

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	12/20/2019
POL-A15-OPC-007.01	Expedited Adverse Event Reporting Policy	08/29/2019
POL-A15-OPC-012.00	Policy for Study Progress, Data, and Safety Monitoring Plan	07/15/2021

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
DWD-SOP-LB-010.02	Procedure for the Destruction of Clinical Trial Specimens Owned by NIAID/DAIDS	10/01/2014
DWD SOP-LB-010.02A1	Appendix 1 - List of Samples from DAIDS - Supported and/or -Sponsored Clinical Research Destined for Destruction	10/01/2014
POL-A-OD-002.01	Requirements for Laboratories Performing Testing for DAIDS-Supported and/or Sponsored Clinical Trials	09/10/2019
APP-A-OD-001.01	Appendix 1 - Guidance to Investigators Participating in DAIDS-Sponsored Clinical Trials Requirements for U.S. Laboratories	09/10/2019
APP-A-OD-002.01	Appendix 2 - Guidance to Investigators Participating in DAIDS-Sponsored Clinical Trials Requirements for Non-U.S. Laboratories	09/10/2019
APP-A-OD-003.01	Appendix 3 - DCLOT Algorithm for Determining Level of Validation Required for Endpoints Assays	09/10/2019

Pharmacy and Study Products Management

Number	Title	Effective Date
N/A	Pharmacy Guidelines and Instructions for DAIDS Clinical Trials Networks	01/15/2021
N/A	DAIDS PAB Chain of Custody Template	01/15/2021
N/A	DAIDS PAB Daily Temperature Log Template	01/15/2021
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
POL-A15-OPC-008.00	Enrolling Children (Including Adolescents) in Clinical Research Policy	03/23/2021
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
POL-A-OD-003.00	Human Subjects Protection (HSP) and Good Clinical Practice (GCP) Training Requirements	06/15/2021
POL-A15-OPC-019.00	Requirements for Essential Documents for DAIDS Sponsored Network Clinical Trials	06/15/2021
POL-A15-OPC-005.00	Requirements for Informed Consent Forms	06/15/2021
POL-A15-OPC-015.00	Storage and Retention of Clinical Research Records Policy	03/23/2021
N/A	DAIDS Guidance on the Use of Gender-Inclusive HIV Research Practices	11/19/2019
N/A	DAIDS Memo Regarding New DAIDS Requirements: Informed Consent Process	11/01/2017
N/A	DAIDS Memo Regarding Timing of Consent and Re-Consent with Updated IRB/EC/Re-Approved Informed Consent Forms	08/20/2018
N/A	DAIDS Memo Regarding the Revised Common Rule and Implementation	01/21/2019

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Number	Title	Effective Date
N/A	DAIDS Memo Regarding an Update on the Single IRB Requirement	02/10/2020
N/A	DAIDS Memo Requesting Exceptions from NIH OD for the sIRB requirement	11/19/2020

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
POL-A15-OPC-013.00	Electronic Information Systems Policy	06/04/2021
APP-A15-OPC-005.00	Appendix A - Requirements for using Electronic Information Systems in Clinical Research	08/21/2020
APP-A15-OPC-006.01	Appendix B - Electronic Information System Evaluation Checklist	06/24/2021
N/A	Electronic Information System Policy FAQ	09/02/2021
N/A	Electronic Information Systems Implementation Memo	08/07/2020
POL-A15-OPC-016.00	Process for Collection of Financial Disclosure	03/23/2021
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