

Life Cycle - IRB Protocol

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Prepare Protocol & Appendices

Rascal Status: Creating

Under the Human Subjects Module in Rascal, select “Create Protocol” and attach all associated documents including but not limited to: Standalone protocol, Investigator’s Brochure, drug package inserts/device manuals, consent/assent forms, information sheet, recruitment materials, study materials, etc.

Refer to the [IRB SOPs – Section III](#) Preparation of Submissions to the IRB for a list of documents to be submitted for specific types of research. ○ In addition, create Haz Mats Appendices from the Haz Mat Module in Rascal, as applicable for your research.

Please see below list of Haz Mats Appendices reviewed by other research compliance offices/committees (i.e. **ancillary reviews**):

- Appendices A (Infectious Agents), D (Laser), E (Hazardous chemicals), E2 (Formaldehyde), I (Controlled substances) or M (Use of Recombinant DNA Molecules in Human Gene Transfer) will be reviewed by the Biosafety Officers at EH&S and/or the Institutional Biosafety Committee (IBC)
- Haz Mat Appendix R (MRI Human Scanning) will be reviewed by the Joint MR Safety Committee.
- Haz Mat Appendix H (Use of ionizing radiation, or radiation therapy) will be reviewed by the Human Use Subcommittee (HUS) of the Joint Radiation Safety Committee (JRSC)

Please refer [to HRPO Newsletter #8](#) for a full description of Ancillary Reviews that may be needed for your protocol

Other Rascal Modules, such as the Proposal Tracking, Consent Forms and HIPAA Forms modules may also need to be accessed to complete the attachments to your protocol.

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Submission in Rascal

Submit your protocol in Rascal: <https://www.rascal.columbia.edu/irb>

Rascal Status: Submitted

The submission is a 2-step process: 1) all individuals listed in the personnel section and department approvers approve the submission, with the process initiating by selecting the Notify Approvers link; 2) the PI or designee (personnel with Edit access) submits the protocol.

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Human Research Protection Office (HRPO) Pre-review

The protocol will be assigned to an HRPO staff member who will review the application to ensure there is sufficient information for the IRB review. An automatic email will be released by Rascal to provide the name and contact information of the HRPO staff member. The protocol may be returned for clarifications/revisions before IRB review as needed.

Rascal Statuses:

- **Logged in** (*protocol was accepted for review and assigned to a specific IRB for review*)
- **Returned** (*protocol was assigned to a specific IRB for review and returned for clarifications before it can be accepted for review*)

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IRB Review Process

Rascal Statuses:

- **Logged in** (*the protocol is in the Chair's queue, and the Chair can confirm whether the protocol is eligible for expedited review*)
- **Distributed** (*the protocol has been distributed by the Chair for review by an IRB member*)
- **Assigned to Meeting** (*the protocol has been added to an IRB meeting agenda*)

- **Returned (the protocol may be returned to the PI by the convened IRB, the IRB Chair or designee, HRPO staff or following ancillary review. A correspondence providing additional information about the reasons for the return and the next steps for IRB review have been released)**

The protocol will be routed to one of the following applicable levels of review:

Convened IRB review: Review at a convened meeting where a valid quorum of IRB members is present - Protocols involving greater than minimal risk or events not eligible to be reviewed by one of the regulatory expedited categories will be reviewed by the convened IRB.

Expedited IRB review: Review by the IRB Chair or designee - Protocols involving minimal risks and eligible to be reviewed under one of the [regulatory expedited categories](#).

Chair Concurrence: Review by the IRB Chair or designee - This is an alternative to the convened review, and this level of review is an option that only applies for the review of non-emergency Individual Patient Expanded Access IND requests (FDA Form 3926).

Limited IRB review: Review by the IRB Chair or designee - This limited IRB review is required for research that falls within one or more of the following four exemption categories:

- Research that only includes interactions involving educational tests when 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 [45 CFR 46.104(d)(2)(iii)],
- Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses when 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 [45 CFR 46.104(d)(3)(i)(C)]
- Secondary research for which consent is not required, [45 CFR 46.104(d)(7)], and 45 CFR 46.104(d)(8). Note that these categories are not applicable at CU.

Under a limited IRB review, the IRB is only required to confirm that one IRB approval criterion is met, which is to confirm that there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data [45 CFR 46.111(a)(7)], as opposed to the seven IRB approval criteria that need to be confirmed under Convened IRB review and Expedited IRB review.

Other review levels, that are not IRB review, are the following:

Exemption determination: Review by an experienced member of the Human Research Protection Office (HRPO) - Exempt research means that it is exempt from the requirements of the Federal Policy for the Protection of Human Subjects. Review by HRPO is required for research that falls within one or more of the exemption categories at 45 CFR 46.104(d)(2) other than the categories that require a limited IRB review.

Not Human Subject Research Determination: Review by an experienced member of the Human Research Protection Office (HRPO)

Additional information about the IRB review process is available in the IRB SOPs: [Processing of Submissions of the IRB SOPS \(Section IV\)](#)

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Ancillary reviews:

Ancillary reviews will begin following submission of the IRB protocol in Rascal.

- Review by the [Herbert Irving Comprehensive Cancer Center's Protocol Review and Monitoring Committee \(PRMC\)](#)
- Review by the [Institutional Biosafety Committee \(IBC\) or Biosafety Officers in Environmental Health & Safety \(EH&S\)](#)
- Review by the [Joint MR Safety Committee \(MRSC\)](#)
- Review by the FCOI Committee: [Conflict of Interest in Research](#)

Rascal Status: Returned: *(The protocol was returned by PRMC or on behalf of the Biosafety Office – A correspondence providing additional information about the reasons of the returned has been released)*

Refer to the **Protocol History Page** for additional information on status of review by other research compliance offices/committees.

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IRB Approval

Rascal Status: Approved

The IRB approval will be granted after all applicable ancillary reviews have been approved in Rascal.

The IRB Determination letter will be posted following IRB approval. It is available under the Print Menu Page. Please make sure to review it to ensure there are no specific IRB stipulations included in the IRB approval.

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Maintain IRB approval

- Any changes to the protocol should be submitted through a Modification for IRB approval before implementation
- Renew your protocol prior to the expiration date. Please refer to additional information on renewals and annual reports available under on the HRPO website under the [Maintaining IRB Approval Page](#), and view the [Timeline for submission of Renewals](#).
- Report Unanticipated problems involving risks to subjects or others promptly: Refer to additional information available at: <https://research.columbia.edu/maintaining-irb-approval>

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Closure

- Submit a Closure Report in Rascal once you have completed the study or if the study will be closed prematurely: Additional information on how to submit a closure report is available at <https://research.columbia.edu/maintaining-irb-approval>.