



MTN Site Protocol Deregistration Guide

DAIDS PRO Deregistration Process

Guideline Purpose

- ✓ Define DAIDS Protocol Registration Office (PRO) deregistration rules
- ✓ Explain additional aspects of deregistration specific to MTN
- ✓ Distinguish between site IRB/EC study closure/termination and DAIDS deregistration
- ✓ Address frequently asked questions

DAIDS PRO Site Deregistration Policy:

<http://rsc.tech-res.com/clinical-research-sites/protocol-registration/deregistration>

What is Protocol Deregistration?

DAIDS PRO requires each clinical research site (CRS) that completes the DAIDS protocol registration process for a protocol to complete the DAIDS deregistration process for that protocol.

- Deregistration is not automatic when a study is completed.
- The DAIDS deregistration policy applies to all MTN study sites.
- Deregistration occurs at the site level and is the responsibility of the site to complete.
- Deregistration ends all submission of study documentation to the DAIDS Protocol Registration System (DPRS), as well as, automated communications from DAIDS Regulatory Support (RSC) to the site.
- A site's completion of the DAIDS deregistration process indicates their involvement with the study's participants is complete.
- Deregistration does not reflect the closure of the multi-site study at all participating sites, completion of all data clean-up activities for their site, or closure with their own IRB/EC.

What Triggers Deregistration?

Study status prompting DAIDS deregistration at a site:

1. All participant follow-up is complete and no new enrollment is planned at the site
2. Accrual is closed and no participants were enrolled at the site

After one of these conditions has been met, a site can consider if they are ready to deregister the protocol by first consulting their IRB/EC and MTN to determine if they have additional requirements that impact deregistration timing.

A site should deregister no later than shortly after primary analysis of the study is complete, unless directed otherwise by MTN LOC or DAIDS.* Sites are encouraged to deregister earlier if possible.

* The Protocol Team will notify all sites when primary analysis is complete and advise them to close with their IRB/ECs and deregister with DAIDS if they have not already done so.

Consult with the Site IRB/EC

What to ask the site IRB/EC

- **Can the study close with the IRB/EC?**
 - Potential reasons why the study must remain open include:
 - Pending updates to Form 1572 and/or DAIDS IoR forms
 - IRB/EC requires continued DAIDS safety/ data reports (while other participating study sites are active)
 - IRB/EC requires study results/final analysis prior to closing study
- **Can the site deregister the protocol with DAIDS PRO?**
 - DAIDS deregistration can occur independently of IRB/EC study closure provided no further protocol related communication/ information exchanges with DAIDS are required by the site IRB/EC or the DAIDS PRO.
 - For studies still open with the IRB/EC, continuing review approval, form updates, or protocol amendments do not need to be submitted to DAIDS PRO after deregistration (but must be submitted to MTN Regulatory).

How Deregistration Impacts Communication from DAIDS RSC

Changes in Safety Report Distributions & IRB/EC Notifications:

- Deregistered sites are removed from the study's automated DAIDS safety report distribution system, managed by the DAIDS RSC, even if safety information is still being collected at other study sites.
- Sites whose IRB/EC still require continued reporting of safety data should not deregister until reports are no longer needed (study closes at all sites).
- Although deregistered sites will not automatically receive safety information, the monthly comprehensive report (MCR) will remain accessible to them on the RSC website.
- Deregistered sites will no longer receive notifications regarding impending expiration of IRB/EC approvals.
- Deregistered sites will need to carefully manage these issues.

Site Responsibilities for Studies Remaining Open with IRB/EC

If deregistration is complete, but the study remains open with the IRB/EC (at their request), a site must still abide by the following:

- Provide updates to Form 1572 or DAIDS IoR to the IRB/EC.
- Follow IRB/EC requirements for submitting protocol changes even if all participants have completed the study.
- Continue with IRB/EC periodic/annual review requirements including keeping approval documentation in the regulatory files at the site and forwarding copies to MTN Regulatory until the study is closed with IRB/EC.
- Submit DAIDS safety information and other data reports to the IRB/EC (as requested by IRB/EC).*
- Respond to and address study data queries even though the site has deregistered with DAIDS. (This should be done even after the study closes with the IRB/EC.)

*Sites are not recommended to deregister when such reporting from DAIDS is still requested.

Common Scenarios

Scenario	Action for DAIDS Deregistration
Site IRB/EC requires continued reporting from DAIDS	<ol style="list-style-type: none">1. Delay DAIDS deregistration until IRB/EC no longer requires reporting (i.e. when study primary analysis is complete)
Study <u>can</u> close with site IRB/EC and DAIDS protocol deregistration is permitted	<ol style="list-style-type: none">1. Complete IRB/EC study closure/termination process2. Complete any site IRB/EC specific requirements for DAIDS deregistration3. Complete DAIDS deregistration process
Study <u>cannot</u> close with site IRB/EC but DAIDS protocol deregistration is permitted	<ol style="list-style-type: none">1. Complete any site IRB/EC specific requirements for DAIDS deregistration2. Complete DAIDS deregistration process

Deregistration Process with DAIDS

STEP 1. Site meets following criteria:

- Participant follow-up is complete and no further enrollments are planned OR no participants were ever enrolled at the site and accrual is closed AND
- Site IRB/EC does not require continued safety/data reporting from DAIDS

STEP 2. Site submits the following documents to the DPRS:

- Memo from the IoR/designee stating that the site no longer intends to participate in the protocol AND/OR
- A copy of the IRB/EC closure/termination letter for the protocol if the protocol has been closed with the IRB/EC at the time of deregistration

STEP 3. DAIDS PRO reviews request

STEP 4. Upon approval, DAIDS provides a Deregistration Notification Form

- A site is not considered deregistered until a Deregistration Notification has been issued by the DAIDS PRO.

Important to Remember

- DAIDS deregistration and site IRB/EC closure of a study protocol occur independently.
- Sites should consult with MTN and their IRB/EC about IRB/EC closure and DAIDS deregistration requirements.
- If an IRB/EC requires continued safety reporting, the site should delay DAIDS deregistration until reporting is no longer required.
- If the site is deregistered with DAIDS but still open with the IRB/EC, it must still follow the IRB/EC's active study policies.
- A site does not have to update or submit additional documentation to DAIDS PRO after the protocol is deregistered, even if the study protocol is still open with the IRB/EC.
 - However, studies still open with the IRB/EC must submit continuing review and amendment approvals to MTN Regulatory.
- A site must submit the appropriate documentation and receive a Deregistration Notification from DAIDS PRO to confirm the protocol is deregistered.
- A site should deregister no later than shortly after study primary analysis is completed.

DAIDS PRO Deregistration Resources

- [DAIDS Protocol Registration Manual \(V3.0\)](#)
 - Deregistration – Section VII.D.ix
- [Guidance Regarding DAIDS Deregistration Process](#)
 - Includes summary of site responsibilities once deregistration has occurred
- [DAIDS PRO Deregistration Process FAQs](#)

For questions, please contact:

- MTN Regulatory (mtnregulatory@mtnstopshiv.org)
- The site's DAIDS Program Officer