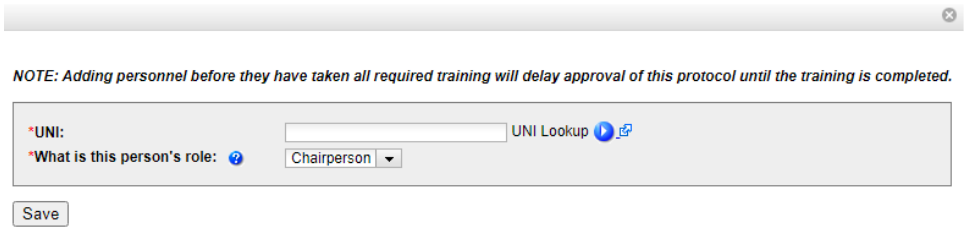


The above screenshot displays the information that must be provided for each approver. Departmental Approvers will be notified to approve the protocol when the **Notify Approvers** option from the left menu is selected, when the protocol is ready for submission. Check with the PI's Department to determine if a Departmental, Division or School Approver is required.

Important:

1. If the PI's Department, Division, or School requires an approval prior to submitting the Protocol (e.g., Pediatrics, Dental, or Emergency Department), this option allows for the designation of the person who must sign off.
2. **If the approval signatures are not complete, you will not be able to submit the Protocol.**

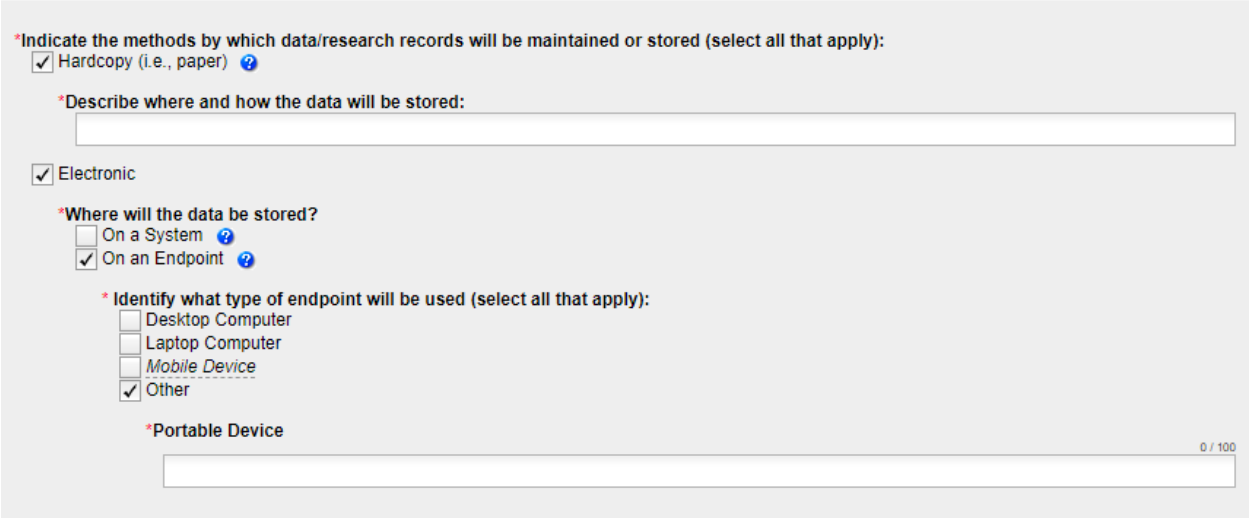
Field 2: What is this person's role



Each approver must be assigned a **Role.** There are five Roles: **Chairperson, Dean, Department Administrator, Director, Division Administrator, and Other.**

SECTION 8: PRIVACY & DATA SECURITY

Field 1: Indicate the methods by which data/research records will be maintained or stored (select all that apply):

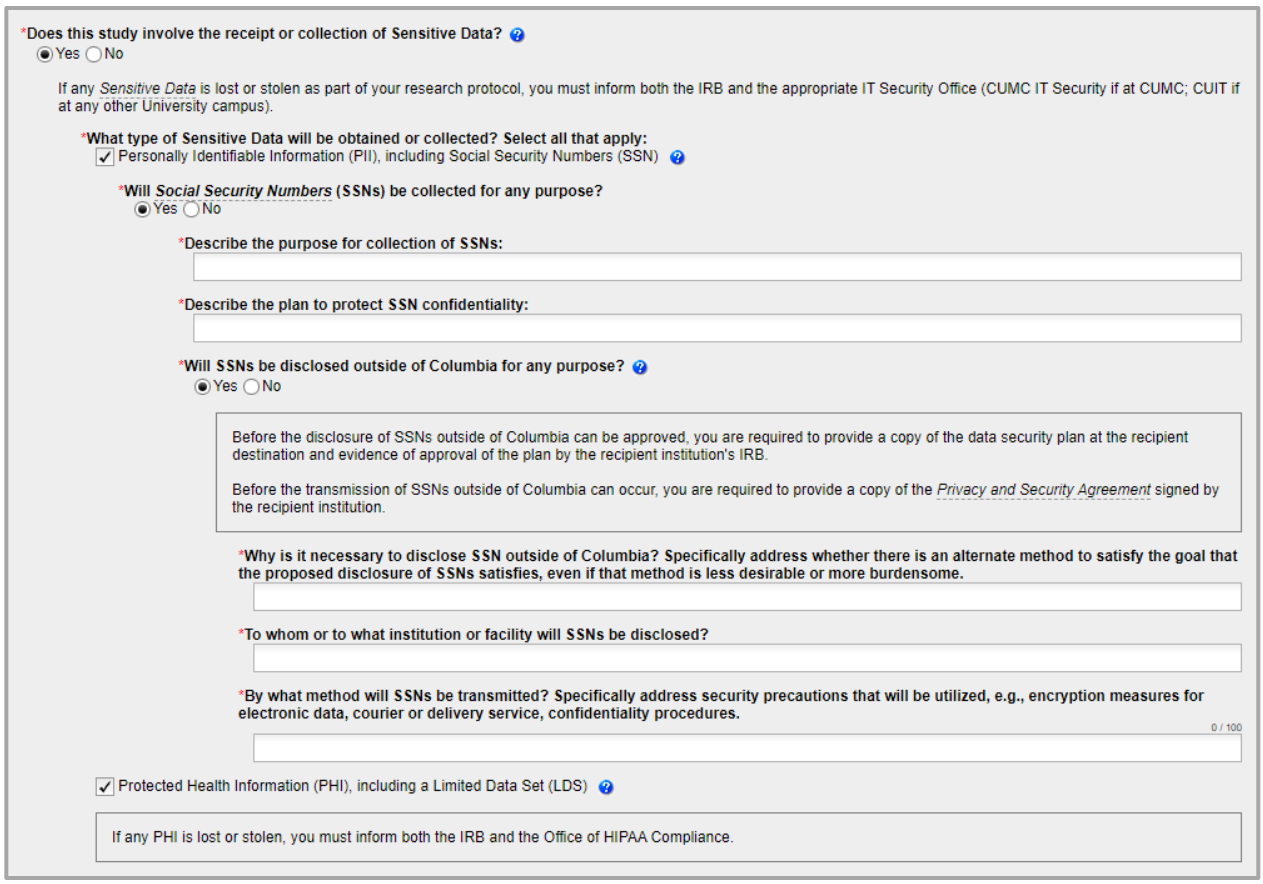


- Select **HARDCOPY** if some or all of your data will be maintained or stored using paper, such as printed forms or physical copies. In the provided text box, describe the physical location and protections in place to secure the documents, such as a locked cabinet, and who will have access to the location.
- Select **ELECTRONIC** if some or all of your data will be maintained or stored electronically, such as in an endpoint device, a multi-user system or an electronic data capture (**EDC**) system. If you select this option, additional required fields will appear, such as **Where will the data be stored?**

    - Select **ON A SYSTEM** if your study is using multi-user, server-based software (e.g. RedCap, Velos, O: Drive, P: Drive, LabArchives, OneDrive, etc.) that resides on a single server or multiple servers and is used for University purposes.
    - Select **ON AN ENDPOINT** if your study is using an endpoint device. An **Endpoint** is any desktop, laptop, or mobile device (smart phone, tablet, or USB/removable drive) used to connect to the University wireless or wired network, access Columbia email from any local or remote location or access any institutional (Columbia, NYP, department or individual) system either owned by the University or by an individual and used for University purposes.

      If you select this option, additional required fields will appear, such as **Identify what type of endpoint will be used**. The four choices are: **Desktop Computer**, **Laptop Computer**, **Mobile Device**, and **Other**. If you select **Other**, enter any **Portable Device** in the text box.

Field 2: Does this study involve the receipt or collection of Sensitive Data?



Definitions:

Sensitive Data is defined in the Columbia University Data Classification Policy as any information protected by federal, state and local laws and regulations such as HIPAA, HITECH, FERPA, the NYS Information Security Breach and Notification Act, and similar state laws and industry standards such as PCI-DSS. The following are types of Data that would constitute Sensitive Data;

Personally Identifiable Information (PII): Any information about an individual that (1) can be used to distinguish or trace an individual's identity, such as name, date and place of birth, mother's maiden nameor biometric records, (2) is linked or linkable to an individual, such as medical, educational, financial and employment information, which if lost, compromised or disclosed without authorization, could result in harm to that indivicual and (3) is protected by federal, state or local laws and regulations or industry standards. *Examples: Social Security Numbers, credit card numbers, passport numbers.*

Protected Health Information (PHI): Individually Identifiable Health Information that is transmitted or maintained by the Columbia Health Care Component I electronic or any

other form or medium, except (1) as provided iin the definition of Protected Health Information in Section 160.103 of the HIPAA Privacy Rule and (2) Research Health Information.
Examples: information in a patient's medical record.

Research Health Information (RHI): Individually Identifiable Health Information that (1) is created or received in connection with research that does not involve a Covered Transaction or although previously considered PHI, has been received in connection with research pursuant to a valid HIPAA authorization or IRB waiver of HIPAA authorization. *RHI must be stored separately from any repository of PHI, such as medical records.*

Individually Identifiable Information (III): Any information processed, transmitted, or stored that relates to (1) the past, present, or future physical or mental health condition of an individual; (2) the provision of health care to an individual; or (3) the past, present, or future payment for health care and (a) identifies the individual or (b) with respect to which there is a reasonable basis to believe that the information can be used to identify the individual.

- **Select NO** if your proposed project **will not** receive or collect Sensitive Data.
- Select **YES** if your project **will** receive or collect Sensitive Data.

If you selected **YES** you will see the following question:

What type of Sensitive Data will be obtained or collected?

- Select **PERSONALLY IDENTIFIABLE INFORMATION (PII), INCLUDING SOCIAL SECURITY NUMBERS (SSNs)** if your project will collect any type of PII.

If you indicate the collection of Social Security Numbers (**SSN**s) for any purpose, additional required fields will appear (see figure above). Please provide information regarding:

- Why is it necessary to disclosure SSN numbers outside of Columbia?
- To whom or what institution or facility will SSNs be disclosed?
- By what method will SSNs be transmitted?

Tip: If SSNs will be disclosed outside of Columbia, a Privacy and Security Agreement must be obtained. The agreement must, at a minimum, confirm that the recipient agrees to:

1. use the SSNs only for the stated purpose;
2. not release the SSNs to any person or organization without prior written approval by the Columbia IRB;
3. not permit copies of the files to be made;
4. maintain the file(s) containing the SSNs only in the secure environment(s) authorized in the data security plan for the recipient organization's IRB approved protocol for the research;

5. destroy the file(s) containing the SSNs when the research is completed;
6. inform the Columbia IRB and the Columbia PI immediately if there is any security breach of the SSNs.

The Columbia template for the Privacy and Security Agreement is posted on the HRPO website. IRB approval for the Disclosure may not be issued until authorization from the appropriate institutional official has been obtained. This is facilitated by the HRPO staff upon submission in Rascal.

Important: If your study collects Research Health Information, please indicate this using the PII designation, as RHI is not currently a separate option in Rascal.

- Select **PROTECTED HEALTH INFORMATION (PHI), INCLUDING A LIMITED DATA SET (LDS)** if your project will collect any PHI.

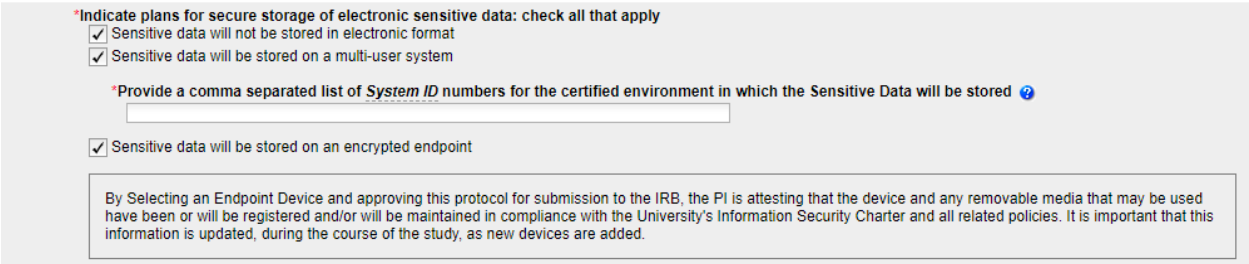
Definition: Limited Data Set is any data set that includes health information that does not contain any HIPAA Identifiers except for the following, to the extent that they are absolutely needed to conduct the research:

- Postal information including zip codes, city, town, and state. The street address may not be included
- Dates, including birth date, admission date, discharge date, date of death
- Ages, including over 89

A Limited Data Set is considered PHI.

The list of HIPAA identifiers can be found in the Columbia University Institutional Review Board Policy on the Privacy Rule and the Use of Health Information in Research.

If you selected **YES** to "Does this study involve the receipt or collection of Sensitive Data", you will see the following question You should select all choices that apply:



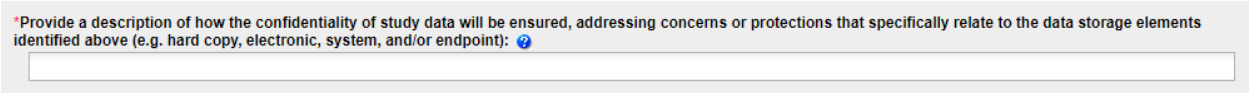
Storage of electronic Sensitive Data on a multi-user System requires that the System (a) be certified by CUIMC IT Security if the research is conducted by anyone affiliated with CUIMC or if PHI is collected, regardless of campus, and (b) the 4-digit certification number (**RSAM number**) entered. Note that the CUIMC "P" drive is certified for storage of Sensitive Data (RSAM #5329).

Please refer to the current RSAM list. If you are working from a remote location, you must log in through VPN to access RSAM.

If electronic Sensitive Data that is limited to RHI or PII will be stored on a multi-user System for CU-MS research, the System must be **registered** in RSAM but is not required to be **certified.**

Note: If Sensitive Data will be stored on an encrypted Endpoint, the PI is attesting that the device will be used in accordance with the Columbia University Information Security Charter and all related policies, particularly the Registration and Protection of Endpoints Policy. The Endpoint devices used should be updated in the list of devices under "Where will the data be stored?"

Field 3: Provide a description of how the confidentiality of study data will be ensured, addressing concerns or protections that specifically relate to the data storage element identified above (e.g., hard copy, electronic, system and/or endpoint)



This description should include the following elements:

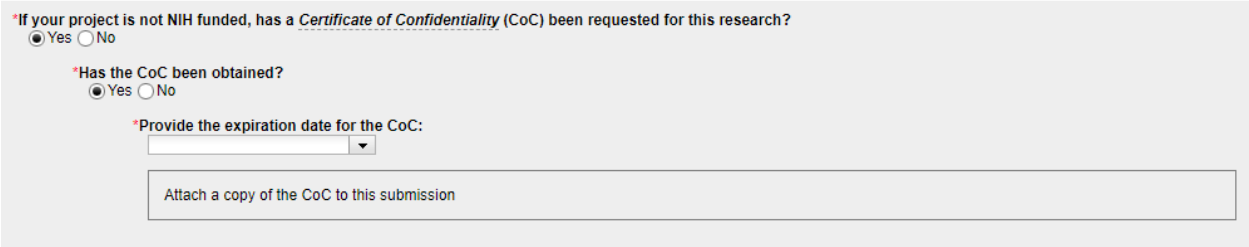
- How the data will be stored and whether or not the data will contain direct or indirect identifiers.
- The protections in place to prevent access to the data that was selected. For example, hard copies will be stored in a locked cabinet or electronic data in a password protected system.

Definitions:

- **Deidentified** means removing from data or a dataset the variables that can directly or indirectly be used to determine the identity of the individual about whom the data were collected.
- **Coded** means that identifying information (e.g., Name, MRN, DOB) is replaced with a number, letter, symbol, or combination thereof (i.e., the code) and a key to decipher the code exists, enabling a linkage of the identifying information to the specimens/data. In the Rascal submission, indicate whom on the research team has access to the key and identifiable data.

Important: Research data that is coded or deidentified is considered identifiable if a member of the research team was involved in the collection or use of the source identifiable data.

Field 4: If your project is not NIH funded, has a Certificate of Confidentiality (CoC) been requested for this research?



Certificates of Confidentiality (**CoCs**) are automatically issued by the NIH and the CDC for human subjects research that will collect or use identifiable, sensitive information (Covered Research) if the research is funded in whole or in part by the NIH or CDC. In such cases, the researcher does not request a CoC.

A recipient of a CoC may not, with certain exceptions,

- Disclose the identity of an individual in any civil, criminal, administrative, legislative or other proceeding, or
- Disclose the name of an individual or any identifiable, sensitive information to any person not connected with the research.

The NIH will also consider requests for a CoC for research that is funded by a non-HHS federal agency, or is not federally funded. The IRB may require the PI to apply for one or the PI can independently make that assessment.

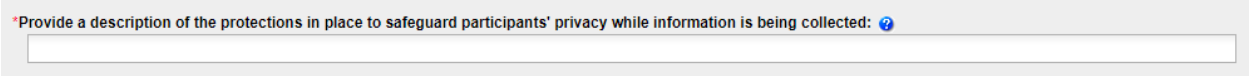
If the research is funded by a federal agency other than the NIH or CDC and the research obtains identifying information of a sensitive nature, the disclosure of which would harm the subject in the ways described above under the definition of PII, then the investigator must apply to either NIH or another federal agency that issues CoCs, such as the Department of Justice, for a CoC.

Select YES, if there is a CoC as a result of a request, and provide the expiration date of the CoC in the drop-down menu.

Note: If CoC is automatically issued, the above question should be answered, "No".

Note: In order to submit a CoC application, the consent form must include the required CoC language. Please update the consent form/information sheet to include details regarding the protections/limitations of the CoC. See the following NIH template language and incorporate the CoC elements into your consent document:

Field 5: Provide a description of the protections in place to safeguard participants' privacy while information is being collected:



Describe how subject privacy will be protected, and the limits to protection in the provided text box. This description should include:

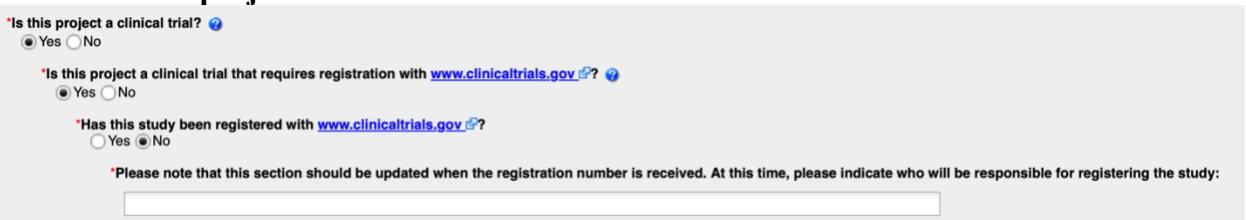
- Situations in which there is the potential for privacy to be compromised such as discussions about research participation, screening activities, forums such as focus groups (in person or video conference) where private information may be shared, study visits (in person or remote), or recordings of research activities. Protections may include having discussions and performing screening activities in a private area, cautioning focus group participants not to disclose information shared with the group and not using names if research procedures are being recorded.
- Limitations such as for compelled disclosure and mandatory reporting.

SECTION 9: PROCEDURES

Identify procedures (invasive or non-invasive), drugs, study instruments such as surveys, interview guides and questionnaires, or tests involved in this project that are used solely for research purposes (and, for clinical research, not for medical care only).

Important: If you select **YES** to any of the procedures below, the left-hand menu will display additional required fields to provide detailed information relating to the research procedures. These pages will not be generated until you select SAVE at the bottom of the page.

Field 1: Is this project a clinical trial?



Definition: A **clinical trial** is a biomedical or behavioral research study of human subjects designed to answer specific questions about biomedical or behavioral interventions (drugs, treatments, devices or new ways of using known drugs, treatments or devices). Clinical trials are used to determine whether new biomedical or behavioral interventions are safe and effective.

- Select **NO** if your proposed project **does not** meet the definition of clinical trial
- Select **YES** if your proposed project **does** meet the definition of clinical trial

If you selected **YES,** the following question will appear:

Is this project a clinical trial that requires registration with www.clinicaltrials.gov

Select **NO** if your proposed project does not require registration under the FDA Amendments Act 801 that requires the registration and reporting of information on "applicable clinical trials (ACT)". ACTs and exceptions are described below.

Tip: The following types of studies are generally excluded from the registration and results submission requirements of FDAAA 801. **This is not a complete list**:

- Phase 1 drug trials, including studies in which investigational drugs are used as research tools to explore biological phenomena or disease processes

- Small clinical trials to determine the feasibility of a device or a clinical trial to test prototype devices, where the primary outcome measure relates to feasibility and not to health outcomes
- Trials that do not include drugs, biologics, or devices (such as behavioral interventions)
- Noninterventional (observational) clinical research (such as cohort or case-control studies)
- Trials that were ongoing as of September 27, 2007, and reached the Completion Date before December 26, 2007

- Select **YES** if your proposed project requires registration.

Additional Tips:

The following clinical trials (**Applicable Clinical Trials)** require registration:

- Trials of drugs and biologics: Controlled clinical investigations, other than phase 1 clinical investigations of drugs or biological products subject to FDA regulation
- Trials of devices:
    - Controlled trials with health outcomes of devices subject to FDA regulation, other than small feasibility studies, and
    - Pediatric post-market surveillance of a device product required by the FDA

Applicable Clinical Trials generally include interventional studies (with one or more arms) of FDA-regulated drugs, biological products, or devices that meet one of the following conditions:

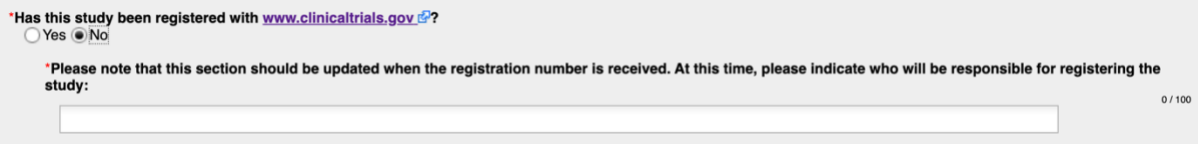
- The trial has one or more sites in the United States
- The trial is conducted under an FDA investigational new drug application or investigational device exemption
- The trial involves a drug, biologic, or device that is manufactured in the United States or its territories and is exported for research

Important: The NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information requires that all clinical trials funded in whole or part by the NIH, regardless of the study phase or type of intervention, be registered in ClinicalTrials.gov. Included in this definition are Phase 1 trials of drug and biological products, small feasibility studies of device products and clinical trials of behavioral, surgical, and other types of health and medical interventions. The 2016 NIH Policy only applies to NIH-funded clinical trials initiated on after January 18, 2017.

Tip: For a description of ClinicalTrials.gov, see **Initiating a Study**: **ClinicalTrials.gov** in the Clinical Research Handbook and What is ClinicalTrials.gov and Who Uses It?

If you selected **YES** to the question as to required registration, the following question will appear, **Has this study been registered with www.clinicaltrials.gov?**

- Select **YES** if the proposed project has been registered. Enter the National Clinical Trial (**NCT)** number that was assigned after the protocol information was released on the Protocol Registration and Results System (**PRS**) and passed review by the ClinicalTrials.gov staff. The number consists of NCT followed by an 8-digit number (i.e., NCT00000419).
- Select **NO** if the proposed project has not yet been registered. You will be asked to indicate who will be responsible for registering the study (see below). The responsible party is designated as the Sponsor, or the Principal Investigator as designated by the Sponsor.



Important: According to the September 2016 Final Rule on Clinical Trials Registration and Results Information Submission (42 CFR Part 11), and the requirements of FDAAA 801, the responsible party must register an applicable clinical trial no later than 21 calendar days after enrolling the first human subject. Criminal actions, civil monetary penalty actions, and grant funding actions may be taken because of responsible parties' failure to comply with 42 CFR Part 11 or FDAAA801. There may also be additional publishing restrictions imposed by the (International Committee of Medical Journal Editors (ICMJE) for NIH or industry sponsored projects if registration on ClincialTrials.gov is not completed prior to enrollment of the first subject. It is recommended that registration of the Protocol occur before subject enrollment begins.

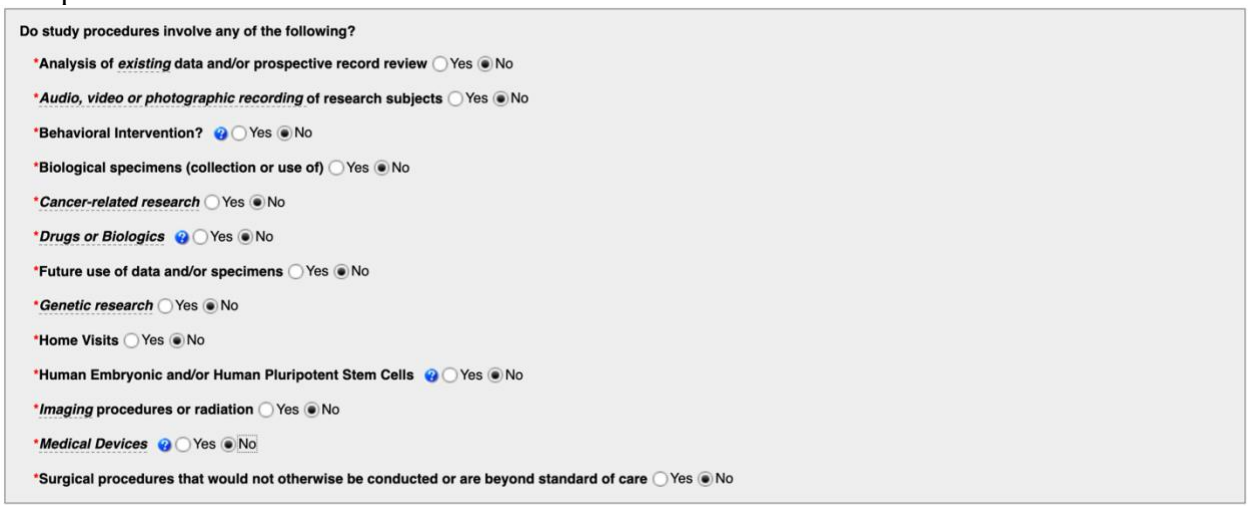
Field 2: Is this project associated with, or an extension of, an existing Rascal protocol?

This is relevant if the source of participant recruitment, data and/or samples is an existing study approved by the Columbia IRB or an IRB to which Columbia has ceded review.

- Select **YES** if this study is associated with, or an extension of, an already existing Rascal Protocol. You will be asked to provide the existing Rascal protocol numbers. At least one should be entered.
- Select **NO** if this study is not associated with, or an extension of, an already existing Rascal protocol.

Field 3: Do study procedures involve any of the following?

You will see the following activities listed. Be sure to select **all** of the study procedures that will take place.



Analysis of existing data and/or prospective record review

- Select **YES** if you will collect any individual-level data or documents. **Once saved, a new page will be generated. See Section 9D below.**
- Select **NO** if this does not apply.

Definition:

Existing data are defined as: data that exist at the time of the Protocol is submitted to the IRB.

Prospective data are defined as: data that will be created after the Protocol is submitted to the IRB.

Tip: Data generated from the submitted research study does not apply to this page. Prospectively generated data refers to the collection of data generated outside of the research and after the Protocol is submitted.

Audio, video or photographic recording of research subjects

- Select **YES** if the research involves audio, video or photographic recording of research subject. If so, certain element must be included in the Data and Security section of the Rascal Submission and the Informed Consent Form. See the Columbia University IRB Recording of Human Subjects Policy for additional information.
- Select **NO** if this does not apply.

Behavioral intervention

Definition:

An **Intervention** is defined as a manipulation of the subject or subject's environment for the purpose of modifying one or more health-related processes and/or endpoints.

Examples: drugs/small molecules/compounds, biologics, devices; procedures (e.g., surgical techniques); delivery systems (e.g., telemedicine, face-to-face); strategies to change health-related behavior (e.g., diet, cognitive therapy, exercise, development of new habits); and treatment, prevention, and diagnostic strategies.

A **Health-related Biomedical or Behavioral Outcome** is defined as the pre-specified effect of an intervention on the study subjects.

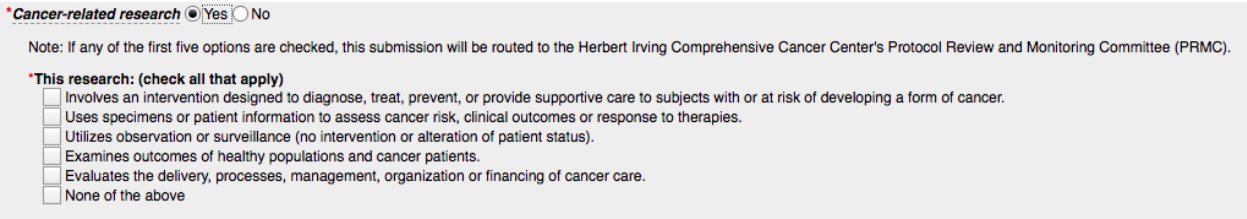
Examples: positive or negative changes to physiological or biological parameters (e.g., improvement of lung capacity, gene expression); positive or negative changes to psychological or neurodevelopmental parameters (e.g., mood management intervention for smokers; reading comprehension and/or information retention); disease processes; health-related behavior and well-being or quality of life.

- Select **YES** if your proposed study includes behavioral interventions.
- Select **NO** if this does not apply.

Biological specimens (collection or use of)

- Select **YES** if biological specimens will be collected or used. **Once saved, a new page will be generated. See Section 9A.**
- Select **NO** if this does not apply.

Cancer-related research



- Select **YES** if the proposed project is cancer-related research. Once selected, a series of questions will appear (see above). If you check any of the first five boxes, the Protocol will be routed to the Herbert Irving Comprehensive Cancer Center's Protocol Review and Monitoring Committee (**PRMC**). **All cancer related protocols must obtain the approval of the PRMC prior to IRB approval.**
- Select **NO** if this does not apply.

Drugs or Biologics

Definitions:

A **Drug** is defined by the FDA as (a) substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease or (b) a substance (other than food) intended to affect the structure or any function of the body.

Biologics include a wide range of products such as vaccines, blood and blood components, allergenics, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins. Biologics are obtained from a variety of natural sources – human, animal, or microorganism – and may also be produced by biotechnology methods.

- Select **YES** if you anticipate the use of either Drugs or Biologics that will be administered as the object of the Protocol or because it is relevant to the aims of the Protocol. This applies whether the Drug or Biologic is not yet FDA-approved (i.e., is investigational), is FDA approved and used in accordance with its labeling or is an approved product that is being used in an investigational manner (i.e., off-label use is being studied). **Once saved, a new page will be generated. See Section 9C.**
- Select **NO** if this does not apply.

Future use of data and/or specimens

- Select **YES** if data and/or specimens will be shared for future uses outside of the current research aim described in the Protocol, either within or outside of Columbia (including pursuant to other IRB protocols) or outside of CU. **Once saved, a new page will be generated. See Section 9D below.**

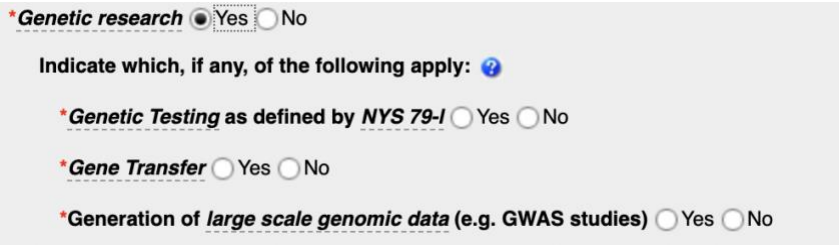
- Select **NO** if this does not apply.

Genetic research

Definition: Genetic Research is the study of human study of genes and their roles in inheritance - in other words, the way that certain traits or conditions are passed down from one generation to another.

- Select **YES** if the proposed project involves genetic research as defined in the above text box.

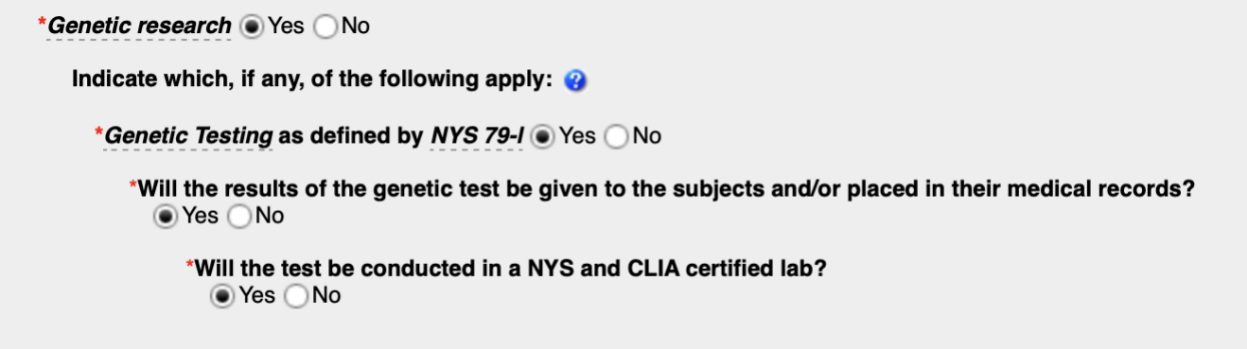
If you **select YES,** the following questions will appear:



Indicate which, if any, of the following apply:

***Genetic Testing* as defined by NYS 79-L**
Section 79-L of the New York State Civil Rights Law was enacted in 1996 to provide asymptomatic individuals with sufficient information to assess the benefits and consequences of predispositional testing. Unlike diagnostic genetic tests that confirm the presence or absence of a disease, predispositional genetic tests cannot predict with certainty the risk of developing a disease. Section 79-L provides that a genetic test may not be performed on any biological sample taken from an individual without their prior written informed consent that meets certain strict disclosure standards. Under Section 79-L, a **Genetic Test** is defined **only** as a laboratory test conducted to learn whether an asymptomatic person or their offspring has a genetic predisposition to a disease or disability.

Note: See the Columbia University Policy on Research Involving Genetic Testing under Section 79-L of the New York State Civil Rights Law and the Research Requirements for Informed Consent Decision Tree.



If you **selected YES** to *Genetic Testing* as defined by NYS 79-L, the following question will appear:
Will the result of the Genetic Test be given to the subjects and/or placed in their medical records?

- **Select NO** if the result of the Genetic Test will not be provided to subjects and/or placed in their medical records.
- Select **YES** if the results of the Genetic Test will be given to participants and/or placed in their medical record. Results of genetic tests may only be returned to a participant whose informed consent included the elements described in **Working with Study Subjects: Informed Consent: Other Consents-Genetic Research** in the **Clinical Research Handbook.**

If you selected **YES**, the following question will appear:
Will the Test be conducted in a NYS and CLIA certified lab?

- **Select NO** if the Test will not be conducted in a lab that is certified to provide results to patients, i.e., CLEP certified in NYS and CLIA certified elsewhere.
- **Select YES** if the Test will be conducted in a lab that is certified to provide results to patients, i.e., CLEP certified in NYS and CLIA certified elsewhere.

Important: It is University policy that if the results of a Genetic Test will be provided to a research subject, the results must be confirmed by a CLIA or NYS-certified laboratory, as applicable, prior to being released.

Gene Transfer

Definition: Human gene transfer involves the deliberate transfer of rDNA or DNA or RNA derived from rDNA into one or more human research participants. The use of recombinant and synthetic nucleic acids (**rDNA)** is regulated by the NIH and the NIH Guidelines on rDNA specifies different requirements for approval and registration prior to initiating work with rDNA. See, generally, **Biological Safety: Biological Materials Research** and **Biological Materials Research: Registrations and Authorizations** in the **Research Environmental Health and Safety Handbook.**

Prior to commencing any research involving human gene transfer, you must complete and submit to the Institutional Biosafety Committee (**IBC)** Hazardous Materials Appendix M:

Institutional Biosafety Committee Application for the use of Recombinant DNA (**rDNA)** Molecules in Human Gene Transfer concurrently with IRB review of your application.

Generation of Large-Scale Genomic Data (e.g., GWAS studies)
Large scale genomic data include genome-wide association studies (**GWAS**), single nucleotide polymorphisms (**SNP**) arrays, and genome sequence, transcriptomic, metagenomic, epigenomic, and gene expression data.
There are additional requirements for studies that involve large scale genomic data and are NIH funded.

Note: If your study is NIH-funded and will generate large scale human or non-human genomic data from more than 100 individuals as well as the use of these data for subsequent research, OR you are planning to submit genotype/phenotype data to one of the NIH-supported repositories, research subjects must be informed in the consent document that their study-related materials will be submitted to public, scientific databases such as the database of genotypes and phenotypes (dbGaP). Please refer to NIH's GDS Policy Sample Informed Consent Language.

***NIH expects that informed consent for future research use and broad data sharing will have been obtained even if the cell lines or clinical specimens are de-identified.**

Home Visits

- Select **YES** if Home Health Visits will be conducted by Columbia personnel, a Home Health Agency, or rarely and for safety reasons only, by a medical device manufacturer. Complete the Home Health Visit checklist and attach it in the Documents section of the Rascal application.
- Select **NO** if this does not apply.

Human Embryonic and/or human pluripotent stem cells

Note: The Columbia University Policy on the Conduct of Research with Human Embryos and Human Pluripotent Stem Cells requires that such research be approved by the University's Human Embryonic and Human Pluripotent Stem Cell Research Committee **(Stem Cell Committee)** prior to review by the IRB of the related protocol. In order to initiate review by the Stem Cell Committee, you should complete a Request for Stem Cell Committee Approval Form and send it to the Vice President for Research Operations and Policy. Please see the Request for Approval form.

- **Select YES** if the research involves human embryos or human pluripotent stem cells.
- Select **NO** if the research involves human cells other than human embryos or human pluripotent stem cells, e.g., fetal tissue or stem cells derived from human adults, umbilical cord blood, placentas or fetuses.

Imaging Procedures or Radiation

- Select **YES** if your protocol involves imaging procedures or radiation. **Once the Procedures page is saved, a new page will be generated. See Section 9F.**
- Select **NO** if this does not apply.

Medical Devices

Definition: A **medical device** is defined as an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part or accessory, that is:

- Recognized in the official National Formulary, or the U.S. Pharmacopoeia, or any supplement thereto;
- Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in humans; or
- Intended to affect the structure or any function of the human body, and that does not achieve its primary intended purposes through chemical action within or on the human body and that is not dependent upon being metabolized for the achievement of any of its primary intended purposes.

Medical Devices range from simple tongue depressors and bedpans to complex programmable pacemakers, and closed loop artificial pancreas systems. Additionally, Medical Devices include in vitro diagnostic (**IVD**) products, such as reagents, test kits, and blood glucose meters. Certain radiation-emitting electronic products that have a medical use or make medical claims are also considered medical devices. Examples of these include diagnostic ultrasound products, x-ray machines and medical lasers. Finally, tools such as genomic sequencing and artificial intelligence models are also considered medical devices when their use meets the criteria of the medical device definition.

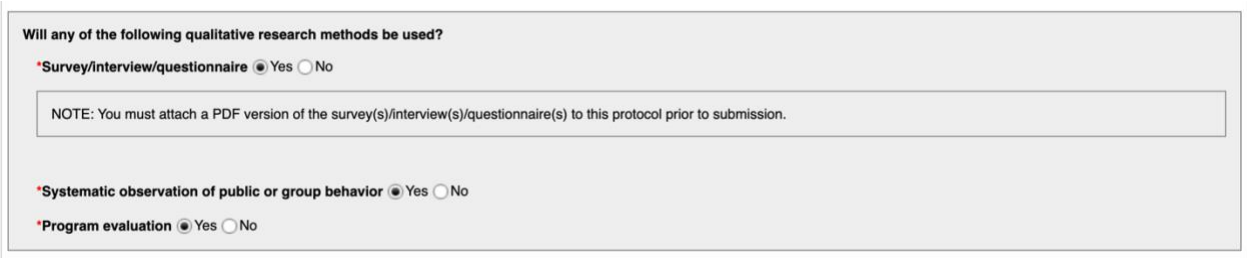
- Select **YES** if **a** Medical Device will be used, administered, implanted, or applied to subjects, as the object of the protocol or because it is relevant to the aims of the protocol. The Device must be listed if the Device is not yet FDA-approved (i.e., investigational) or is FDA-approved and being used in an investigational manner, i.e., off label. **Once saved, a new page will be generated. See Section 9F.**
- Select **NO** if a Medical Device will not be used, administered, implanted or applied to subjects.

Important: In accordance with FDA regulations, **if the ultimate goal** of an assay under development is to diagnose, cure, treat, mitigate, or prevent disease, then once any human specimens are being used, **the investigational device exemption (IDE) regulation (21 CFR Part 812) must be followed.**

Surgical procedures that would not otherwise be conducted or are beyond standard of care

- Select **YES** if surgical procedures are conducted solely for research purposes.
- Select **NO** if this does not apply.

Field 4: Will any of the following qualitative research methods be used?



Survey/interview/questionnaire

- **Select YES** if your proposed project involves a survey, interview, and/or questionnaire distributed for research. A clean, PDF version of the survey, text of the structured or semi-structured interview, and/or questionnaire must be attached in the Documents section under Attachments. If the survey is administered on an electronic platform, such as Qualtrics or REDCap, a copy of the electronic survey should be attached.
- Select **NO** if this does not apply.

Note: If sensitive data will be collected on survey platforms or via interviews on video-conferencing platforms, these platforms must be listed in the Privacy and Data Security page. The System ID #s should be listed to confirm all platforms are certified RSAM systems.

Systematic observation or public or group behavior

- Select **YES** if the proposed project involves a systematic observation or public or group behavior.
- Select **NO** if this does not apply.

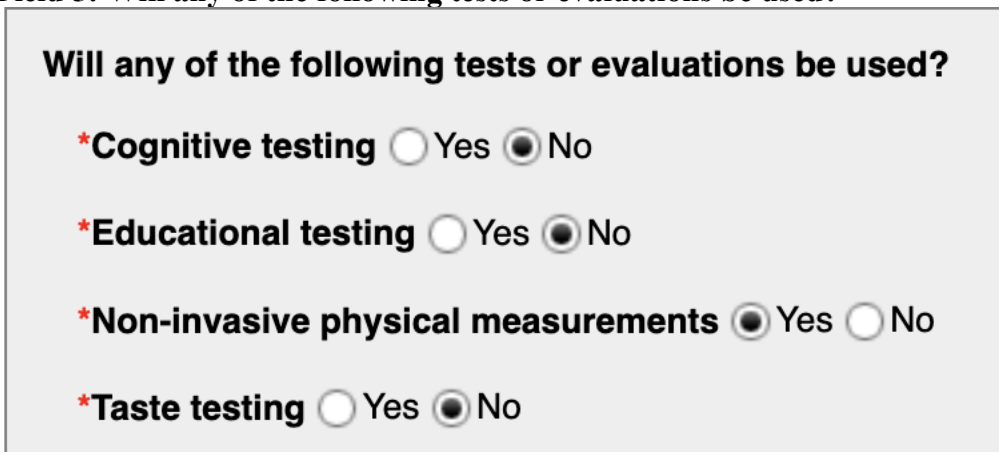
Tip: To determine if observations are public, consider the expectation of privacy of those being observed. For observations in private spaces, authorization or approval to conduct research activities may be required.

Program evaluation

- Select **YES** if the proposed project involves a program evaluation.
- Select **NO** if this does not apply.

Note: If the only research aim is to evaluate a program, your study may constitute a QI/QA project that is not subject to IRB oversight. See the tripartite (Columbia University and Weill Cornell Medicine Institutional Review Board and the Quality and Patient Safety Department at NewYork-Presbyterian) Guidance For the Classification of Quality Improvement Activities Versus Research With Human Subjects.

Field 5: Will any of the following tests or evaluations be used?

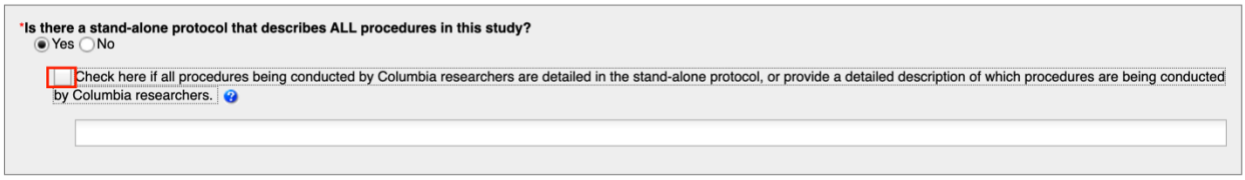


- **Select YES** to any of the above procedures that are involved in your proposed project.
- Select **NO** if these does not apply.

Tip: Non-invasive physical measurements include, but are not limited to, the following:

1. Height
2. Weight
3. Blood Pressure
4. Pulse Ox

Field 6: Is there a stand-alone protocol that describes ALL of the procedures in this study?



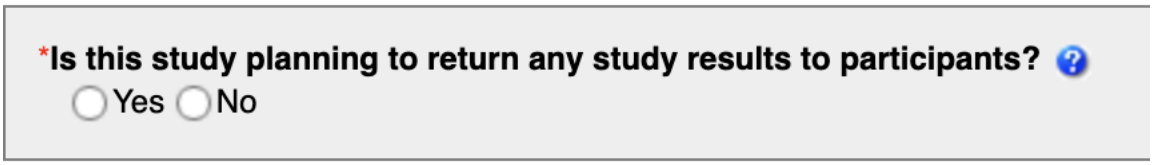
- Select **YES** if the study team has received or created a separate standalone protocol that describes all study procedures conducted by Columbia investigators. Check the box if all procedures being conducted by Columbia researchers are described in the standalone protocol or provide a detailed description of which procedures are being conducted by Columbia researchers.
    - If there are procedures in the standalone protocol that will not be conducted under the auspices of Columbia researchers, those procedures should be described so the IRB review can appropriately focus on the Columbia procedures.
- Select **NO** if there is not a standalone protocol for the proposed study. If so, the details of the procedures must be described using the field text box.
    - Be sure to describe all study procedures in detail, including links to publicly available data and all locations where procedures will take place. **Also, describe any additional procedures that do not fall into the categories listed above.**

Additional Tips:

1. If you selected **YES** to Imaging Procedures and/or Radiation, and (1) the imaging procedures provide anatomic or physiological data and (2) the images are for research purposes only (i.e., beyond standard of care), the images must be read by a credentialed reader, in order to ascertain whether there are incidental findings. In addition, certain additional information must be included in the protocol and consent documents. Use the free text box to include your Incidental Findings plan as required by the Columbia University Institutional Review Board Policy on Incidental Findings from Imaging Procedures Conducted for Research Studies.
2. If you **selected YES** to Survey/interview/questionnaires, and the content involves questions that may result in self-harm and/or harm to others, use the free text box to describe a safety action plan, resources that will be provided, referrals that will be made, or other actions that will be taken. Please ensure that this information is communicated to the participants in the consent form, information sheet, or recruitment material, if applicable.

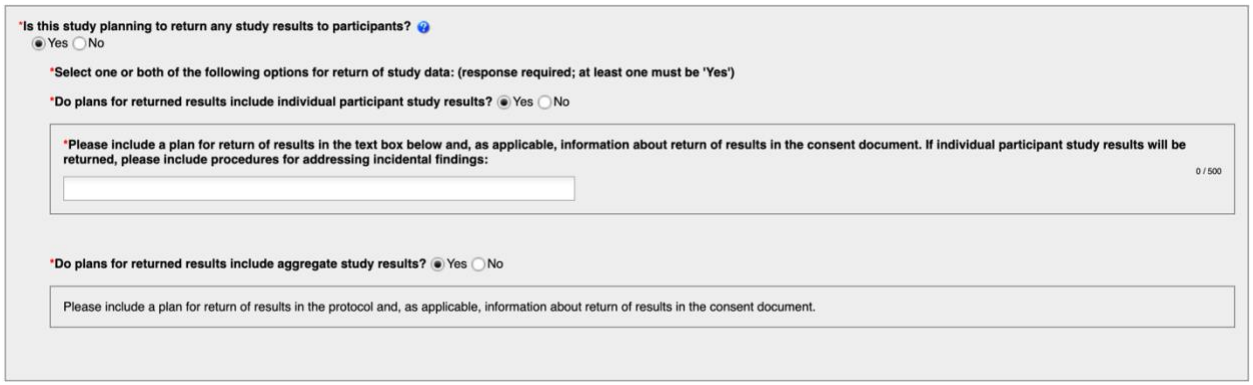
Important: Text that is copied and pasted from a standalone protocol, grant application, or any pdf document can result in distorted text, e.g., special characters, odd spacing, or varied font sizes. Before submitting the protocol, go to **View Datasheet** to ensure that the text is clean to avoid an automatic return of the submission for edits.

Please note that upon completing the Recruitment & Consent page, if your research involves the recruitment of subjects, you will need to come back to this page to answer the following question (this question only populates in Rascal if, on the Recruitment and Consent page, under "Select all methods by which participants will be recruited", a recruitment method selection is made).



Note: Information about return or non-return of results should be noted in the consent form.

If you select **YES**, the following questions will appear (select one or both of the following options; at least one must be **YES**):

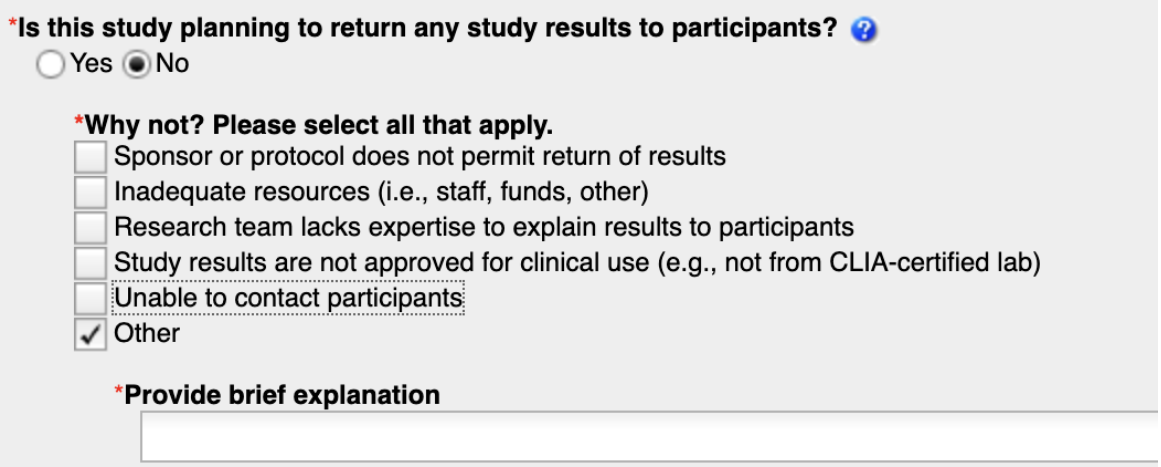


Do plans for returned results include individual participant study results?
If you select **YES,** you will be asked to include a plan for return of results in the text box and, as applicable, information about return of results in the consent document. If individual participant study results will be returned, you must include procedures for addressing incidental findings.
Do plans for returned results include aggregate study results?

- If you select **YES,** you must include a plan for return of results in the protocol and, as applicable, information about return of results in the consent document.

Tip: Individual study results vs. overall results: any results related to a primary and/or secondary study outcome, for individual study participants and/or for the overall study at Columbia or at all sites in a multi-site study. Returned individual results may also include procedures for addressing incidental findings.

If you select **NO**, the following question will appear. If you select **OTHER,** you will be asked to explain further:

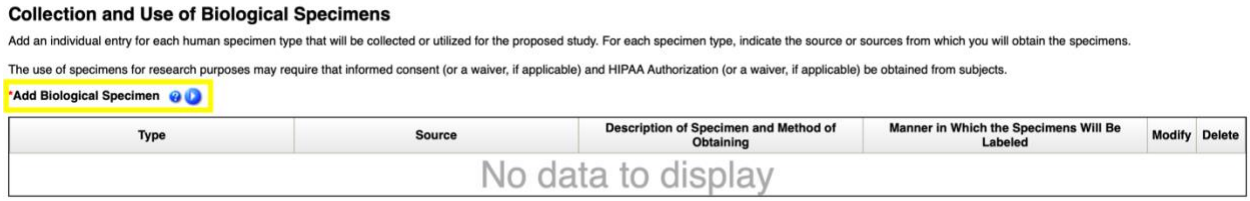


Usual requirements for return of individual level results, e.g., conducted in an appropriately certified lab or confirmed by a medically established test, apply.

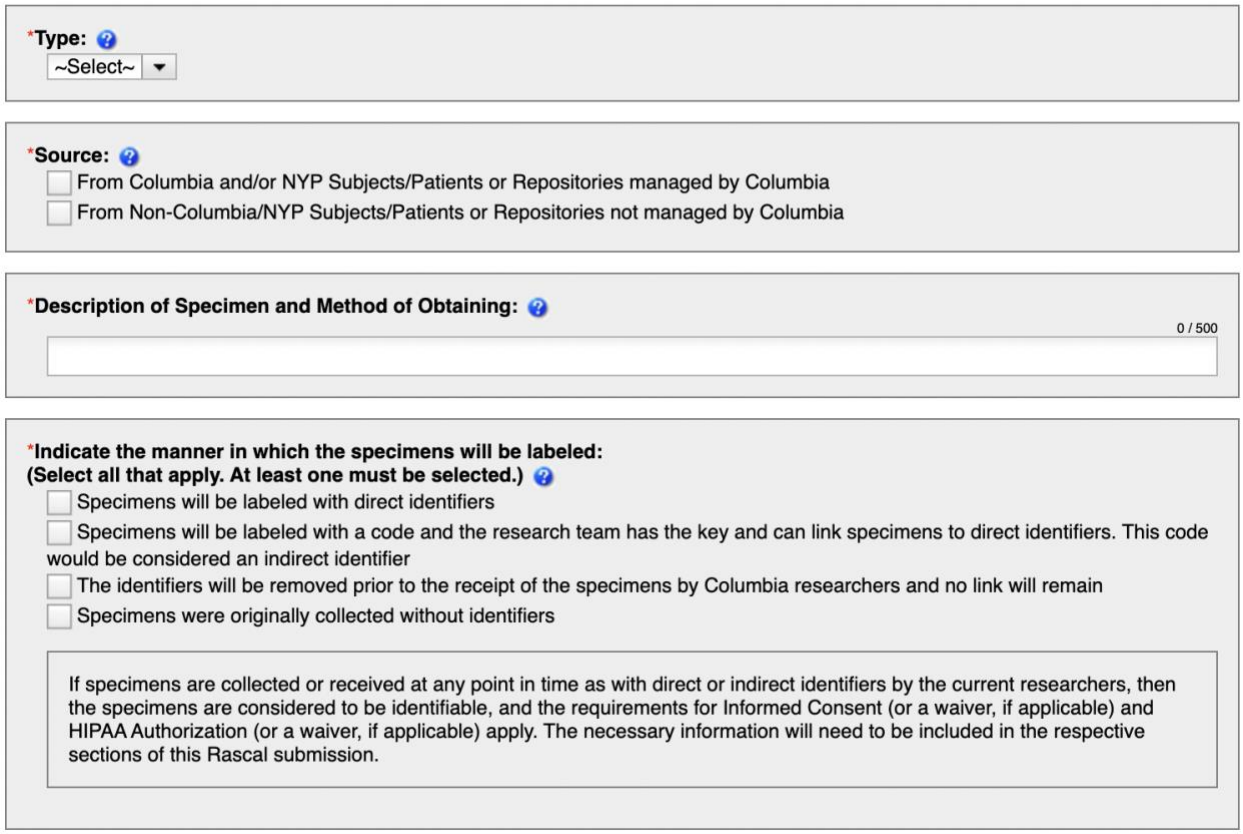
SECTION 9A: BIOLOGICAL SPECIMEN: COLLECTION OR USE OF

If you selected **YES** to the question as to whether biological specimens will be collected or used, a new page will be generated (see below).

Click on the blue arrow icon to enter specimen collection information.



You must add an individual entry for each human specimen type that will be collected or utilized for the proposed study. For each specimen type, indicate the source or sources from which you will obtain the specimens and add the additional information required.



Field 1: Type
Choose the type of human specimen from the drop-down list. The choices are: Cerebrospinal Fluid, Blood, Placenta, Saliva, Stool, Tissue, Urine or Other.

Field 2: Source
You must select at least one source or select all that apply to this specimen type if specimens are being received from multiple sources.

- Select **FROM COLUMBIA AND/OR NYP SUBJECTS/PATIENTS OR REPOSITORIES MANAGED BY COLUMBIA**, if a specimen is obtained from within Columbia or NYP. If you select this designation, the following choices that apply to this specimen type will come up:
    - **Specimens will be prospectively collected specifically for this research**: specimens that are obtained from the consented subject as a study procedure.
    - **Residual specimens from clinical care that would otherwise be discarded have been or will be collected**
    - **Specimens to be analyzed will be (or have been) collected from a commercial source**: if you select this item, you must provide the identity of the owner/provider in the space provided.
    - **Specimens to be analyzed will be (or have been) collected under a separate Columbia IRB-approved protocol: this could be an approved research repository protocol:** if you select this item, you must provide the applicable IRB Protocol Number.

Additional Tips:

- You are required to obtain approval from the Division of Anatomic Pathology **(AP)** when:
    - A research protocol involves a procedure that will obtain or produce, in part or in whole, tissue that will be sent for diagnostic purposes to the Division of AP in the Department of Pathology and Cell Biology (**Pathology)**. Tissue that is maintained by AP and access to use a portion of it for research purposes requires Pathology approval.
    - A research protocol requires the use of any material maintained by the Division of AP (e.g., diagnostic or research formalin-fixed paraffin-embedded **(FFPE**) tissue slides/blocks, fresh tissue, frozen tissue, etc.).

*Most research biopsies should have at least a component (1-3 cores) sent to the Division of AP to confirm the diagnosis (standard of care) and obtain Department of Pathology approval. **In the rare exception when a procedure is performed for research only and specimen(s) will not transit through the Division of AP, Department of Pathology approval is not required (e.g., material normally discarded during a procedure in which no diagnostic tissue is taken). All such instances should be verified by the Division of AP and require email communication and confirmation from the Department of Pathology.**

Note: A request for Pathology approval for a specific research study is documented via the completed Anatomic Pathology Approval form.

- Select **FROM NON-COLUMBIA/NYP SUBJECTS/PATIENTS OR REPOSITORIES NOT MANAGED BY COLUMBIA**, if a specimen is obtained from

outside Columbia or NYP. For this designation, you must list the owner/provider of the samples.

Note: For specimens obtained from outside source(s), additional documentation and authorization, such as a Material Transfer Agreement (**MTA),** may be necessary and should be attached in the DOCUMENTS section if available. If the fully-executed versions are not available, please attach the draft agreements and provide the signed version when available. Sharing may not commence until agreements are fully executed.

Field 3: Description of Specimens and Method of Obtaining
Provide a description of the type of tissue or bodily fluid that you plan to use in the study and information relating to how the specimen will be or has been obtained. For example, "15 ml of blood will be collected through a vein in the arm and an existing IV catheter". Please also include who will be conducting the collection (e.g., research team, commercial source, clinical team, etc.).

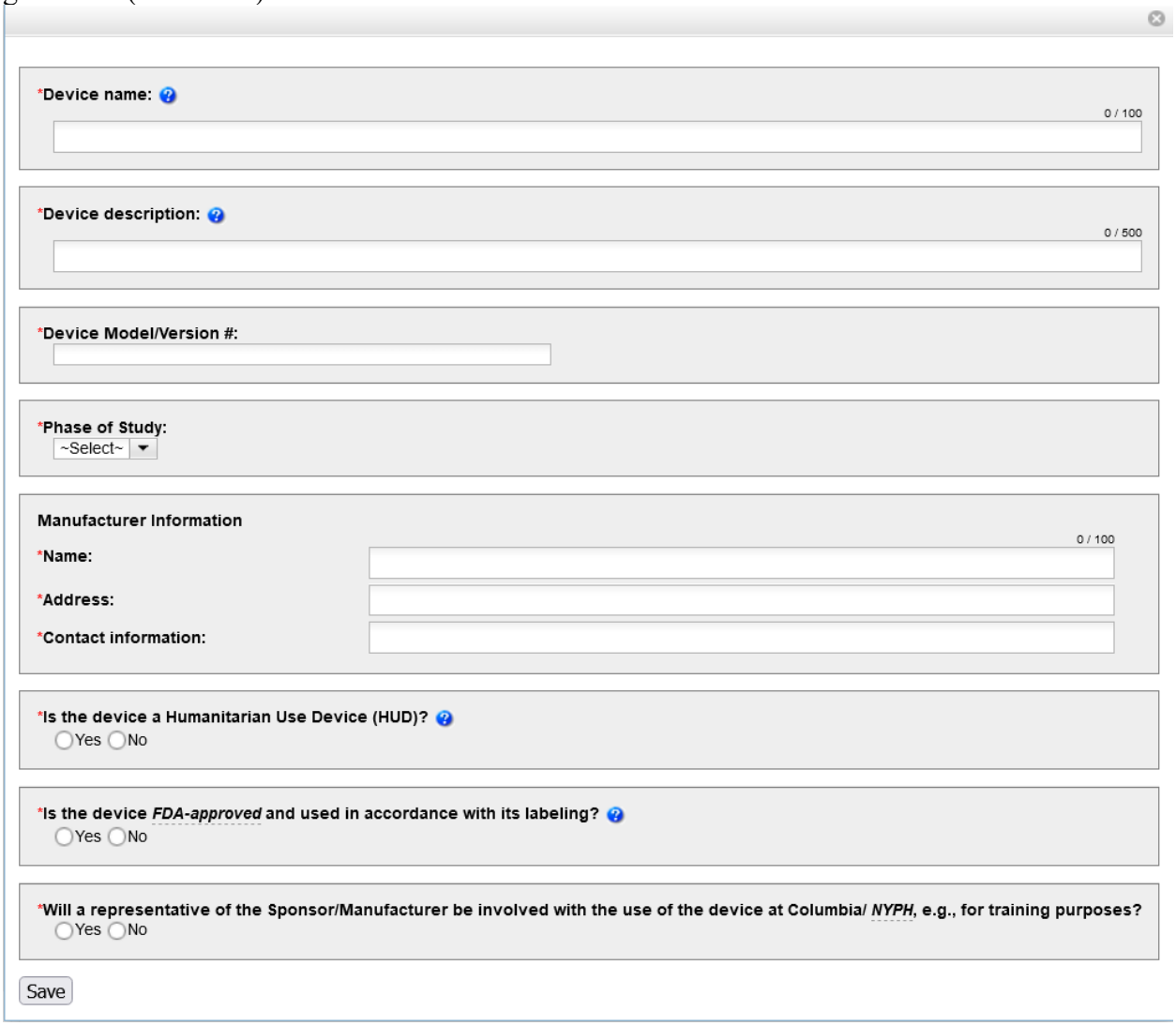
Field 4: Indicate the manner in which the specimens will be labeled.
Select at least one and all that apply. The options listed describe the likelihood of the researcher's ability to use the data to identify the individual from whom the specimen was or will be obtained.

- **Specimens will be labeled with direct identifiers.**
- **Specimens will be labeled with a code and the research team has the key and can link specimens to direct identifiers. This code would be considered an indirect identifier**.
- **The identifiers will be removed prior to the receipt of the specimens by the Columbia researcher and no link will remain:** if you select this item, you must list who is removing the identifiers.
- **Specimens were originally collected without identifiers.**

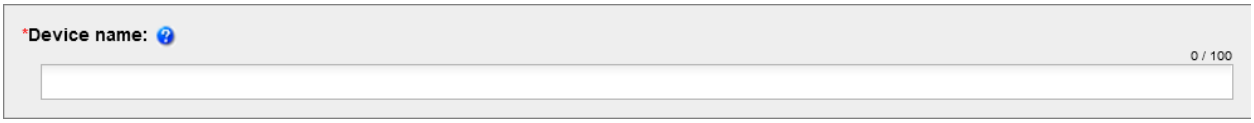
Important: If the first two options are selected, the specimens are considered identifiable and the requirements for Informed Consent and HIPAA Authorization apply, unless a waiver is approved by the IRB. Specific criteria must be met for a waiver to be issued by the IRB. The information that the IRB needs to assess the applicability of a waiver is provided under the Section 10: Recruitment and Consent.

SECTION 9B: DEVICES

If you selected **YES** to the question as to whether devices will be used, a new page will be generated (see below).



Field 1: Device name



Provide the commercial name for the device, if marketed, then name on the IDE, or the name that is being used for research purposes if there is no FDA-issued IDE.

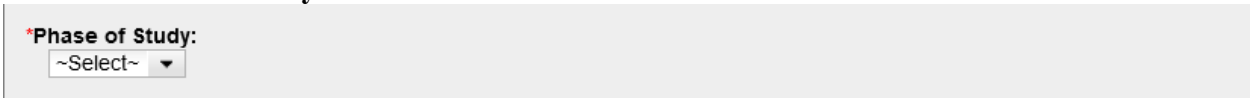
Field 2: Device description

Provide a brief description of the device and include factors such as whether this is a novel device or an iteration of an existing device.

Field 3: Device Model/Version

List the device model or version number.

Field 4: Phase of Study

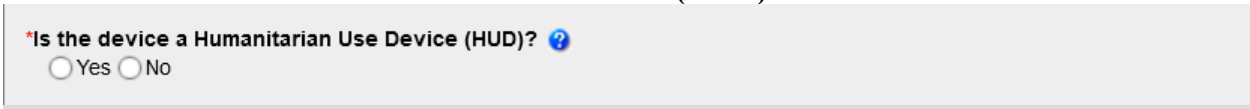


Pick one of the following: Feasibility, Pilot, Pivotal or Other

Field 5: Manufacturer Information

Provide the Name, Address and Contact Information of the Manufacturer.

Field 6: Is the device a Humanitarian Use Device (HUD)?



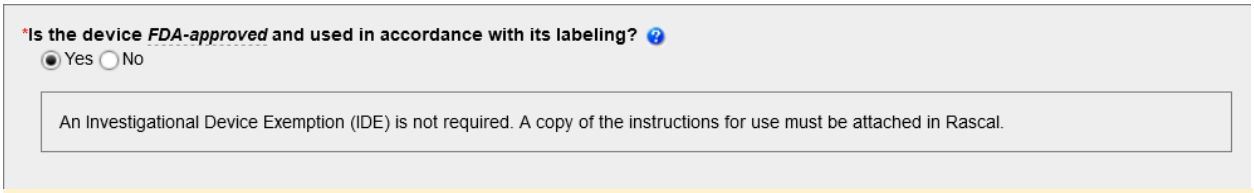
Definition: As defined in 21 CFR 814.3(n), a **HUD** is a medical device intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in fewer than 8,000 individuals in the United States.

- Select **YES** if the device is a humanitarian use device.
- Select **NO** if the device is not a humanitarian use device.

Field 7: Is the device *FDA-approved* and used in accordance with its labeling?

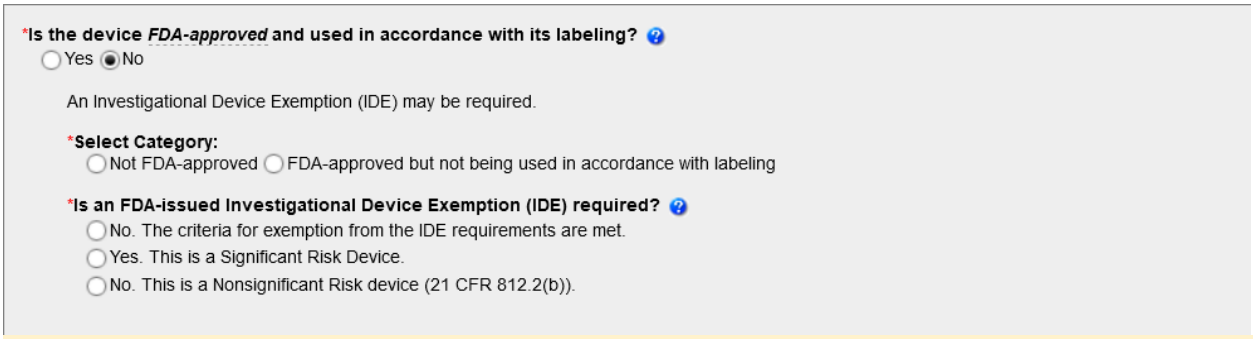
A device is FDA-approved if it has received FDA clearance for marketing (a) through a Premarket Approval (for high risk devices), a De Novo Classification Request (for low to moderate risk devices when there is no legally marketed predicate device) or a Premarket Notification under Section 510(k) of the Food, Drug and Cosmetic Act (for low to moderate risk devices when there is a legally marketed predicate device) or (b) through the issuance of a Humanitarian Device Exemption (**HDE**) which exempts a device from the effectiveness requirements for premarket approval.

- Select **YES** if the device is FDA-approved and used in accordance with its labeling.



Note: An IDE is not required, but a copy of the instructions for use must be attached in the Documents section of Rascal.

- Select **NO** if the device is not FDA-approved or if it is FDA-approved but is not used in accordance with its labeling.



Note: An IDE may be required. Columbia researchers may want to consult the CTO IND/IDE Assistance Program for advice.

Field 7a: **Select Category**

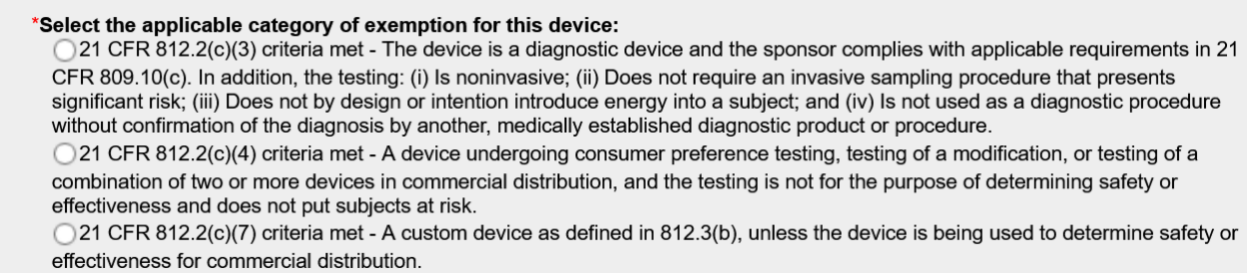
- If you select **NOT FDA-APPROVED** you will need to indicate your plans for storage, control, and accounting of the device.

Note: IDE regulations at 21 CFR 812.110 require that the investigator manage the device supply such that they are used only with subjects under the investigator's supervision. In addition, the investigator may not supply an investigational device to any person not authorized to receive it. Upon completion or termination of the clinical investigation or the investigator's part of the investigation, or at the sponsor's request, the investigator must return to the sponsor any remaining supply of the device or otherwise dispose of the device as the sponsor directs. Device use must be tracked, and records retained of each device and its disposition; this is particularly important for implantable devices.

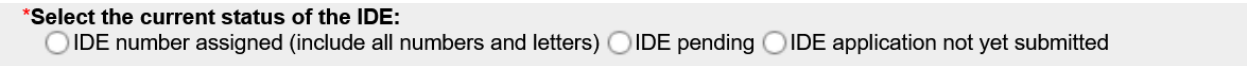
- Select **FDA-APPROVED BUT NOT BEING USED IN ACCORDANCE WITH LABELING** if applicable.

Field 7b: Is an FDA-issued Investigational Device Exemption (IDE) required?

- **Select NO**. THE CRITERIA FOR EXEMPTION FROM THE IDE REQUIREMENTS ARE MET if your device meets one of the three categories of exemption below:



- Select **YES This is a Significant Risk Device** if the device has been issued an IDE number by the FDA, the IDE number is pending, or the IDE application has not yet been submitted.



- **IDE number assigned (include all numbers and letters).** If you select this choice, you will be asked for the IDE number, the name, address and contact information of the IDE holder and the type of IDE holder: Columbia Faculty, Industry (e.g., pharma company or device manufacturer), Federal Agency, non-profit organization or other.
- **IDE pending.** If you select this choice, you will be asked for the date of submission to the FDA and the same information regarding the IDE holder described above.
- **IDE application not yet submitted.** If you select this choice, you will be asked for the same information regarding the IDE holder described above.

Important: When an IDE application has been submitted to the FDA, the IRB will not approve the protocol until the end of FDA's 30 day waiting period after the IDE application is submitted

Definition: A **significant risk device** is defined in 21 CFR 812.3 as an investigational device that:

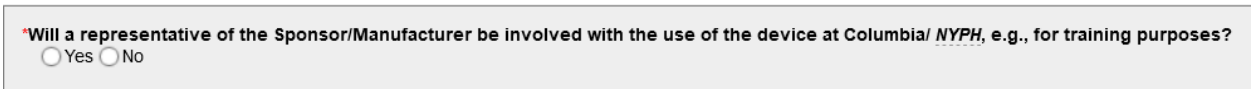
- Is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject;
- Is purported or represented to be for a use in supporting or sustaining human life and presents a potential for risk to the health, safety, or welfare of a subject
- Is for a use of substantial importance in diagnosing, curing, mitigating or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject; or
- Otherwise presents a potential for serious risk to the health, safety or welfare of a subject.

Note: The IRB will make the final decision as to whether or not a device is a significant risk device.

- Select **NO THIS IS A NONSIGNFICANT RISK DEVICE (21 CFR 812.2(B))** if the device does not meet the criteria for IDE exemption or a significant risk device.

Note: If this option is selected, justification for this assessment should be attached in the Documents section in Rascal.

Field 8: Will a representative of the Sponsor/Manufacturer be involved with the use of the device at Columbia/NYP, e.g., for training purposes?

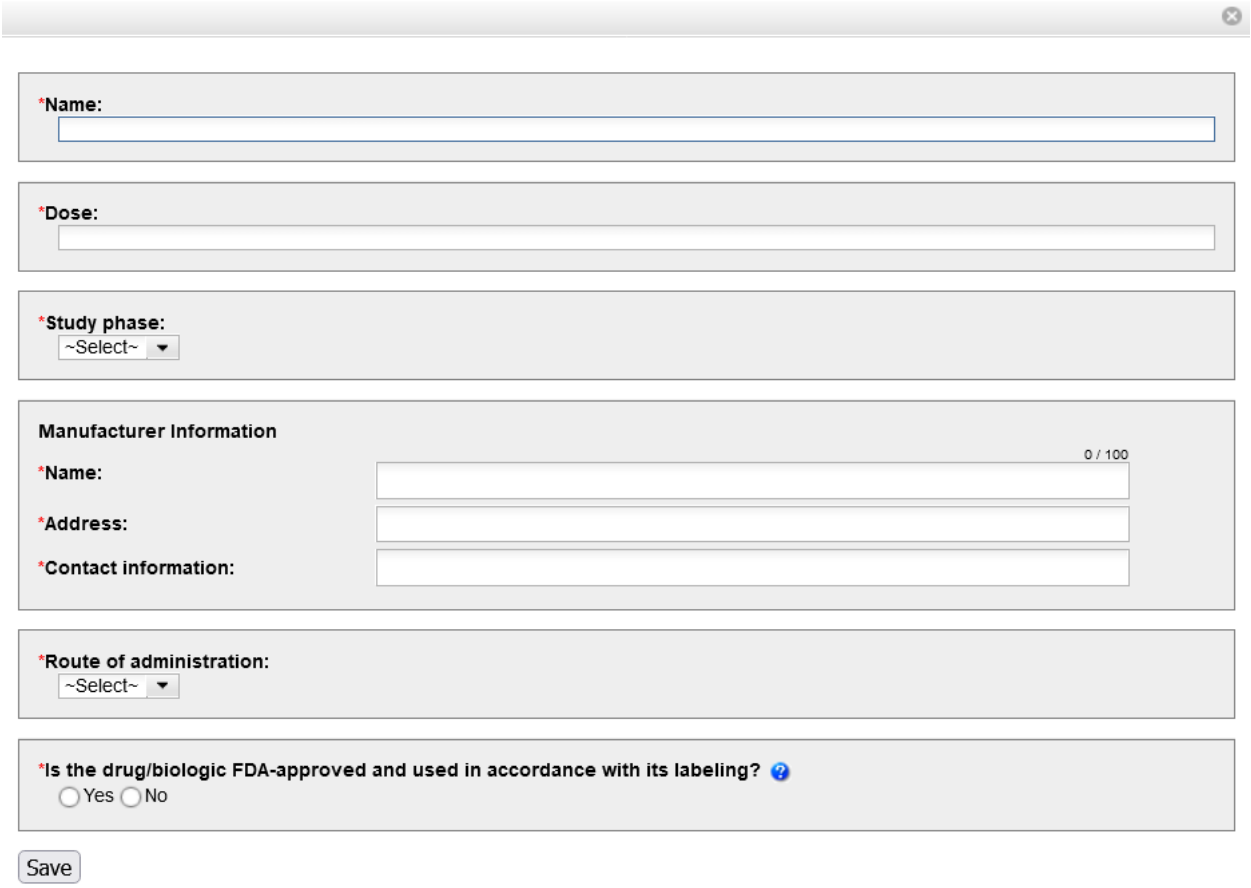


- Select **NO** if a sponsor or manufacturer representative will not be involved.
- Otherwise, select **YES** and confirm that all the necessary requirements for the non-Columbia individual to have privileges and access to facilities, patients, and confidential information have been, or will be, reviewed prior to involvement of the representative.

SECTION 9C: DRUGS/BIOLOGICS

Click on the blue arrow icon to enter information about each drug or biologic that will be administered as the object of the protocol or because it is relevant to the aims of the protocol. This applies whether the drug or biologic is not yet FDA-approved (i.e., is investigational), is FDA-approved and used in accordance with its labeling or is an approved product that is being used in an investigational manner (i.e., off-label use is being studied).

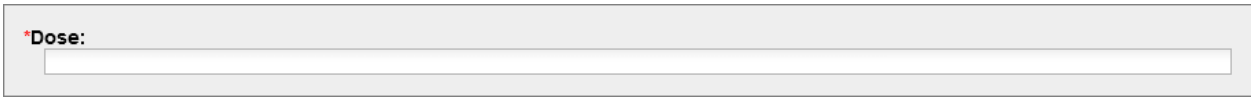
Once you click the icon the following will appear.



Field 1: Name

Enter the name of the drug.

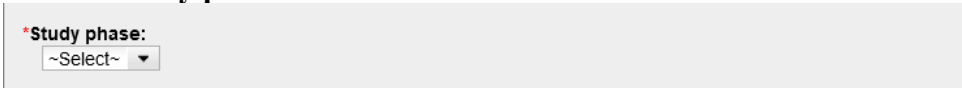
Field 2: Dose



Enter the dose of the drug.

Note: If there is a standalone protocol attached, the dose should correspond to that listed in the standalone protocol.

Field 3: Study phase



Select the phase of the study from the drop-down menu.

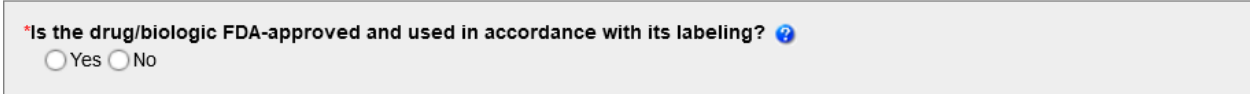
Field 4: Manufacturer Information

Provide the manufacturer information for the drug.

Field 5: Route of administration

Select the route of administration from the drop-down menu.

Field 6: Is the drug/biologic FDA-approved and used in accordance with its labeling?

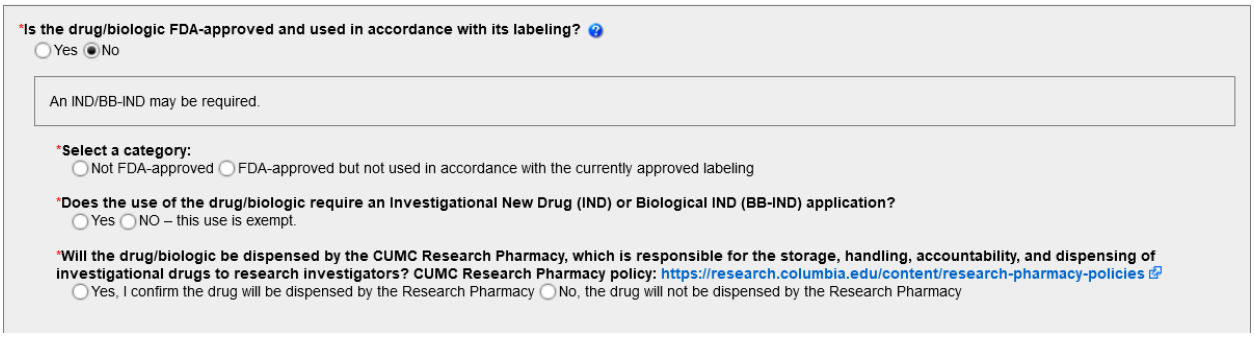


- Select Y**ES** if this applies; an Investigational New Drug Application (IND) / Biologic IND (BB-IND) is not required.

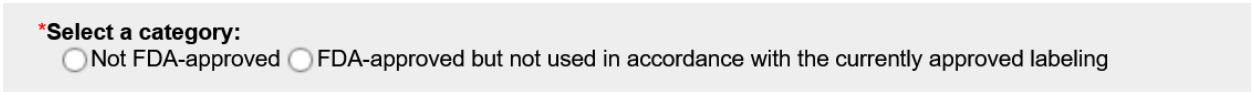
Important: A copy of the package insert must be attached in the Documents section in Rascal.

- Select **NO** if an IND/BB-IND is required or the drug or biologic is FDA-approved but not being used in accordance with its approved labeling.

Note: Columbia Sponsor-Investigators should consult the CTO IND/IDE Assistance Program for assistance submitting an IND/BB-IND to the FDA.



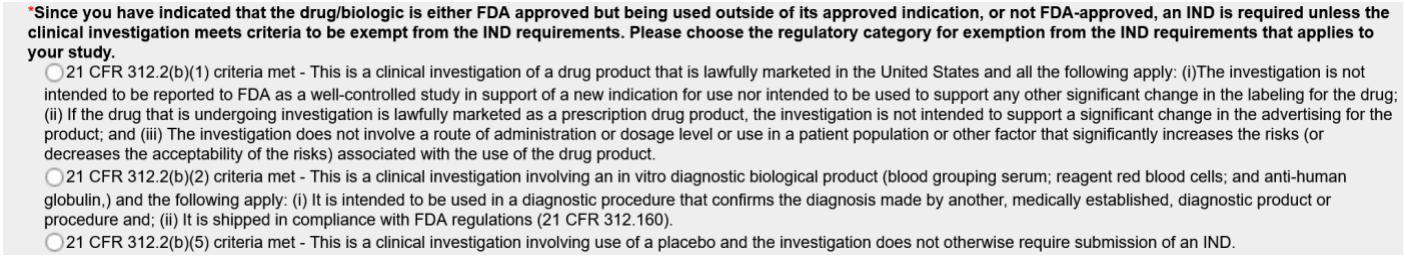
Field 6a: Select a category



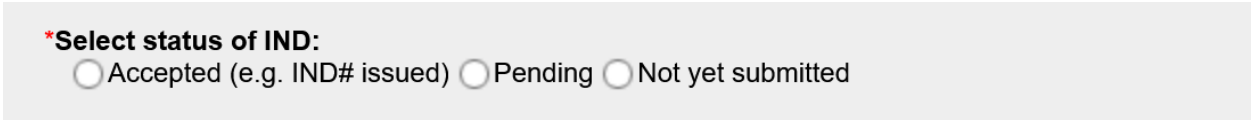
- Select **NOT FDA APPROVED** if an IND/BB-IND has been issued or applied for.
- Select **FDA-APPROVED BUT NOT USED IN ACCORDANCE WITH THE CURRENTLY APPROVED LABELING** if the drug or biologic is approved but is being used off label.

Field 6b: Does the use of the drug/biologic require an Investigational New Drug (IND) or Biological IND (BB-IND) application?

- Select **NO** if the use of the drug/biologic meets one of the criteria for IND exemption below:



- Select **YES** if the drug/biologic has been issued an IND, the IND is pending, or the IND application has not yet been submitted to the FDA. Then indicate the IND status:



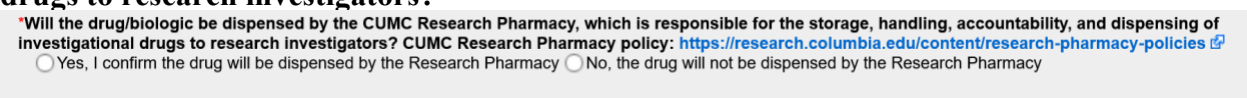
- If you select **Accepted**, you must provide the IND number.
- If you select **Pending**, you must provide the date of submission to the FDA.
- **Not yet Submitted**

Important: The IRB cannot approve the protocol until the IND application has been submitted to the FDA and either the FDA Study May Proceed letter has been received or it has been 31 days since submission to the FDA. Convened IRB review will generally not occur until the letter has been received or 30 days have passed since the IND application has been submitted.

Regardless of the status of the IND, the following information is required:

- If the IND holder is a member of the Columbia Faculty, the following documents must be submitted to the IRB:
    - Most recent protocol submitted to the FDA (**before** IRB review)
    - FDA Form 1571
    - FDA Form 1572
    - FDA acknowledgement letter or FDA "Safe to Proceed" documentation, including conditional approval letter if one has been received
    - Form of Notice by Columbia faculty IND/IDE holder. This form provides "acknowledges that the Sponsor-Investigator**,** or Sponsor and PI if they are different people, have "additional responsibilities under the FDA regulations" and "confirms that [they have] adequate resources to fulfill such responsibilities in full compliance with such regulations. This form must be approved by the Chair of the PI's Department.
- If the IND Holder is an external pharmaceutical company or drug manufacturer, the FDA Form 1572 must be submitted to the IRB.

Field 7: Will the drug/biologic be dispensed by the CUMC Research Pharmacy, which is responsible for the storage, handling, accountability, and dispensing of investigational drugs to research investigators?

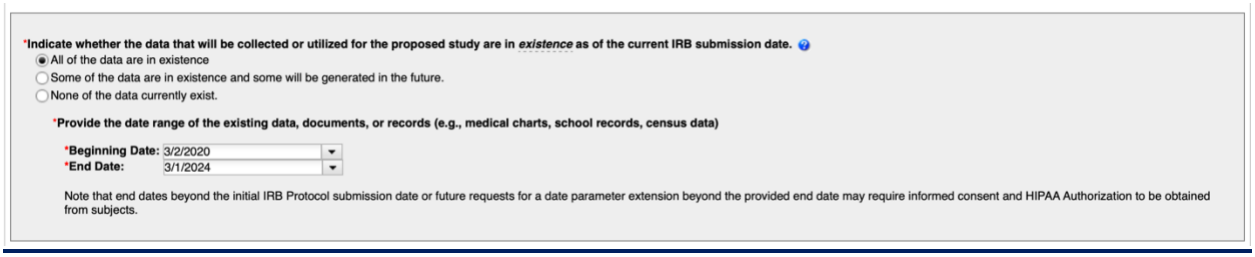


- Select **YES** if the drug or biologic will be dispensed by the Research Pharmacy.
- Select **NO** if the drug or biologic will not be dispensed by the Research Pharmacy and, if so, provide an explanation.

Note: More information regarding dispensation of research drugs/biologics can be found in the Columbia University Medical Center Policy Relating to the Use and Control of Investigational Drugs for Outpatients and the Columbia University Medical Center Policy Relating to the Use and Control of Investigational Drugs for Inpatients at New York-Presbyterian Hospital.

SECTION 9D: ANALYSIS OF EXISTING DATA AND/OR PROSPECTIVE RECORD REVIEW

Field 1: Indicate whether the data that will be collected or utilized for the proposed study are in existence as of the current IRB submission date.



- Select **ALL OF THE DATA ARE IN EXISTENCE,** if all relevant data already resides in records/documents at the time of the IRB protocol submission.

  If you select this option, additional required fields will appear, including **Provide the date range of the existing data, documents, or records (e.g. medical charts, school records, census data).** List the beginning and end date for existing data. Both dates should be dates should be prior to the submission date.

Tip: If you will collect data via the Tripartite Request Assessment Committee (TRAC), the date range dates must be consistent with your TRAC submission.

- Select **SOME OF THE DATA ARE IN EXISTENCE AND SOME WILL BE GENERATED IN THE FUTURE,** if some relevant data resides in records/documents at the time of the IRB protocol submission and some data is generated after the IRB protocol submission.

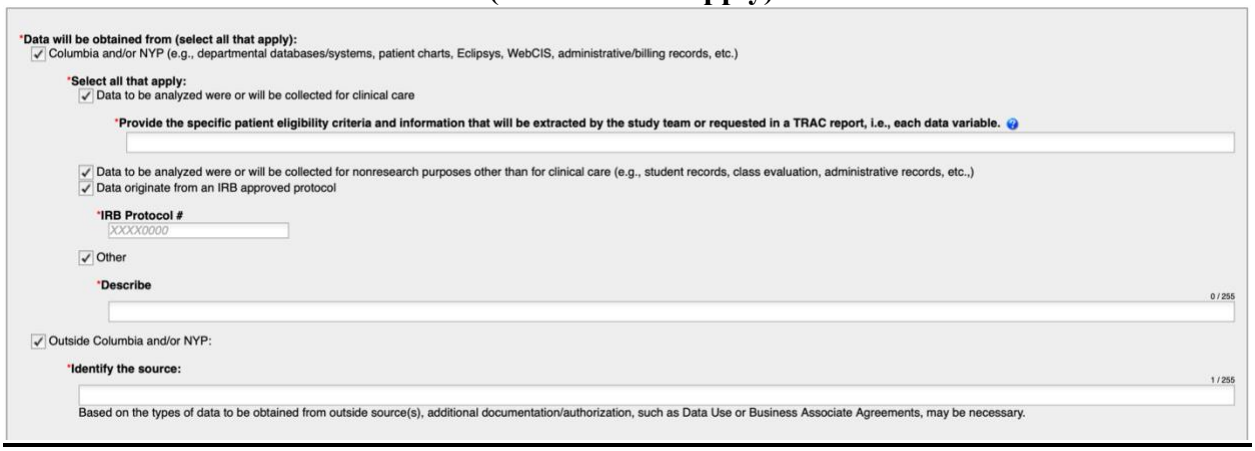
  If you select this option, the same additional fields generated under **All of the data are in existence** will appear. See above for guidance.

- Select **NONE OF THE DATA CURRENTLY EXIST,** if all relevant data will be generated after the IRB protocol submission.

Note: If you've selected **Some of the data are in existence and some will be generated in the future** OR **None of the data currently exist,** informed consent and HIPAA Authorization may be required from subjects as a waiver of consent is typically not granted for prospective chart reviews. If a waiver is requested, the Recruitment and Consent page must clearly indicate why the waiver of consent should apply to data generated in the future. Note that the Chair would have to comment on this request and it would need to be explained why it would be

impracticable to conduct the study without this waiver. **It is not appropriate to wait for another year to pass then request another retrospective cohort.**

Field 2: Data will be obtained from (select all that apply):



- Select **COLUMBIA AND/OR NYP** if data will be obtained from various Columbia/NYP providers, including but not limited to systems like EPIC or MyChart, the TRAC request, or from administrative/billing records.

  If you select this option, an additional field will appear that states, **Provide the specific patient eligibility criteria and information that will be extracted by the study team or requested in a TRAC report, i.e. each data variable.**

Tip: List each data variable that will be obtained from the medical record for the purposes of the research. If this information is included in an attached standalone protocol, reference the specific page number.

Notes:

a. Please enter the **criteria** for the data that will be extracted manually by the study team or requested in a TRAC report, which should be consistent in scope with aims and procedures of the IRB protocol.
b. If the CCR (Consent to Contact for Research) Registry will be used to contact patients who have consented to be contacted for research and may be eligible for this protocol, please enter the variables that will be requested through TRAC, e.g., patient name, patient preferred contact information, MRN, and the eligibility criteria, which will form the basis for identifying the potentially eligible patients.
c. Inconsistencies between TRAC request and the IRB approved protocol will result in delay of approval of the TRAC request

- Select **DATA TO BE ANALYZED WERE OR WILL BE COLLECTED FOR NONRESEEARCH PURPOSES OTHER THAN FOR CLINICAL CARE**, if data is obtained from datasets including student records, class evaluations, administrative records, etc. The specific type of data obtained and how this will be requested should be described in the Procedures page.
- Select **DATA ORIGINATE FROM AN IRB APPROVED PRTOOCOL**, if data was previously generated or collected under a separate IRB protocol.

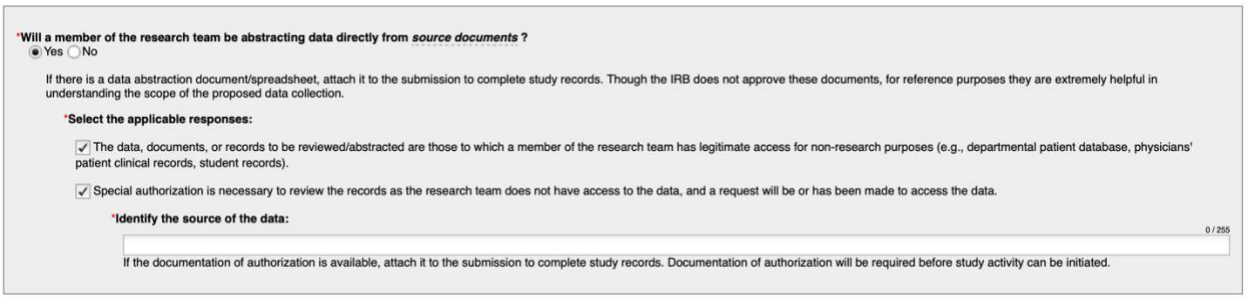
  If you select this option, an additional field will appear that requests the **IRB Protocol #.** Include all relevant data protocols where data will be collected from. If there are not enough text characters to include all relevant protocols, the below **Other** may be used for additional text space.

- Select **OTHER**, if the above options do not capture where Columbia/NYP data will be obtained from and describe using the generated text field.

- Select **OUTSIDE COLUMBIA AND/OR NYP,** if data will be obtained from external organizations or institutions and identify the provider in the text field. Based on the type of data, additional documentation or authorization, such as a Data Use or Business Associate Agreement, may be necessary.

Note: At minimum, a draft data use agreement or purchase ordes should be submitted in Rascal for review. If these are not required by the provider, documentation should be submitted or a link to the data request site should be included in the Procedures page.

Field 3: Will a member of the research team be abstracting data directly from source documents?

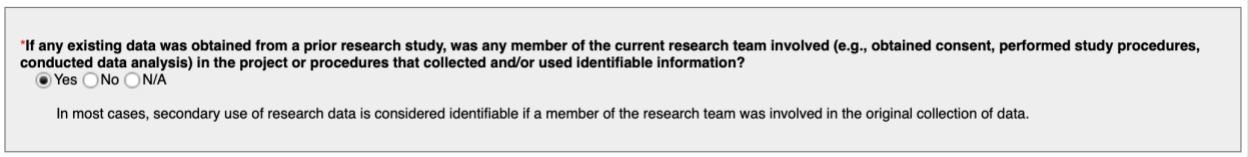


Definition:

Source documents are original documents from which data will be abstracted; these include but are not limited to departmental databases, patient records, and school records. For the purpose of this question, ‘source documents’ do not include study instruments such as surveys or questionnaires that will be used to generate data for the study.

- Select **NO** if this does not apply.
- Select **YES** if a member of the research team will abstract data directly from source documents. If you select this option, additional required fields will appear to reflect the source documents:
    - Select **THE DATA, DOCUMENTS, OR RECORDS TO BE REVIEWED/ABSTRACTED ARE THOSE TO WHICH A MEMBER OF THE RESEARCH TEAM HAS LEGITIMATE ACCESS FOR NON-RESEARCH PURPOSES** if a member of the research team has access to source data through their regular clinical or research duties.
    - Select **SPECIAL AUTHORIZATION IS NECESSARY TO REVIEW THE RECORDS AS THE RESEARCH TEAM DOES NOT HAVE ACCESS TO THE DATA, AND A REQUEST WILL BE MADE OR HAS BEEN MADE TO ACCESS THE DATA**, if none of the research team members have authorization but will be given authorization to directly access source material. If you select this option, identify the source in the provided text field.

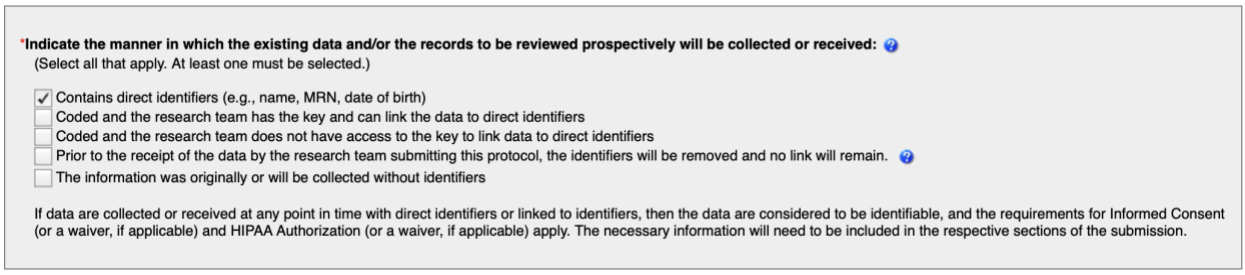
Field 4: If any existing data was obtained from a prior research study, was any member of the current research team involved (e.g. obtained consent, performed study procedures, conducted data analysis) in the project or procedures that collected and/or used identifiable information?



- Select **N/A** if existing data was not obtained from a prior research study.
- Select **NO** if existing data was obtained from a prior research study, but those involved in the prior study were non-engaged personnel for the entire duration of the study.
- Select **YES** if existing data was obtained from a prior research study, and those involved in the prior study were engaged in human subjects research.

Note: In most cases, secondary use of research data is considered identifiable if a member of the research team was involved in the original data collection **at any point.**

Field 5: Indicate the manner in which the existing data and/or records to be reviewed prospectively will be collected or received


*Indicate the manner in which the existing data and/or the records to be reviewed prospectively will be collected or received:
(Select all that apply. At least one must be selected.)

- [x] Contains direct identifiers (e.g., name, MRN, date of birth)
- [ ] Coded and the research team has the key and can link the data to direct identifiers
- [ ] Coded and the research team does not have access to the key to link data to direct identifiers
- [ ] Prior to the receipt of the data by the research team submitting this protocol, the identifiers will be removed and no link will remain.
- [ ] The information was originally or will be collected without identifiers

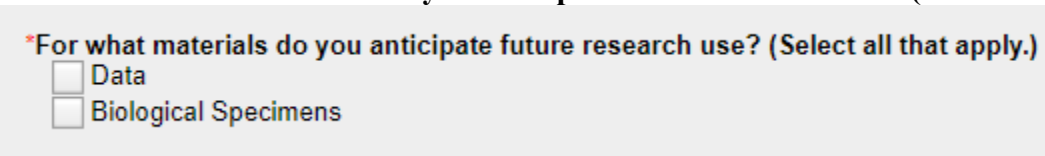
If data are collected or received at any point in time with direct identifiers or linked to identifiers, then the data are considered to be identifiable, and the requirements for Informed Consent (or a waiver, if applicable) and HIPAA Authorization (or a waiver, if applicable) apply. The necessary information will need to be included in the respective sections of the submission.

- Select **CONTAINS DIRECT IDENTIFIERS** if data will include identifiable information.
- Select **CODED AND THE RESEARCH TEAM HAS THE KEY AND CAN LINK THE DATA TO DIRECT IDENTIFIERS** if research data is stored separate from the identifiable data and can be linked back by a key code.
- Select **CODED AND THE RESEARCH TEAM DOES NOT HAVE ACCESS TO THE KEY TO LINK DATA TO DIRECT IDENTIFIERS** if research data is stored separate from the identifiable data and can be linked back by a key code, but the research team does not have access to this code or the identifiers.
- Select **PRIOR TO THE RECEIPT OF THE DATA BY THE RESEARCH TEAM SUBMTTING THIS PROTOCOL, THE IDENTIFEIRS WILL BE REMOVED AND NO LINK WILL REMAIN** if the research data was originally collected with identifiers or linked key a key but was destroyed and no current link remains. If you select this option, specifically list who will remove the identifiers and destroy the key using the generated text field.
- Select **THE INFORMATION WAS ORIGINALLY OR WILL BE COLLECTED WITHOUT IDENTIFIERS** if no identifiers included with existing data.

Note: Ensure your selections made in this field are consistent with the description of data provided in the Privacy and Data Security page.

SECTION 9E: FUTURE USE

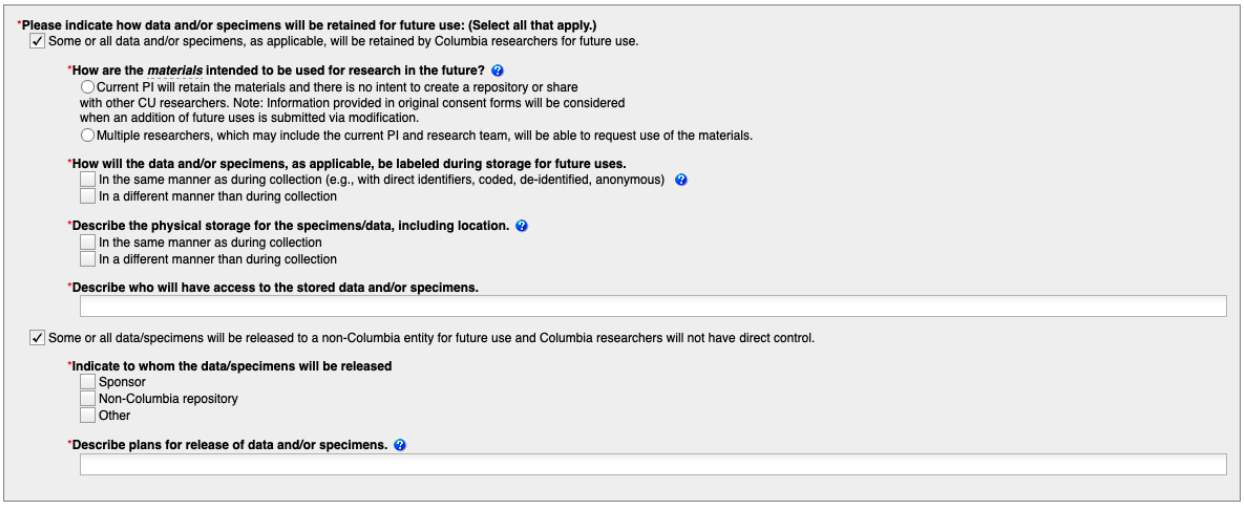
Field 1: For what materials do you anticipate future research use? (Select all that apply.)



- Select **DATA** if previously collected data **or** data created under this protocol may be shared for research outside of the research aims of this Rascal application and/or standalone protocol.
- Select **BIOLOGICAL SPECIMENS** if specimens collected or obtained under this protocol may be shared for research outside of the research aims of this Rascal application and/or standalone protocol.

Important: If you have selected either of the above, please note that any future use of specimens and/or data must be reflected within the informed consent document or information sheet, as applicable.

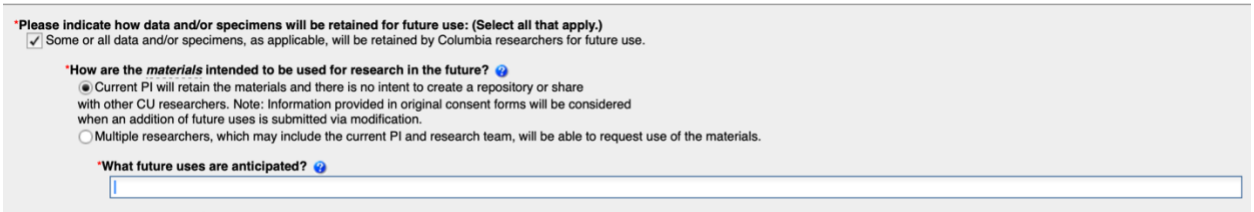
Field 2: Please indicate how data and/or specimens will be retained for future use: (Select all that apply.)



- Select **SOME OF THE DATA AND/OR SPECIMENS, AS APPLICABLE, WILL BE RETAINED BY COLUMBIA RESEACHERS FOR FUTURE USE** if data and/or specimens may be shared for future use within the Columbia University community.
- Select **SOME OR ALL DATA/SPECIMENS WILL BE RELEASED TO A NON-COLMBIA ENTITY FOR FUTURE USE AND COLUMBIA RESEARCHERS WILL NOT HAVE DIRECT CONTROL** if data and/or specimens may be shared for future use outside of Columbia University.

If you selected **Some or all data and/or specimens, as applicable will be retained by Columbia researchers for future use,** you will see the following question appear:
Field 2a: How are the materials intended to be used for research in the future?

- Select **CURRENT PI WILL RETAIN MATERIALS AND THERE IS NO INTENT TO CREATE A REPOSITORY OR SHARE WITH OTHER CU RESEARCHERS** if the materials will **only** be reused for future use under the current PI and study team. If this selection is made, an additional field will appear asking **What future uses are anticipated?** If applicable, please include the associated Rascal protocol number for the proposed future use by the current researchers.



Definition:

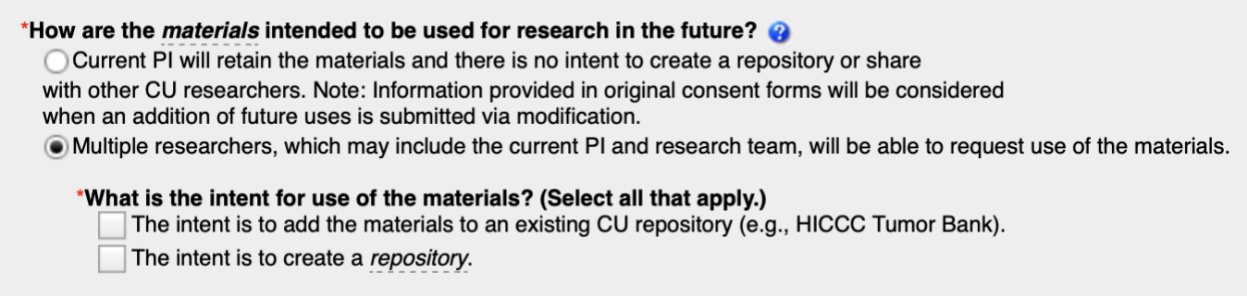
Research Repository:

- A collection of Biospecimens and/or Data that are processed, stored and (a) distributed to multiple investigators for use in research or (b) used by a single researcher or research team for multiple research projects. Repositories include registries, data banks and tissue banks. A collection of Biospecimens and/or Data routinely collected during the conduct of an IRB-approved research study that generated the Biospecimens and/or Data does not inherently constitute a Research Repository. Any collection of such Biospecimens and/or Data is considered to be a Research Repository when there is no explicit plan to destroy the Biospecimens or Data at the conclusion of the specific research project that generated the Biospecimens and/or Data and the Research Repository criteria are met; or
- A collection of biological specimens or data that are processed and stored with the intent of distribution to multiple investigators for use in research.

Note: If any member of the research team has identifiers linked to the data and/or specimens, the retained data and/or specimens are considered to be **identifiable**. Additional IRB approval may be required for future use of the specimens and/or data.

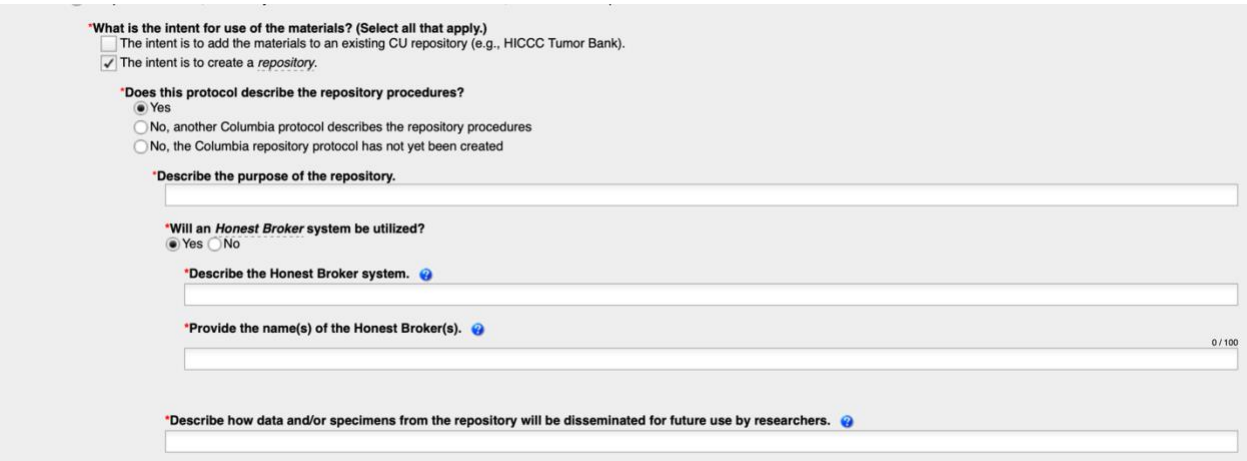
- Select **MULTIPLE RESEARCHERS, WHICH MAY INCLDUE THE CURRENT PI AND RESEARCH TEAM, WILL BE ABLE TO REQUEST THE USE OF MATERIALS** if the materials will be used for future use by the PI or study team and/or

other Columbia University researchers outside of the study team. If this selection is made, the following additional fields will appear:



What is the intent for use of the materials? (Select all that apply.)

- Select **THE INTENT IS TO ADD THE MATERIALS TO AN EXISTING CU REPOSITORY (E.G., HICC TUMOR BANK)** if materials collected or obtained under this protocol will be shared with an existing Columbia repository. If this selection is made, a text field will appear to include the existing repository's Rascal protocol number.
- Select **THE INTENT IS TO CREATE A REPOSITORY** if the intent is to distribute materials to multiple Columbia University researchers for various uses in research. If this selection is made, the following additional fields will appear:



Does this protocol describe repository procedures?

- Select **YES** if the intent is to create a repository and the Rascal application describes the repository procedures. If this selection is made, the following additional fields will appear:
    - **Describe the purpose of the repository**
        - In general, if it is known that a project will collect materials to conduct research for a specific question/aim and subsequently share materials with multiple researchers for future use, and such sharing will be in a manner that constitutes a repository, a separate protocol should be

submitted for the repository procedures. The repository protocol would describe the source of the materials, i.e., the primary collection/use protocol, and elaborate on the operational procedures of the repository.

- **Will an Honest Broker system be utilized and, if so, Describe the Honest Broker system, Provide the name(s) of the Honest Broker(s), and Describe how data and/or specimens from the repository will be disseminated for future use by researchers.**

Note: Please be sure the text fields address the following:

- **Information about collection and storage of data and/or specimens**
  - Purpose of the repository
  - Identify the source of the data (including data in medical records) and/or specimens that will be stored in the repository. Specify if this will involve a single collection of data and specimens vs. ongoing collections.
  - List all types of Sensitive Data, e.g., PHI, RHI and PII, that will accompany the data and specimens

- **Information about the database or repository itself:**
  - Where will the database or repository be located? If at a non-Columbia site, does Columbia provide funding for the maintenance of the database or repository? If so, and such funding is from a federal agency, a Federal Wide Assurance is needed.
  - How will the data and/or specimens be maintained? Describe physical mechanisms for storage.
  - What data security measures will be in place to maintain the confidentiality of stored data or specimens, including who has access to specimens and associated data, and security during transmission of data and specimens.
  - How long will the repository exist?
  - Can subjects withdraw their samples or data? If so, procedures should be described.

- **Information about who will be the users of the specimens or data collected and who will authorize the use:**
  - Describe the process for allowing researchers to use data or specimens from the repository, i.e., only Columbia researchers listed on protocol, and/or other Columbia researchers and/or external researchers?
  - Who will have control and/or ownership of the tissue sample(s) and the data derived from the tissue sample(s)?
  - Information about how specimens and data will be distributed to others for research:
    i. Will material be released in de-identified form or will they be coded? You must have a data or material use agreement in place between provider and recipient) before providing materials. A template agreement should be attached to the protocol.

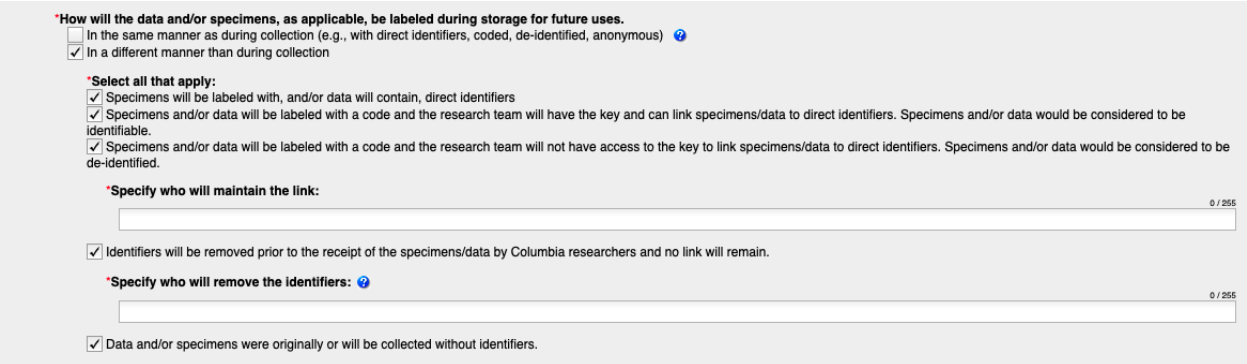
ii. Who will review the requests for material and make sure it is to be used within the intended purposes of the approved repository and the consent under which the materials were obtained?
iii. Who will make sure IRB approval is obtained by the researcher receiving data (if the recipient receives identifiable data and/or PHI)?

- Select **NO, ANOTHER COLUBMIA PROTOCOL DESCRIBES THE REPOSITORY PROCEDURES** if the intent is to create a repository, but the repository procedures are described under a separate Rascal IRB protocol. If this selection is made, a text field will appear to provide the Columbia IRB protocol number.
- Select **NO, THE COLUMBIA REPOSITORY HAS NOT YET BEEN CREATED** if the repository procedures will be developed in the future. Once developed, this field should be updated under one of the above selections.

Important: The repository protocol should be reviewed and approved by the IRB before material and/or data is collected and ready to be entered into the repository.

Field 2b: How will the data and/or specimens, as applicable, be labeled during storage for future uses.

- Select **IN THE SAME MANNER AS DURING COLLECTION** if data and/or specimens will be labeled during storage in the same manner as described in other sections of the Rascal application (e.g., Background, Privacy and Data Security, Existing Data, Biological Specimens, etc.)
- Select **IN A DIFFERENT MANNER THAN DURING COLLECTION** if data will be labeled for storage differently than as described in other sections of the Rascal application. If this selection is made, the following additional selections will appear:



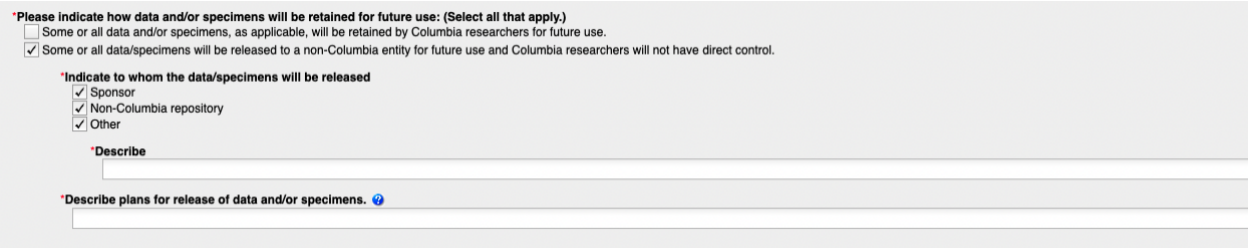
Please select all that are applicable to labeling during storage for future uses. Be sure to describe such factors as:
- If material will be labeled with a unique identifier that is managed through a key to the code, who has access to the key and where and how will it be stored?
- If material will be stored in an identifiable manner, what safeguards are in place?

Field 2c: Describe the physical storage for the specimens/data, including location:

- Select **IN THE SAME MANNER AS DURING COLLECTION** if applicable.
- Select **IN A DIFFERENT MANNER THAN AS DURING COLLECTION** if applicable. If this selection is made, an open text field will appear. In the field, describe the physical storage, including whether materials are stored at Columbia or elsewhere; the mechanisms in place to physically secure the materials (e.g. back-up generators for freezers, automatic nightly backup of data); and the physical security of the storage.

Field 2d: Describe who will have access to the stored data and/or specimens
Use the open text field to describe whom at Columbia University will have access to the stored materials. If data will be analyzed for separate aims under a different Columbia protocol, please include that IRB protocol number.

Field 3: Some or all data/specimens will be released to a non-Columbia entity for future use and Columbia researchers will not have direct control.



Indicate to whom the data/specimens will be released:

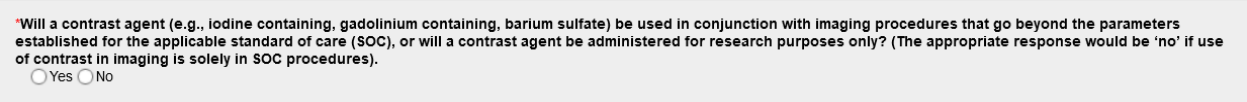
- Select **SPONSOR** if your protocol is externally funded and data/specimens will be shared with the study sponsor. In general, material released to sponsors will not be released in an identifiable format.
- Select **NON-COLUMBIA REPOSITORY** if study data/specimens will be shared with a non-Columbia repository.
- Select **OTHER** if study data/specimens will be shared with other individuals outside of Columbia for research aims not detailed in the Rascal application. Use the subsequently generated open text field to describe the individuals, institutions, and/or organizations.

Field 3a: Describe plans for release of data and/or specimens
Use the open text field to describe how study materials will be released to non-Columbia entities for future use. Describe who will receive the data, the confidentiality of data (coded, de-identified, direct identifiers, etc., method of transfer, and the security utilized during transfer. Describe plans for tracking all releases and indicate such factors as whether results of recipient research will be provided back to the provider and expectations for the management of material that has been distributed but will not be used, e.g., disposal, return or other.

Note: An agreement that specifies the acceptable use, storage, and return or destruction of the specimens and data may be required. For guidance and assistance, please refer to SPA's Request a DUA or MTA for Research Purposes.

SECTION 9F: IMAGING PROCEDURES/RADIATION THERAPY

Field 1: Will a contrast agent (e.g., containing iodine, containing gadolinium, barium sulfate) be used in conjunction with imaging procedures that go beyond the parameters established for the applicable standard of care (SOC), or will a contrast agent be administered for research purposes only?



- **Select NO** if either no contrast agents will be used or if the use of contrast is solely for SOC procedures.

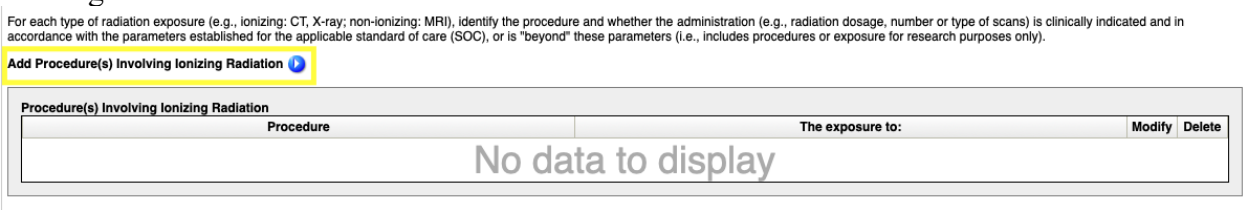
Tip: Even if contrast is used in clinical imaging, if the research calls for additional imaging beyond clinical use, the additional scan with contrast would be beyond SOC.

- Select **YES** if contrast will be used for research imaging or a contrast agent will be administered for research purposes only.

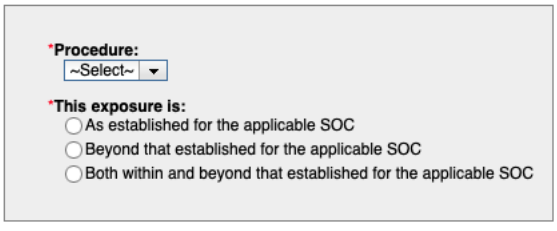
Important: If **YES** is selected, you must include an entry for the contrast agent in the Drugs/Biologics page **and** attach the package insert in the Documents section in Rascal.

Field 2: Add Procedure(s) Involving Ionizing Radiation

Click on the blue arrow icon to enter information about each imaging procedure that involves ionizing radiation.



A pop-up window (see below image) will display additional required fields, such as **Procedure and level of exposure.**



Field 2a: Procedure:

Select the appropriate imaging procedure from the drop-down menu. If more than one procedure is conducted under the proposed research, **SAVE** and repeat the steps under **Field 2: Add Procedure(s) Involving Ionizing Radiation** to add an additional imaging procedure.

Field 2b: This exposure is:

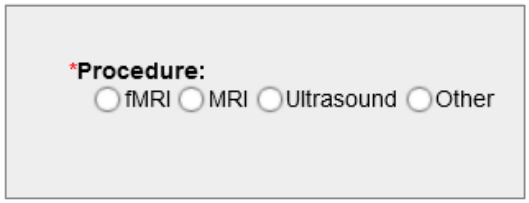
- Select **AS ESTALISHED FOR THE APPLICABLE** if exposure is standard of care.
- Select **BEYOND THAT ESTABLISHED FOR THE APPLICABLE SOC** if exposure is beyond standard of care.
- Select **BOTH WITHIN AND BEYOND THAT ESTABLISHED FOR THE APPLICABLE SOC** if multiple scans will occur that are both standard and beyond standard of care.

Important: If you choose the second or third options, you will need to create an Appendix H in the Rascal Hazardous Materials (Haz Mat) module and attach it to the human subjects application. This will allow review by the Human Use Subcommittee of the Joint Radiation Safety Committee or the Radioactive Drug Research Committee.

Field 3: Add Procedure(s) Involving Non-Ionizing Radiation

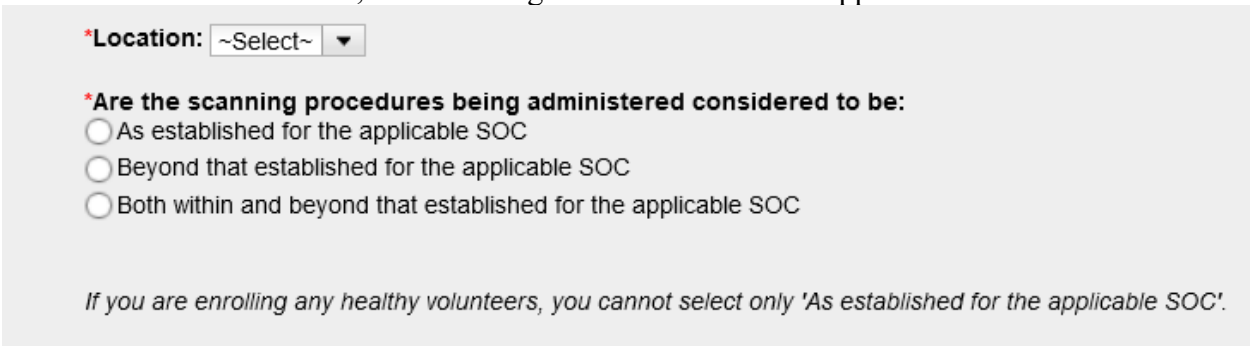
Click on the blue arrow icon to enter information about each imaging procedure that involves non-ionizing radiation.

A pop-up window (see below image) will display the **Procedure** field.



Select the appropriate imaging procedure. If more than one procedure is conducted under the proposed research, please **SAVE** and repeat the steps under **Field 3: Add Procedure(s) Involving Non-Ionizing Radiation.**

If **fMRI** or **MRI** is selected, the following additional fields will appear:



Field 3a: Location

Select the appropriate location where imaging will occur.

Tip: The imaging procedure location selected in this field should also be included within the Locations page in Rascal (Section 6).

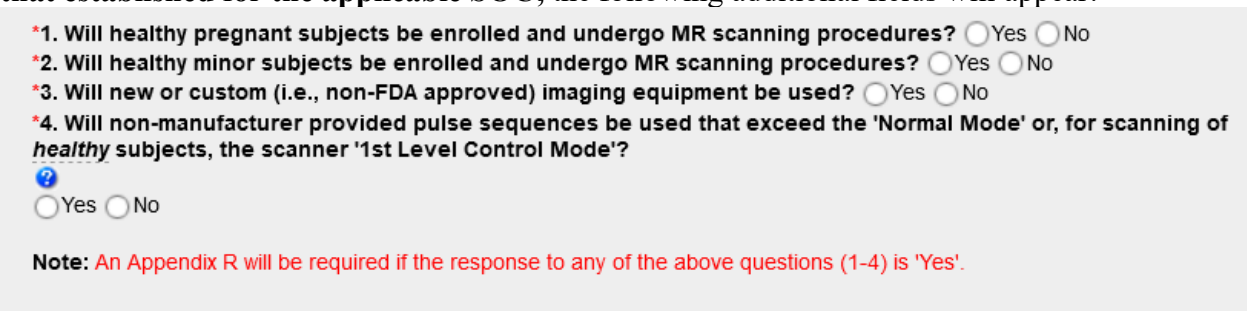
Field 3b: Are the scanning procedures being administered considered to be

- Select **AS ESTABLISHED FOR THE APPLICABLE SOC,** if exposure is standard of care.

Important: If you are enrolling any "healthy volunteers", i.e., individuals who do not have the disease or condition that is the focus of the research, **do not** select "As established for the applicable SOC" as there would be no clinically-indicated imaging for them for the targeted disease or condition. All research imaging with healthy volunteers is considered to be beyond SOC.

- Select **BEYOND THAT ESTABLISHED FOR THE APPLICABLE SOC**, if exposure is beyond standard of care.
- Select **BOTH WITHIN AND BEYOND THAT ESTABLISHED FOR THEAPPLICABLE SOC**, if multiple scans will occur that are both standard and beyond standard of care.

If you selected **Beyond that established for the applicable SOC** or **Both within and beyond that established for the applicable SOC,** the following additional fields will appear:



Note: If **YES** is selected for either questions 1 or 2, you must also select **YES** to the corresponding questions on the Subjects page ("Will pregnant women/fetuses/neonates be targeted for enrollment'' or "Will children/minors be enrolled"). If you completed the Subjects page prior to the Imaging page, you will need to return to the Subjects page to make the revision. They system will check for concordance between the two pages when the Notify Approvers link is selected.

Regarding question 4, select **YES** if the operating mode is unknown or consult with the MR staff in the EH&S Office. For previously used imaging procedures (or minor modifications) where the operating mode has been established, select **YES** or **NO** as appropriate. If using only manufacturer-programmed pulse sequences, select **NO**.

Important: If **YES** is selected to any of the above questions, a Hazardous Materials Appendix R will be required. As the procedures listed above may involve greater risk than for standard MRI procedures, the questions in Appendix R will provide the MR staff in the EH&S Office with the information they will need to determine whether your application should be reviewed by the Protocol Review Subcommittee of the MR Safety Committee.

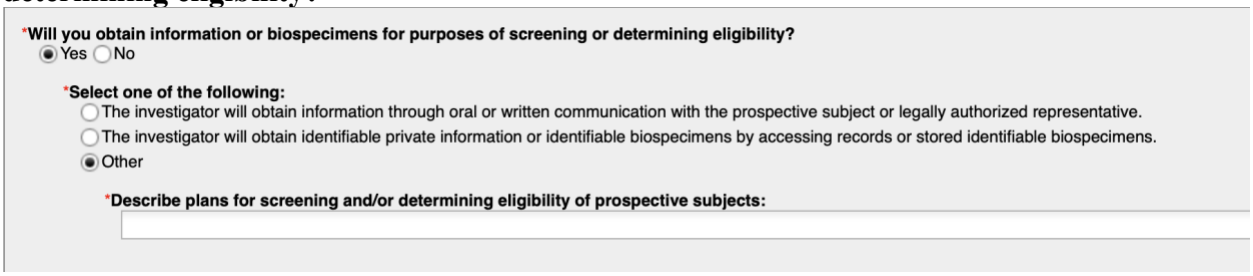
Important: Study procedures that include images that provide anatomic or physiological data of the type that is used for clinical diagnosis or treatment, such as MRI scans, CT scans, PET scans and X-rays:

- Must have a plan to address Incidental Findings of Clinical Significance (**IF**s). Refer to the Columbia University Institutional Review Board Policy on Incidental Findings from Imaging Procedures Conducted for Research Studies **(IF Policy).**
- If applicable, you must include language in the consent form required by the IF Policy; IRB sample language.

Any documentation of procedures that is provided by the imaging facility should be retained with research records.

SECTION 10: RECRUITMENT AND CONSENT

Field 1: Will you obtain information or biospecimens for purposes of screening or determining eligibility?



This question pertains to procedures that occur prior to a prospective participant providing consent for participation in a study. "Screening" and "determining eligibility" in this context refer to procedures to identify potential participants that may include but are not limited to in-person or remote interactions with prospective participants, or review information in research or clinical databases such as PHI (personal health information). If private, identifiable information or identifiable biospecimens are obtained (i.e., accessed, collected, used or analyzed), a waiver of consent and/or HIPAA authorization will likely be necessary.

- Select **NO** if the research does not involve screening procedures.
- Select **YES** if the research includes inclusion/exclusion criteria and you will conduct screening procedures prior to obtaining consent.

Note: If your study **only** involves a retrospective chart review, the screening procedure questions are not applicable to the analyses that will be conducted on the dataset of eligible participants. An example is a study for which a TRAC request provides data for all eligible patients; the screening/determining eligibility question does not apply, and the appropriate response is "NO".

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In some instances, a retrospective chart review involves obtaining data about both eligible and ineligible individuals to determine which ones may be eligible; in such cases, the screening/determining eligibility question applies, and the appropriate response is "YES". For example, if your study is a retrospective review of information about patients who have condition x **and** have certain pre-existing conditions, and you will have to manually review the charts of all patients with condition x to identify those with the pre-existing conditions, such review is for determining eligibility.

If you selected **YES** to **Field 1**, the following additional fields will appear:

- Select **THE INVESTIGATOR WILL OBTAIN INFORMATION THROUGH ORAL OR WRITTEN COMMUNICATION WITH THE PROSPECTIVE SUBJECT OR LEGALLY AUTHORIZED REPRESENTATIVE** if there will be interaction with the subject or legally authorized representative (e.g., in person, or by phone, mail, email) for screening purposes.
- Select **THE INVESTIGATOR WILL OBTAIN IDENTIFIABLE PRIVATE INFORMATION OF IDENTIFIABLE BIOSPECIMENS BY ACCESSING**

RECORDS OR STORED IDENTIFIABLE BIOSPECIMEN if data or other materials will be accessed, used, analyzed or collected to assess study eligibility.

- Select **OTHER** if your screening procedures include both options above OR does not align with either designation.

Important: If the research involves direct or indirect access to Columbia/NYP electronic medical records for screening purposes and HIPAA authorization is not obtained, a HIPAA Form D (preparatory to research) or a HIPAA Form B or C (waiver of authorization) must be submitted in Rascal. Which form is appropriate will depend upon whether the PHI is used by someone within the Columbia Covered Healthcare Component (CCHCC), which may fall under preparatory to research, or disclosed to someone outside of the CCHCC, which would require a waiver.

Note: Whichever option you select, you must provide text indicating your plans for screening and/or determining eligibility of prospective subjects. If your plan involves direct communication with prospective subjects, please attach all screening materials under Documents in Rascal.

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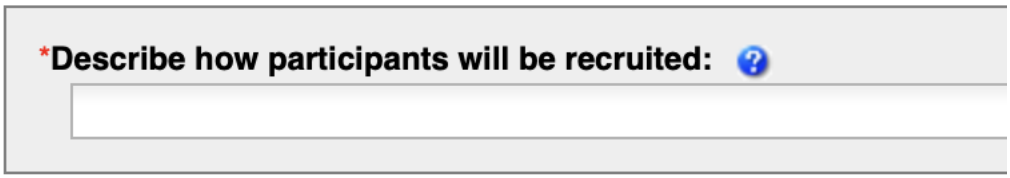
Field 2: Describe in detail how potential subjects will be recruited.



Provide specific information about how potential subjects will be recruited and enrolled, including information on how and when prospective subjects will be identified and approached.
For all studies, if recruitment material will be used, provide the type (e.g., advertisement, posters) and location (e.g., Columbia Morningside or Lamont campus, CUIMC, NYP, NYSPI, private practices, clinics, schools, community centers, social media) of recruitment media. In addition, attach a copy of each written advertisement (i.e., any recruitment material that a potential subject will see), and the script for each recruitment medium or method that is delivered verbally (e.g., video, telephone script). If sensitive information will be used, additional precautions may be required for access to the data and additional permissions may be required for members of the study team to contact potential participants.

Note: Any recruitment through social media must be posted through Columbia accounts. It is not appropriate to use personal accounts to publish recruitment material. Please review CUIMC Communication's Social Media Policy.

ADDITIONAL INFORMATION ABOUT RECRUITMENT OF PATIENTS

When CUIMC/NYP patients are the target population and will be approached based upon information in their medical record, it is institutional practice that introduction of the research must be made by their **treating physician.** If the setting is one in which patients may have a transient relationship with the provider, e.g., the emergency department, or is a resident-based setting, introduction may be made by or, if described in the IRB protocol and approved by the IRB, on behalf of, the medical director of the unit. The IRB may also approve introduction through the medical director in other units with appropriate justification. In all cases in which the introduction involves the medical director through use of recruitment material, the following procedures are required and must be documented:

- Providers in the unit are notified about the research;
- Providers have the option of requesting that specific patients or all of their patients be omitted from contact;
- Agreement of the medical director is documented and reflected in the recruitment materials.

When a treating physician introduces a study to a patient, the patient who is the potential subject should not be approached by the researchers unless the treating physician has documented in the medical record that the potential subject has agreed to discuss the study with the researchers. Alternatively, the treating physician may provide recruitment material, such as a flyer or information sheet about the study, which must include the contact information for the researchers, so the patient can initiate contact if they are interested in learning more about the research.

Definition:

"Treating physician" refers to a clinician with whom the prospective subject has a relationship that predates introduction of the research. When the treating physician is also the researcher, the IRB must assess whether the consent process, beginning with the recruitment, can be conducted without undue influence or elements of coercion, whether due to inherent aspects of the physician-patient relationship or intentional.

Note: **Recruitment of patients via the treating physician is the most favorable method of recruitment**

It is **not** appropriate in most situations for researchers to contact patients directly, using information in the medical record. However, depending on the specific circumstances of the study, the IRB may permit the introduction letter to be structured using an *opt-in* format, such that the patient is given contact information for the study team and initiates contact if he or she

wishes to learn more about the study. The introduction letter must be co-signed by the medical director of the unit or participating treating physician(s).

Alternatively, the introduction letter may use an *opt-out* format, in which the patient must take action within a specified interval if they do not wish to be contacted by the study team about the research study. The length of the interval during which outreach will be conducted, method of contact, and frequency of contact must be considered and explicitly stated in the recruitment text field and introductory letter. In general, it is not appropriate to contact patients more than three times, regardless of the interval. Additionally, if the medical director will sign the introductory letter, you must provide a plan to inform treating physicians about the research and give them an opportunity to decline outreach to some or all of their patients if they deem that participation in the research is not appropriate from a clinical perspective. A temporary waiver of consent for use of contact information, a HIPAA form D for screening of the medical record, and a HIPAA form B for use of the contact information must be submitted.

While *opt-in* is the preferred method of the two, **both *opt-in* and *opt-out* recruitment methods require additional consideration by the IRB prior to approval.**

ADDITIONAL INFORMATION: EPIC CONSENT TO CONTACT FOR RESEARCH (CCR) REGISTRY

The Consent to Contact for Research (CCR) Registry enables researchers to access and contact patents who indicate their willingness to be contacted for research, based on information in their medical records, without an initial connection through their treating physician or medical director. Patients can elect to be included in this registry of patients to be contacted for research opportunities by completing a consent form in the EPIC patient portal (Connect). They are then contacted via a Connect message and can provide their interest in a study, after which researchers can contact the potential participants. For a full description of the policy, specific protocol requirements for submission, and other Q/A on this recruitment method please see CU's Consent to Contact for Research (CCR) Registry.

Important: The CCR registry does **not** currently include minors, as the CCR consent form is only presented to patients who are at least 18 years old.

ADDITIONAL INFORMATION: FOR RECRUITMENT OF CU/NYP AFFILIATES (INCLUDING: EMPLOYEES, RESIDENTS, FELLOWS, INTERNS, STUDENTS)

Review by an institutional official, defined here as an individual who signs an applicable Federalwide Assurance, or designee is required for studies that propose to target CU or New York-Presbyterian (NYP) affiliates, including faculty, students and staff. Rascal submissions that describe the enrollment of CU or NYP affiliates must include the information described below:

1. Ensure that the following population **"[] CU/NYP Employees/Residents/Fellows/Interns/Students"** has been selected in the Vulnerable Populations section of the Subjects page.
2. Using the Recruitment text field, **explicitly state from which campus** students will be enrolled in, if applicable (e.g., Morningside, Medical Center, Manhattanville), or faculty/staff are affiliated with, **AND/OR** if NYP affiliates will be recruited and enrolled in research.
3. Attach a letter of support from the Chair, or other authorized representative, **of each department** in which affiliates are targeted. HRPO staff will initiate the review by the Institutional Official that is required when research involves this population.
4. Ensure that a plan for avoiding elements of coercion or undue influence of these populations is described in the Recruitment & Consent page . In general, **any member of the study team that oversees or is the supervisor/instructor of the population being targeted should not be involved in the recruitment/consent process** to avoid the potential for coercion/undue influence in their decision to participate. Neither should such individuals have access to identifiable data about the participants for which they have supervisory or other oversight.
5. Provide justification as to **why affiliates are being targeted** for research and advise if research aims and abstracts can be met with another population.
6. When CU or NYP employees will be enrolled, **add the following statements to the Confidentiality section of the Informed Consent Form/Information Sheet**:
    a. Medical Center studies: *"Participation in research is entirely voluntary. Your decision whether or not to participate will have no impact on your employment, student status, or any other entitlements. If you do choose to participate, the answers given will have no impact on salary, grade, or employment with Columbia University Irving Medical Center (CUIMC) or New-York Presbyterian (NYP)."*
    b. Morningside studies: *"Participation in research is entirely voluntary. Your decision whether or not to participate will have no impact on your employment, student status, or any other entitlements. If you do choose to participate, the answers given will have no impact on salary, grade, or employment with Columbia University."*

Notes:

1. If research will be targeting students enrolled in the CU Vagelos College of Physicians and Surgeons, the investigator must seek clearance of this targeted population by the VP&S Advisory Group and provide documentation in the IRB submission.
2. Additional requirements may be necessary for students enrolled as subjects in research. For guidance, please refer to Guidance on the Involvement of Students as Research Subjects.

ADDITIONAL INFORMATION: FOR RECRUITMENT OF PARTICIPANTS FROM ANOTHER RESEARCH STUDY

If potential participants who previously enrolled in completed or ongoing CU research protocols will be recruited, they must have provided consent to **future research contact for other studies under the original CU consent form**. Additionally, the recruitment material (email template, phone script, text script, etc.) should clearly state the research team is contacting them because

1. The individual previously participated in Columbia University Research Protocol AAAX-XXXX, AND ACYYXXXX.
2. The individual provided consent to future research contact.

If the consent documents for the index study were silent with respect to future contact, the investigator must provide justification as to why it may be appropriate to contact the subjects and the IRB will need to consider whether a waiver of consent to use prior study data for recruitment is appropriate.

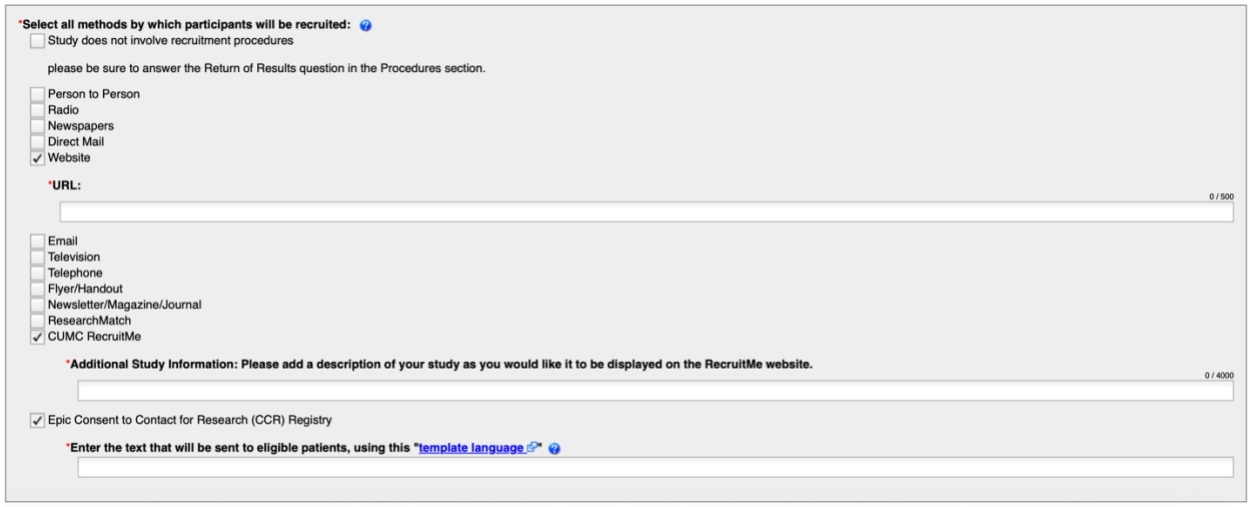
Note: For recruitment of participants from other research studies, the IRB will check the original consent form to assess whether it indicated that future research contact is applicable to:

a. Related research studies,
b. Unrelated research studies from the original protocol investigators, or
c. Unrelated research studies from other investigators at Columbia University.

Study teams should carefully track subject selections in all of their projects to ensure no efforts are made to contact individuals who indicated that they did not want to be contacted. If these specific considerations were not met in the original CU consent form, then additional consent may be required from the research participants.

Important: If you will recruit students or employees within NYC Public Schools, NYC DOE IRB approval, or confirmation that its IRB oversight is not needed, is required. If you are accessing school records, FERPA may be applicable.

Field 3: Select all methods by which participants will be recruited:



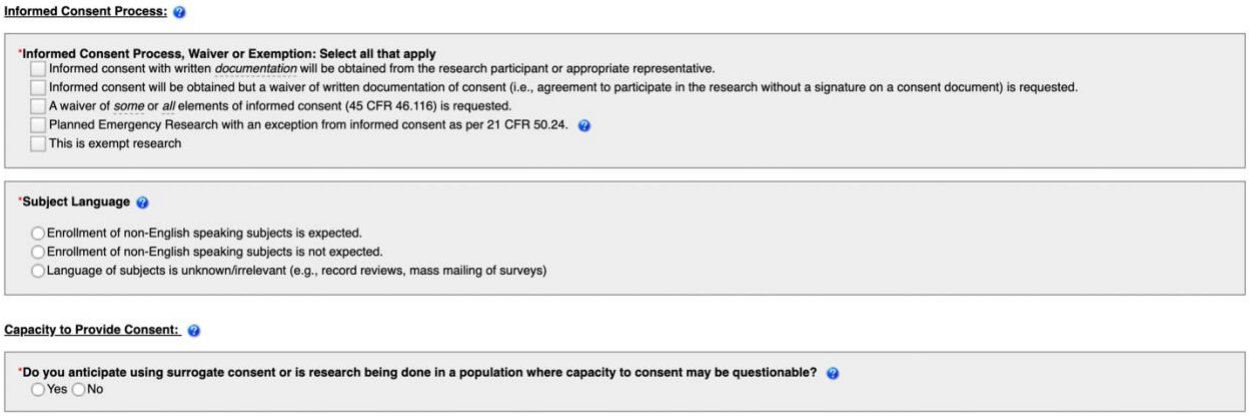
Select all applicable recruitment methods. Recruitment materials must be submitted as a pdf document in the "Documents" section in Rascal. All material utilized in the recruitment process must be approved by the IRB prior to use.

Note: "[] Study does not involve recruitment procedures" should only be selected if there is no recruitment and consent (verbal or written documentation) involved.

Important:

1. Review by Columbia's Communications and Public Affairs office **may be required** for recruitment outside of CU that involves public service announcements or press releases.
2. Permission should be obtained when posting recruitment flyers in both public and private places.
3. For **exempt** research, recruitment material should address any relevant elements required by institutional policy (audio/video recording, IO requirements) although a consent document is not required per federal regulations. Note that a consent form may be appropriate in some cases.

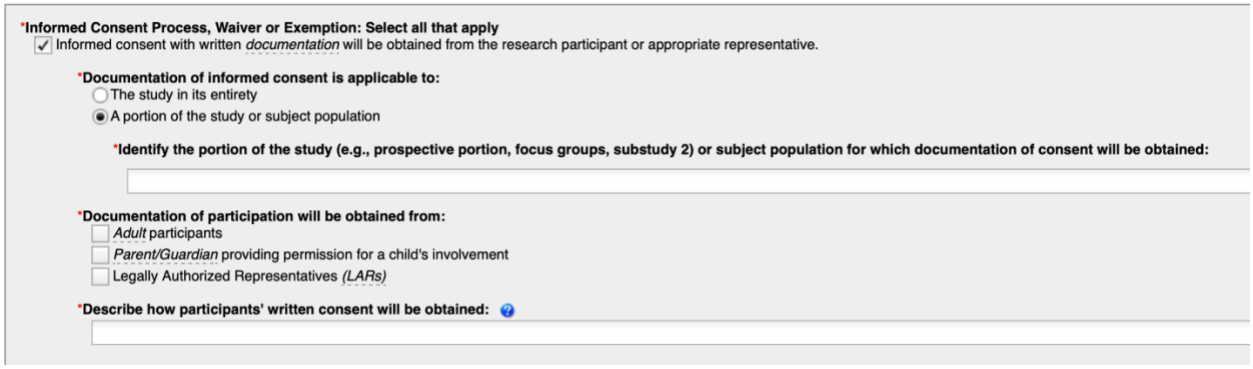
Field 4: Informed Consent Process, Waiver, or Exemption: Select all that apply



Informed consent, or an appropriate waiver thereof, is required for all non-exempt research involving human subjects, including research that only involves collection, use or analysis of data and/or biospecimen of subjects. Although informed consent is not required for exempt research, it is recommended when there will be interaction with research participants.

Tip: Please see the CU Informed Consent Policy for additional information regarding consent of human research subjects.

- **Select INFORMED CONSENT WITH WRITTEN DOCUMENTATION WILL BE OBTAINED FROM THE RESEARCH PARTICIPANT OR APPROPRIATE RESPRESENTATIVE** if a signature on a hardcopy or electronic consent document will be obtained from the research participant or authorized representative.



Documentation of informed consent is applicable to:

- Select **THE STUDY IN ITS ENTIRETY** if this consent process is applicable to all study participants/data.
- Select **A PORTION OF THE STUDY OR SUBJECT POPULATION** identify the portion of the study (e.g., prospective portion, focus groups, sub study (2 or more subject population) for which documentation of consent will be obtained.

Note: If the consent process is applicable to the study in its entirety, then another consent process (waiver of documentation, waiver of consent) should not be selected. If the consent

process is only applicable to a portion of the study, you must indicate which, if any, consent process is applicable to the additional cohort.

Documentation or participation will be obtained from:

- Select **ADULT PARTICIPANTS,** if consent will be obtained from individuals who have reached the legal age of consent, for the procedures that are involved, in the state where consent takes place.

Note: The legal age of consent for New York State is 18.

- Select **PARENT/GUARDIAN PROVIDING PERMISSION FOR THE CHILD'S INVOLVEMENT** if minors will be enrolled and written consent will be obtained from at least one parent/guardian.
- Select **LEGALLY AUTHORIZED REPRESENATIVE (LAR)** if individuals lacking capacity to consent will be enrolled and written consent will be obtained from the court-appointed legally authorized representative or allowable surrogate.

Important: ****The Columbia IRB distinguishes Parents/Guardians from LARs for minors, while noting that a legal Guardian is a type of LAR. In some cases, a minor's Parent or Guardian may not be able to provide permission for the minor to be enrolled in research, in which case a LAR or allowable surrogate may need to be involved.

Tips:

- **Parent/Guardian providing permission for a child's involvement**
  - Please see here for additional information regarding research involving children. Note that Parent refers to the minor's biological or adoptive parent, and Guardian refers to an individual who is authorized under applicable state or local law to consent on behalf of a child to general medical care.
- **Legally authorized representative**
  - Please see our informed consent policy for additional information regarding Legally Authorized Representative (**LAR).**

Describe how participants' written consent will be obtained:
Describe how consent will be obtained, including by whom, listing one or more titles or roles (e.g., PI, CO-I, coordinator), when (e.g., same day, prior to screening procedures) and by what method (e.g., in-person, remote, and if electronic consent may be used).
Additional elements to include are:

- A statement indicating the informed consent process will begin with a concise and focused presentation of the key information about the study
- A statement indicating that potential subjects will have an opportunity to ask questions and discuss the information provided
- Confirmation that the informed consent process presents information in sufficient detail relating to the research study.

Be sure to describe the means of communicating if non-English speaking, illiterate or other vulnerable persons will be included among study subjects. Also, if necessary, describe any visual aids or devices that may be used to help explain a complicated procedure or process.

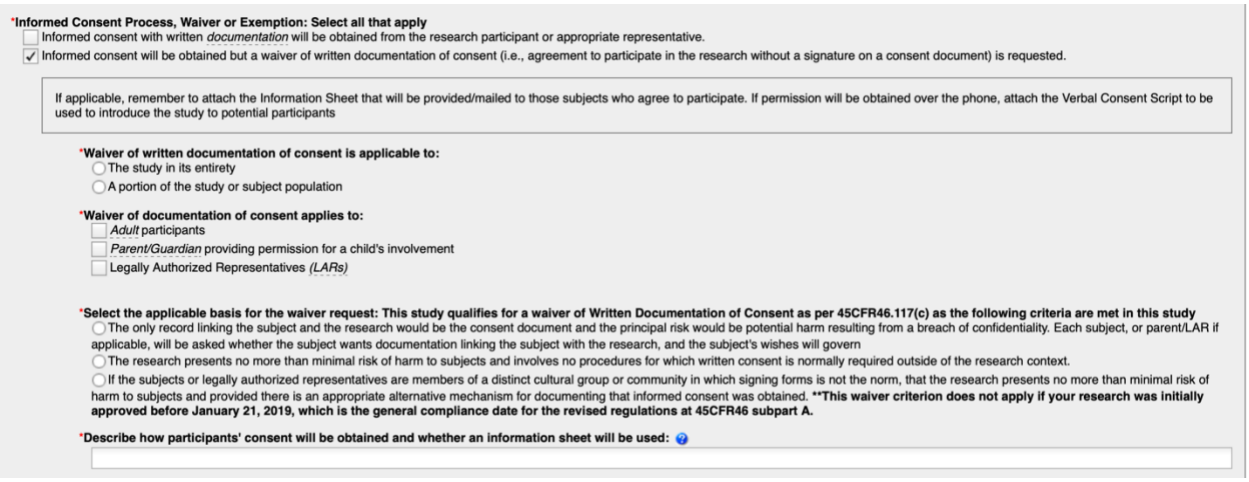
Note:

If e-consent is proposed, please address the following elements:

(a) Please describe what e-consent platform will be used.
(b) Is the e-consent program easy to navigate, allowing the user to proceed forward or backward within the system and to stop and continue at a later time?
(c) Will the e-consent platform allow for generation of a copy of the informed consent form signed by the Subject? The copy provided to the Subject can be paper or electronic and may be provided on an electronic storage device or via email. If the copy provided includes one or more hyperlinks to information on the Internet, the hyperlinks should be maintained and the information should be accessible until study completion.
(d) Is the e-consent process secure with restricted access along with methods to ensure confidentiality of the Subject's identity, study participation and personal information? Does the system comply with the Columbia University Information Security Charter and the other Information Security Policies referred to in such Charter to the extent applicable?
(e) Will HIPAA authorization be obtained electronically, either separately or as part of the e-Consent? If separate, a copy of the HIPAA Authorization Form must be provided to the Subject.
(f) Does the e-consent process incorporate procedures to ensure that electronic documents can be archived appropriately and that all versions of the IRB-approved e-Consent Form and all signed e-Consent Forms can be accessed and retrieved easily. If an electronic system is used exclusively for storage of e-Consent Forms, proper data backup should be maintained.
(g) Which type of e-consent is proposed, remote or in-person?
(h) If remote e-consent is proposed:
    i) Please explain how questions from Subjects may be asked and answered from a remote location.
    ii) Please clarify who will answer questions from Subjects.

- **Select INFORMED CONSENT WILL BE OBTAINED BUT A WAIVER OF WRITTEN DOCUMENTATION OF CONSENT (I.E. AGREEMENT TO PARTICIPATE IN THE RESEARCH WITHOUT A SIGNATURE ON A CONSENT DOCUMENT) IS REQUESTED,** if consent will be obtained from a

participant or authorized representative without a signature. Note that an online process that confirms the user's identity, e.g., through a log in system, and involves confirmation of consent through an action taken by the user, with documentation available to the research team, may be considered as written documentation. The IRB will make the assessment based on details that are provided.



Waiver of documentation of informed consent is applicable:

- Select **THE STUDY IN ITS ENTIRETY** if this consent process is applicable to all study participants/data.
- Select **A PORTION OF THE STUDY OR SUBJECT POPULATION** if this consent process is applicable to a certain portion of the study design and/or participants and identify the portion of the study for which documentation of consent will not be obtained. (e.g., prospective portion, focus groups, sub study, etc.)

Documentation or participation will be obtained from:

- Select **ADULT PARTICIPANTS** if consent will be obtained from individuals who have reached the legal age of consent in the state where consent takes place.
- Select **PARENT/GUARDIAN PROVIDING PERMISSION FOR THE CHILD'S INVOLVEMENT** if minors will be enrolled and permission will be obtained from at least one parent/guardian. Note that, for some research, permission from two parents is required.
- Select **LEGALLY AUTHORIZED REPRESENATIVE (LAR)** if individuals lacking capacity to consent will be enrolled and consent will be obtained from the appointed legally authorized representative or surrogate. ******Parents/Guardians are distinguished from LARs for minors. See additional information in this document here.**

Note: For additional information regarding the selections above, please refer to the information listed under **INFORMED CONSENT WITH WRITTEN DOCUMENTATION WILL BE OBTAINED FROM THE RESEARCH PARTICIPANT OR APPROPRIATE RESPRESENTATIVE**

Important: If applicable, remember to attach the Information Sheet that will be provided/mailed to those subjects who agree to participate. If permission will be obtained remotely, attach the Verbal Consent Script to be used to introduce the study to potential participants.

Select the applicable basis for the waiver request: This study qualifies for a waiver of Written Documentation of Consent as per 45CFR46.117(c) as the following criteria are met in this study

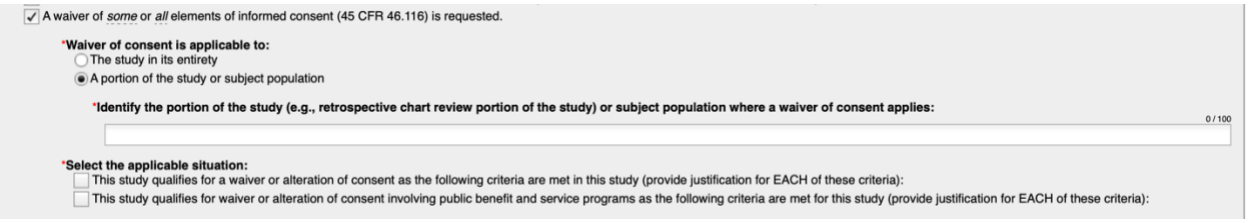
- Select **THE ONLY RECORD LINKING THE SUBJECT AND THE RESEARCH WOULD BE THE CONSENT DOCUMENT AND THE PRINCIPAL RISK WOULD BE POTENTIAL HARM RESULTING FROM A BREACH OF CONFIDENTIALITY** if applicable. Note that all subjects or authorized representatives must be asked if the subject wants documentation linking the subject with the research, and the subject's wishes will govern.
- Select **THE RESEARCH PRESENTS NO MORE THAN MINIMAL RISK OF HARM TO SUBJECTS AND INVOLVE NO PROCEDURES FOR WHICH WRITTEN CONSENT IS NORMALLY REQUIRED OUTSIDE OF THE RESEARCH CONTEXT** if applicable. Note that sufficient justification is required. Procedures involving invasive measures (e.g. blood draws) or scans (e.g. MRIs, Ultrasounds) are not acceptable under this designation.
- Select **IF THE SUBJECTS OR LARS ARE MEMBERS OF A DISTINCT CULTRUAL GROUP OR COMMUNITY IN WHICH SIGNING FORMS IS NOT THE NORM, THAT THE RESEARCH PRESENTS NO MORE THAN MINIMAL HARM TO SUBJECTS, AND PROVIDED THERE IS AN APPROPRIATE ALTERNATIVE MECHANISM FOR DOCUMENTING THAT INFORMED CONSENT WAS OBTAINED** if applicable. Note that all three criteria must apply.

Describe how participants' consent will be obtained and whether an information sheet will be used:

Describe how consent will be obtained, including by whom, listing one or more titles or roles (e.g., PI, CO-I, coordinator), when (e.g., same day, prior to screening procedures) and by what method (e.g., in-person, remote, mail, fax).

Please refer to the additional information provided above in the same field under the written documentation section.

- **Select A WAIVER OF SOME OR ALL ELEMENTS OF INFORMED CONSENT (45 CFR 46.116) IS REQUESTED,** if consent will not be obtained from any subject or authorized representative.

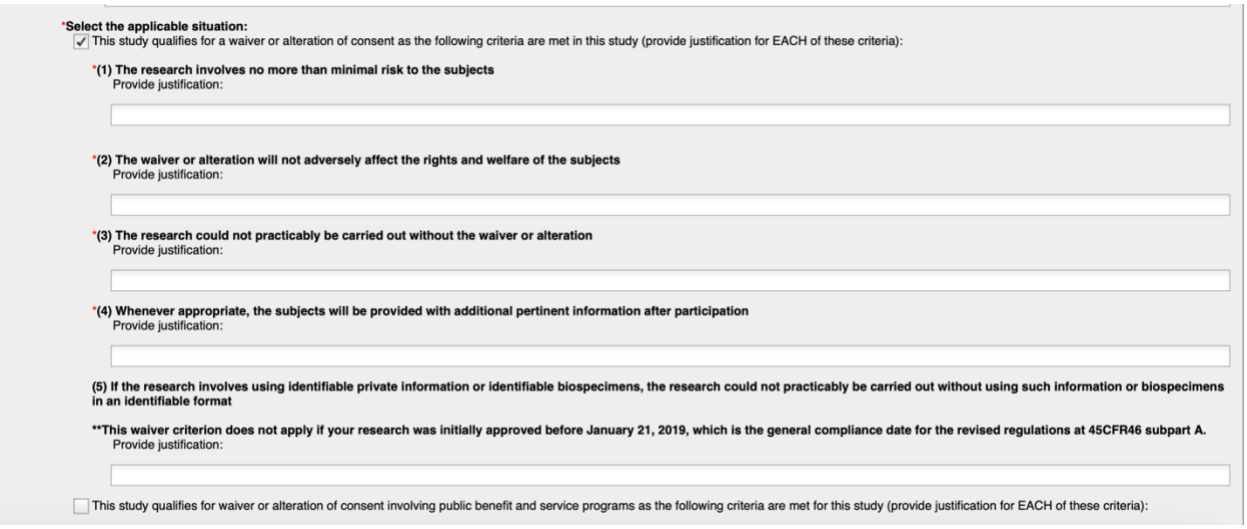


Waiver of consent is applicable to:

- Select **THE STUDY IN ITS ENTIRETY** if the waiver is applicable to all study participants/data.
- Select **A PORTION OF THE STUDY OR SUBJECT POPULATION** identify the portion of the study (e.g., prospective portion, focus groups, sub study, 2 or more subject populations) for which consent will be waived.

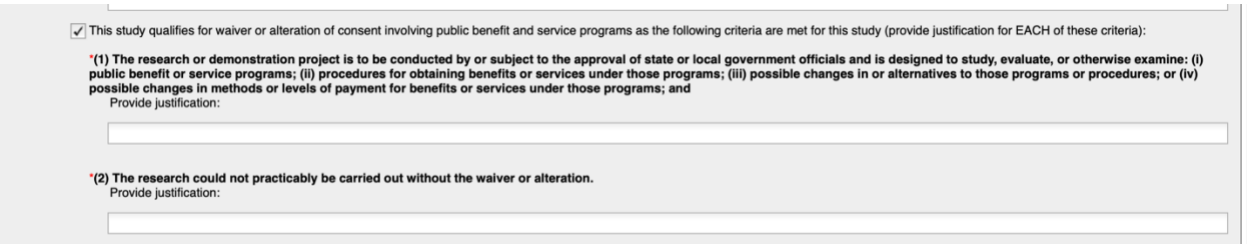
Select the applicable situation:

- Select **THE STUDY QUALIFIES FOR A WAIVER OR ALTERATION OF CONSENT AS THE FOLLOWING CRITERIA ARE MET IN THIS STUDY** to provide justification in the following fields:

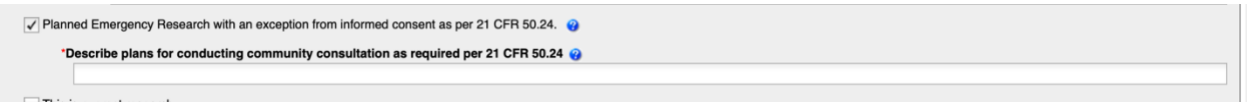


Definition: "Minimal Risk" means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests (45 CFR 46.102)

- Select **THE STUDY QUALIFIES FOR WAIVER OR ALTERATION OF CONSENT INVOLVING PUBLIC BENEFIT AND SERVICE PROGRAMS AS THE FOLLOWING CRITERIA ARE MET FOR THIS STUDY**, and provide justifications in the following fields:



- **Select PLANNED EMERGENCY RESEARCH WITH AN EXCEPTION FROM INFORMED CONSENT AS PER 21 CFR 50.24,** if the following section is applicable to your proposed study.



Planned emergency research refers to the study of acute, life-threatening clinical situations, most of which will occur in an emergency department. Often, informed consent from the subjects is not feasible because the subject lacks the capacity to provide his/her own consent (e.g., may be unconscious or have received medications that may impair judgement or awareness) and/or there is insufficient time because treatment must be promptly administered. The conduct of the **planned** research in life-threatening situations requires special consideration by the IRB, including consideration of whether consent by an individual subject may be waived. A consultation process is required to gain input from the local community as to whether an exception from the requirement for informed consent is acceptable. This is distinct from a waiver of informed consent.

Important: Planned Emergency Research is not to be confused with the emergency use of an investigational agent or device in a single patient. Planned Emergency Research is a rare occurrence. **Potential study participants must meet all previously determined study eligibility criteria to be enrolled in the proposed study protocol.**

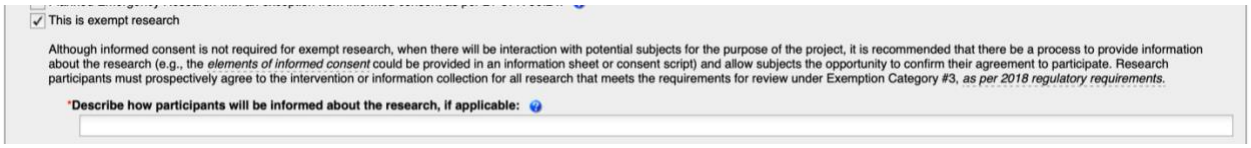
Per the FDA, the term "emergency research" refers to an investigation involving human subjects who have a life-threatening medical condition that necessitates urgent intervention (for which available treatments are unproven or unsatisfactory), and who, because of their condition (e.g., traumatic brain injury) cannot provide informed consent. The research must have the prospect of direct benefit to the patient and must involve an investigational product that, to be effective, must be administered before informed consent from the subject or the subject's LAR can be obtained and in which there is no reasonable way to identify prospectively individuals likely to become eligible for participation.

Describe plans for conducting community consultation as required per 21 CFR 50.24
If waiver of consent is proposed for those subjects who are not capable of providing consent, and do not have a LAR or other authorized surrogate present, the research plan must include not only public disclosure of the study to the community in which the research will be conducted, but also community consultation. The purpose of the community consultation is to assess whether members of the local population would approve of the conduct of the emergency research, i.e., whether they are in favor of such procedures being performed on them if they were in a particular emergency

situation. The community consultation should include individuals representing the targeted subject population enrolled in the study. The community consultation must be completed before IRB approval. It is recommended that the research team meet with the HRPO staff to discuss the plan for community consultation before its initiation.

Note: For additional guidance, please see the full federal regulatory policy for 21 CFR 50.24

- **Select THIS IS EXEMPT RESEARCH,** if your study meets the exempt or limited IRB eligibility criteria described under the Exempt and Expedited page (Section 4)

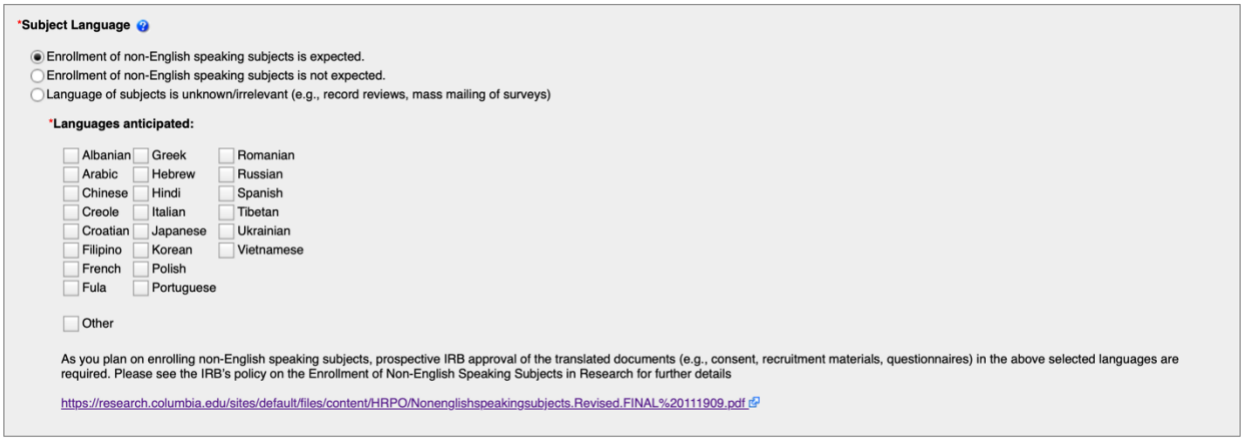


Although informed consent is not required for exempt research, when there will be interaction with potential subjects for the purpose of the project, it is recommended that there be a process to provide information about the research (e.g., the elements of informed consent could be provided in an information sheet or consent script) and allow subjects the opportunity to confirm their agreement to participate.

*****If the proposed research does not meet any of the categories for exempt human subjects research, DO NOT select this category*****

Important: Research participants must **prospectively agree** to the intervention, withholding of information, or information collection for all research that meets the requirements for review under Exemption, as per 2018 regulatory requirements.

Field 5: Subject Language



"Non-English-speaking subjects" are defined as individuals whose primary language is not English, and the English language proficiency is not at a level that would permit legally effective informed consent to be obtained in English. In addition, the term "expected" is defined as the

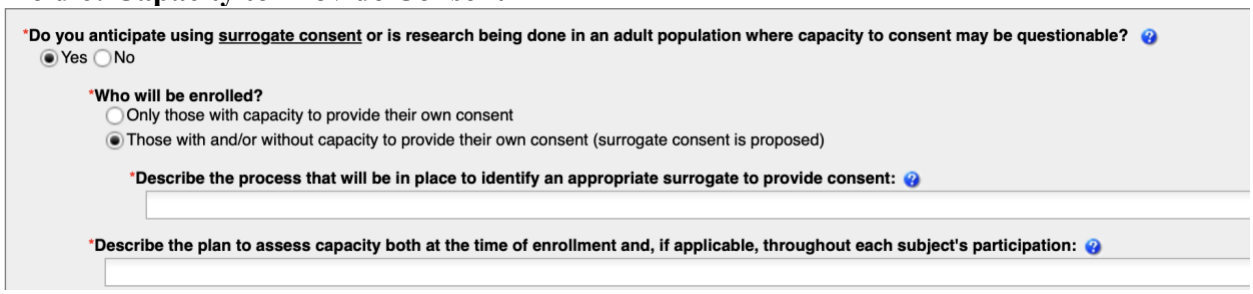
research team anticipates that a significant number of subjects who are fluent in any single language other than English will be eligible for the study.

Before completing this section, please refer to the University's policy on the Enrollment of Non-English-speaking Subjects to be familiar the University's expectations, particularly for CUIMC, based upon the demographics of the community served.

Important: If recruitment will occur from within the Northern Manhattan neighborhood wherein the medical center is located, given the predominantly Spanish speaking population within this neighborhood, and noting that broad representation in clinical research may benefit generalizability of research findings and the population of participants, please either reflect that you will enroll Spanish-speaking participants or provide a justification as to why non-English speaking subjects are not expected.

Note: If you plan on enrolling non-English speaking subjects, prospective IRB approval of the translated documents (e.g., consent, recruitment materials, questionnaires) in the above selected languages with an accompanying certificate of translation are required. These must be submitted via a modification **after** the English versions of these documents are submitted and approved by the IRB in the event the HRPO staff (for exempt research) or an IRB member or convened board require revisions to the English versions (for non-exempt research).

Field 6: Capacity to Provide Consent



Field 6a: Do you anticipate using surrogate consent or is research being done in a population where capacity to consent may be questionable?

- Select **NO** if surrogate consent or legally authorized representatives will not be used, or if research is being done in an adult population where capacity to consent is certain.

- Select **YES** if surrogate consent or legally authorized representatives will be used, or if capacity to consent an adult population may be evaluated.

If the answer is **YES** additional fields (shown above) will come up.

NOTES:

1. If research is being done in a population where capacity to consent may be questionable (e.g., mild cognitive impairment), but only those with capacity to provide their own consent will be enrolled, this question should be answered YES.
2. The IRB will generally consider the use of surrogate consent for research that would:
   a. provide the prospect of direct benefit to subjects who lack capacity; or,
   b. study disorders, conditions, or factors that affect individuals who lack capacity when the research is minimal risk, with or without the prospect of direct benefit, and the research could not otherwise be conducted on subjects who have capacity. When the IRBs review protocols in category (b) above, they are more likely to favorably consider them if they include only the types of minimal risk procedures that are routinely performed in a clinical setting without specific informed consent for all patients whether they have, or lack, the capacity for consent. The IRBs will also consider other minimal risk protocols.

Field 6b: Who will be enrolled?

- Select **ONLY THOSE WITH CAPACITY TO PROVIDE THEIR OWN CONSENT** if consent will be obtained only from those with capacity to provide consent.
- Select **THOSE WITH AND/OR WITHOUT CAPACITY TO PROVIDE THEIR OWN CONSENT (SURROGATE CONSENT IS PROPOSED)** if you will enroll individuals without capacity to provide consent. If this selection is made, the following field will come up:

Describe the process that will be in place to identify an appropriate surrogate to provide consent

Note: Columbia IRB policy for surrogate consent limits who may act as a representative to individuals permitted by the statutes of the jurisdiction within which the research is conducted. Furthermore, in New York State, surrogate options are defined in the Family Health Care Decisions Act.

- Section F of CU IRB's Informed Consent Policy
- Family Health Care Decisions Act

Field 6c: Describe the plan to assess capacity both at the time of enrollment and, if applicable, throughout each subject's participation:

Subjects who appear to lack capacity must have the assessment of capacity made by a licensed physician(s) in accordance with standard practice and applicable state law. In general, the determination that the subject lacks capacity must be made by someone other than the study investigators or study staff. For a given study, the IRB may approve an exception to this requirement. For an exception to be granted

by the IRB, the investigator must submit a specific request for such an exception that includes a justification and written plan for assessment of capacity.

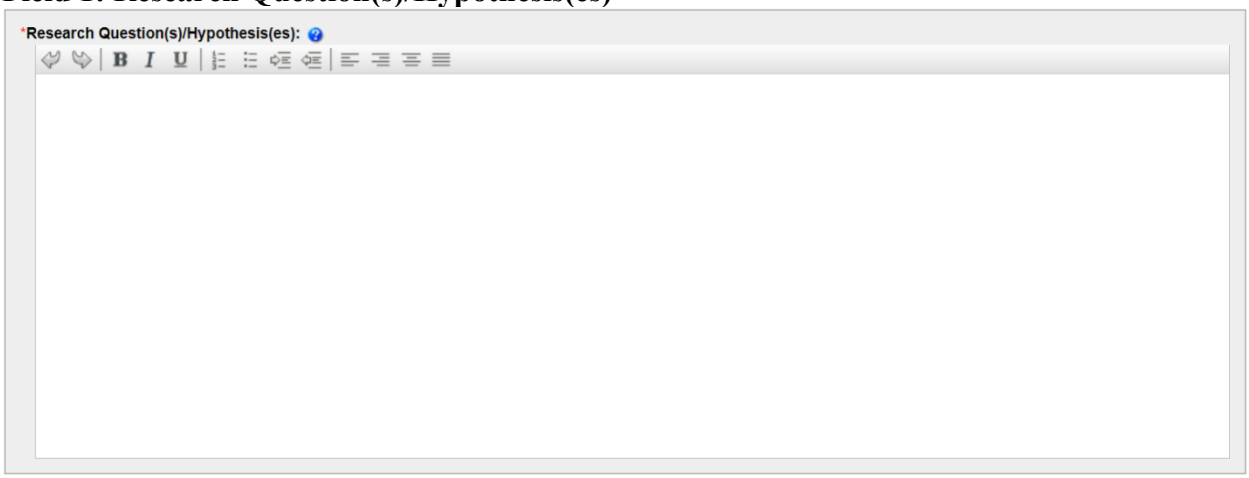
Include a plan for obtaining consent from the participant at such time as participants regain the capacity to provide consent, if participants may regain such capacity.

SECTION 11: RESEARCH AIMS & ABSTRACTS

The following free text boxes should be completed, where applicable.

Note: The text boxes on this page do not provide an "Abbreviated Submission" option. As such, please ensure that a response is provided within each field.

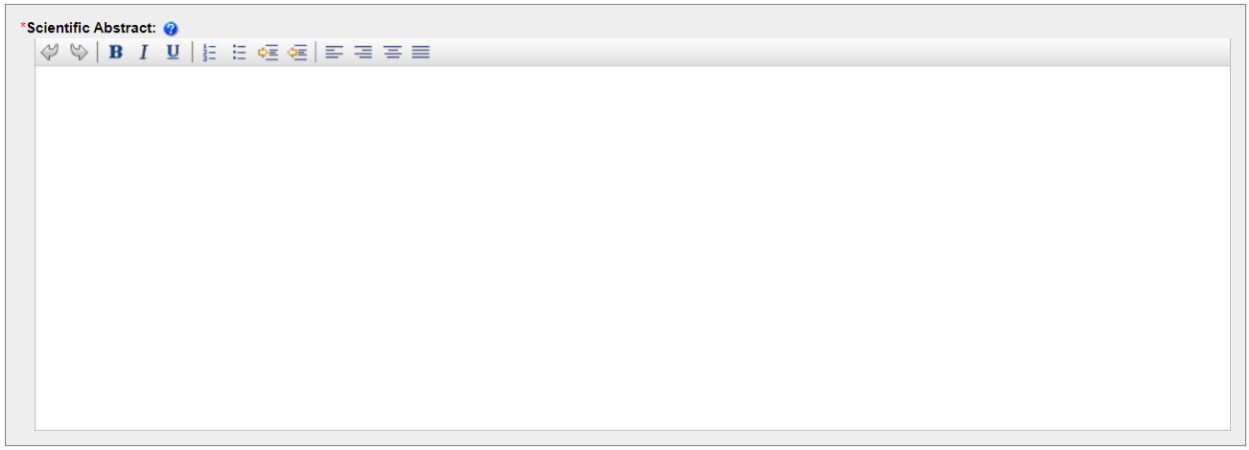
Field 1: Research Question(s)/Hypothesis(es)



Add the hypothesis(es) or research question(s) to be investigated in this study. If more than one hypothesis or research question will be investigated, consider which one is primary, secondary, etc. If these are outlined in a standalone protocol or grant application, they can be copied and pasted.

Important: Protocols should address defined research questions. **Broad protocols that permit the addition of multiple future analysis, or don't present defined goals and analyses, do not meet the IRB submission requirements and will be returned by the IRB.** This guidance applies to standard study designs. Adaptive clinical trials, which are designed to allow for pre-planned adaptive changes to the conduct of research, and do not always have very defined analyses, are not included in this description. Specific goals will allow the IRB to assess the research risk-benefit, scientific merit or relevance and avoid burdening subjects.

Field 2: Scientific Abstract

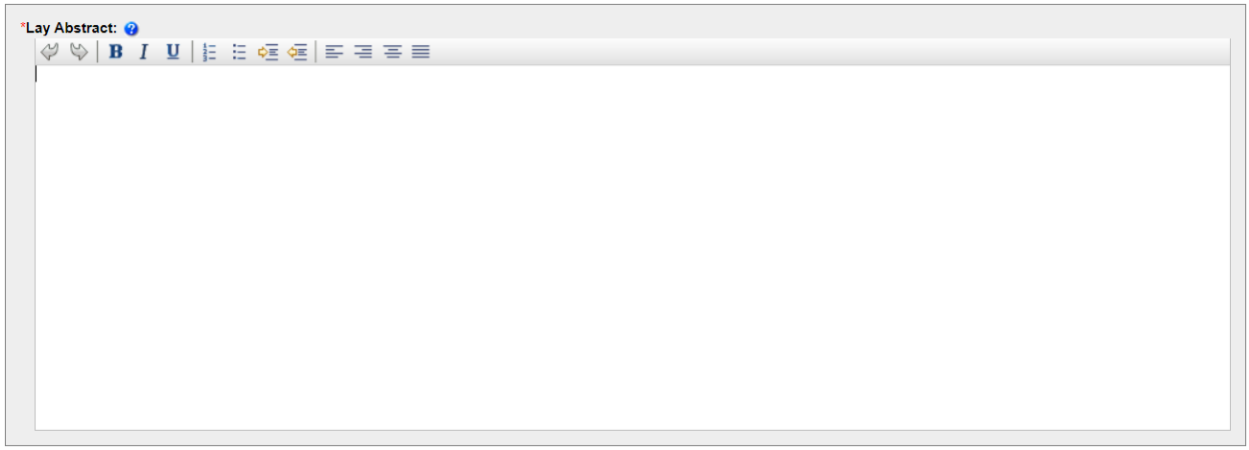


Describe clearly and concisely the broad objectives, subject population, types of general procedures, and the potential significance of the research. All acronyms should be spelled out in full the first time they are used, e.g. New York State Department of Health (NYSDOH). If a clear and concise scientific abstract is included in the standalone protocol or grant application, it can be copied and pasted.

The following elements should be included in the scientific abstract:

1. Who are the subjects?
2. What methods will be used to answer the research question(s)?
3. What will the subjects be asked to do?
4. What is the potential significance of the project?

Field 3: Lay Abstract



The required information about the study should be presented clearly and concisely in language that is understandable to a non-scientific reader, such as HRPO staff and the nonscientist member of the IRB.

Note: Although the scientific and lay abstracts summarize the same research and the elements to include are the same, the language should be different because the audience intended for each abstract is not the same.

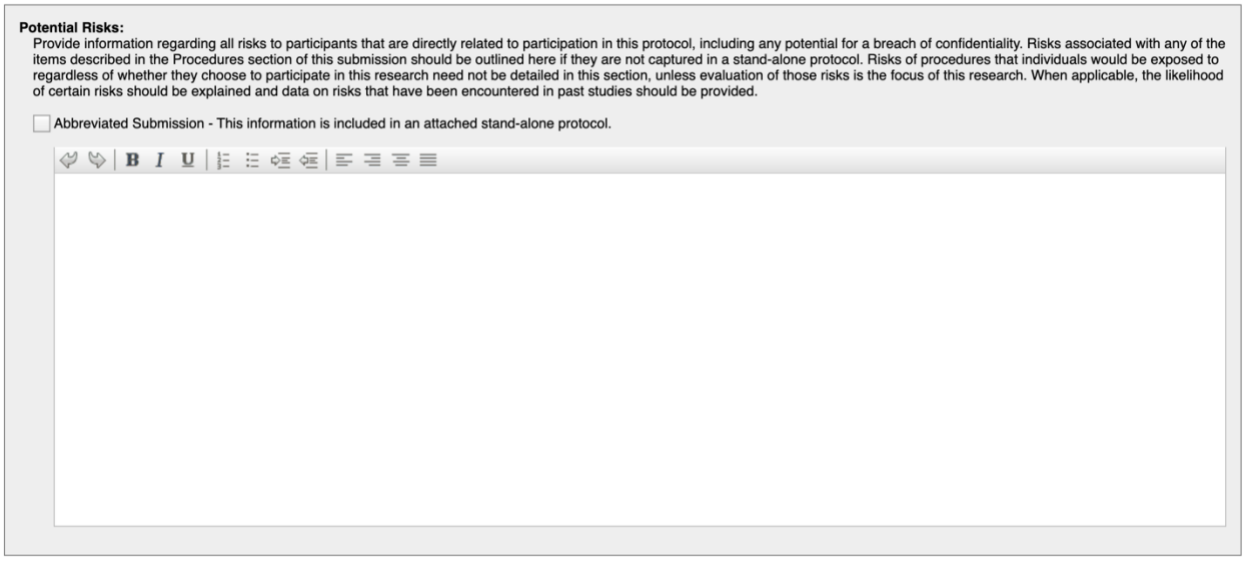
Important: Text that is copied and pasted from a standalone protocol, grant application, or any pdf document can result in distorted text, e.g., special characters, odd spacing, or varied font sizes. Before submitting the protocol, "View Datasheet" to ensure that the text is clean to avoid an automatic return of the submission for edits.

SECTION 12: RISKS, BENEFITS & MONITORING

Note: If the study team has developed or has received a standalone protocol document from the lead site or the Sponsor of the study, there is check box in each of the text fields to indicate that an Abbreviated Submission approach is an option (see below). If selected, it will remove text fields from the page and direct HRPO staff to the attached "standalone/sponsor's protocol" document in the Documents section.

*Grant proposal pages are not appropriate alternatives to a standalone protocol.

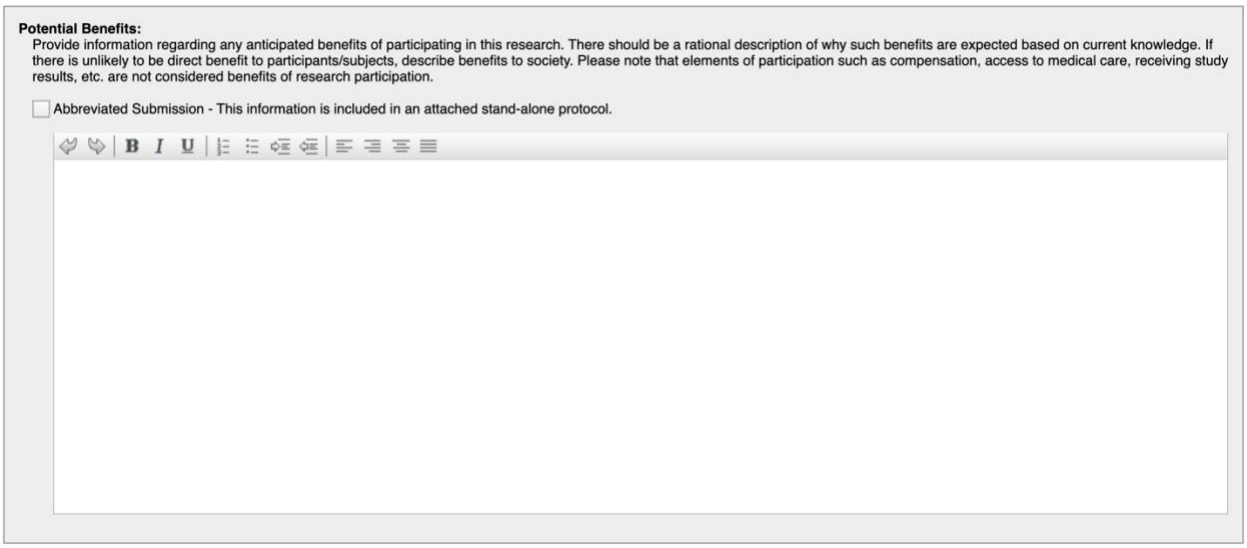
Field 1: Potential Risks



Please provide information regarding all risks to participants that are directly related to participation in the protocol, including any potential for a breach of confidentiality. Risks associated with any of the items described in the Procedures section should be outlined in this section if they are not captured in a standalone protocol.
Risks of procedures that individuals would be exposed to regardless of whether they choose to participate in the research need not be detailed, unless evaluation of those risks is the focus of the research. When applicable, the likelihood of certain risks should be explained and data on risks that have been encountered in past studies should be provided.

Note: At a minimum, most research involves the risk of breach of confidentiality.

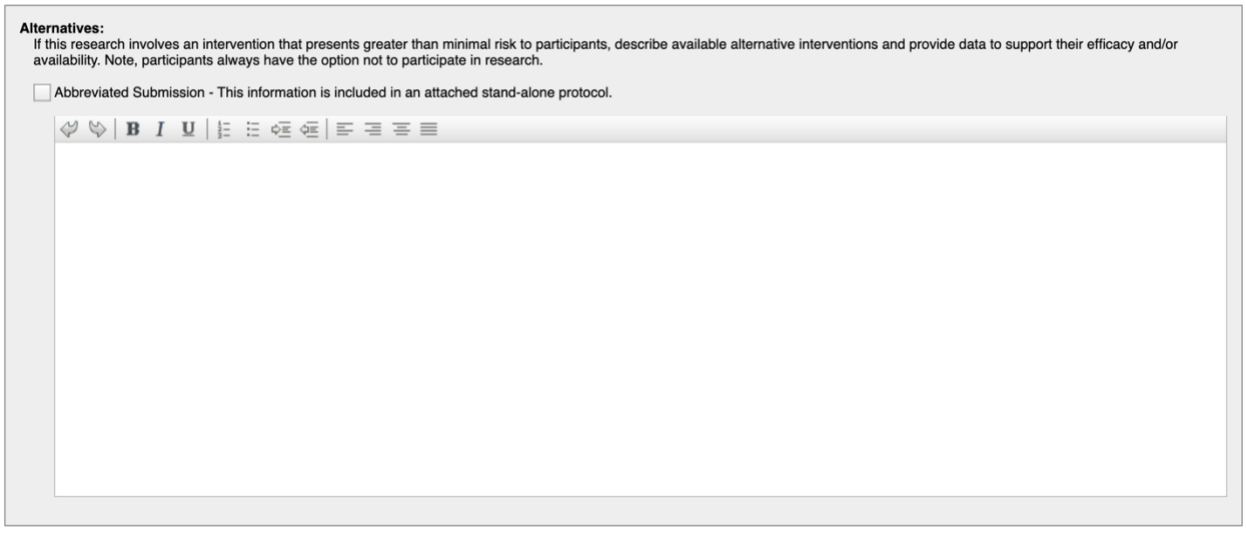
Field 2: Potential Benefits



You should provide information regarding any anticipated benefits of participating in the research. There should be a rational description of why such benefits are expected based on current knowledge. If there is unlikely to be direct benefit to participants/subjects, describe benefits to society.

Note: Elements of participation such as compensation, access to medical care, and receiving study results are not considered *benefits* of research participation.

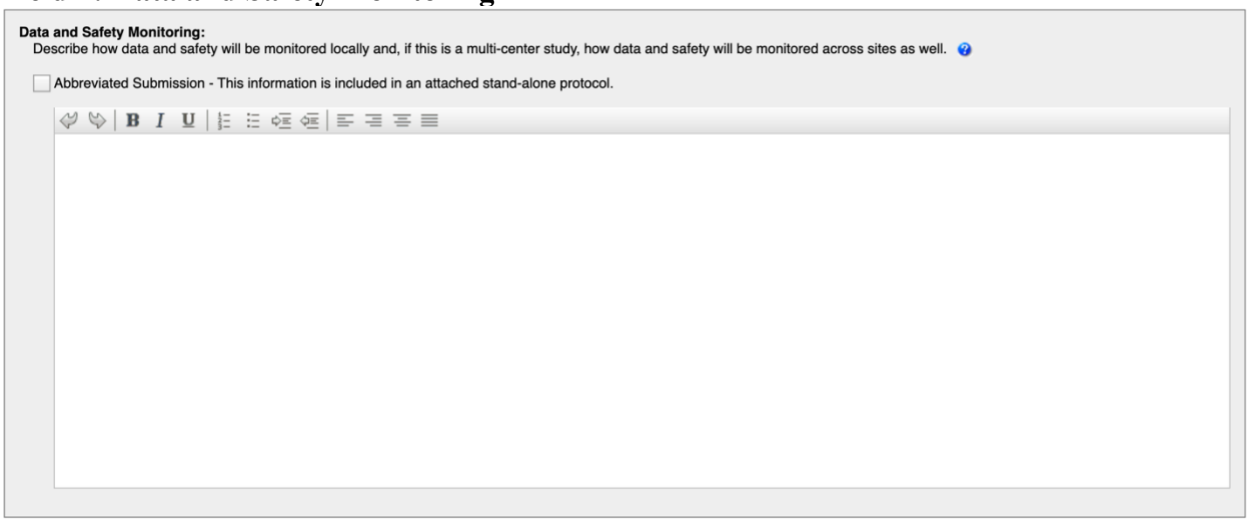
Field 3: Alternatives



Describe available alternative interventions and provide data to support their efficacy and/or availability.

Important: Participants always have the option not to participate in research or withdraw their consent at any time.

Field 4: Data and Safety Monitoring



Provide detailed information regarding who will be performing the data and safety monitoring for the study and how the monitoring plan will be carried out. Describe local monitoring to track adverse events **(AEs)** (as applicable) and identify unanticipated problems (**UPs) (**i.e., events, outcomes, or occurrences that are unexpected, at least possibly related to the research, and suggest an increase in risk of harm to subjects or others). Note that only the AEs that also meet the UP criteria require reporting to the IRB. The IRB does not have the information that is necessary to assess AEs that are not UPs.
Indicate whether a Data and Safety Monitoring Board (DSMB), Data Monitoring Committee (DMC) or other monitoring entity will be put in place for this project and, if yes, provide membership details and frequency of meetings. If this project is more than minimal risk AND a DSMB/DMC will not be formed, please describe the plans for data and safety monitoring for your site and if applicable, the lead site.

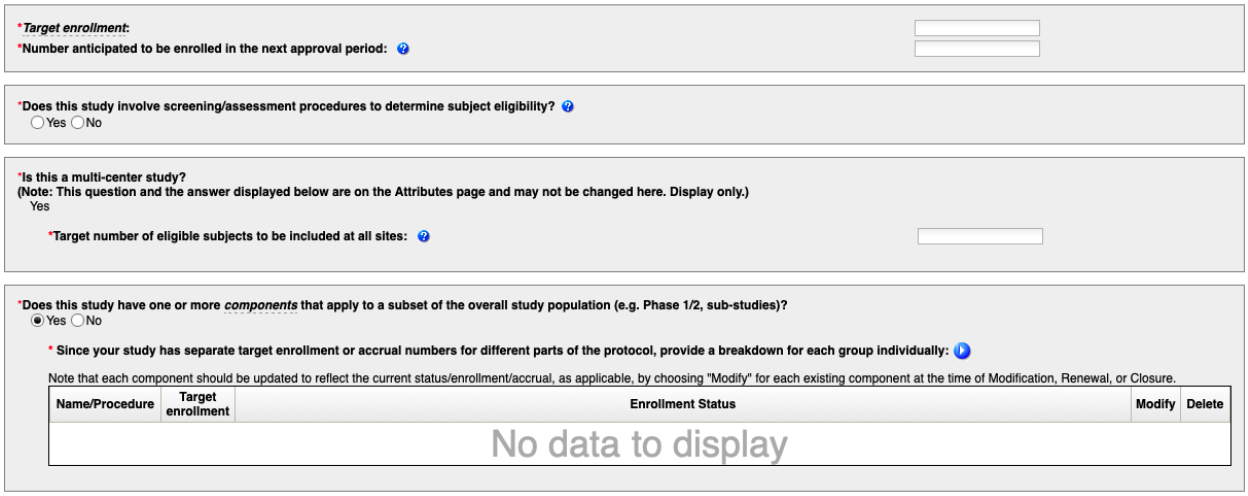
Note: If you are describing local monitoring plans in this section, and additional monitoring is described in the stand-alone protocol, please provide the page number of the additional information in the text box below.

SECTION 13: SUBJECTS

The information entered in this section should reflect the number of subjects enrolled, i.e., who provided consent or for whom the requirement for consent was waived, or accrued (if applicable, i.e., passed screening procedures), under the purview of Columbia researchers. If Columbia is the lead site of a multi-center study, this section should reflect the number of subjects enrolled or accrued at all sites.

Note: "Subjects" and "Participants" refers to the individuals from whom consent is obtained, when consent is required, and to the unique individuals about whom data is collected or from whom biological samples are collected, when consent is not required.

The following fields should be completed as requested:



Field 1: Target enrollment

This number refers to the number of individuals anticipated to agree to participate in this study, even if just for screening/assessment purposes, or all unique individuals about whom data may be collected or from whom specimens may be collected.

Note: For multi-center studies where Columbia is the lead site, the target enrollment should reflect the total target number for all study sites.

Field 2: Number anticipated to be enrolled in the next approval period

This is the estimated number of participants you expect to enroll from the time the protocol is approved until the renewal or annual report date reported on your determination letter (in **most** cases, this is 1 year).

Field 3: Does this study involve screening/assessment procedures to determine eligibility?

- Select **NO** if there are no screening procedures after consent is obtained and all consented participants are eligible to participate in research or, if consent has been waived, only data or biospecimens of individuals deemed eligible will be collected.
- Select **YES** if there are screening/assessment procedures that occur after the consent process to determine if participants meet the study eligibility criteria.

If **YES** is selected, please complete the subsequently generated fields (see screenshot above).

Note: Your target enrollment should not be the same value as your target accrual. Target enrollment includes all individuals who agree to screening procedures, consent procedures, and study procedures. Your target accrual is a subset of your target enrollment, and includes all individuals who pass screening procedures.

Field 4: Is this a multi-center study?

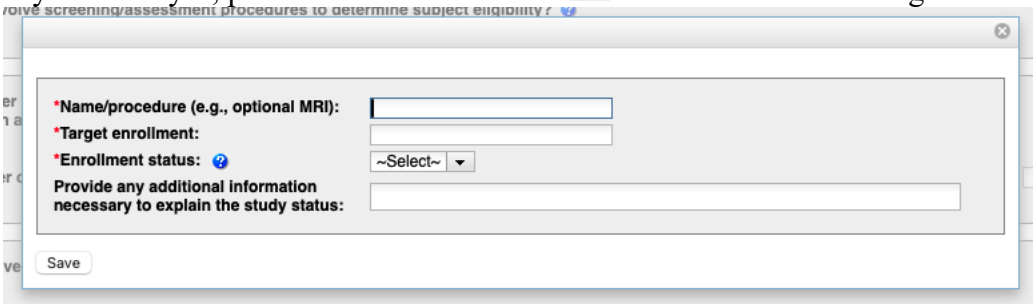
This question will only appear if you've indicated **YES** to **IS THIS RESEARCH PART OF A MULTICENTER STUDY?** on the **ATTRIBUTES** page. The answer "**Yes**" will appear along with the question, and the following secondary question will appear and require a response: *TARGET NUMBER OF ELIGIBLE SUBJECTS TO BE INCLUDED AT ALL SITES.

- For protocols without screening procedures after consent, this field should reflect the anticipated target enrollment for participants across ALL sites.
- For protocols with a screening procedure after consent, this field should reflect the anticipated target accrual (i.e. enrolled subjects who are screened and found to be eligible to participate in the intervention) for participants across ALL sites.

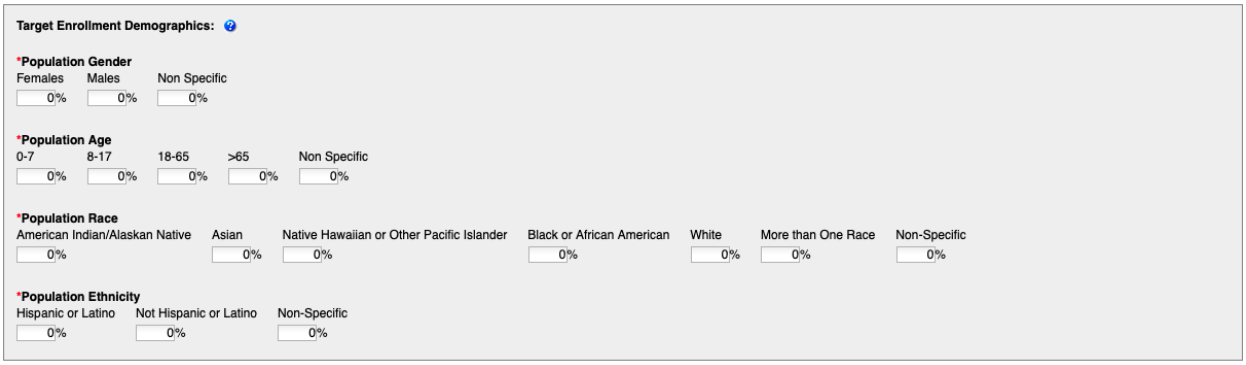
Field 5: Does this study have one or more components that apply to a subset of the overall study population (e.g. Phase 1/2, sub-studies)?

- Select **NO** if there is only one phase and/or cohort of the study or study population.
- Select **YES** if the study has more than one phase and/or cohort of the study or study population.

If you select yes, please select the blue icon to include the following information:



Field 6: Target Enrollment Demographics

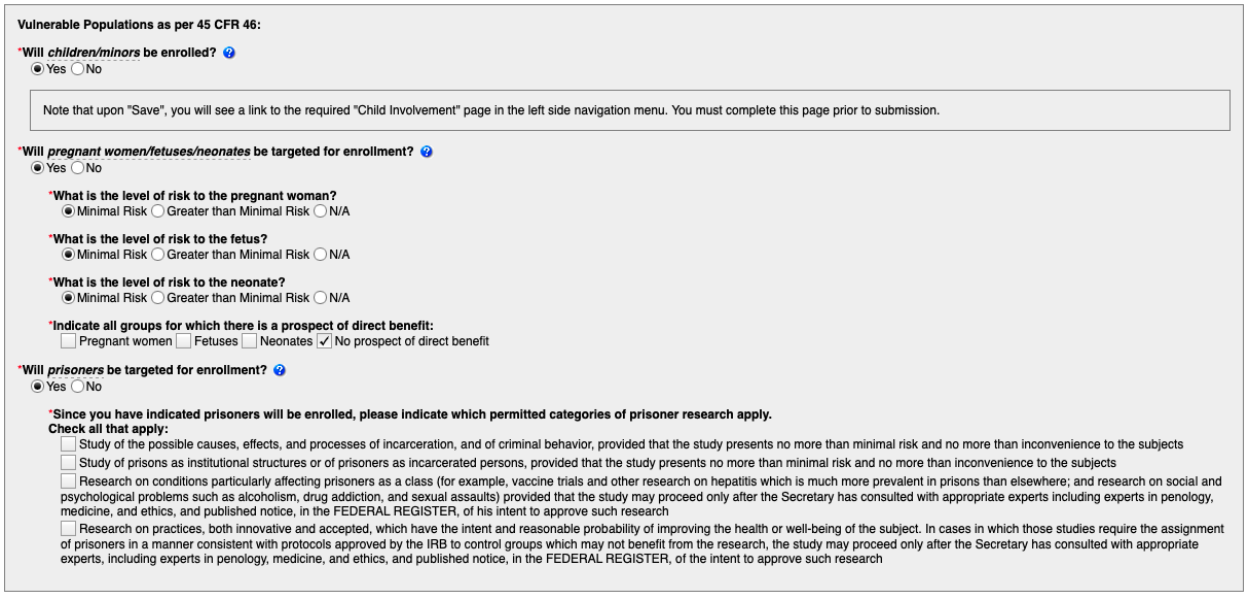


Each category must add up to 100%. "Non-Specific" may be used if Gender, Race, and Ethnicity are unknown or not relevant to the study.

Important: Population Age should clearly indicate whether children/minors are included. It is not appropriate to indicate "100% Non-Specific" for Population Age. The IRB must make additional determinations if the study population includes anyone that does not meet the age of majority in the study location, so this information is very important.

Field 7: Vulnerable Populations as per 45 CFR 46

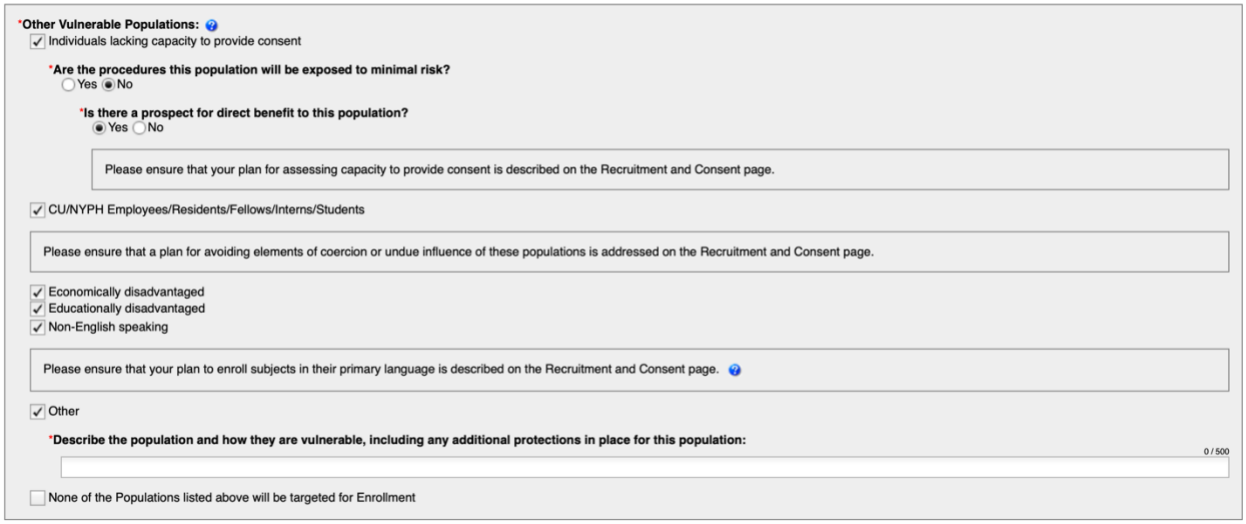
The HHS regulations at 45 CFR 46 include additional requirements for specific categories of vulnerable populations. If you plan to enroll subjects from any of these federally recognized vulnerable populations, which include children/minors, pregnant women/fetuses/neonates, and prisoners, please make the appropriate selection in the section below.



Definition: *Neonates* are defined by the Columbia IRB as newborns 28 days or younger.

Note: Additional justification is required for the inclusion of pregnant women/fetuses/neonates. Please see Field 9: Subject Population Justification.

Field 8: Other Vulnerable Populations



Please review the list of vulnerable populations identified by the Columbia IRB and select those that will be enrolled in your proposed study.

Important: These fields must be consistent with your proposed recruitment plans detailed in the Recruitment and Consent page.

Field 9: Subject Population Justification

Describe the characteristics of the proposed subject population, including any factors not captured above that are relevant to this research. Explain why you will be targeting the proposed subject population, or if you are excluding a specific population.
Reminder: If recruitment will occur from within the Northern Manhattan neighborhood wherein the medical center is located, given the predominantly Spanish speaking population within this neighborhood, and noting that broad representation in clinical research may benefit generalizability of research findings and the population of participants, please either reflect that you will enroll Spanish-speaking participants or provide a justification as to why non-English speaking subjects are not expected within the text field.

Important:

If you are enrolling neonates, you must address the following regulatory requirements:

Viability (viable, non-viable, neonates of uncertain viability, or mix of multiple categories)

1. **For both non-viable neonates and neonates of uncertain viability**, the following conditions must be confirmed:
    a. Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates.
    b. Each individual providing consent under paragraph (b)(2) or (c)(5) of this section is fully informed regarding the reasonably foreseeable impact of the research on the neonate.
    c. Individuals engaged in the research will have no part in determining the viability of a neonate.
    d. The requirements of paragraph (b) or (c) (see below) of this section have been met as applicable.
2. **For non-viable neonates,** the following conditions must be confirmed:
    a. Vital functions of the neonate will not be artificially maintained;
    b. The research will not terminate the heartbeat or respiration of the neonate;
    c. There will be no added risk to the neonate resulting from the research;
    d. The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means; and
    e. The legally effective informed consent of both parents of the neonate is obtained in accord with subpart A of this part, except that the waiver and alteration provisions of §46.116(c) and (d) do not apply. However, if either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the informed consent of one parent of a nonviable neonate will suffice to meet the requirements of this paragraph (c)(5), except that the consent of the father need not be obtained if the pregnancy resulted from rape or incest. The consent of a legally authorized representative of either or both of the parents of a nonviable neonate will not suffice to meet the requirements of this paragraph (c)(5).
3. **For neonates of uncertain viability,** the following conditions must be confirmed:
    a. 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, or
    b. 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; and
    c. The legally effective informed consent of either parent of the neonate or, if neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the legally effective informed consent of either parent's legally authorized representative is obtained in accord with subpart A of this part (see above), except that the consent of the father or his legally authorized representative need not be obtained if the pregnancy resulted from rape or incest.

Important:

If you are enrolling pregnant women and/or fetuses, you must provide information to address the following regulatory requirements:

1. Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on nonpregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses;
2. The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus; or, if there is no such prospect of benefit, the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means;
3. Any risk is the least possible for achieving the objectives of the research;
4. If the research holds out the prospect of direct benefit to the pregnant woman, the prospect of a direct benefit both to the pregnant woman and the fetus, or no prospect of benefit for the woman nor the fetus when risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means, her consent is obtained in accord with the informed consent provisions of the pre-2018 Requirements or the 2018 Requirements, as applicable;
    a. If the research holds out the prospect of direct benefit solely to the fetus then the consent of the pregnant woman and the father is obtained in accord with the informed consent provisions of the pre-2018 Requirements or the 2018 Requirements, as applicable, except that the father's consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest;
    b. Each individual providing consent under paragraph (3) or (4) of this section is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate;
    c. For children as defined in §46.402(a) who are pregnant, assent and permission are obtained in accord with the provisions of subpart D of this part;
    d. No inducements, monetary or otherwise, will be offered to terminate a pregnancy;
    e. Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy; and
    f. Individuals engaged in the research will have no part in determining the viability of a neonate.

Field 10: Does this study involve compensation or reimbursement to subjects?

Describe any payment, reimbursement, or other compensation that will be offered to prospective subjects. Explain why the subjects will be offered payment or other compensation for study participation, or if they will be reimbursed for out-of-pocket expenses. State the terms of any

payment, including the amount, what form it will take, the formula for prorating (if applicable), and when it will be paid.

Those subjects qualifying for compensation of $2000 or more in calendar year 2026 will need to complete a W9 form and provide their social security number for IRS reporting purposes. IRS has indicated that the reporting threshold will increase in each calendar year after 2026. If your study includes more than the IRB threshold in compensation for individual participants in a calendar year, the following should be added to the consent document: *According to IRS regulations, payments totaling more than $[threshold amount] in a calendar year may be considered taxable compensation and will be reported to the Internal Revenue Service (IRS).* **The fact that social security numbers will be collected must also be reflected in the Privacy and Data Security page.**

The following payment options, when the payment is made by CU, should be considered and have been endorsed by the University:

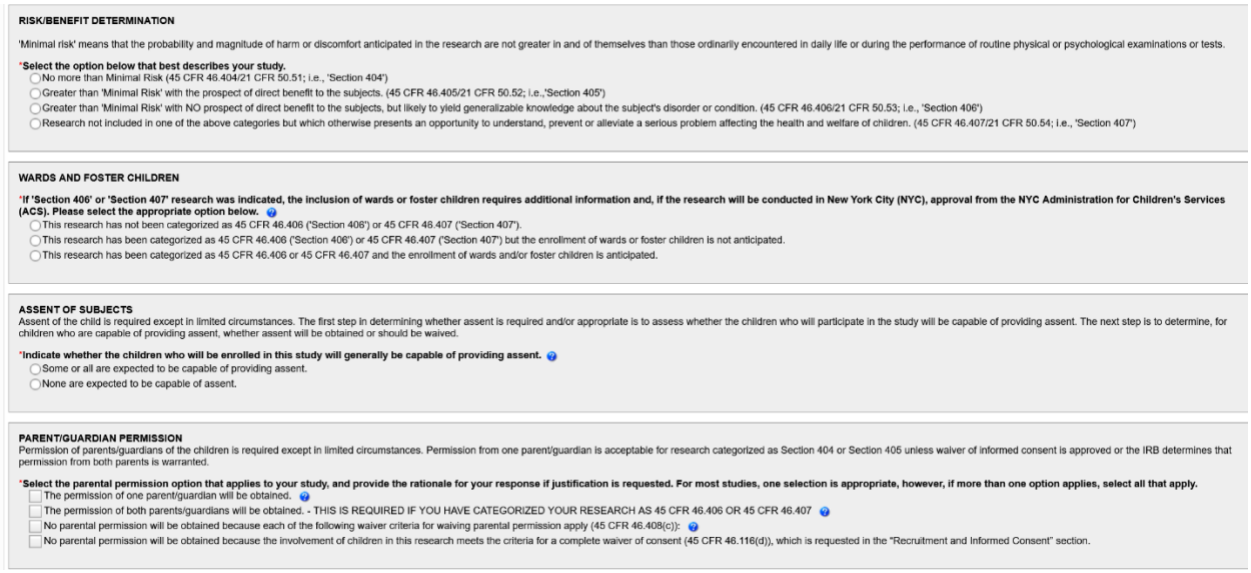
- For all campuses: U.S. Bank Paycard, check, petty cash
- For CUIMC: digital compensation (e.g. gift cards, Venmo, PayPal, direct bank account deposit, deposit to debit card) or physical debit card via TruCentive.

For additional information regarding appropriate methods of compensation, including updates to the types of permissible methods and IRS threshold, please refer to the Reimbursement and Compensation of Research Participants section on the Columbia IRB's Policy page.

Important: Cash is generally not an acceptable form of payment to participants according to guidance from Columbia financial leadership. Requests for the use of cash compensation must be approved by the appropriate institutional financial office. HRPO staff will facilitate review of proposed compensation through petty cash with the applicable office. This approval must be attached in Rascal.

SECTION 13A: CHILD INVOLVEMENT

The Child Involvement page asks for a lot of information, as indicated below. You should review the University's IRB Policy on Research Involving Children for further information as you fill out the responses.



RISK/BENEFIT DETERMINATION

'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.

*Select the option below that best describes your study.
- No more than Minimal Risk (45 CFR 46.404/21 CFR 50.51; i.e., 'Section 404')
- Greater than 'Minimal Risk' with the prospect of direct benefit to the subjects. (45 CFR 46.405/21 CFR 50.52; i.e.,'Section 405')
- Greater than 'Minimal Risk' with NO prospect of direct benefit to the subjects, but likely to yield generalizable knowledge about the subject's disorder or condition. (45 CFR 46.406/21 CFR 50.53; i.e., 'Section 406')
- Research not included in one of the above categories but which otherwise presents an opportunity to understand, prevent or alleviate a serious problem affecting the health and welfare of children. (45 CFR 46.407/21 CFR 50.54; i.e., 'Section 407')

WARDS AND FOSTER CHILDREN

*If 'Section 406' or 'Section 407' research was indicated, the inclusion of wards or foster children requires additional information and, if the research will be conducted in New York City (NYC), approval from the NYC Administration for Children's Services (ACS). Please select the appropriate option below.
- This research has not been categorized as 45 CFR 46.406 ('Section 406') or 45 CFR 46.407 ('Section 407').
- This research has been categorized as 45 CFR 46.406 ('Section 406') or 45 CFR 46.407 ('Section 407') but the enrollment of wards or foster children is not anticipated.
- This research has been categorized as 45 CFR 46.406 or 45 CFR 46.407 and the enrollment of wards and/or foster children is anticipated.

ASSENT OF SUBJECTS

Assent of the child is required except in limited circumstances. The first step in determining whether assent is required and/or appropriate is to assess whether the children who will participate in the study will be capable of providing assent. The next step is to determine, for children who are capable of providing assent, whether assent will be obtained or should be waived.

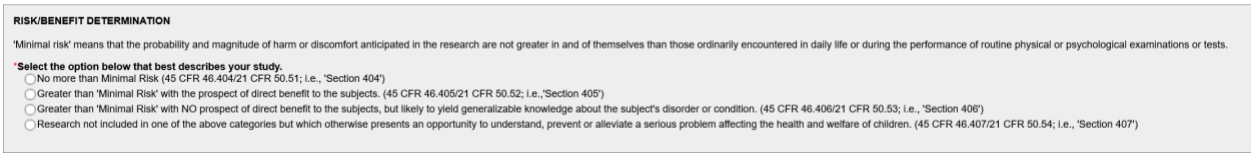
*Indicate whether the children who will be enrolled in this study will generally be capable of providing assent.
- Some or all are expected to be capable of providing assent.
- None are expected to be capable of assent.

PARENT/GUARDIAN PERMISSION

Permission of parents/guardians of the children is required except in limited circumstances. Permission from one parent/guardian is acceptable for research categorized as Section 404 or Section 405 unless waiver of informed consent is approved or the IRB determines that permission from both parents is warranted.

*Select the parental permission option that applies to your study, and provide the rationale for your response if justification is requested. For most studies, one selection is appropriate, however, if more than one option applies, select all that apply.
- The permission of one parent/guardian will be obtained.
- The permission of both parents/guardians will be obtained. - THIS IS REQUIRED IF YOU HAVE CATEGORIZED YOUR RESEARCH AS 45 CFR 46.406 OR 45 CFR 46.407
- No parental permission will be obtained because each of the following waiver criteria for waiving parental permission apply (45 CFR 46.408(c)):
- No parental permission will be obtained because the involvement of children in this research meets the criteria for a complete waiver of consent (45 CFR 46.116(d)), which is requested in the "Recruitment and Informed Consent" section.

Field 1: Risk/Benefit Determination



RISK/BENEFIT DETERMINATION

'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.

*Select the option below that best describes your study.
- No more than Minimal Risk (45 CFR 46.404/21 CFR 50.51; i.e., 'Section 404')
- Greater than 'Minimal Risk' with the prospect of direct benefit to the subjects. (45 CFR 46.405/21 CFR 50.52; i.e.,'Section 405')
- Greater than 'Minimal Risk' with NO prospect of direct benefit to the subjects, but likely to yield generalizable knowledge about the subject's disorder or condition. (45 CFR 46.406/21 CFR 50.53; i.e., 'Section 406')
- Research not included in one of the above categories but which otherwise presents an opportunity to understand, prevent or alleviate a serious problem affecting the health and welfare of children. (45 CFR 46.407/21 CFR 50.54; i.e., 'Section 407')

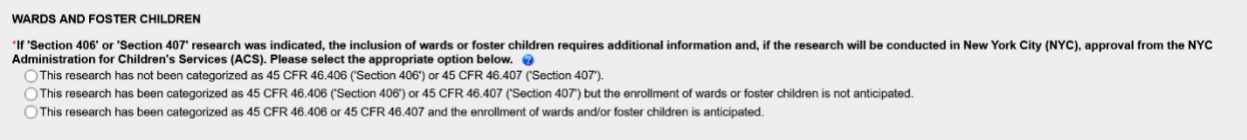
Definition: "Minimal Risk" means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Select the option below that best describes your study:

- Select **NO MORE THAN MINIMAL RISK (45 CFR 46.404/21 CFR 50.51, i.e., Section 404 research),** if your protocol presents only minimal risk to children. If you select this option, you must explain how the risks are no more than minimal, i.e., satisfying the regulatory definition of minimal risk.
    - Note that the permission of one parent will generally suffice for this category of research.
- Select **GREATER THAN 'MINIMAL RISK' WITH THE PROSPECT OF DIRECT BENEFIT TO SUBJECTS (45 CFR 46.405/21 CFR 50.52, i.e., Section 405 Research),**

if your protocol meets this description. If you select this option, you must explain how this risk is justified by the anticipated benefit to the subjects and justify that the relation of anticipated benefit to risk is at least as favorable to subjects as that presented by available alternative approaches.
    - Note that the permission of one parent will generally suffice for this category of research.
- Select **GREATER THAN 'MINIMAL RISK' WITH NO PROSPECT OF DIRECT BENEFIT TO THE SUBJECTS, BUT LIKELY TO YIELD GENERALIZABLE KNOWLEDGE ABOUT THE SUBJECT'S DISORDER OR CONDITION (45 CFR 46.406/21 CFR 50.53, i.e., Section 406 Research),** if your protocol meets this description. If you select this option, you must (1) justify the level of risk, (2) explain how the interventions or procedures present experiences to the subjects that are reasonably commensurate with those inherent in their actual or expected situations, and (3) explain how the interventions or procedures are likely to produce generalizable knowledge about the subject's disorder or condition that is of vital importance for the understanding or amelioration of the subject's disorder or condition.
    - Note that the permission of both parents will generally be required for this category of research.
- Select **RESEARCH NOT INCLUDED IN ONE OF THE ABOVE CATEGORIES BUT WHICH OTHERWISE PRESENTS AN OPPORTUNITY TO UNDERSAND, PREVENT OR ALLEVIATE A SERIOUS PROBLEM AFFECTING THE HEALTH AND WELFARE OF CHILDREN (45 CFR 46.407/21 CFR 50.54, i.e., Section 407 Research),** if your protocol meets this description. If you select this option, (1) explain how the proposed research does not meet the criteria of 404, 405 or 406 Research, and (2) explain how the proposed research presents a reasonable opportunity to further the understanding, prevention or alleviation of a serious problem affecting the health and welfare of children.
    - Note that the permission of both parents will generally be required for this category of research.
    - If the research is federally funded, review by a panel of experts constituted by the Secretary of HHS will be required. If the research is not federally funded, review by a similarly constituted panel at Columbia is required.

Field 2: Wards and Foster Children



Children who are wards of the State or any other agency, institution or entity can be included in research approved under Section 406 or Section 407 only if such research is:

(a) Related to their status as a ward or foster child; or

(b) Conducted in schools, camps, hospitals, institutions or similar settings in which the majority of children involved as subjects are not wards.

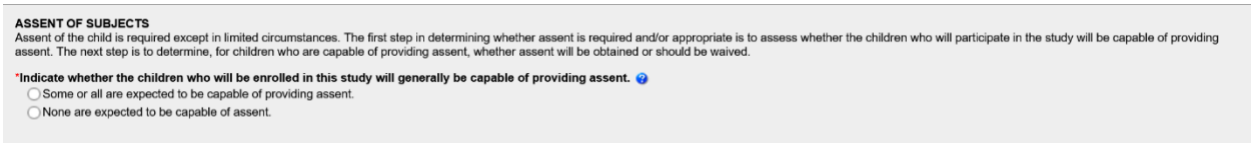
Important: If the research involving wards is approved, the IRB shall require appointment of an advocate for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or in loco parentis. The advocate must be an individual who has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child's participation in the research and who is not associated in any way (except in the role as advocate or member of the IRB) with the research, the investigator(s) or the guardian organization.

If Section 406 or Section 407 Research was indicated, the inclusion of wards or foster children requires additional information and, if the research will be conducted in NYC, approval from the NYC Administration for Children's Services (ACS).

- Select **THIS RESEARCH HAS NOT BEEN CATEGORIZED AS 45 CFR 46.406 ('Section 406') OR 45 CFR 46.407 ('Section 407').**
- Select **THIS RESEARCH HAS BEEN CATEGORIZED AS 45 CFR 46.406 ('Section 406') OR 45 CFR 46.407 ('Section 407') BUT THE ENROLLMENT OF WARDS OR FOSTER CHILDREN IS NOT ANTICIPATED.**
- Select **THIS RESEARCH HAS BEEN CATEGORIZED AS 45 CFR 46.406 or 45 CFR 46.407 AND ENROLLMENT OF WARDS AND/OR FOSTER CHILDREN IS ANTICIPATED.** If you select this option, **Select the category that applies to your research**:
    - Select **THIS RESEARCH IS RELATED TO THE SUBJECTS' STATUS AS A WARD OR FOSTER CHILD**, if the research potentially involves the enrollment of wards or foster children as subjects, and the research relates to the subject's status as wards or foster children. Explain in the text box provided how your research relates to the subject's status as wards or foster children.
    - Select **THIS RESEARCH WILL BE CONDUCTED IN SCHOOLS, CAMPS, INSTITUTIONS, OR SIMILAR SETTINGS IN WHICH A MAJORITY OF THE CHILDREN INVOLVED AS SUBJECTS ARE NOT WARDS OR FOSTER CHILDREN**, if the research potentially involves the enrollment of wards or foster children as subjects, and the research will be conducted in schools, camps, institutions, or similar settings in which a majority of the children involved as subjects are NOT wards or foster children. Please justify this selection in the text box provided.

- Regardless of which option above is selected, describe who is intended to serve as an advocate for the wards/foster children and provide the advocate's background and experience.

Field 3: Assent of Subjects

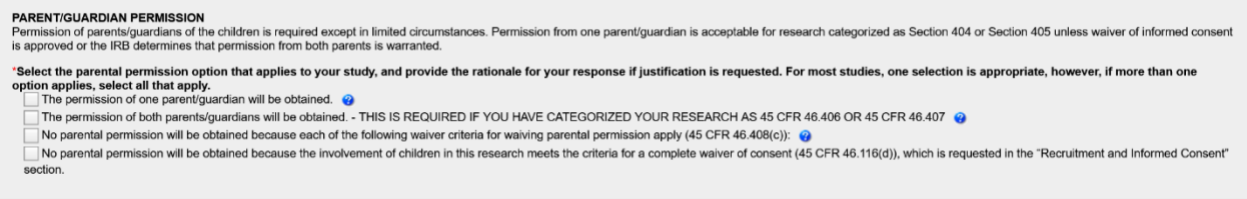


Indicate whether the children who will be enrolled in this study will generally be capable of providing assent.

Note: In answering this question consider such factors as age, maturity, psychological state and medical or cognitive conditions.

- Select **SOME OR ALL ARE EXPECTED TO BE CAPABLE OF PROVIDING ASSENT**, if your protocol meets this description. If you choose this option, you must explain why some or all of the children are expected to be capable of providing assent, and if applicable, why some may not be capable.
  - For the children who are capable of providing assent, indicate whether you propose to obtain assent or to request a waiver of the requirement to obtain assent.
    - Select **A WAIVER OF ASSENT FOR CHILDREN WHO ARE CAPABLE OF PROVIDING ASSENT IS REQUESTED**, select the waiver criteria that are most applicable to the research, and provide justification for each criterion.
    - Select **ASSENT WILL BE OBTAINED FROM CHILDREN WHO ARE CAPABLE OF PROVIDING VOLUNTARY AND INFORMED AGREEMENT TO PARTICIPATE,** describe the assent process that will be used, and describe how assent will be documented.
- Select **NONE ARE EXPECTED TO BE CAPABLE OF ASSENT**, if your protocol meets this description. For the children who are not capable of providing assent, indicate the reasons why (e.g., the children are too young or lack the capacity due to immaturity, psychological state, medical or cognitive condition).

Field 4: Parent/Guardian Permission


PARENT/GUARDIAN PERMISSION
Permission of parents/guardians of the children is required except in limited circumstances. Permission from one parent/guardian is acceptable for research categorized as Section 404 or Section 405 unless waiver of informed consent is approved or the IRB determines that permission from both parents is warranted.

*Select the parental permission option that applies to your study, and provide the rationale for your response if justification is requested. For most studies, one selection is appropriate, however, if more than one option applies, select all that apply.

- ☐ The permission of one parent/guardian will be obtained.
- ☐ The permission of both parents/guardians will be obtained. - THIS IS REQUIRED IF YOU HAVE CATEGORIZED YOUR RESEARCH AS 45 CFR 46.406 OR 45 CFR 46.407
- ☐ No parental permission will be obtained because each of the following waiver criteria for waiving parental permission apply (45 CFR 46.408(c)):
- ☐ No parental permission will be obtained because the involvement of children in this research meets the criteria for a complete waiver of consent (45 CFR 46.116(d)), which is requested in the "Recruitment and Informed Consent" section.

Definition: Federal regulations define parents as biological or adoptive. A guardian is someone who is appointed by a court and who can authorize medical care for a child. A guardian may or may not be authorized to enroll a child in research. Foster parents are not ordinarily authorized to provide permission to enroll a child in research.

- Select **THE PERMISSION OF ONE PARENT/GUARDIAN WILL BE OBTAINED** if your research falls under section 404 or 405.
- Select **THE PERMISSION OF BOTH PARENTS/GUARDIANS WILL BE OBTAINED** if your research falls under Section 406 or 407. Permission of BOTH parents or guardians (if there is more than one guardian) will be required unless one parent is deceased, unknown or lacks capacity to provide permission; one parent is reasonably not available; or only one parent has legal responsibility for the care and custody of a child.
- Select **NO PARENTAL PERMISSION WILL BE OBTAINED BECAUSE EACH OF THE FOLLOWING CRITERIA FOR WAIVING PARENTAL PERMISSION APPLY (45 CFR 46.408I)** and provide justification for each of the waiver criteria:
  - The research is designed for conditions or for a subject population for whom parental or guardian permission is not a reasonable requirement to protect the subjects (i.e., neglected or abused children); and
  - An appropriate mechanism for protecting children who will be subjects is justified; and
  - The waiver is not inconsistent with federal, state, or local law

Notes:

- Choose the above option when agreement to participate in the study will be provided directly by the minor subjects.
- This waiver option does not apply to FDA-regulated research.

- Select **NO PARENTAL PERMISSION WILL BE OBTAINED BECAUSE THE INVOLVEMENT OF CHILDREN IN THIS RESEARCH MEETS THE**

CRITERIA FOR A COMPLETE WAIVER OF CONSENT (45 CFR 46.116(d)), which is requested in the "Recruitment and Informed Consent" section.