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Tips for Creating Rascal Tracking Protocol Scope: CU Research Being Submitted to an External IRB

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Abbreviations Used

CU	Columbia University
CUIMC	CU Irving Medical Center
HRPO	CU Human Research Protection Office
HSR	Human subjects research
IT	Information Technology
NHSR	Not human subjects research
PT	Proposal Tracking
UNI	A CU workforce member's unique identification number
WCG	WIRB-Copernicus Group, which provides independent IRB review services

General Tips

Personnel

- Only CU personnel should serve as Initiator of a Rascal protocol and be named as research personnel in the Personnel section of a Rascal protocol.
- Faculty with joint appointments at Columbia and another institution should only be named on Rascal protocols if they are participating in the study under their CU effort.

Procedures must be described with consideration as to how CU is involved with and engaged in the research, including CU's and the PI's roles, locations, and details of the procedures that will be conducted under the direction of a CU investigator.

Accessing the Rascal Human Subjects Module

1. Go to rascal.columbia.edu and select Human Subjects.
2. Log in using your Columbia UNI.
3. Select Create Protocol.

1. "Protocol" is a Rascal Event type and refers to the package/folder of information about a study that is submitted for initial IRB review.
2. Other Event types can only be submitted after a Protocol has been approved by the IRB.
    1. "Modification" means proposed changes to information or documentation previously approved.
    2. "Renewal" means a request for continuing review, submitted prior to expiration of IRB approval, which may include proposed changes to previously approved information or documentation.
    3. "Annual Report" means a report to the IRB of approved studies that do not require continuing review; subject numbers are reported; no other changes can be made.
    4. "Unanticipated Problem" means a report to the IRB of an incident, experience, or outcome on an approved study that is unanticipated, at least possibly related to the research, and suggests an increase in risk of harm to subjects or others.
    5. "Closure" means a very brief report submitted with a request to close out the IRB file and end IRB approval.

General Information Page

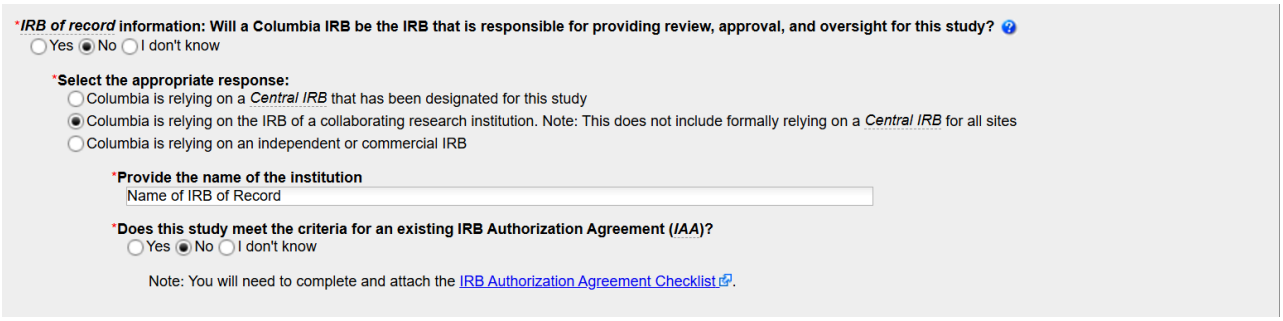
1. Review the General Instructions.
2. Note that the header is mostly empty; it will populate upon saving this page.
    1. **Initiator:** This is the person who created the protocol and cannot be removed from this Event.
    2. **Protocol Year:** Each Rascal Event will have a Y00M00 identifier.
        1. Y01M00 is the Protocol: first year, no modifications.
        2. Example: Y01M01 is the first modification submitted during the first approval period of a protocol.
        3. Example: Y02M00 is the first Renewal: second year of study, with no modifications in this year yet.
    3. **Principal Investigator:** Will populate upon assignment of PI in the Personnel page.
        1. Columbia policy requires the PI to be a full-time Officer of Instruction or full-time Officer of Research; exceptions are rarely approved.
        2. Only one PI can be named in the IRB protocol.
3. Scroll down and respond to all required questions.
    1. **Originating department:** Enter at least three characters of the department code or name; the system will provide possible options.
    2. **Originating campus:** Select the campus on which the originating department is located. This information is needed to appropriately route funding or other processes and does not relate to the location at which the study will be conducted. If the PI has appointments in more than one department, select the campus/department to which the research will be attributed.
    3. **Long title:** Enter the title as it should appear in IRB official letters.
    4. **Protocol version:** Not required unless an investigational drug or device is involved; this will appear in IRB official letters.
    5. **Short title:** Used in reports and in the list of "My Protocols."
    6. **Previously assigned a number:** Select "Yes" and provide the IRB number assigned by the non-Columbia IRB in the Previous External IRB# field.
    7. **Purpose to obtain a NHSR determination:** Select "No" for expediency. Regardless of your response, HRPO staff and the CU IRB will make the determination; the information and algorithm are provided for investigators as a worksheet when deciding whether a protocol requires IRB review.

4. Select Save and confirm Save.
5. Upon saving, the header will populate and additional options will appear in the left-hand navigation menu.
    1. Access each page in the Protocol Content section in order, beginning with Attributes.
    2. You can access any page at any time by selecting it from the menu.
6. **View Datasheet:** Use this option to see what the datasheet will look like when compiled.
7. **Submit Protocol:** Use this option to see what remains to be completed. It will not actually submit the protocol until after all approvers have been notified and signed off.

Protocol Content Section

Attributes

1. Select "None of the above" for special review types.
2. For IRB of Record, select "No."
    1. If Columbia will rely on the IRB of a collaborating institution, select the option stating that Columbia is relying on the IRB of a collaborating research institution.
    2. If Columbia is relying on an independent or commercial IRB, such as WCG or Advarra, select the independent/commercial IRB option.
3. For multicenter study, select "Yes." A "Yes" response will prompt a branching question to designate Columbia's involvement in the study. Select the most appropriate role(s). If Columbia is the Lead Institution, Coordinating Center, or Data Coordinating Center, a separate page will request details.
4. Indicate whether any University resources are utilized, such as CPDM, CRR, CCPH, or CUB. If not, select "None of the above."
5. Save the page.



Background

This page has the option of indicating "Abbreviated Submission" if the requested information is included in a separate document, such as a standalone protocol, that you will attach. Checking the box removes the text field.

Note: The Master protocol approved by the Reviewing IRB must be attached in the Documents section with the Document Type listed as "Standalone/Sponsor's Protocol."

Study Purpose and Rationale:
Provide pertinent background information with references that are related to the need to conduct this study. If this is a clinical trial, the background should include both preclinical and clinical data. Be brief and to the point.

☑ Abbreviated Submission - This information is included in an attached stand-alone protocol.

Study Design:
Describe the methodology that will be used in this study, covering such factors as retrospective vs. prospective data collection, interventional vs. non-interventional, randomized vs. non-randomized, observational, experimental, ethnography, etc.

☑ Abbreviated Submission - This information is included in an attached stand-alone protocol.

Statistical Procedures:
Provide sufficient details so that the adequacy of the statistical procedures can be evaluated including power calculations to justify the number of participants to be enrolled into the study. Definitions of subject terms such as enrolled and accrued as used for Rascal submissions can be found in the Subjects section.

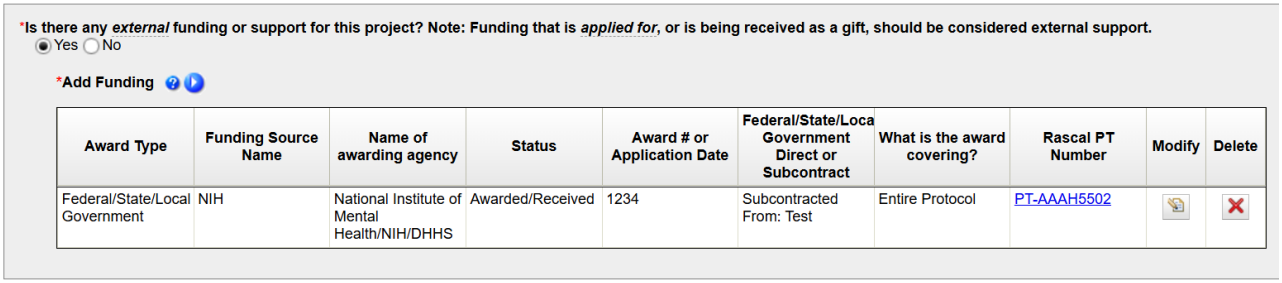
☑ Abbreviated Submission - This information is included in an attached stand-alone protocol.

Exempt and Expedited

1. Select "No" for each response for expediency.
2. Regardless of your response, HRPO staff and the CU IRB will make the determination; the information and algorithm are provided as reference for investigators.
3. Save the page.

Funding

1. Respond "Yes" to the external funding question and select the blue arrow to add your award.
2. Enter each type and source of external funding.
3. For federal funding:
    1. In the "Name of awarding agency" field, begin typing the full name of the agency and select from the options that appear. Abbreviations will return an error message.
    2. Enter the respective PT number, which can be selected from a list of PT forms linked to you. If you have not created a Proposal, create one in Proposal Tracking in Rascal.
    3. Designate whether Columbia is the recipient of a direct award or a subcontract recipient. If Columbia is a subcontract recipient, provide the name of the direct recipient.
4. Save the page.


*Is there any *external* funding or support for this project? Note: Funding that is *applied for*, or is being received as a gift, should be considered external support.
◉ Yes ○ No

*Add Funding

Award Type	Funding Source Name	Name of awarding agency	Status	Award # or Application Date	Federal/State/Loca Government Direct or Subcontract	What is the award covering?	Rascal PT Number	Modify	Delete
Federal/State/Local Government	NIH	National Institute of Mental Health/NIH/DHHS	Awarded/Received	1234	Subcontracted From: Test	Entire Protocol	PT-AAAH5502		

Locations

1. Select "Add Location."
2. Add all locations where study procedures will occur, including data analysis.
3. Local site approval may be required for a location such as a school where study procedures will occur and individuals affiliated with the site will not be involved in the conduct of the study. A letter of authorization to conduct study procedures at the site would be appropriate documentation.
4. Local IRB/Ethics Approval is required when a site is engaged in human subjects research.
5. Save each location as added; there is no page Save.

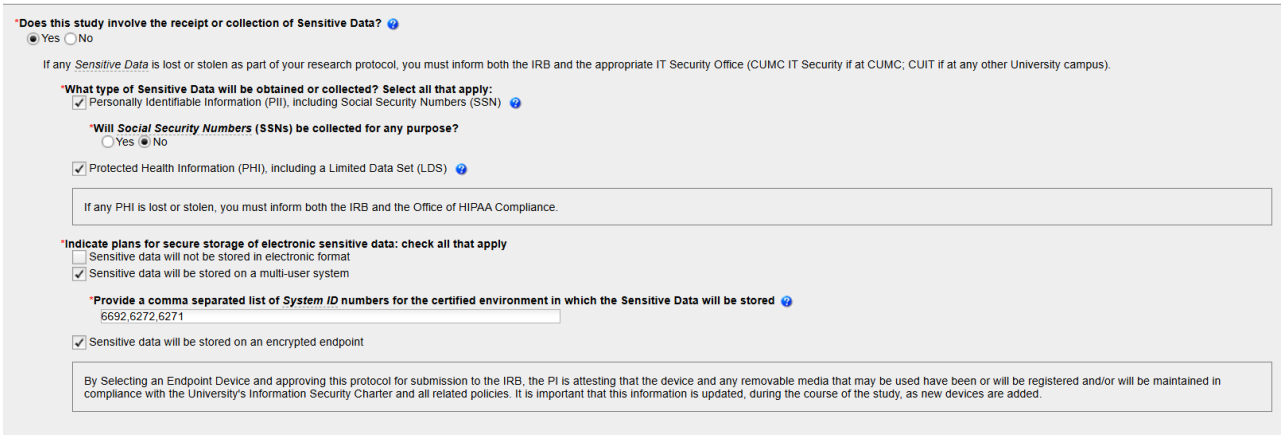
Personnel

1. Select "Add Personnel."

2. The “Describe role and experience” field is optional but helpful to the Reviewing IRB.
3. Save each personnel entry as added; there is no page Save.
    1. Each person’s training will appear in a table on the page when added.
    2. CITI courses are used for some requirements; access these courses through Rascal so data can be uploaded to Rascal.
4. Personnel must complete required training courses:
    1. Access “TC” courses through the Training Center link in Rascal.
    2. HSP (Rascal course TC0087) for all engaged personnel.
        1. Research with Minors and FDA-regulated Research courses are electives within TC0087.
        2. Select these electives while taking HSP if the study involves FDA-regulated products and/or minors as subjects.
    3. HIPAA and Research (Rascal course TC0019) for all CUIMC personnel and CU personnel from other campuses who access PHI or are named on a protocol originating from CUIMC.
    4. CRC (Rascal course TC0098) for all coordinators.
    5. Sponsor-Investigator (S-I) (Rascal course TC0096) for CU personnel who hold an IND or IDE.
    6. Annual COI must be current for all personnel and is managed through the Conflict of Interest module in Rascal.
5. **Departmental Approvers:**
    1. This is not a required entry.
    2. Consult with your division/department for requirements for internal signoff.

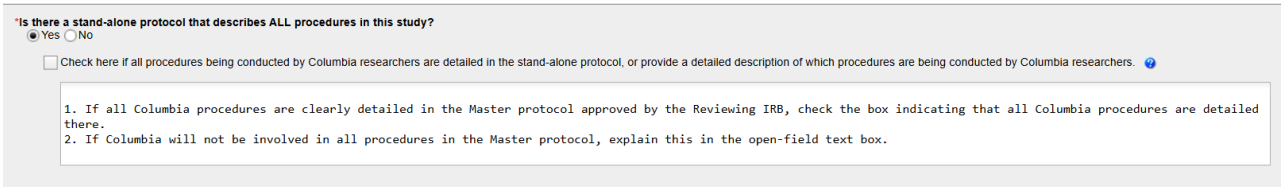
Privacy & Data Security

1. Sensitive Data is defined in the CU IT Data Classification policy and requires additional protections.
2. For studies originating from the Medical Center, all Sensitive electronic data stored in a multi-user system must use a system certified by CUIMC IT Security, and the 4-digit certification number must be entered on this page.
3. For studies originating from the Morningside campus, any Protected Health Information stored in a multi-user system must use a system certified by CUIMC IT Security. Other Sensitive Data may be stored in a multi-user system registered by CUIT Security.
4. Commonly certified systems include:
    1. Network File Storage, including P-Drive — #6692
    2. Office 365: OneDrive for Business — #6271
    3. Office 365: SharePoint — #6272
    4. Office 365: Groups, Teams, Planner, Stream — #6274
    5. VP&S REDCap — #7156
5. In the confidentiality field, describe how data will be maintained locally at Columbia and during transmission to another site. If data will be shared with a collaborating institution, explain how it will be transferred, who will have access, and whether it will be de-identified, coded, or identifiable.
6. For the privacy-protection field, use the Help text for guidance on what should be included.
7. **Tip:** Make sure responses to open-text fields are specific to what is occurring at Columbia.
8. Save the page.



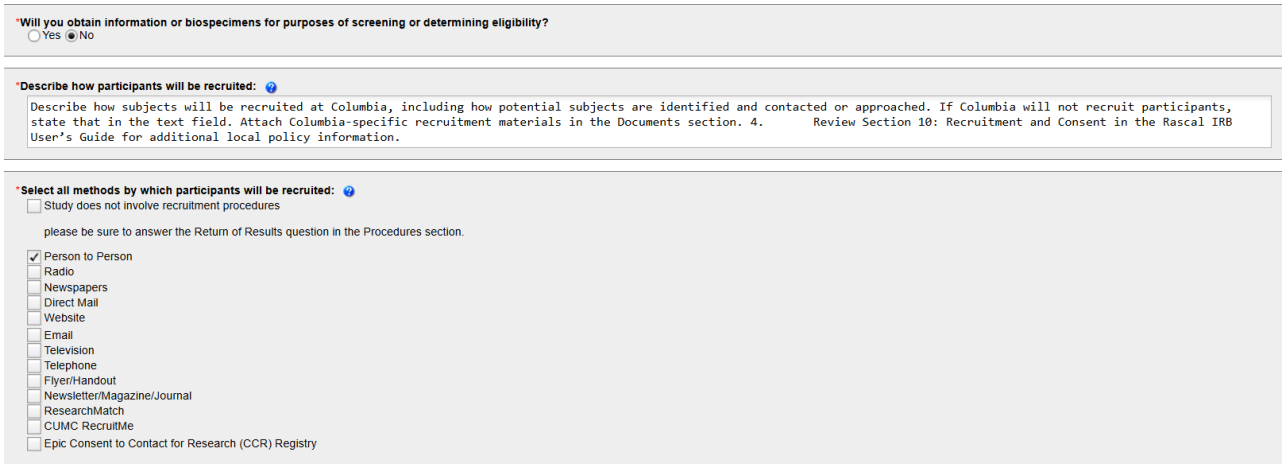
Procedures

1. Select “Yes” for all procedures that occur at Columbia. Select “No” for procedures not relevant to the study or not occurring at Columbia.
2. Select “Yes” to the question asking whether there is a standalone protocol describing all procedures in the study.
    1. If all Columbia procedures are clearly detailed in the Master protocol approved by the Reviewing IRB, check the box indicating that all Columbia procedures are detailed there.
    2. If Columbia will not be involved in all procedures in the Master protocol, explain this in the open-field text box.
3. Upon saving, additional links may appear in the left-hand navigation menu for additional pages to complete.
4. Save the page.

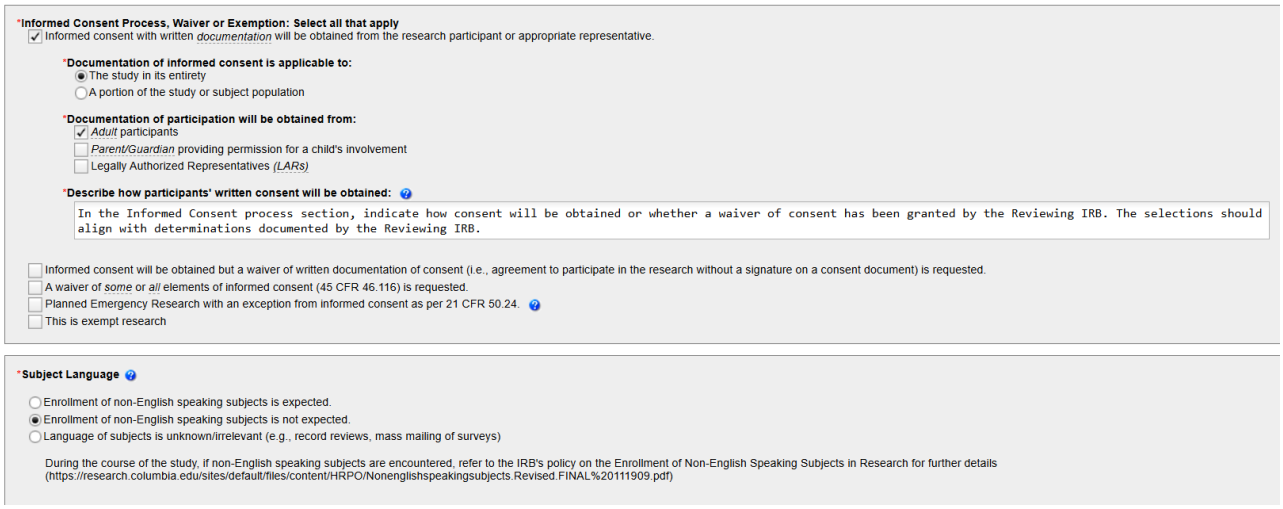


Recruitment and Informed Consent

1. For the recruitment question, describe how subjects will be recruited at Columbia, including how potential subjects are identified and contacted or approached. If Columbia will not recruit participants, state that in the text field.
2. Select all methods by which participants will be recruited. If Columbia will not recruit participants, select “Study does not involve recruitment procedures.”
3. Attach Columbia-specific recruitment materials in the Documents section.
4. Review Section 10: Recruitment and Consent in the Rascal IRB User’s Guide for additional local policy information.



5. In the Informed Consent process section, indicate how consent will be obtained or whether a waiver of consent has been granted by the Reviewing IRB. The selections should align with determinations documented by the Reviewing IRB.
6. Indicate whether you anticipate enrollment of non-English speaking subjects or individuals lacking capacity to consent at Columbia. Columbia has local requirements for these populations.



Research Aims & Abstracts

1. Enter a response in each field because reviewers rely on this information in the datasheet when initiating review.
2. Full details of the aims/hypothesis do not need to be entered if they are included in the attached Master protocol.
3. Save the page.

Risks, Benefits & Monitoring

1. Select "Abbreviated Submission" if all relevant information is contained in an attached document.
2. Save the page.

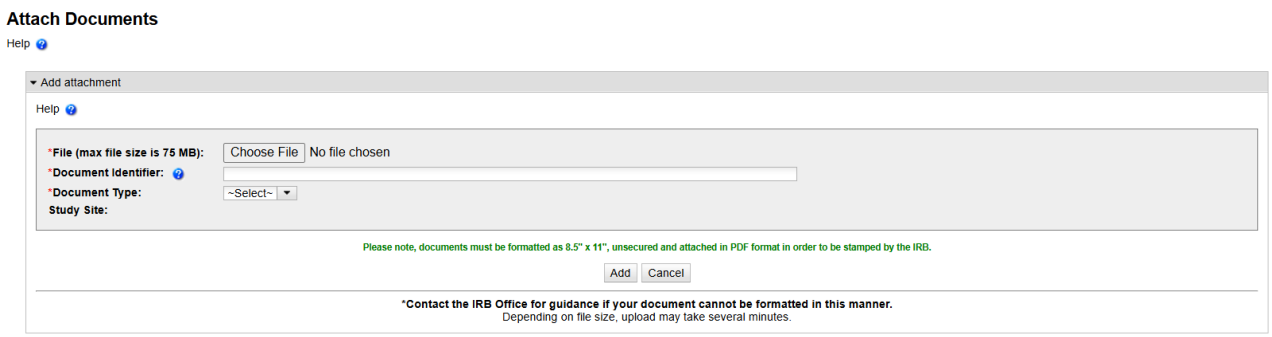
Subjects

1. CU IRBs use two terms for subject numbers:
    1. *Enrollment* indicates subjects who have signed consent forms, verbally or electronically provided consent, or whose data will be collected under a waiver of consent.
    2. *Accrual* indicates subjects who have passed screening procedures, when applicable.

2. If “CU/NYPH Employees/Residents/Fellows/Interns/Students” is checked, additional requirements apply.
    1. A letter of support from the head of the unit from which affiliated personnel will be recruited is required.
    2. HRPO staff will forward the proposal to recruit affiliates to the respective IO(s), and approval must be obtained before the IRB can approve the protocol.
3. In the Subject Justification field, enter “See standalone protocol” or “See document titled XYZ” if all information is included in an attached document.

Attach Documents

1. **Important:** After attaching a document, select Add at the bottom of the screen.
2. Initial IRB determination letter from the Reviewing IRB.
3. Approved Master protocol.
4. Approved recruitment materials.
5. Approved study instruments.
6. Approved Master consent form templates.
7. CU-specific consent forms (tracked and clean).
8. Local context form. If the Reviewing IRB does not provide one, use the Columbia local context form.
9. Draft of reliance agreement.



HIPAA Forms

1. Columbia encourages use of a combined informed consent and HIPAA authorization form to reduce noncompliance from failure to obtain a signed HIPAA authorization.
2. If 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 may be needed.
3. HIPAA forms can be created in Rascal by using the HIPAA link in the Human Subjects/IRB menu or at the top of screens in the Human Subjects module.
4. Attach other documents as relevant.
5. Attached documents will be listed at the bottom of the datasheet.

Signoff and Submission

1. To see if any pages or fields are incomplete, select “Submit Protocol.”
2. When all pages and fields are complete:
    1. **Step 1:** Select “Notify Approvers.”
        1. All engaged personnel must electronically sign off on the submission.
        2. Signoff includes completion of a study-specific COI disclosure.

3. The initiator will be notified by email when all approvers have signed off.

2. **Step 2:** Select “Submit Protocol.”
    1. When the protocol is successfully submitted, the status will change from “Creating” to “Submitted.”
    2. Status is reflected in the upper-left corner of each page and in the list of protocols that appears when selecting “My Protocols” from the Human Subjects/IRB menu.

Assistance

For questions about any aspect of the protocol creation or submission process, send an email to irbreliance@columbia.edu.