SOP#: PM-1	**Principal Investigator (PI) Delegation of Activities for Research**
Version #: 2.3	**Next Review Date: 05/2026**
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NCI Clinical Director Signature/ Effective Date:	James Gulley, M.D., Ph.D. Digitally signed by James Gulley, M.D., Ph.D. Date: 2024.05.08 07:32:42 -04'00'

POLICY

The Principal Investigator (PI) is responsible for supervising the conduct of the clinical study and to protect the rights, safety, and welfare of participants. It is common for the PI to delegate certain study-related activities/tasks to employees, colleagues, or others. When activities are delegated, the PI is responsible for providing adequate training and supervision of those to whom activities are delegated. The PI is accountable for regulatory non-compliance resulting from failure to adequately train staff and/or supervise the conduct of the clinical study.

All research studies (interventional and observational) are required to have a Delegation of Activities (DoA) Log. The PI is responsible for ensuring the person to whom the research activity has been delegated has appropriate training, licensure and Clinical Center credentialing if appropriate to perform the activity.

If during the study, there is a change in the PI, the existing DoA log will be closed out and a new DoA log is required.

Activities delegated by the PI on the DoA log must be consistent with roles identified in PROTECT and the protocol, if any. An individual who is delegated to assume PI responsibilities must be an Associate Investigator (AI) on the study.

For IND studies:

- The person delegated to assume PI responsibilities must also be listed on the FDA Form 1572.
- The sponsor may have additional requirements for delegation of activities which should be followed as long as the requirements are not less restrictive than this SOP. (e.g., the sponsor may not require PI confirmation for eligibility, DLT or AE assessment but the PI is still required to perform the confirmation for studies conducted at the CCR). Please contact the Office of Education and Compliance for questions.

PURPOSE

The purpose of this Standard Operating Procedure is to clarify for PIs what research-related activities can be delegated to whom by providing a list of common activities and to whom they may be delegated, provided the staff member is adequately trained and credentialed, if required, to perform the activities.

A blank DoA log and guidelines on how to complete the log can be found on the CCR SOP website under this SOP. This log is to be used when no sponsor log is available.

Note: Some sponsors refer to a "Delegation of Authority" log which is a similar concept, but a PI cannot delegate his/her authority and responsibilities for oversight of a research study; instead, the PI may delegate research activities/tasks to appropriate team members.

REFERENCES

Code of Maryland Regulations (COMAR) Title 10

- Subtitle 27 Board of Nursing, Chapter 07 *Practice of the Nurse Practitioner*
- Subtitle 27 Board of Nursing, Chapter 09 *Standards of Practice for Registered Nurses*
- Subtitle 32 Board of Physicians, Chapter 01 *General Licensure Regulations*
- Subtitle 32 Board of Physicians, Chapter 03 *Delegation of Duties by a Licensed Physician – Physician Assistant*
- Subtitle 32 Board of Physicians, Chapter 12 *Delegation of Acts by a Licensed Physician to an Assistant Not Otherwise Authorized under the Health Occupations Article or the Education Article*

National Cancer Institute. (2014). *A Handbook for Clinical Investigators Conducting Therapeutic Clinical Trials Supported by CTEP, NCI*

U. S. Food and Drug Administration. (2009, October). *Investigator Responsibilities – Protecting the Rights, Safety, and Welfare of Study Subjects; Guidance for Industry*

U. S. Food and Drug Administration. (2010, May). *Information Sheet - Guidance for Sponsors, Clinical Investigators, and IRBs: Frequently Asked Questions—Statement of Investigator (Form FDA 1572)*

U. S. Food and Drug Administration. (2018, March). *E6(R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1), Guidance for Industry*

U. S. Food and Drug Administration. (3/22). *Statement of Investigator*

Research Activities	MD/DO	Nurse Practitioner (NP) / Physician Assistant (PA)	Research Nurse Specialist / Study Coordinator	Clinical Data Manager
GENERAL ACTIVITY				
Assume PI responsibilities when PI is unavailable (e.g., at a meeting, vacation, etc.) ***NOTE**: Must be listed as an AI on the study*	Yes	Yes, if qualified and listed as an AI on the study	No	No
Assessment of eligibility criteria[1]	Yes, with confirmation by PI	Yes, with confirmation by PI	Yes, with confirmation by PI	No
Informed consent (IC)/assent ***NOTE**: Must be listed as AI on the study and not a trainee or volunteer. The MD/DO/NP/PA must conduct initial treatment options discussion for an individual patient and document discussion in CRIS*	Yes	Yes	Yes	No
Vital signs	Yes	Yes	Yes	No
Physical exams	Yes	Yes	No	No
Medical history	Yes	Yes	Intake only; Medically focused evaluations done by MD/PA/NP	No
Clinical orders, including medical consults	Yes	Yes	No	No
Develop and maintain Research Protocol CRIS Order Sets	Yes	Yes, with review/sign off by PI	Yes, with review/sign off by PI	No
Orders for study specific drugs/biologics ***NOTE:** For IND studies, ordering individual must be an AI on the study and be listed as a sub-investigator on FDA Form 1572.*	Yes	Yes, except for CTEP sponsored studies where they must be registered as a Non-Physician Investigator (NPIVR). Otherwise, a co-signature by an MD who has a current CTEP ID is required; other sponsors may prohibit NP/PA from ordering study products	No	No
Administration of test article	Yes	Yes	Yes, if credentialed	No
DLT determination[1]	Yes, with confirmation by PI	Yes, with confirmation by PI	Initial assessment with confirmation by PI	No
MTD determination[1]	Yes, with confirmation by PI	Yes, with confirmation by PI	Initial assessment with confirmation by PI	No
Dose modification (including reductions, holds or restarts)[1]	Yes, with confirmation by PI	Yes, with confirmation by PI	Initial assessment with confirmation by PI	No

Research Activities	MD/DO	Nurse Practitioner (NP) / Physician Assistant (PA)	Research Nurse Specialist / Study Coordinator	Clinical Data Manager
GENERAL ACTIVITY, cont.				
Address participant medical questions/concerns and document information	Yes	Yes	May triage to provider (must document initial contact in CRIS)	No
ADVERSE EVENTS (AE) and EXPEDITED REPORTABLE EVENTS				
Intake/documentation of symptoms	Yes	Yes	Yes	No
Assessment of grade and term using CTCAE[1]	Yes, with confirmation by PI	Yes, with confirmation by PI	Yes, with confirmation by PI	Initial determination with confirmation by PI
Assessment of clinical significance	Yes	Yes	Yes, with confirmation by MD/DO/NP/PA	No
Assessment of expectedness and seriousness[1]	Yes, with confirmation by PI	Yes, with confirmation by PI	Yes, with confirmation by PI	No
Assessment of relationship to test article (i.e., attribution/causality)[1]	Yes, with confirmation by PI	Yes, with confirmation by PI	Yes, with confirmation by PI	No
Determining need for expedited AE reporting to IRB, sponsor, or IBC	Yes	Yes	Yes	No
Review IND Safety Reports to determine if information meets the definition of an unanticipated problem	PI only	No	No	No
Submission of SAEs, expedited AEs and events, unanticipated problems, protocol deviations, or Non-compliance to IRB, sponsor, or IBC	Yes	Yes	Yes	No
STUDY DRUG (ORAL)				
Documentation of participant adherence[2]	Yes	Yes	Yes	No
Drug accountability[3]	Yes	Yes	Yes	No
SOURCE DOCUMENTS				
Provide accurate, timely, and complete documentation in participant's medical record[2]	Yes	Yes	Yes	No
Maintain research chart as needed[4]	No	No	Yes	No
STUDY PROCEDURES				
Lab sample processing, shipping or receiving, ***NOTE****: For shipping, appropriate IATA training is required and needs to be current.*	Yes	Yes	Yes	No

Research Activities	MD/DO	Nurse Practitioner (NP) / Physician Assistant (PA)	Research Nurse Specialist / Study Coordinator	Clinical Data Manager
STUDY PROCEDURES, cont.				
Participant education related to completion of forms (e.g., questionnaires, surveys, diaries) and review forms upon completion.	Yes	Yes	Yes	No
Determination of response[1]	Yes, with confirmation by PI	Yes, with confirmation by PI	No	No
Assessment of study endpoints[1]	Yes, with confirmation by PI	No	No	No
STUDY REGULATORY DOCUMENTS				
Maintain essential documents in the e-regulatory file	To be maintained by the CCR Protocol Support Office staff. See SOPs PM-6 and RPS-1			
DATA MANAGEMENT				
Data abstraction from source documents to database/case report forms (CRF)	Yes	Yes	Yes	Yes
Quality check CRF completion against source documentation ***NOTE**: When using C3D, use the verification feature in the database*	No	No	Yes	No
Data query resolution	Yes	No	Yes	Yes
Sign completed CRF to verify quality and accuracy of data	PI only	No	No	No

[1] The PI or individual delegated PI responsibilities must document confirmation in CRIS (e.g., reviewing and signing note written by another team member, writing an addendum to a note written by another team member, writing separate note)
[2] See CCR SOP PM-3 "Clinical Research Documentation"
[3] See CCR SOP PM-8 "Conducting and Documenting Drug Accountability for Oral Investigational Agents that are Self-Administered by Patients."
[4] Documents not included in the medical record (e.g., subject diaries, QOL or other participant completed documents, PK worksheets)

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