

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

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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
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DWD-POL-DM-01.00A2	Data Management Requirements for Data Collection Sites Appendix 2	02/26/2021
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DWD-POL-RA-017.01	Critical Events Manual	05/14/2021
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DAIDS-OD-A-POL-00004	Guidance to Investigators Participating in DAIDS-Sponsored Clinical Trials- Requirements for U.S. Laboratories	03/05/2025
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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
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DWD-POL-LB-012.01	Access to Archived Specimens and Data from Completed Study: Women and Infants Transmission Study (WITS) VS.01	10/01/2014
DWD-POL LB-010.01	Destruction of Clinical Research Specimens Owned by NIAID VS.01	10/01/2014

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MAN-A-OD-001.00	DAIDS Good Clinical Laboratory Practice (GCLP) Standards for archive	N/A

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TEMP-A15-OPC-001.00	Delegation of Duties (DOD) Log Template	01/26/2021
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APP-A15-OPC-006.01	Appendix B: Electronic Information System Evaluation Checklist	05/10/2024
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N/A	Protocol Registration Manual VS.03	N/A

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---Clinical Research Event Reporting and Safety Monitoring

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APP-A28-OCS-002.00	Appendix 2 - Clinical Quality Management Plan (CQMP): Protocol Regulatory File Review Tool	01/26/2021
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

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