

DAIDS
Bethesda, MD USA

ARCHIVED POLICY
Protocol Registration

Approval Date: 29 APR 2015
Effective Date: 27 MAY 2015

No.: DWD-POL-RA-011.05

CHANGE SUMMARY: This policy and associated manual have been reviewed for accuracy and updated to meet 508 compliance guidelines. This version supersedes version 4.0 dated 04 MAY 2012.

1.0 PURPOSE

The purpose of this policy is to describe the protocol registration requirements for National Institute of Allergy and Infectious Diseases (NIAID) Division of AIDS (DAIDS)-supported and/or -sponsored clinical research that is reviewed and approved by a DAIDS Scientific Review Committee.

2.0 SCOPE

This policy applies to all clinical research supported and/or sponsored by NIAID (DAIDS) that is reviewed by DAIDS Scientific Review Committees, namely the Prevention Sciences Review Committee (PSRC) and the Clinical Sciences Review Committee (CSRC).

3.0 BACKGROUND

NIAID (DAIDS) sponsors and provides support for clinical research conducted within the

U.S. and around the world. In order to ensure that this research is conducted in compliance with applicable standards and regulations, DAIDS has developed specific protocol registration requirements and a web-based Protocol Registration (PR) System.

The PR System receives and tracks certain regulatory documents that must be submitted by Clinical Research Sites (CRSs) throughout the conduct of a study. The DAIDS PR process verifies that CRSs have received the necessary Institutional Review Board (IRB)/Ethics Committee (EC), Institutional Biosafety Committee (IBC), and other Regulatory Entity (RE) approvals and have provided to DAIDS all documentation pertaining to investigator qualifications and responsibilities required by the U.S. Food and Drug Administration (FDA), the National Institutes of Health (NIH), and DAIDS. In addition, all IRB/EC- approved site-specific informed consent forms that will be used to consent study participants must be submitted.

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This policy describes when a CRS must submit certain materials to DAIDS through the PR System (i.e., the time period from initial protocol registration through deregistration) and the communications the CRS will receive in response to their submissions.

4.0 DEFINITIONS

For definitions, see [DAIDS glossary](#).

For additional information about the PR process, see the [DAIDS Protocol Registration Manual](#).

5.0 RESPONSIBILITIES

CRS Leader

For Network studies, the CRS Leader is responsible for ensuring that his/her site adheres to the Protocol Registration policy. The CRS Leader may delegate PR-associated tasks to another qualified individual, such as the IoR.

IoR/Grant PI/Contract PI

After receiving final IRB/EC approval, IBC approval and other applicable regulatory entity approval of the protocol and site-specific informed consent, the IoR/Grant PI/Contract PI will ensure that their CRS submits all the required PR documents to the DAIDS PRO and all PR requirements are met, as specified in the Protocol Registration manual.

Program Officer/Contracting Officer's Representative (COR)

For non-network studies, the Program Officer/COR or designee will make the Grant/Contract PI aware of PR requirements at the time of protocol development and the need to include language (pertaining to PR requirements) in the initial version of the protocol. The Program Officer/COR or designee will refer the Grant/Contract PI to the DAIDS Protocol Registration manual for additional information.

DAIDS RSC

The PRO at the DAIDS RSC implements and manages the day-to-day operations of the PR process. All required PR documents are submitted to the DAIDS PRO through the DAIDS PR System (DPRS). RSC personnel, under DAIDS PRT oversight, review the registration materials.

DAIDS PRT

The PRT manages the PR process, including oversight of the DAIDS PRO. The DAIDS PRT is responsible for determining protocol registration requirements for each protocol at the time of DAIDS SRC review or regulatory review. The DAIDS PRT makes final decisions regarding exceptions from the PR process.

Director of OPCRO or designee

Under circumstances when a decision cannot be reached by the DAIDS PRT and DAIDS Program staff, the Director of OPCRO or designee will make the final decision regarding an exception from the PR process.

6.0 POLICY

Each CRS will complete the PR process for all clinical research supported and/or sponsored by NIAID (DAIDS) reviewed and approved by a DAIDS SRC. [See the Protocol Registration Manual](#) for instructions and additional information on the PR process.

6.1 Upon receiving IRB/EC/RE/Approving Entity approval(s), and IBC approval if applicable, the CRS will submit all required PR documents to the DAIDS PRO via the DAIDS PR System (DPRS).

Upon making ANY submission to the DAIDS PRO, a CRS will receive a confirmation of submission notice that indicates that the DAIDS PRO has received materials.

The CRS must place a copy of all final registration notifications from the DAIDS PRO in the site's regulatory files.

6.1.1 Initial Protocol Registration

Prior to implementing the protocol and enrolling participants, the CRS must receive approval to conduct a study from their IRB/EC and other applicable regulatory entity(ies). In addition, the CRS must successfully

complete the PR process with the DAIDS PRO. Requirements for PR will be decided during the review of the protocol at the time of the DAIDS SRC assessment or regulatory review. Information on the PR process will be included in each protocol.

In rare cases, requests to modify the type of PR process determined at the SRC review will be submitted, via email, from DAIDS staff to the DAIDS PRT.

Final decisions regarding modification of the PR process will be made by the DAIDS PRT and appropriate DAIDS staff. All final decisions will be documented and shared with the DAIDS staff and the Protocol Team/Protocol PI/Grant PI/Contract PI, as applicable. OPCRO staff will serve as consultants when needed.

Under circumstances when a decision cannot be reached by the DAIDS PRT and DAIDS Program staff, the Director of OPCRO or designee will make the final decision regarding an exception from the determined PR process.

Successfully completing the PR process does not authorize the CRS to begin enrollment of participants. CRSs will be notified by the appropriate DAIDS scientific program (i.e., Program Officer, Contracting Officer's Representative), Operations Center or Data Management Center when enrollment may begin.

A CRS will receive a Registration Notification from the DAIDS PRO that indicates successful completion of the initial PR process. See the Protocol Registration Manual for further details.

NOTE - A Disapproval Notification is not a final Registration Notification since corrective materials must be resubmitted to the DAIDS PRO. See the Protocol Registration Manual for further details.

6.1.2 Full Version Protocol Amendment Registration

CRSs will submit the DAIDS-approved amended protocol including the sample informed consent form(s) (ICFs), site-specific ICF(s) and other required materials to their local IRBs/ECs within 45 calendar days for U.S.

sites or 75 calendar days for non-U.S. sites from the date the amendment was approved by DAIDS and distributed to the sites. Sites must also submit the required materials to any additional regulatory entity(s) in a timely manner.

NOTE: The 45 or 75 calendar day site requirement for submission of amendment materials is for local IRB/EC submission only.

NOTE: If a CRS is unable to submit amendment materials within the designated timelines to the local IRB/EC, the site should provide justification with the registration packet submission to the DAIDS PRO and a copy of the justification should be kept in the site's regulatory file.

Once a CRS has received approval from their IRB/EC and other applicable regulatory entity, the amended protocol and site-specific ICF (s) must be implemented immediately.

Refer to the Protocol Registration Manual for additional information regarding the timeline for the implementation of protocol amendments

NOTE - A final Registration Notification from the DAIDS PRO is not required prior to implementing an amendment.

A CRS must submit the required IRB/EC and other applicable regulatory entity(s) approved amendment registration documents to the DAIDS PRO within 14 calendar days after receipt of all final written documentation of IRB/EC/RE/approving entity approval for the amendment. The submitted documents must include documentation of the date that the amended protocol and site-specific ICF(s) was submitted to the local IRB/EC.

NOTE: A CRS should document the date the CRS receives approval letter(s) from IRB/EC/RE/approving entity in the site's regulatory files.

A CRS will receive a Registration Notification from the DAIDS PRO that indicates successful completion of the amendment PR process.

6.1.3 Letter of Amendment (LoA) Registration

CRSs will submit the DAIDS-approved LoA and other required materials to their local IRBs/ECs within 45 calendar days for U.S. sites or within 75 calendar days for non-U.S. sites from the date the LoA was approved by DAIDS and distributed to the sites. Sites must also submit the required materials to any additional regulatory entity(ies) in a timely manner.

NOTE: The 45 or 75 calendar day site requirement for submission of amendment materials is for local IRB/EC submission only.

NOTE: If a CRS is unable to submit the LoA and other required materials within the designated timelines to the local IRB/EC, the site should provide justification with the registration packet submission to the DAIDS PRO and a copy of the justification should be kept in the site's regulatory file.

Once a CRS has received approval from the IRB/EC and other applicable regulatory entity, the LoA and any revised site-specific ICF(s) must be implemented immediately.

Refer to the Protocol Registration Manual for additional information regarding the timeline for the implementation of LoAs

NOTE: A final Registration Notification from the DAIDS PRO is not required prior to implementing an LoA.

A CRS must submit the final IRB/EC and other applicable REs/approving entity(ies) approval letter(s) for the LoA and any revised site-specific ICF(s) to the DAIDS PRO within 14 calendar days after receipt of final written documentation of a IRB/EC/RE/approving entity approval(s) for the LoA. The submitted documents must include documentation of the date that the LoA and any revised site-specific ICF(s) were submitted to the local IRB/EC.

NOTE: A CRS should document the date the CRS receives approval letter(s) from IRB/EC/RE/approving entity in the site's regulatory files.

A CRS will receive a Registration Notification from the DAIDS PRO that indicates successful completion of the LoA registration process.

6.1.4 Continuing/Annual Review

CRSs are required to submit documentation of IRB/EC continuing/annual review to the DAIDS PRO.

A CRS must submit the required IRB/EC approved Continuing/Annual review documentation to the DAIDS PRO within 14 calendar days after receipt of final written documentation of IRB/EC approval(s).

NOTE: A CRS should document the date the CRS receives approval letter(s) from IRB/EC in the site's regulatory files

CRSs will only receive confirmation of submission for continuing/annual review documentation submitted to the DAIDS PRO.

6.1.5 Change of IoR

When there is a change in the Investigator of Record listed in item 1 on the Form FDA 1572 or DAIDS IoR Form, a CRS must submit the required documentation to the DAIDS PRO to officially change the IoR for a protocol(s) at a CRS. The submission must be done within 30 calendar days from the time the CRS is informed that the current IoR will no longer serve as the IoR for the study.

A CRS will receive a final Change of IoR Approval Notification from the DAIDS PRO when the change of IoR has been approved by the DAIDS PRT.

NOTE – The Change of IoR is NOT official until the CRS receives the Approval notification for the change of IoR from the DAIDS PRO.

6.1.6 Deregistration

A CRS will notify the DAIDS PRO when a study is completed at the CRS by submitting a request for deregistration from the study and all associated

sub- studies. See the Protocol Registration Manual for additional information.

A CRS will receive a Deregistration Notification from the DAIDS PRO when the CRS has been deregistered from a study and all associated sub-studies.

NOTE: A CRS is not considered deregistered from a study/sub-study until the CRS receives the Deregistration notification from the DAIDS PRO.

NOTE: Upon completion of the deregistration process for a protocol, a CRS will no longer receive safety information from DAIDS related to that protocol.

7.0 REFERENCES

DAIDS Protocol Registration Manual

8.0 INQUIRIES

Questions and comments regarding this SOP may be directed to the [OPCRO POLICY GROUP](#).

9.0 AVAILABILITY

This policy is available electronically on the [Division of AIDS \(DAIDS\) Clinical Research Policies and Standard Procedures](#) webpage.

10.0 APPENDICES

None

11.0 APPROVAL

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