

**SOP#: PM-7**

**Clinical Research Study Initiation**

**Version #: 4.1**

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**Review Interval Period: Biennial**

**NCI Clinical Director Signature:**

## **POLICY**

All protocol initiation activities must be completed before the clinical research study opens to participant recruitment. This requirement applies all research studies, including observational (screening, tissue acquisition, natural history) studies.

Note: Institutional Review Board (IRB) approval does not automatically signify that a clinical research study may be opened for participant recruitment.

## **PURPOSE**

To clarify the study initiation activities that are required to be completed prior to opening the study for participant recruitment. While the PI is responsible for ensuring that all of these activities are completed prior to participant recruitment, assistance is provided by the office or group identified with the activity.

## **RESOURCES**

- Center for Cancer Research [Standard Operating Procedures](#)
- CCR Office of Sponsor and Regulatory Oversight (OSRO) [website](#)
- [CCR Office of the Director](#)
- [CC-DCRI Protocol Order Sets](#)
- [Clinical Center Pharmacy Department](#)
- [NCI Technology Transfer Center](#)
- [NIH Intramural Institutional Review Board Office \(IRBO\)](#) – includes the NIH Office of Human Subjects Research Protections (OHSRP)
  - NIH Clinical Research Studies Active Consent/Assent Documents [website](#)
- [NIH Office of Science Policy](#)
- [NIH Office of Technology Transfer](#)

## **STEP 1: Review Study Initiation Activities**

The Principal Investigator (PI), Research Nurse Coordinator and Protocol Support Office (PSO) staff will review the study initiation activities listed below to determine which activities are applicable to the study. The majority of these activities are relevant to most treatment research studies and must be completed prior to the study being opened for participant recruitment. See Appendix B for types of studies and the associated study initiation activities.

### **REQUIRED STUDY INITIATION ACTIVITIES**

1. All contracts and funding agreements fully executed and/or approved

The NCI Technology Transfer Center (TTC) will assist with any contracts/agreements [e.g., Clinical Trial Agreement (CTA), Cooperative Research and Development Agreement (CRADAs), Material Transfer Agreement (MTA)] with industry sponsors, manufacturers or other external collaborators. TTC will also assist with patents and licensing if required. TTC should be contacted early in the concept/study process.

Some studies will need funding for equipment, special lab supplies, and study medication not supplied by the manufacturer. The PI should work with their branch chief and administrative officers in the CCR Office of the Director (not Office of the *Clinical* Director) to determine if a Resource Request System (RRS) form is required for the study.

2. Communication from FDA that CCR-sponsored Investigational New Drug (IND) / Investigational Device Exception (IDE) study is “safe to proceed” (without contingencies)

The CCR Office of Sponsor and Regulatory Oversight (OSRO) will manage all required IND / IDE submissions to the FDA. OSRO will send an activation memo to the PI once the FDA has indicated the study is safe to proceed.

Note: The FDA safe to proceed letter is required PRIOR to study submission to the IRB.

3. Reliance agreements with any outside investigators/collaborators fully executed

If the study involves a non-NIH investigator who is involved in the research but not located at the Clinical Center, a reliance (authorization) agreement may need to be executed. The Office of Human Subjects Research Protections (OHSRP) and CCR PSO staff will assist with this agreement.

4. Genomic Data Sharing (GDS) Plan and Institutional Certification (IC) Memo approved by CCR Scientific Director

All research studies that generate genomic data and meet the GDS policy requirements are required to have a Genomic Data Sharing Plan and Institutional Certification Memo completed and approved. Refer to CCR SOPs RPS-21 “Establishing a Genomic Data Sharing Project and Required Documents” and RPS-23 “Registering a Clinical Trial in dbGaP” for more information.

5. IRB approval

The PSO staff will assist with required submissions to oversight committees. The IRB will communicate its decisions to the PI and PSO staff via email.

For Network studies (i.e., ETCTN, NCTN), approval of Local Context Worksheet is also required – this will come from the NCI Central IRB.

Note: For more information about required activities prior to IRB approval, please see CCR SOP RPS-5 “NIH IRB Submission and Response: New Protocol.”

The following activities occur after IRB approval:

6. Site initiation visit (SIV) completed for IND/IDE studies

All industry-sponsored studies will have SIVs coordinated by the sponsor and communicated to the CCR via the [QA Mailbox](#).

All CCR-sponsored IND/IDE studies will have SIVs coordinated by the CCR Office of Sponsor and Regulatory Oversight (OSRO). If the study includes multiple institutions, OSRO will coordinate SIVs for each site. See OSRO’s website for documents/activities required prior the SIV.

CTEP does not perform SIVs for their sponsored studies. Therefore, CCR Office of Education and Compliance will conduct the visit prior to the study being open to recruitment. Please contact CCR [Office of Education and Compliance](#) to schedule SIV.

7. Site initiation visit completed for CCR coordinated multi-site studies (non CCR-sponsored INDs)

All multi-institutional studies for which CCR is the Coordinating Center are required to have a site initiation visit completed prior to opening the study for recruitment. This will ensure that research staff are aware of responsibilities associated with coordinating a multi-site study. Each participating site will also need to have a SIV prior to enrolling participants at that site. Contact the CCR [Office of Education and Compliance](#) to schedule SIV.

Note: All participating sites must have a GDS Institutional Certification (see #4 above) unless there is an executed Reliance Agreement in place with the participating site.

8. Communication received from CC Department of Transfusion Medicine (CC DTM) that cell processing facility is ready to process cells, if protocol requires cell processing

The research team must request an email from CC DTM personnel indicating that the cell processing facility is ready to process cells. This email is required to be maintained with the completed Study Initiation Activities Checklist.

9. Communication received from research lab performing research sample processing, shipping and/or storage that the research lab is ready to accept specimens

If the protocol is going to utilize a research lab (e.g., Dr. Figg’s lab) for research sample processing, shipping, and/or storage, the research team must request an email from lab personnel indicating that the lab can accept specimens. This email is required to be maintained with the completed Study Initiation Activities Checklist.

10. CCR study database built

For studies using a CCR electronic data capture system (e.g., C3D, LabMatrix, Medidata Rave), the study-specific database must be completed and ready for data entry.

11. CRIS order sets submitted to the Department of Clinical Research Informatics (DCRI)

The Research Nurse Coordinator should work with DCRI to create study-specific order sets in CRIS. Finalized order sets must be signed off by the PI per MAS policy.

12. Written notification that study may be activated at site, if applicable

For CCR-sponsored INDs, notification will come from OSRO.

13. Manufacturer notified that investigational product can be shipped

Once required agreements/contracts are fully executed and study has been processed by OPS, PI must notify the drug manufacturer that study drug can be shipped.

14. Communication received from pharmacy that all investigational products and other drugs/biologics used in the study are available in the pharmacy

The research team must request an email from pharmacy personnel indicating that investigational products and other protocol-specified drugs/biologics are available in the pharmacy. This email is required to be maintained with the completed Study Initiation Activities Checklist. If the protocol does not allow for “starter supplies,” please note that on the checklist (e.g., CTEP sponsored studies).

15. For industry-sponsored studies, the following additional activities must also be completed:

- Study team training on sponsor electronic data capture system.
- Required supplies (e.g., blood collection kits, shipping materials) and documents (e.g., study Manual of Procedures, sponsor SOPs) received on site.

Note: There may be other sponsor-specific activities that are required prior to study initiation.

## **STEP 2: Complete Study Initiation Activities Checklist**

The Study Initiation Activities Checklist in Appendix A must be completed with the date each applicable study initiation activity was completed. If an activity is not applicable, note “N/A” for that activity. The PI must sign and date the completed checklist and send to [PSO staff](#).

**Important:** Inpatient and/or Day Hospital nursing unit and outpatient clinic protocol-specific education must be completed prior to the first participant receiving treatment. A sign-in sheet should be completed for each in-service provided. A scanned copy of the sign-in sheet and any presentation materials should be maintained in the protocol’s regulatory file.

## **STEP 3: Change Study Status in iRIS**

Once the completed, signed checklist is received by PSO staff, the PSO staff will change the study status in iRIS to reflect “Open – Recruiting” and save the checklist and related documentation in the protocol’s electronic regulatory folder.

**Appendix A**

**Study Initiation Activities Checklist**

**Protocol – Abbreviated Title:** \_\_\_\_\_

**Protocol #:** \_\_\_\_\_ **PI:** \_\_\_\_\_

| <b>Study Initiation Activity</b> (see SOP for specifics)   | <b>Completed on</b><br>(mark N/A if not applicable) |
|--|---|
| All contracts and funding agreements fully executed and/or approved  |   |
| CCR sponsored-IND, protocol submitted to FDA and activation memo sent by OSRO  |   |
| Reliance Agreement for outside investigators/collaborators fully executed  |   |
| Genomic Data Sharing (GDS) Plan and Institutional Certification (IC)Memo approved (or GDS exception approved)          |   |
| IRB approval, including approval of Local Context Worksheet, if applicable   |   |
| Site initiation visit complete, including Study Start Up for CTEP-sponsored studies                                    |   |
| Communication from CC DTM that cells can be processed  |   |
| Communication from research lab that specimens can be processed, etc.  |   |
| CCR study database built   |   |
| CRIS order sets submitted to DCRI  |   |
| Notification from study sponsor that study may be activated at site  |   |
| Manufacturer notified that investigational product can be shipped  |   |
| Communication from pharmacy that protocol agents are available in pharmacy   |   |
| The below activities are for industry-sponsored studies:   |   |
| <ul style="list-style-type: none"> <li>• Research Team training on sponsor’s electronic data capture system</li> </ul> |   |
| <ul style="list-style-type: none"> <li>• Study-specific supplies and documents received</li> </ul>                     |   |

\_\_\_\_\_  
PI Signature

\_\_\_\_\_  
Date

**Appendix B**

| <b>List of Activities</b>   | <b>Observational</b><br>(including specimen collection<br>and natural history) | <b>Interventional:</b><br><b>non-IND/IDE</b> | <b>Interventional:</b><br><b>CCR-sponsored</b><br><b>IND/IDE</b> | <b>Interventional:</b><br><b>industry-sponsored</b><br><b>IND/IDE</b> |
|---|--|--|--|---|
| Contracts and funding agreements fully executed and/or approved               | Possibly   | Possibly                                     | Possibly   | Required  |
| CCR sponsored-IND, protocol submitted to FDA and activation memo sent by OSRO | N/A  | N/A  | Required   | Held by sponsor   |
| Reliance Agreement for outside investigators/ collaborators fully executed    | Possibly   | Possibly                                     | Possibly   | Possibly  |
| GDS Plan and IC Memo approved (or GDS exception)                              | Possibly   | Possibly                                     | Possibly   | Possibly  |
| IRB approval, including approval of Local Context                             | Required   | Required                                     | Required   | Required  |
| Site initiation visit complete / Study Start Up for CTEP studies              | If multi-site  | If multi-site                                | Required   | Required  |
| Communication from CC DTM that cells can be processed                         | N/A  | N/A  | Possibly   | N/A   |
| Communication from research lab that specimens can be processed, etc.         | Possibly   | Possibly                                     | Possibly   | Possibly  |
| CCR database built  | Possibly   | Required                                     | Required   | Possibly  |
| CRIS order sets submitted to DCRI   | Possibly   | Required                                     | Required   | Required  |
| Notification from sponsor to activate site                                    | N/A  | Possibly                                     | Required   | Possibly  |
| Manufacturer notified investigational product can be shipped                  | N/A  | Possibly                                     | Required   | Required  |
| Communication from pharmacy that protocol agents are available in pharmacy    | N/A  | Possibly                                     | Required   | Required  |
| Research Team training on sponsor's EDC                                       | N/A  | N/A  | N/A  | Required  |
| Industry-sponsor study-specific supplies and documents received               | N/A  | N/A  | N/A  | Required  |