

# DIVISION OF AIDS (DAIDS) CLINICAL RESEARCH POLICY ARCHIVE

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*Archived policies (policies that are no longer effective) are no longer available on this site. If you need a previous version of a DAIDS clinical research policy, please contact your DAIDS POC (e.g., your Program Officer) with a justification for the request.*

### ***Event Reporting and Safety Monitoring***

<b>Number</b>	<b>Title</b>	<b>Date Archived</b>
DWD-POL CL-013.03	Expedited Adverse Event Reporting Policy VS.03	06/20/2016
DWD-POL CL-013.04	Expedited Adverse Event Reporting Policy VS.04	08/29/2019
DWD-POL-DM-01.00	Requirements for Data Management and Statistics for DAIDS Funded and/or Sponsored Clinical Trials	02/26/2021
DWD-POL-DM-01.00A1	Data Management Requirements for Data Collection Sites Appendix 1	02/26/2021
DWD-POL-DM-01.00A2	Data Management Requirements for Data Collection Sites Appendix 2	02/26/2021
DWD-POL-DM-01.00A3	Data Management Requirements for Data Collection Sites Appendix 3	02/26/2021
DWD-POL-RA-017.01	Critical Events Manual	05/14/2021
DWD-POL-RA-017.01A1	Appendix 1 - Examples of Critical Events	05/14/2021
DWD-POL-RA-017.01A2	Appendix 2 - Determining Which Adverse Events are Unanticipated Problems	05/14/2021
DWD-POL-RA-017.01A3	Appendix 3 - Examples of Corrective Actions	05/14/2021
DWD-POL-RA-017.01A4	Appendix 4- Reporting Critical Events to DAIDS	05/14/2021
DWD-POL-CL-017.01	Identification and Classification of Critical Events: Site Responsibilities	05/14/2021
DWD-POL-SR-01.00	Study Progress and Safety Monitoring	07/15/2021
POL-A15-OPC-012.00	Policy for Study Progress, Data, and Safety Monitoring Plan	12/22/2022
DWD-POL-SR-01.00A1	Appendix 1 - Guidance on Study Monitoring Reports	07/15/2021
DWD-POL-SR-01.00A2	Appendix 2 - Study Progress and Safety Monitoring Plan (SPSMP) Template	07/15/2021
DWD-POL-SR-01.00A3	Appendix 3 - DAIDS Standing Data and Safety Monitoring Boards (DSMBs)	07/15/2021
NA	Appendix 4 - Charter for the Data and Safety Monitoring Boards of the Division of AIDS	07/15/2021
DWD-POL-SR-01.00A5	Appendix 5 - DAIDS Safety Monitoring Committee (SMC) Guidelines	07/15/2021
DWD-POL-SR-01.00A6	Appendix 6 - DAIDS Independent Safety Monitor (ISM) Guidelines	07/15/2021

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POL-A15-OPC-006.00	DAIDS Emergency Unblinding Policy	10/10/2022

### *Laboratory and Specimens Management*

Number	Title	Date Archived
DWD-SOP-LB-010.02	Destruction of Clinical Research Specimens Owned by NIAID/DAIDS	05/19/2022
POL-A-OD-002.01	Requirements for Laboratories Performing Testing for DAIDS-Supported and/or Sponsored Clinical Trials	05/19/2022
APP-A-OD-001.01	Appendix I - Guidance to Investigators Participating in DAIDS-Sponsored Clinical Trials Requirements for U.S. Laboratories	05/19/2022
APP-A-OD-002.01	Appendix II - Guidance to Investigators Participating in DAIDS-Sponsored Clinical Trials Requirements for Non-U.S. Laboratories	05/19/2022
APP-A-OD-003.01	Appendix III - DCLOT Algorithm for Determining Level of Validation Required for Endpoints Assays	05/23/2022
N/A	DAIDS Guidelines for Good Clinical Laboratory Practice (GCLP) Standards	08/16/2021
N/A	Memo for DAIDS Guidelines for Good Clinical Laboratory Practice (GCLP) Standards	08/16/2021
POL-A-OD-002.00	DAIDS Laboratories Clinical Trials Policy QMS VS	09/10/2019
APP-A-OD-001.00	DAIDS Laboratories Clinical Trials Policy Appendix 1 US Labs QMS VS	09/10/2019
APP-A-OD-002.00	DAIDS Laboratories Clinical Trials Policy Appendix 2 Non-US Labs QMS VS	09/10/2019
APP-A-OD-003.00	DAIDS Laboratories Clinical Trials Policy Appendix 3 Endpoint Assays QMS VS	09/10/2019
DWD-POL-LB-005.03	DAIDS Laboratories Clinical Trials Policy VS 3	12/12/2013
DWD-POL-LB-005.04	DAIDS Laboratories Clinical Trials Policy VS 4	06/21/2019
N/A	DAIDS Laboratories Clinical Trials Appendix US Labs VS 4	06/21/2019
N/A	DAIDS Laboratories Clinical Trials Appendix II Non-US Labs VS 4	06/21/2019
DWD-POL-LB-012.02	Access to Archived Specimens and Data from Completed Study: Women and Infants Transmission Study (WITS) VS.02	Unknown

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DWD-POL LB-010.01	Destruction of Clinical Research Specimens Owned by NIAID VS.01	10/01/2014

#### *---Laboratory and Specimens Management – Other Documents*

Number	Title	Date Archived
N/A	DAIDS Guidelines for Good Clinical Laboratory Practice Standards VS3	N/A
MAN-A-OD-001.00	DAIDS Good Clinical Laboratory Practice (GCLP) Standards for archive	N/A

#### *Pharmacy and Study Products Management*

Number	Title	Date Archived
DWD-POL-PH-004.03	Requirements for Pharmacy Facilities at DAIDS-Supported Clinical Research Sites Conducting Trials Outside of the HIV/AIDS Clinical Trials Networks VS.03	09/22/2014
DWD-POL-PH-002.03	Requirements for Pharmacy Activities at DAIDS-Supported Clinical Research Sites Conducting Trials Outside of the HIV/AIDS Clinical Trials Networks VS.03	09/22/2014
DWD-POL-PH-003.03	Requirements for Pharmacy Personnel at DAIDS-Supported Clinical Research Sites Conducting Trials Outside of the HIV/AIDS Clinical Trials Networks VS.03	09/22/2014

#### *Protocol and Informed Consent Development*

Number	Title	Date Archived
DWD-POL-CL-08.01	Enrolling Children (including Adolescents) in Clinical Research: Protocol Document Requirements VS.01	11/02/2015
DWD-POL-CL-008.01A1	Appendix 1 - Risk/Benefits Categories VS.01	11/02/2015
DWD-POL-CL-008.01A2	Appendix 2 - Examples of Templated Language VS.01	11/02/2015
DWD-POL-CL-008.01A3	Appendix 3 - Wards VS.01	11/02/2015

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DWD-POL-CL-08.02	Enrolling Children (including Adolescents) in Clinical Research	03/23/2021
POL-A15-OPC-008.00	Enrolling Children (including Adolescents) in Clinical Research Policy	01/06/2023
DWD-POL-CL-008.02A1	Appendix 1 - Risk/Benefits Categories	03/23/2021
DWD-POL-CL-008.02A2	Appendix 2 - Examples of Templated Language	03/23/2021
DWD-POL-CL-008.02A3	Appendix 3 - Wards	03/23/2021
DWD-POL-CL-008.02A4	Appendix 4 - Waivers of Parental/Guardian Permissions or Child Assent (Archived)	03/23/2021
DWD-POL-CL-01.02	DAIDS Protocol Documents Policy	05/20/2021
N/A	DAIDS Protocol Documents Manual	05/20/2021
N/A	DAIDS Protocol Documents Template	05/20/2021
DWD-POL-CL-01.00	Requirements for Protocol Documents for DAIDS Funded and/or Sponsored Clinical Trials VS.01	10/30/2014
DWD-POL-CL-01.00A1	Appendix 1 - DAIDS Guidance for Protocol Documents VS.01	10/30/2014
POL-A-OD-003.00	Human Subjects Protection (HSP) and Good Clinical Practice (GCP) Training Requirements	01/06/2023
POL-A15-OPC-019.00	Requirements for Essential Documents for DAIDS Sponsored Network Clinical Trials	3/15/2023
DWD-POL-RA-03.00	Requirements for Essential Documents	06/14/2021
DWD-POL-RA-03.00A1	Appendix 1 - Essential Documents Recordkeeping Requirements	06/14/2021
DWD-POL-RA-03.00	Requirements for Essential Documents at Clinical Research Sites Conducting DAIDS Funded and/or Sponsored Clinical Trials	06/14/2021
POL-A15-OPC-005.00	Requirements for Informed Consent Forms	3/15/2023
DWD-POL-CL-02.00	Requirements for Informed Consent Development	06/14/2021
DWD-POL-CL-006.02	Storage and Retention of Clinical Research Records	03/23/2021
POL-A15-OPC-015.00	Storage and Retention of Clinical Research Records Policy	12/22/2022
N/A	Appendix 1 - Record Retention Flowchart	03/23/2021
CL-201.01A	Appendix 2 - Record Retention Flowchart Text Only Version	03/23/2021
DWD-POL-RA-014.01	Use of Study Products Not Marketed in the United States Policy VS.01	02/23/2015
N/A	DAIDS Guidance on the Use of Gender-Inclusive HIV Research Practices	06/06/2022

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N/A	DAIDS Memo Regarding Timing of Consent and Re-Consent with Updated IRB/EC/Re-Approved Informed Consent Forms	06/06/2022
N/A	DAIDS Memo Regarding the Revised Common Rule and Implementation	06/06/2022
N/A	DAIDS Memo Regarding an Update on the Single IRB Requirement	06/06/2022
N/A	DAIDS Memo Requesting Exceptions from NIH OD for the sIRB requirement	06/06/2022

### *Site Implementation and Operations*

Number	Title	Date Archived
POL-A15-OPC-002.00	Delegation of Duties (DOD) Log	01/26/2021
TEMP-A15-OPC-001.00	Delegation of Duties (DOD) Log Template	01/26/2021
N/A	DOD Template (Staff Information Additional Lines)	01/26/2021
N/A	DOD Template (Research Related Duties Additional Lines)	01/26/2021
N/A	DOD Template (Investigator Additional Lines)	01/26/2021
WI-A15-OPC-001.00	Delegation of Duties (DOD) Log Instructions	01/26/2021
POL-A15-OPC-013.00	Electronic Information Systems Policy	06/04/2021
APP-A15-OPC-006.00	Appendix B- Electronic Information System Evaluation Checklist	06/23/2021
N/A	Electronic Information Systems Policy Frequently Asked Questions (FAQ)	8/31/2021
N/A	Electronic Information System Policy FAQ	09/02/2021
N/A	Electronic Information System Policy FAQ	03/04/2022
POL-A15-OPC-016.00	Collection of Financial Disclosure by Clinical Investigators Conducting DAIDS-Sponsored IND Trials	12/22/2022

### *---Enrolling Children (including Adolescents) in Clinical Research*

Number	Title	Date Archived
DWD-POL-CL-007.01	Enrolling Children (including Adolescents) in Clinical Research: Clinical Site Requirements VS.01	11/02/2015
DWD-POL-CL-007.02	Enrolling Children (including Adolescents) in Clinical Research: Clinical Site Requirements	01/26/2021

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DWD-POL-CL-007.01	Enrolling Children (including Adolescents) in Clinical Research: Clinical Site Requirements	01/26/2021
DWD-POL-CL-03.03	Human Subjects Protection (HSP) and Good Clinical Practice (GCP) Training Requirements	06/14/2021

***---Protocol Registration Policy***

<b>Number</b>	<b>Title</b>	<b>Date Archived</b>
DWD-POL-RA-011.04	Protocol Registration Policy VS.04	05/27/2015
DWD-POL-RA-011.05	Protocol Registration Policy VS.05	03/01/2019

***---Protocol Registration Policy – Other Documents***

<b>Number</b>	<b>Title</b>	<b>Date Archived</b>
N/A	Protocol Registration Manual VS.02	N/A
N/A	Protocol Registration Manual VS.03	N/A

***---Requirements for Source Documentation***

<b>Number</b>	<b>Title</b>	<b>Date Archived</b>
DWD-POL-CL-04.00A1	Requirements for Source Documentation	01/26/2021
DWD-POL-CL-04.00	Appendix 1 - Source Documentation Requirements	01/26/2021

***---Requirements for Manual of Operational Procedures (MOP)***

<b>Number</b>	<b>Title</b>	<b>Date Archived</b>
DWD-POL-CL-05.00	Requirements for Manual of Operational Procedures (MOP)	01/26/2021
DWD-POL-CL-05.00A1	Appendix 1 - Required Site SOPs	01/26/2021
DWD-POL-CL-05.00A2	Appendix 2 - Sample Table of Contents	01/26/2021

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### *---Clinical Research Event Reporting and Safety Monitoring*

Number	Title	Date Archived
DWD-POL-CL-009.03	Requirements for Clinical Quality Management Plans VS.03	04/17/2015
DWD-POL-CL-009.03A1	Appendix 1 - Sample Clinical Quality Management Plan (CQMP) [CL.205] VS.03	04/17/2015
DWD-POL-CL-009.03A2	Appendix 2 - Sample Clinical Quality Management Chart Review Tool [CL.206] VS.03	04/17/2015
DWD-POL-CL-009.03A3	Appendix 3 - Sample Clinical Quality Management Regulatory File Review Tool [CL.207] VS.03	04/17/2015
DWD-POL-CL-009.03A4	Appendix 4 - Sample Clinical Quality Management Summary of Activities Tool [CL.208] VS.03	04/17/2015
DWD-POL-CL-009.03A5	Appendix 5 - Sample Clinical Quality Management Plan Annual Summary Report [CL.209] VS.03	04/17/2015
DWD-POL-CL-009.04	Requirements for Clinical Quality Management Plans VS.04	07/05/2019
DWD-POL-CL-009.04A2	Appendix 1 - Sample Clinical Quality Management Plan (CQMP) VS.04	07/05/2019
DWD-POL-CL-009.04A3	Appendix 2 - Sample Clinical Quality Management Chart Review Tool VS.04	07/05/2019
N/A	Appendix 3 - Sample Clinical Quality Management Regulatory File Review Tool VS.04	07/05/2019
N/A	Sample Clinical Quality Management Plan Annual Summary Report VS.04	07/05/2019
POL-A28-OCS-001.00	Requirements for Clinical Quality Management Plans	01/26/2021
APP-A28-OCS-001.00	Appendix 1 - Clinical Quality Management Plan (CQMP): Participant CHART Review Tool	01/26/2021
APP-A28-OCS-002.00	Appendix 2 - Clinical Quality Management Plan (CQMP): Protocol Regulatory File Review Tool	01/26/2021

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APP-A28-OCS-003.01	Appendix 3 - Clinical Research Site (CRS) Quality Assurance (QA) Summary Report	01/26/2021
N/A	Appendix 3 Clinical Research Site (CRS) Quality Assurance (QA) Summary Report Section IV Additional Lines	01/26/2021
N/A	Guidelines for Clinical Research Site (CRS) staff on Preparation of the Bi-annual Quality Assurance (QA) Summary Report	01/26/2021

#### *---Storage and Retention of Clinical Research Records*

<b>Number</b>	<b>Title</b>	<b>Date Archived</b>
DWD-POL-CL-006.01	Storage and Retention of Clinical Research Records VS.01	07/11/2016