

SOP#: RPS-5

NIH IRB Submission and Response: New Protocol

Version #: 3.1

Next Review Date: 07/2022

Approved Date: 12/2020

Review Interval Period: Biennial

NCI Clinical Director Signature:



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POLICY

All human subjects research that is not exempt must be reviewed by the National Institutes of Health Institutional Review Board (NIH IRB) prior to the initiation of any research activities and must take into account federal regulatory requirements and those of the Office of Human Subjects Research Protections (OHSRP). All protocols submitted to the IRB must first have a scientific review and/or other ancillary approvals as explained below.

PURPOSE

Identify the steps required for the Center of Cancer Research (CCR), Protocol Support Office (PSO) to submit a new protocol to the NIH IRB and respond to IRB pre-review corrections/stipulations.

RESOURCES

- NIH Office of Intramural Research Policies & Guidance [website](#)
 - Policy 106 - *Ancillary Reviews*
 - Policy 204 - *Levels of IRB Review and Criteria for IRB*
 - Policy 205 - *Requirements for IRB Submissions*
 - 400 Series - Regulatory Protections for Vulnerable Populations, as applicable
 - 500 Series - FDA Requirements for Human Subjects Research and Data and Safety Monitoring, as applicable
 - 700 Series - International Research Requirements, as applicable
- iRIS Helpful Documents [website](#)
- Institutional Review Board Office (IRBO) Ancillary Reviews [website](#)

PROCEDURES

STEP 1: Create Protocol Files and Folders on the Secure Server

- In the Principal Investigator's (PI) specified protocol folder, create a new subfolder titled "Initial IRB Submission." Create and save the following documents in the new "Initial submission" subfolder:
 - Protocol
 - NIH Supplement (if applicable)
 - Informed Consent Document(s)

- Study Personnel Page
- FDA IND or IDE Safe to Proceed or documentation from the Sponsor that the protocol has been submitted to an active IND (if applicable)
- Investigator's Brochure (if available) and/or Package Insert (if applicable)
- Scientific Review Approval Package: This should be a single pdf document to include the CCR Scientific Review meeting minutes, Response to SRC Stipulations or Recommendations (if applicable), final SRC approval outcome letter, and outcome letter from Chief Scientific Officer (CSO)
- Protocol Resource Impact Assessment (PRIA) approval: If PI has not received official PRIA approval by the time of the IRB submission take a snapshot of the iRIS workflow showing that PRIA has been approved. If the PRIA has not been submitted for review, submit ASAP.

STEP 2: Complete the Study Application

Log-in to iRIS, find the correct project and complete the study application.

Information to note about the study application in iRIS:

- Refer to the Instruction Sheet 1 - *iRIS New Study Application* and Checklist *Initial Review Submission* (in above Resources) to help complete the study application, as needed
- In the section "Setup Branch(s) Access," verify the branch the PI is affiliated with and confirm that branch as the primary branch
- In the section "Grant Key Personnel access to the study," review the list of NIH investigators associated with the protocol and their roles. Revise as needed.
 - Be sure to indicate NIH investigators in different sections based on their NED status
 - Be sure the referral contact, research nurse coordinator, and accountable investigator (if applicable) roles are assigned
 - If an investigator serves in more than one role on the study (e.g., PI who is also Branch Chief or AI who is also study coordinator), ensure that person(s) is assigned to all applicable roles
- The Study Contact role is for people who should receive all iRIS communications about the study. Be sure to add PSO director and "NCI IC IRB Actions" as study contacts. Anyone can be added as a Study Contact including non-NIH employees.
- Be sure to add Branch Chief (or Clinical Director if PI is Branch Chief) under "designated Branch/IC approval." (This is required for Initial Review only)
- In the section "General Protocol Information," verify that the Précis matches what is written in the protocol/supplement. This should have been started at the time of SRC submission and may need to be updated.
- In the section "Data Collection for Non-IRB Use," assign the "Z" number. Ask the PI for the primary Z number that will be used to report this protocol. If the PI does not know what this is, refer the PI to their Branch Chief to obtain this information.

- In the section “Subject Participation,” list the responsible party for the study and provide the accrual ceiling. Mention any groups or categories of subjects that will be excluded from enrollment.
- In the section “Observational Studies”:
 - Accurately label and describe the study cohorts, arms, and outcomes
 - Complete both primary and secondary outcomes

STEP 3: Obtain Other Ancillary Approvals from These Groups Before IRB Submission (these ancillary submission processes should be started no later than post-SRC approval):

- Deputy Ethics Counselor (DEC) approval (if this is a covered protocol)
- Radiation Safety Committee (RSC) approval: See IRBO guidance to determine if your protocol meets any of the criteria for RSC submission. Submit the required form using iRIS. Once approval received, save the RSC Approval document in the initial submission folder and the RSC Folder.
- Institutional Biosafety Committee (IBC) approval: If the protocol involves gene therapy, IBC is required. The final approval document should be attached in iRIS with the initial review submission form. Once IBC approval is received, save the approval packet in the initial submission folder and in the IBC folder.

STEP 4: Complete Other Initial iRIS Submission Forms

- Designation of Reimbursement for Travel and Subsistence (DRTS) form (requires PI signature)
 - Note that a DRTS form is only required when participants are being seen at the NIH Clinical Center and reimbursement will be provided.
- Additional Study Information Form (PI signature not required)

STEP 5: Send for QC

- Send the JIRA Task to PSO Director for QC
- Do not create pdf documents until after QC
- Do not attach protocol or consent to the Initial Review Submission Form until after QC

STEP 6: Complete the Initial Review Submission Form by Attaching the Following Documents in iRIS

- Attach the following required documents to the Initial Review Submission Form:
 - Protocol
 - NIH Supplement (if applicable)
 - Informed Consent Document(s)
 - Scientific Review Approval Package with CSO approval
 - Key Study Personnel List

- Attach the following documents to the Initial Review Submission Form (if applicable as explained under step 3):
 - DEC approval
 - Radiation Safety Committee approval
 - Investigator's Brochure/Package Insert
 - IBC approval
 - FDA IND or IDE Safe to Proceed or documentation from the Sponsor that the protocol has been submitted to an active IND
 - Other documents (e.g., Questionnaires, Recruitment material, Participant card, etc.) as applicable
- Assign protocol for sign-off
 - Required Signatures include PI, Branch Chief (or Clinical Director if PI is Branch Chief) and Study Contact prepping submission form
 - IRB will receive the completed submission once all required signatures are obtained.

STEP 7: Response to Pre-review Corrections and/or Stipulations

- Create a new subfolder in the Initial submission folder in the protocol folder on the secure server, titled "Response to pre-review corrections and /or IRB Stipulations"
- Draft the response to required documents (Protocol and/or Consent)
 - Save the protocol and/or consent (s) document reviewed by the IRB
 - In 'tracked changes,' make the revisions in response to the pre-review corrections/stipulations set forth by the IRB. Make sure to update the version date.
 - Ask for PI or AI input necessary to complete required revisions
 - In iRIS, explain the changes for each pre-review correction/ stipulation contained in the IRB review
 - Incorporate any outstanding changes at this point (if applicable)
- Create a final version of the response to stipulations documents
 - Review the tracked changed protocol and consent to ensure the changes have been made consistently throughout the protocol and consent. Review the changes against the stipulations itemized in iRIS to ensure that all changes are documented.
 - Create clean and tracked versions of the protocol and consent, update TOC and pagination as needed
- Upload response in iRIS and attach the applicable documents by checking out the older version and checking in again for proper stacking
 - Protocol (clean/tracked)
 - Consent (clean/tracked)
 - Other documents (if required)
- Review response to stipulations in iRIS for accuracy (verify that responses have been saved and correct documents uploaded), update as needed, and then submit in iRIS
- Assign for signature as indicated in iRIS

STEP 8: IRB Approval

- Create a new subfolder in the protocol file titled “Approved Documents” and save the following documents:
 - IRB outcome letter(s)
 - Approved Protocol Clean (MS Word version)
 - IRB approved pdf version of the consent (downloaded from iRIS)
 - Study Application and/or IRB Initial Submission Form (If required by Sponsor)
 - If creating an optional Approval Package, include all the above documents
- If this is a CCR Sponsored Study, create a tracked version of protocol and consent with a linked cover memo and notify the IND manager that it is ready for FDA submission (save the copy in the FDA folder). Note: Notification to other parties (i.e. Sponsor, manufacturer, and/or participating sites) may be required.

STEP 9: Steps for Implementation

Once the protocol is IRB approved:

- Prepare or complete the regulatory binder
- For studies recruiting participants, prepare the Study Initiation Activities Checklist and send this to the team to complete.
- When the Study Coordinator returns the completed Study Initiation Activities Checklist, signed by the PI, submit the study status change form in iRIS to open the study to enrollment.