NYU SoM Institutional Review Board
Human Research Regulatory Affairs
1 Park Avenue | 6th Floor | New York, NY 10016
http://irb.med.nyu.edu

STUDY TEAM GUIDANCE CHECKLIST

INSTITUTIONAL REVIEW OF NEW EXTERNAL IRB SUBMISSIONS

Status	Steps
☐	**1. Obtain Required CITI Certification** CITI Human Subjects Protection Training. All investigators and research staff must complete Collaborative Institutional Training Initiative (CITI) training on human subjects protection. Click here for additional information regarding acceptable basic courses. Click here for instructions regarding account linking and Rnav training status issues
☐	**2. Registered the New Submission within Research Navigator MyStudies** Research Navigator registration will ensure an NYU Langone Health/NYUSoM study number is assigned to your study and that pertinent information is filtered to all relevant review bodies. ***Ensure the following before submitting:*** The Application for New Human Subjects Research has been completed within Research Navigator Use of an External IRB has been indicated Required Documents have been uploaded to relevant sections – See Required Attachments list (Page 3) Upload NYU SoM Financial Interest Forms for the PI and all members of the study team
☐	**3. Obtain Clinical Research Support Unit (CRSU) Fee Acceptance Confirmation** CRSU will review the study budget and coverage analysis and initiate the creation of billing grids in the Clinical Research Management System (CRMS) and the EPIC system. They will conduct an administrative review to confirm that the study sponsor accepts all fees associated with the use of an external IRB. The study Pi will be notified if there is an issue that prohibits them from submitting the study to an External IRB.
☐	**4. Manage Conflicts of Interest- Conflict of Interest Management Unit (CIMU)** Regardless of the use of an external IRB, financial conflict of interest disclosures for all investigators and research staff must be reported to NYU Langone's CIMU by uploading completed forms into the MyStudies module of Research Navigator as noted in step 1. If a financial conflict of interest is indicated, the NYU SoM IRB Operations team notifies NYU Langone's CIMU which conducts it's review and assigns a management plan, if necessary. The CIMU notifies both the principal investigator and the External Review Unit of the outcome. Should language within any of the submitted study documents required editing, ensure you have
☐ ☐ N/A	**5. Obtain clearance from the Laura and Isaac Perlmutter Cancer Center Clinical Trials Office- Regulatory Affairs unit (if applicable)** If the study is conducted by the Laura and Isaac Perlmutter Cancer Center, the study team must obtain approval from the Protocol Review and Monitoring Committee.
☐	**6. Obtain Clearance from Ancillary Review Body and Service Provider Clearance** The use of an external IRB does not replace the need for applicable internal reviews and approvals related to the conduct of your study at NYU Langone and its facilities. Examples include radiation safety, Department of Radiology, Center for Biospecimen Research and Development, Department of Pathology, and others. The principal investigator ensures that all such approvals are obtained before beginning the study.

	The principal investigator is responsible for obtaining all institutional approvals and clearances before initiating the study. Need for various reviews will be indicated once you have completed
☐	**7. Obtain Institutional Clearance via External Review Unit** The External Review Unit will conduct an administrative review of your study to confirm that all institutional requirements have been addressed within the study documents prior to submitting to the External IRB. They will issue clearance to begin your research once all ancillary and local context reviews are complete and external IRBs have issued approval. You will receive a notification via Research Navigator Comment to submit to the central IRB for review once institutional clearance has been confirmed. The study status within Research Navigator will be "External IRB" once institutional clearance has been issued. IRB-approved documents will be available in the external IRB's electronic software and/or Research Navigator.
☐	**8. Submit to External IRB** Follow the submission instructions of your selected commercial or academic IRB

No research with human subjects may commence without the approval of an authorized IRB and institutional clearance of NYU & SoM External Review Unit &

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Institutional Review of New External IRB Submissions

LIST OF REQUIRED ATTACHMENTS

Please be sure to upload documents to proper upload sections within the research navigator system. Each section is indicated in bold lettering below.

Protocol

- ☐ Protocol

Devices

- ☐ Investigator's brochure / device manual

Drugs

- ☐ Investigator's brochure / package insert !
- ☐ Form 1571/1572 (N/A for cooperative group studies) !

Consent Forms

- ☐ Written Consent
- ☐ Key Information Sheet
- ☐ Assent forms
- ☐ Other ICF/authorization (data from subject's parents; specimen banking, sub-studies, HIV, A/V, authorization, etc.)
- ☐ Verbal Consent
- ☐ Standalone HIPAA authorization (*NCI ONLY)*
- ☐ Waiver of HIPAA authorization *(NCI ONLY- requires review by NYU SoM Privacy Board)*
- ☐ Waiver of documentation of consent
- ☐ Waiver of consent/alteration of consent
- ☐ Capacity assessment tools

Supporting Documents

- ☐ CVs for all listed staff !
- ☐ NYS Licensure listed !
- ☐ Licensure not required !
- ☐ Financial Disclosures for all listed staff !