

POLICY
Protocol Registration

Effective Date: **03/01/19**

Document No.: **POL-A15-OPC-003.00**

1.0 PURPOSE

1.1 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

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

3.0 BACKGROUND

3.1 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 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)/Regulatory Authority 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.

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.

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4.0 DEFINITIONS

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

5.0 RESPONSIBILITIES

5.1 Clinical Research Site (CRS) Leader

For Network studies, the CRS Leader is responsible for ensuring that his/her site adheres to the Protocol Registration policy and the requirements in the DAIDS Protocol Registration (PR) Manual. The CRS Leader may delegate PR-associated tasks to another qualified individual, such as the IOR.

5.2 Investigator of Record (IOR)/Grant PI/Contract PI

After receiving final IRB/EC/RE/Regulatory Authority approval, IBC approval, if applicable 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.

5.3 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.

5.4 DAIDS Regulatory Support Center (RSC)

The Protocol Registration Office (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.

5.5 DAIDS Protocol Registration Team (PRT)

The PRT manages the PR process, including oversight of the DAIDS PRO. The DAIDS

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PRT works with DAIDS Program Officers/DAIDS Medical Officers/ DAIDS RSC to determine protocol registration requirements for each protocol prior to the finalization of the initial version of a protocol. The DAIDS PRT makes final decisions regarding exceptions from the PR process.

6.0 POLICY

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

Upon receiving IRB/EC/RE/Regulatory Authority approval(s), and IBC approval if applicable, the CRS will submit all required PR documents to the DAIDS PRO via the 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/RE and applicable Regulatory Authority. In addition, the CRS must successfully complete the PR process with the DAIDS PRO. Requirements for PR will be decided prior to the finalization of the initial version of a protocol. 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 Scientific Review Committee (SRC) review will be submitted, via email to the DAIDS PRT.

Final decisions regarding modification of the PR process will be made by the DAIDS PRT. All final decisions will be documented and

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shared with the DAIDS staff and the Protocol Team/Protocol PI/Grant PI/Contract PI, as applicable.

. 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.

If CRS receives a Registration Notification from the DAIDS PRO that indicates successful completion of the initial PR process, though this does not authorize a CRS to begin enrollment of participants. If a Disapproval Notification is received by a CRS, corrective materials must be submitted to the DAIDS PRO so that the requirements to get a Registration Notification are completed. See the [DAIDS Protocol Registration Manual](#) for further details.

6.1.2 Clinical Trial Applications (CTA)

CRS/Sponsor Representative/Designee must submit a copy of the Clinical Trial Applications (CTA) Form/document(s) submitted to the in-country regulatory authority. The CTA Form/ Document(s) must indicate the study Sponsor for the study. The application can be submitted to the DAIDS RSC prior to submission of an initial protocol registration submission or included as part of the initial protocol registration submission. Refer to the [DAIDS Protocol Registration Manual](#) for further details.

6.1.3 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 Authority in a timely manner.

Once a CRS has received approval from their IRB/EC/RE/Regulatory Authority, the amended protocol and site-specific ICF (s) must be

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implemented immediately (i.e., without delay not later than 5 business days, usually at the participant's next scheduled visit).

Refer to the [DAIDS Protocol Registration Manual](#) for further details regarding full version protocol amendment registration.

A CRS must submit the required IRB/EC/RE and applicable Regulatory Authority approved amendment registration documents to the DAIDS PRO within 14 calendar days after receipt of all final written documentation of IRB/EC/RE and Regulatory Authority 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.

6.1.4 Letter of Amendment (LoA) Registration

CRSs will submit the DAIDS-approved LoA and other required materials to their local IRBs/EC/RE 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 Authority in a timely manner.

Once a CRS has received approval from the IRB/EC/RE and applicable Regulatory Authority, the LoA and any revised site-specific ICF(s) must be implemented immediately (i.e., without delay not later than 5 business days, usually at the participant's next scheduled visit).

Refer to the [DAIDS Protocol Registration Manual](#) for further details regarding LoA registration.

A CRS must submit the final IRB/EC/RE/Regulatory Authority 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/Regulatory Authority approval(s) for the LoA. The submitted documents must include

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documentation of the date that the LoA and any revised site-specific ICF(s) were submitted to the local IRB/EC.

Continuing/Annual Review

CRSs participating in NIAID (DAIDS)-supported and/or -sponsored clinical trials, and are protocol registered are required to submit documentation of IRB/EC Continuing/Annual review approval to the DAIDS PRO. Continuing review must be performed prior to the expiration date specified on the IRB/EC approval letter(s) and/or site-specific ICFs.

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).

Refer to the [DAIDS Protocol Registration Manual](#) for further details regarding continuing/annual review.

6.1.5 Change of IOR

When there is a change in the IOR 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 15 calendar days from the time the CRS is informed that the current IOR will no longer serve as the IOR for the study.

Refer to the [DAIDS Protocol Registration Manual](#) for further details regarding Change of IOR.

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.

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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.

Refer to the [DAIDS Protocol Registration Manual](#) for further details regarding deregistration.

7.0 REFERENCES

7.1 [DAIDS Protocol Registration Manual](#)

8.0 APPENDICIES

Not applicable

9.0 REVISION HISTORY

9.1 POL-A15-OPC-003.00 is the initial version of the DAIDS Protocol Registration Policy submitted to the DAIDS QMS as version 00. There were five previous versions of the DAIDS Protocol Registration Policy, version 1.0 July 2006, version 2.0 December 2006, version 3.0 March 2010, version 4.0 May 2012, and version 5.0 April 2015 published on the DAIDS Clinical Research Policies webpage prior to the implementation of the DAIDS QMS in 2018.