

**SOP#: PM-1**

**Version #: 2.0**

**Approved Date: 05/2019**

**NCI Clinical Director Signature:**

**Principal Investigator (PI) Delegation of Tasks for Research**

**Next Review Date: 05/2021**

**Review Interval Period: Biennial**

### **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 tasks to employees, colleagues, or others. When tasks are delegated, the PI is responsible for providing adequate training and supervision of those to whom tasks 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 Tasks (DoT) Log, which can be combined with a Signature Log. The PI is responsible for ensuring the person to whom the task has been delegated has appropriate training, licensure and Clinical Center credentialing if appropriate to perform the task.

Tasks delegated by the PI on the DoT/Signature log must be consistent with roles listed on the Key Study Personnel (KSP) form in iRIS if the person is also identified on the protocol or KSP. An individual who is delegated to assume PI responsibilities must be an Associate Investigator (AI) on the study

Note: The KSP form is used by the IRB to guide decisions about research team members' engagement in research and roles on the study. The KSP form DOES NOT take the place of a DoT log.

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 tasks 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 tasks can be delegated to whom by providing a list of common tasks and to whom they may be delegated, provided the staff member is adequately trained to perform the task.

A sample Site [Delegation of Tasks/Signature Log](#) is available on the Center for Cancer Research website, under CCR SOPs and Related Forms.

**Note:** Some sponsors refer to a “Delegation of Authority” or “DoA” 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 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, DCTD, NCI](#)

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

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. (2019, March). [Statement of Investigator](#)

Research Tasks	MD/DO	Nurse Practitioner (NP)/ Physician Assistant (PA)	Research Nurse Specialist/Study Coordinator	Clinical Data Manager
<b>GENERAL ACTIVITY</b>				
Assume PI responsibilities when PI is unavailable (e.g., at a meeting, vacation, etc.) <b>NOTE: Must be listed as an AI on the study</b>	Yes	No	No	No
Assessment of eligibility criteria <sup>1</sup>	Yes with confirmation by PI	Yes with confirmation by PI	Yes with confirmation by PI	No
Informed consent (IC)/assent <b>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</b>	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
Orders for study specific drugs/biologics <b>NOTE: For IND studies, ordering individual must be an AI on the study and be listed as a sub-investigator on FDA Form 1572.</b>	Yes	Yes, except for CTEP sponsored studies where 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 <sup>1</sup>	Yes with confirmation by PI	Yes with confirmation by PI	Initial assessment with confirmation by PI	No
MTD determination <sup>1</sup>	Yes with confirmation by PI	Yes with confirmation by PI	Initial assessment with confirmation by PI	No
Dose modification (including reductions, holds or restarts) <sup>1</sup>	Yes with confirmation by PI	Yes with confirmation by PI	Initial assessment with confirmation by PI	No

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<b>ADVERSE EVENTS (AE) and EXPEDITED REPORTABLE EVENTS</b>				
Intake/documentation of symptoms	Yes	Yes	Yes	No
Assessment of grade and term using CTCAE <sup>1</sup>	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 <sup>1</sup>	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) <sup>1</sup>	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
<b>STUDY DRUG (ORAL)</b>				
Documentation of participant adherence <sup>2</sup>	Yes	Yes	Yes	No
Drug accountability <sup>3</sup>	Yes	Yes	Yes	No
<b>SOURCE DOCUMENTS</b>				
Provide accurate, timely, and complete documentation in participant's medical record <sup>2</sup>	Yes	Yes	Yes	No
Maintain research chart as needed <sup>4</sup>	No	No	Yes	No
<b>STUDY PROCEDURES</b>				
Lab sample processing, shipping or receiving, <b>NOTE: For shipping, appropriate IATA training is required and needs to be current.</b>	Yes	Yes	Yes	No
Participant education related to completion of forms (e.g., questionnaires, surveys, diaries) and review forms upon completion.	Yes	Yes	Yes	No
Determination of response <sup>1</sup>	Yes with confirmation by PI	Yes with confirmation by PI	No	No
Assessment of study endpoints <sup>1</sup>	Yes with confirmation by PI	No	No	No

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<b>STUDY REGULATORY DOCUMENTS</b>				
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			
<b>DATA MANAGEMENT</b>				
Data abstraction from source documents to database/case report forms (CRF)	Yes	Yes	Yes	Yes
Quality check CRF completion against source documentation <i>NOTE: When using C3D, use the verification feature in the database</i>	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
<sup>1</sup> 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) <sup>2</sup> See CCR SOP PM-3 “Clinical Research Documentation” <sup>3</sup> See CCR SOP PM-8 “Conducting and Documenting Drug Accountability for Oral Investigational Agents that are Self-Administered by Patients” <sup>4</sup> Documents not included in the medical record (e.g., subject diaries, QOL or other participant completed documents, PK worksheets)				
<i>Adapted from Dana Farber/Harvard Cancer Center with permission</i>				