

DIVISION OF AIDS CLINICAL RESEARCH POLICIES AND OTHER INFORMATION

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Event Reporting and Safety Monitoring

Number	Title	Effective Date
POL-A15-OPC-006.00	DAIDS Emergency Unblinding Policy	10/18/2022
POL-A15-OPC-007.01	Expedited Adverse Event Reporting Policy	08/29/2019
DAIDS-OPC-A15-POL-00012	Policy for Study Progress, Data, and Safety Monitoring Plan	11/29/2022

Laboratory and Specimens Management

Number	Title	Effective Date
N/A	Capturing Participant Data for Mucosal Sample Interpretation: A Guide for HIV Investigators	04/01/2016
MAN-A-OD-001.01	DAIDS Good Clinical Laboratory Practices (GCLP) Standards	08/16/2021
N/A	DAIDS GCLP Training Related FAQs	05/11/2023
DAIDS-OD-A-SOP-00008	Destruction of Clinical Research Specimens Owned by NIAID/DAIDS	04/08/2022
DWD SOP-LB-010.02A1	Appendix 1 - List of Samples from DAIDS -Supported and/or -Sponsored Clinical Research Destined for Destruction	10/01/2014
DAIDS-OD-A-POL-00002	Policy for Laboratories Performing Testing for DAIDS Sponsored and/or Supported Clinical Trials	02/05/2025
DAIDS-OD-A-POL-00004	Requirements for U.S. Laboratories Participating in DAIDS-Sponsored and or Supported Clinical Trials	02/05/2025
DAIDS-OD-A-POL-00005	Requirements for Non-U.S. Laboratories participating in DAIDS-Supported and/or Sponsored Clinical Trials	02/05/2025

Pharmacy and Study Products Management

Number	Title	Effective Date
N/A	Pharmacy Guidelines and Instructions for DAIDS Clinical Trials Networks	08/16/2023
N/A	DAIDS PAB Chain of Custody Template	01/15/2021
N/A	DAIDS PAB Daily Temperature Log Template	05/03/2024
N/A	DAIDS PAB Product Accountability Record Template	01/15/2021
DWD-POL-PH-004.04	Requirements for Pharmacy Facilities at DAIDS Supported Clinical Research Sites	09/22/2014

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	Conducting Trials Outside of the HIV/AIDS Clinical Trials Networks	
DWD-POL-PH-002.04	Requirements for Pharmacy Activities at DAIDS Supported Clinical Research Sites Conducting Clinical Trials Outside of the HIV/AIDS Clinical Trials Networks	09/22/2014
DWD-POL-PH-003.04	Requirements for Pharmacy Personnel at DAIDS Supported Clinical Research Sites Conducting Trials Outside of the HIV/AIDS Clinical Trials Networks	09/22/2014
DWD-POL-RA-014.02	Use of Drug Products Not Marketed in the United States	02/23/2015

Protocol and Informed Consent Development

Number	Title	Effective Date
DAIDS-OPC-A15-POL-00008	Enrolling Children (Including Adolescents) in Clinical Research Policy	10/28/2022
N/A	Enrolling Children (Including Adolescents) in Clinical Research Policy, Job Aid	03/23/2021
N/A	Enrolling Children (Including Adolescents) in Clinical Research Policy, Recommended Language	03/23/2021
POL-A15-OPC-014.00	Good Documentation Policy	03/23/2021
APP-A15-OPC-007.00	Appendix A - Good Documentation Policy Practice, Job Aid	03/23/2021
DAIDS-OD-A-POL-00003	Human Subjects Protection (HSP) and Good Clinical Practice (GCP) Training Requirements	10/28/2022
DAIDS-OPC-A15-POL-00019	Requirements for Essential Documents for DAIDS Sponsored Network Clinical Trials	03/31/2023
DAIDS-OPC-A15-POL-00005	Requirements for Informed Consent Forms	03/31/2023
N/A	DAIDS Protocol/Sample Informed Consent Template—General Use	05/10/2022
DAIDS-OPC-A15-POL-00015	Storage and Retention of Clinical Research Records Policy	12/15/2022
N/A	NIAID HIV Language Guide	04/20/2022
N/A	Information Sheet: Single Institutional Review Board Requirements	06/28/2022

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Site Implementation and Operations

Number	Title	Effective Date
POL-A28-OCS-003.00	DAIDS Site Clinical Operations and Research Essentials (SCORE) Policy	01/26/2021
N/A	DAIDS Site Clinical Operations and Research Essentials (SCORE) Manual	01/26/2021
DAIDS-OD-A-POL-00014	Electronic Case Report Form (eCRF) data review and sign off by Investigator	07/05/2024
DAIDS-OPC-A15-POL-00013	Electronic Information Systems Policy	05/25/2024
DAIDS-OPC-A15-GUD-00005	Appendix A - Requirements for using Electronic Information Systems in Clinical Research	05/29/2024
DAIDS-OPC-A15-GUD-00006	Appendix B - Electronic Information System Evaluation Checklist	05/29/2024
N/A	Electronic Information System Policy FAQ	July 2024
N/A	Electronic Information Systems Implementation Memo	08/07/2020
DAIDS-OPC-A15-POL-00016	Process for Collection of Financial Disclosure	11/29/2022
POL-A15-OPC-003.00	Protocol Registration Policy	03/01/2019
N/A	Protocol Registration Algorithm	NA
MAN-A15-OPC-001.00	Protocol Registration Manual	03/01/2019

Resources

Number	Title	Effective Date
DAIDS-OPC-A15-MAN-00003	Trial Master File (TMF) Manual	1/15/2025