

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

Table of Contents

- [Abbreviations used](#)
- [General Tips](#)
- [Accessing the Rascal Human Subjects module](#)
- [General Information page](#)
- [Protocol Content section](#)
 - [Attributes page](#)
 - [Background page](#)
 - [Exempt and Expedited page](#)
 - [Funding page](#)
 - [Location page](#)
 - [Personnel page](#)
 - [Departmental approvers section](#)
- [Privacy & Data Security](#)
- [Procedures](#)
- [Recruitment and Informed Consent](#)
- [Research Aims & Abstracts](#)
- [Risks, Benefits & Monitoring](#)
- [Subjects](#)
- [Attach Documents](#)
- [Signoff and Submission](#)
- [Assistance](#)

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

- I. General Tips
 - A. Personnel
 1. Only CU personnel should serve as Initiator (explained below) of a Rascal protocol and be named as research personnel in the Personnel section of a Rascal protocol.
 2. Faculty with joint CU/NYSPI appointments should only be named on Rascal protocols if they are participating in the study under their CU effort.
 - B. Create a standalone protocol that describes the research in detail, including background, procedures, monitoring and analysis

1. Procedures must be described with consideration as to how CU is involved with and engaged in the research, e.g., CU's and the PI's roles, locations and details of the procedures that will be conducted under the direction of a CU investigator.
 2. Diagrams of the overall study structure are helpful
- II. Accessing the Rascal Human Subjects module
- A. Go to rascal.columbia.edu and select Human Subjects
 - B. log in using your Columbia UNI
 - C. 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
 - a. 'Modification' = proposed changes to information or documentation previously approved
 - b. 'Renewal' = request for continuing review, to be submitted prior to expiration of IRB approval, which may include proposed changes to information or documentation previously approved
 - c. 'Annual Report' = report to the IRB of approved studies that do not require continuing review; subject numbers are reported; no other changes can be made
 - d. 'Unanticipated Problem' = 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
 - e. 'Closure' = very brief report submitted with a request to close out the IRB file and end IRB approval
 - D. A list of all the protocols that name you as Personnel can be viewed by selecting 'My Protocols' after logging into the Human Subjects module
- III. General Information page
- A. Review the General Instructions
 - B. Note that the header is mostly empty; it will populate upon saving of this page
 1. Initiator: This is the person who created the protocol, and this person cannot be removed from this Event
 2. Protocol Year: Each Rascal Event will have a Y00M00 identifier
 - a. Y01M00 is the Protocol (first year, no modifications)
 - b. Example: Y01M01 is the first modification submitted during the first approval period of a protocol
 - c. Example: Y02M00 is the first Renewal (second year of study, no modifications in this year as yet)
 3. Principal Investigator: will populate upon assignment of PI in the Personnel page
 - a. Columbia policy requires the PI to be a full-time Officer of Instruction (Prof., Assoc. Prof., Asst. Prof., Instructor) or full-time Officer of Research (Senior Research Scientist/Scholar, Research Scientist/Scholar); exceptions are rarely approved
 - b. Only one PI can be named in the IRB protocol
 - C. Scroll down and respond to all required questions
 1. Originating department: type in "psy" and a drop down menu will appear, from which the appropriate Psychiatry department can be selected

2. Originating campus: select Medical Center for all protocols originating from the CU Dept of Psychiatry
 3. Long title: as the title should appear in IRB official letters
 4. Protocol version: not required unless an investigational drug or device is involved; will appear in IRB official letters
 5. Short title: used in reports and in the list of 'My Protocols'
 6. Previously assigned a number: If this is a study that has (or has previously had) NYSPI IRB review, even if not yet approved, enter the NYSPI protocol number in the Previous External IRB# field
 7. Purpose to obtain a NHR determination: select No for expediency; regardless of your response, the HRPO staff and CU IRB will make the determination; the information and algorithm are provided for investigators to use as a worksheet when deciding whether a protocol requires IRB review
- D. Select the Save button and confirm Save (green confirmation text)
- E. Upon saving, the header will populate and additional options will appear in the left hand navigation menu
1. It is recommended that you access each page in the Protocol Content section of the menu in order beginning with Attributes
 2. You can access any page at any time by selecting it from the menu
- F. View Datasheet from left hand menu: At any time, you can select this option to see what your datasheet, which is the document that HRPO and IRB reviewers review first, will look like when compiled
- G. Submit Protocol (left hand menu): At any time, you can select this option to see what remains to be completed; it will NOT actually submit the protocol until after all approvers have been notified and have signed off
- IV. Protocol Content section
- A. Attributes
1. Special review types: "None" is the appropriate response for the CU prime awards being transferred from NYSPI IRB oversight to WCG oversight.
 2. IRB of Record: select "No"
 - a. Select: "Columbia is relying on an independent or commercial IRB"
 - b. Enter: WCG
 - c. Select: "Yes" in response to "Does a Master Agreement...."
 3. Multicenter study: select "yes" because, at a minimum, CU and NYSPI are involved
 - a. CU and NYSPI are two legally separate institutions; the involvement of both is what resulted in the requirement for a Safety Review
 - b. A "yes" response will prompt a branching question to enter the institutions
 4. Be sure to Save the page
- B. Background
1. This page has the option of indicating "Abbreviated Submission" if the requested information is included in a separate document (i.e., a standalone protocol) that you will attach; simply check the box and the text field disappears
 - a. NIH provides [templates](#) for the standalone protocol, depending on type of research, each of which identifies the elements that must be addressed, including but not

limited to Study Purpose and Rationale, Study Design, Recruitment, Informed Consent, Statistical Procedures

2. Be sure to Save the page
- C. Exempt and Expedited
 1. It is recommended that you simply select “no” for each of these responses for expediency
 2. Regardless of your response, the HRPO staff and CU IRB will make the determination; the information and algorithm are provided as reference for investigators
 3. Be sure to Save the page
- D. Funding
 1. Respond “yes” to the external funding question; branching questions will appear
 2. Enter each type and source of external funding
 3. For federal funding:
 - a. In the ‘Name of awarding agency’ field, begin typing the full name of the agency and options should appear for you to select; abbreviations will return an error message
 - b. You will need to enter the respective PT number, which you can select on the page from a list of PT forms that are linked to you
 4. Be sure to Save the page
- E. Locations
 1. Select ‘Add Location’
 2. Add all locations where study procedures will occur, including data analysis
 3. NYSPI locations are considered ‘Offsite’
 4. ‘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
 5. ‘Local IRB/Ethics Approval’ is required when a site is engaged in human subjects research
 6. Save each location as added; there is no page Save
- F. Personnel
 1. Select ‘Add Personnel’
 2. Note that 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
 - a. Each person’s training will appear in a table on the page when added
 - b. CITI courses are utilized for some requirements; you must access these courses through Rascal for data to be uploaded to Rascal
 - c. CU and NYSPI training requirements that use CITI may overlap; when you access CITI courses through Rascal, be sure to add CU affiliation in CITI and the system will identify requirements that are already met through NYSPI affiliation
 4. Personnel must complete certain training courses:
 - a. Access ‘TC’ courses through the Training Center link in Rascal (top of page)
 - b. HSP (Rascal course TC0087) for all engaged personnel
 - 1) Research with Minors (CITI) and FDA-regulated Research (CITI) courses are electives within the TC0087 course

- 2) These electives should be selected while taking the HSP course if the study involves FDA-regulated products (i.e., drug, device or biologic) and/or will involve minors as subjects
 - c. HIPAA and Research (Rascal course TC0019) for all CUIMC personnel, including Psychiatry, and CU personnel from other campuses who access PHI or are named on a protocol originating from CUIMC
 - d. CRC (Rascal course TC0098) for all coordinators
 - e. Sponsor-Investigator (S-I) (Rascal course TC0096) for CU personnel who hold an IND or IDE
 - f. Annual COI must be current for all personnel and is managed through the Conflict of Interest module in Rascal (link at top of all screens)
5. Departmental Approvers
- a. This is not a required entry
 - b. Consult with your division/department for requirements for internal signoff
- G. Privacy & Data Security
1. Sensitive Data is defined in the CU IT [Data Classification policy](#) and requires additional protections
 2. In general, Sensitive electronic data that is stored in a multi-user system requires that such system has been certified by CUIMC IT Security, and the 4-digit certification number ("RSAM" number) is entered on this page; the CUIMC 'P' drive is certified for storage of Sensitive Data (#5329, to be confirmed)
 3. 0000 should be entered as the system number for Sensitive Electronic data that is stored in a NYSPI multi-user system until further guidance is obtained; include in the text field for the subsequent question ("**Provide a description of how the confidentiality of study data will be ensured...**") a description and name of the system that is being utilized
 4. For the two 'Provide a description...' questions, enter "See standalone protocol" or "See document titled XYZ" if all information is included in such attached document
 5. Be sure to Save the page
- H. Procedures
1. Select all applicable procedures
 2. Upon saving of this page, additional links may appear in the left hand navigation menu, indicating additional pages to be completed
 3. Be sure to Save the page
- I. Recruitment and Informed Consent
1. For the "Describe recruitment..." question, enter "See standalone protocol" or "See document titled XYZ" if all information is included in such attached document
- J. Research Aims & Abstracts
1. Please enter a response in each field, as reviewers rely on this information in the datasheet when initiating their review
 2. Full details of the Aims/Hypothesis do not need to be entered here, if they are included in an attached document such as the grant application or standalone protocol
 3. Be sure to Save the page
- K. Risks, Benefits & Monitoring
1. Select 'Abbreviated Submission' if all relevant information is contained in an attached document such as the standalone protocol

2. Be sure to Save the page
- L. Subjects
1. CU IRBs use two terms for subject numbers
 - a. *Enrollment* to indicate subjects who have signed consent forms, verbally or electronically provided consent, or whose data will be collected under a waiver of consent
 - b. *Accrual* to indicate subjects who have passed screening procedures, when applicable
 2. If “CU/NYPH Employees/Residents/Fellows/Interns/Students” is checked, additional requirements apply
 - a. A letter of support from the head of the unit from which affiliated personnel will be recruited is required to be included in the Rascal submission
 - b. HRPO staff will forward to the respective IO(s) the proposal to recruit affiliates 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 such attached document
- V. Attach Documents
- A. Important: After you have attached a document, select ADD at the bottom of the screen
 - B. Usual [CU coverpage for WCG submissions]
 - C. Completed [Engagement checklist]
 - D. WCG IRB transfer checklist
 - E. Advarra safety review summary
 - F. Approved CAPA
 - G. Outcome letter
 - H. Greenlight letter
 - I. Full HHS grant
 - J. Standalone Protocol: For these CU prime awards, this will be a research protocol prepared by the PI or collaborators. If the standalone protocol is being created for the Rascal/WCG submission, use of the [template protocol] is requested.
 - K. Current NYSPI approved PSF: This document can be a handy reference for the CU IRB but generally will not serve well as a Standalone Protocol; it should be attached in Rascal for CU reference and will also need to be submitted in the application to WCG to transfer IRB oversight.
 - L. Recruitment Material
 1. If any recruitment option that involves a document such as ‘flyer’ is selected, a document of that type must be attached
 2. All recruitment material must be pdf documents for stamping
 - M. Study Instruments: All subject-facing material, e.g., surveys, questionnaires and test instruments, and documents that will be used to guide procedures, such as interview guides
 1. All must be pdf documents for stamping
 - N. NYSPI IRB approval letter: The most recent letter is required if the protocol currently has or has had NYSPI IRB approval
 1. The NYSPI IRB approval letter will also need to be submitted in the application to WCG to transfer IRB oversight.
 - O. Consent documents

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1. A Word version of the template (aka model or master) consent form if recruitment will occur at multiple sites
 2. CU-specific consent form if recruitment will occur at CU or under the direction of CU research personnel. The CU-specific consent should be a tracked Word version of the template
 3. NYSPI IRB approved consent document(s): The most recent version(s) are required if the protocol currently has or has had NYSPI IRB approval, for reference, and will also need to be submitted in the application to WCG to transfer IRB oversight.
- P. HIPAA forms
1. Columbia encourages use of a combined informed consent and HIPAA authorization form, to reduce incidence of noncompliance created by failure to have a HIPAA authorization form signed
 2. HIPAA forms can be created in Rascal by accessing the HIPAA link in the Human Subjects/IRB menu or at the top of screens in the Human Subjects module
- Q. Other documents as relevant
- R. Attached documents will be listed at the bottom of the datasheet
- VI. Signoff and Submission
- A. To see if any pages or fields are not yet complete, select “Submit Protocol”
- B. When all pages and fields are complete:
1. Step 1: Select “Notify Approvers”
 - a. All ‘engaged’ personnel (PI, investigators, coordinators, other engaged personnel) must electronically sign off on the submission
 - b. Signoff includes completion of a study-specific COI disclosure
 - c. The initiator will be notified by email when all approvers have signed off
 2. Step 2: Select “Submit Protocol”
 - a. When the protocol is successfully submitted, the status will change from “Creating” to “Submitted”
 - b. Status is reflected in the upper left corner of each page and in the list of your protocols that appear when you select ‘My Protocols’ from the Human Subjects/IRB menu
- VII. Assistance
- A. For questions about any aspect of the protocol creation or submission process, send an email to irbreliance@columbia.edu