

SOP#: RPS-19

Requirements for NCI Clinical Director Signature

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NCI Clinical Director Signature:

POLICY

The NIH Intramural Research Program (IRP) requires that the Clinical Director (CD) of each institute review and approve certain protocol submissions to the IRB prior to final approval of that action.

PURPOSE

To outline the actions that require CD signature per the NCI IRP and outline the delegation for that signature should the CD be unavailable.

RESOURCES

NIH HRPP SOPs: <https://ohsr.od.nih.gov/nih/pnp.php>

- SOP 16, Reporting Requirements for Unanticipated Problems, Adverse Events, and Protocol Deviations
- SOP 10, Amendments to IRB-Approved Research
- SOP 15A: Research Regulated by the FDA: Information and Policies Specific to Research involving Investigational New Drugs (including biological products).

NIH MAS policy 93-1: Research Involving Human Subjects at the Clinical Center: Structure and Process <http://cc-internal.cc.nih.gov/policies/PDF/M93-1.pdf>

PROCEDURES

Step 1: Actions the NCI Clinical Director must review and approve prior to final approval per HRPP SOPs and NIH MAS policy

- Initial review of protocols being submitted to the IRB;
- Amendments: All amendment actions that are reviewed by the convened IRB should be routed to the NCI CD for review and signature. The NCI CD does not need to review actions that are approved by expedited review;
- Problems: Only unanticipated problems (UPs), serious protocol deviations, deaths, unanticipated adverse device effects (UADEs) and serious or continuing non-compliance;
- Single patient emergency use.

Step 2: Additional actions that the NCI Clinical Director must review and approve per NCI directive

- Scientific review of new protocols;
- Study closures
- All events reported to the NIH IRB on the problem report form

Step 3: Assignment of CD signature in iRIS

- All actions, except for problem forms, study closures and scientific review, requiring CD signature should be routed to William Dahut, NCI CD. These actions must be routed on the study side of iRIS prior to IRB receipt:
 - The initial review of protocols
 - Single patient emergency use protocols
 - Amendments requiring review by the convened IRB
- All problem report forms, study closures and scientific review should be routed to Caryn Steakley, NCI Deputy Clinical Director.
 - All problems forms should be routed to the CD on the study side prior to IRB receipt
 - All study closures should be routed to the CD on the study side prior to IRB receipt
 - The scientific review approval will be routed to the CD at the time of approval by the Committee

When Caryn Steakley is not available for signature, route those actions to William Dahut.

When William Dahut is not available for signature, he will notify the IRB and Protocol Support Office in advance to inform them of who will be providing signature on his behalf while he is out of office.

Step 4: Routing to CDs of other institutes in iRIS

Per MAS policy 93-1, if a protocol involves, as principal (PI) or associate (AI) investigator(s), staff of more than one Institute, the study must be approved by the IRB of the PI and by the Clinical Directors of *all* involved Institutes before it is submitted to the Director, CC, for final approval.

Routing to other IC Clinical Directors should be done on the study side in iRIS prior to the action being received by the IRB.

Step 5: The NCI Clinical Director must be informed of the following items when the NIH IRB is not the IRB of record

- Deaths that occur within 30 days of completing treatment or receiving a research intervention should be reported via email to the Clinical Director. If a death occurs after 30 days, it should be reported only if the death is at least possibly related to the research treatment or intervention.
 - To report these deaths, please send an email describing the circumstances of the death to Dr. Dahut at dahutw@mail.nih.gov and to CCRsafety@mail.nih.gov within one business day of learning of the death.
- All unanticipated problems, serious protocol deviations, UADEs and serious or continuing non-compliance
 - To report these events, please send an email to the NCI CD at CCRsafety@mail.nih.gov. The report that is submitted to the outside IRB can be used to report to the NCI CD.
- Initial review and amendments should be routed to the CD as above in iRIS.