SOP#: PM-1 **Principal Investigator (PI) Delegation of Tasks for Research Involving a Drug or Device**

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NCI Clinical Director Signature:

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 other third parties (individuals or entities not under the direct supervision of the investigator). When tasks are delegated, the PI is responsible for providing adequate supervision of those to whom tasks are delegated. The investigator is accountable for regulatory violations resulting from failure to adequately supervise the conduct of the clinical study.

Purpose

The purpose of this Standard Operating Procedure is to clarify for PIs what research-related tasks can be delegated to others when research involves a drug or device by providing a list of common tasks and to whom they may be delegated.

References

Code of Maryland Regulations (COMAR) Title 10 (http://www.dsd.state.md.us/comar/comar.aspx):

- 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. (2013). *A Handbook for Clinical Investigators Conducting Therapeutic Clinical Trials Supported by CTEP, DCTD, NCI.* Retrieved from http://ctep.cancer.gov/investigatorResources/docs/InvestigatorHandbook.pdf

U. S. Food and Drug Administration. (2009, October). Guidance for Industry Investigator Responsibilities – Protecting the Rights, Safety, and Welfare of Study Subjects. Retrieved from http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM187772.pdf

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*). Retrieved from http://www.fda.gov/downloads/regulatoryinformation/guidances/ucm214282.pdf

U. S. Food and Drug Administriaon. (2013, February). *Statement of Investigator.* Retrieved from http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM074728.pdf

Research Tasks	MD/DO	Nurse Practitioner (NP)/ Physician Assistant (PA)	Research Nurse Specialist	Clinical Data Manager
GENERAL ACTIVITY				
Assessment of inclusion/exclusion criteria	yes	yes	Initial documentation; Requires evidence of confirmation by MD[1]	no
Informed consent (IC)/assent Note: 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
Orders for study specific drugs/biologics ***NOTE:*** *For IND studies, ordering individual must be on FDA Form 1572. For CTEP studies, each MD must be registered with CTEP and have a current CTEP ID.*	Yes	Yes, except for CTEP sponsored studies where co-signature by an MD who has a current CTEP ID is required	no	no
Administration of test article	yes	yes	yes	no
DLT determination	yes	yes	Initial assessment; Requires evidence of confirmation by MD[1]	no
MTD determination	Initial assessment; Requires evidence of confirmation by PI	Initial assessment; Requires evidence of confirmation by PI	Initial assessment; Requires evidence of confirmation by PI	no
Dose modification (including reductions, holds or restarts)	yes	yes	Initial assessment; Requires evidence of confirmation by MD[1]	no
ADVERSE EVENTS (AE)				
Intake/documentation of symptoms	yes	yes	yes	no
Assessment of grade and term using CTCAE	yes	yes	Initial determination; Requires evidence of confirmation by MD[1]	Initial determination; Requires confirmation by licensed member of the research team
Assessment of clinical significance	yes	yes	Initial determination; Requires evidence of confirmation by MD[1]	no

Assessment of expectedness and seriousness	yes	yes	Initial determination; Requires evidence of confirmation by MD	no
Assessment of relationship to test article (i.e., attribution/causality)	yes	yes	Initial determination; Requires evidence of confirmation by MD[1]	no
Determining need for expedited AE reporting to IRB, sponsor or FDA, or IBC/OBA	yes	yes	yes	no
Submission of expedited events, unanticipated problems, protocol deviations, or non-compliance to IRB, sponsor or FDA, or IBC/OBA[1]	yes if also AI	yes if also AI	Yes	No
DRUG ACCOUNTABILITY				
Documentation of accountability and adherence by review of subject diary and/or count of test article returned by subject	yes	yes	yes	no
SOURCE DOCUMENTS				
Writing in subject's medical record (i.e., CRIS) or research chart	yes	yes	yes	no
STUDY PROCEDURES				
Subject Randomization *if other than sponsor or the CCR Central Registration Office*	yes	yes	yes	In collaboration with MD/PA/NP/Research Nurse
Lab sample processing, shipping or receiving, *NOTE: For shipping, appropriate IATA training is required and needs to be current.*	yes	yes	yes	yes
Determination of response	yes	Requires evidence of review with MD directly, by phone or email prior to research-related decisions	no	no
Assessment of primary study endpoints	yes	Requires evidence of review with MD directly, by phone or email prior to research-related decisions	no	no
STUDY REGULATORY DOCUMENTS				
Maintain regulatory binder or study manuals[2]	yes	yes	yes	yes
CASE REPORT FORMS (CRFs)				
Data transfer from source documents to CRF	yes	yes	yes	yes
Sign completed CRF*, if applicable*	yes	no	no	no

Data query resolution	yes	yes	If other than abnormal lab values, requires evidence of collaboration with MD	If other than abnormal lab values, requires evidence of collaboration with MD
COMMUNICATIONS				
Communication with sponsors, IRB or federal authorities[2]	yes	yes	yes	Yes
[1] The Research Nurse Specialist is to confirm with an MD and document in CRIS to whom they spoke [2] Also may be done in part or completely by Protocol Support Office staff				
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