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COVID-19 Resources

Number	Title	Effective Date
NA	FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic	04/02/2020
NA	EMA Guidance on the Management of Clinical Trials during the COVID-19 (Coronavirus) pandemic	03/27/2020
NA	Guidance Regarding COVID-19 Impact on Clinical Trials	NA
NA	Use of Alternative/Remote Informed Consent Process during the COVID-19 Pandemic	04/08/2020
NA	OHRP Guidance on COVID-19	04/10/2020

Event Reporting and Safety Monitoring

Number	Title	Effective Date
POL-A15-OPC-007.01	Expedited Adverse Event Reporting	08/29/2019
DWD-POL-SR-01.00	Study Progress and Safety Monitoring	02/05/2007
DWD-POL-SR-01.00A1	Appendix 1 - Guidance on Study Monitoring Reports	12/20/2006
DWD-POL-SR-01.00A2	Appendix 2 - Study Progress and Safety Monitoring Plan (SPSMP) Template	12/20/2006
DWD-POL-SR-01.00A3	Appendix 3 - DAIDS Standing Data and Safety Monitoring Boards (DSMBs)	12/20/2006
NA	Appendix 4 - Charter for the Data and Safety Monitoring Boards of the Division of AIDS	06/24/2015
DWD-POL-SR-01.00A5	Appendix 5 - DAIDS Safety Monitoring Committee (SMC) Guidelines	12/20/2006
DWD-POL-SR-01.00A6	Appendix 6 - DAIDS Independent Safety Monitor (ISM) Guidelines	12/20/2006
DWD-POL-DM-01.00	Requirements for Data Management and Statistics for DAIDS Funded and/or Sponsored Clinical Trials	02/05/2007
DWD-POL-DM-01.00A1	Appendix 1 - Data Management Requirements for Data Collection Sites	12/20/2006
DWD-POL-DM-01.00A2	Appendix 2 - Data Management Requirements for Central Data Management Facilities	12/20/2006
DWD-POL-DM-01.00A3	Appendix 3 - Statistical Requirements	12/20/2006
DWD-POL-CL-017.01	Identification and Classification of Critical Events: Site Responsibilities	06/22/2012
NA	Critical Events Manual	05/2012
DWD-POL-RA-017.01A1	Appendix 1 - Examples of Critical Events	06/22/2012

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DWD-POL-RA-017.01A2	Appendix 2 - Determining Which Adverse Events are Unanticipated Problems	06/22/2012
DWD-POL-RA-017.01A3	Appendix 3 - Examples of Corrective Actions	06/22/2012
DWD-POL-RA-017.01A4	Appendix 4 - Reporting Critical Events to DAIDS	06/22/2012
POL-A15-OPC-006.00	DAIDS Emergency Unblinding Policy	12/20/2019

Laboratory and Specimens Management

Number	Title	Effective Date
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
MAN-A-OD-001.00	DAIDS Guidelines for Good Clinical Laboratory Practice Standards	09/28/2019
DWD-SOP-LB-010.02	Destruction of Clinical Research 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
NA	Capturing Participant Data for Mucosal Sample Interpretation: A Guide for HIV Investigators	04/01/2016

Pharmacy and Study Products Management

Number	Title	Effective Date
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	09/22/2014

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	Conducting Trials Outside of the HIV/AIDS Clinical Trials Networks	
DWD-POL-PH-004.04	Requirements for Pharmacy Facilities 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
DWD-POL-CL-08.02	Enrolling Children (Including Adolescents) in Clinical Research: Protocol Document Requirements	11/02/2015
DWD-POL-CL-008.02A1	Appendix 1 - Risk/Benefits Categories	11/02/2015
DWD-POL-CL-008.02A2	Appendix 2 - Examples of Templated Language	11/02/2015
DWD-POL-CL-008.02A3	Appendix 3 - Wards	11/02/2015
DWD-POL-CL-008.02A4	Appendix 4 - Waivers of Parental/Guardian Permissions or Child Assent	11/02/2015
DWD-POL-CL-01.02	DAIDS Protocol Documents Policy	10/30/2014
NA	DAIDS Protocol Documents Manual	09/2014
NA	DAIDS Protocol Documents Template	09/2014
DWD-POL-CL-02.00	Requirements for Informed Consent Development	02/05/2007
NA	DAIDS Guidance on the Use of Gender-Inclusive HIV Research Practices	11/19/2019
NA	DAIDS Memo Regarding New DAIDS Requirements: Informed Consent Process	11/01/2017
NA	DAIDS Memo Regarding Timing of Consent and Re-Consent with Updated IRB/EC/Re-Approved Informed Consent Forms	08/20/2018
NA	DAIDS Memo Regarding the Revised Common Rule and Implementation	01/21/2019
NA	DAIDS Memo Regarding an Update on the Single IRB Requirement	02/10/2020

Site Implementation and Operations

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DWD-POL-RA-03.00	Requirements for Essential Documents at Clinical Research Sites Conducting DAIDS Funded and/or Sponsored Clinical Trials	02/05/2007
DWD-POL-RA-03.00A1	Appendix 1 - Essential Documents Recordkeeping Requirements	12/20/2006
POL-A15-OPC-002.00	Delegation of Duties (DOD) Log Policy	03/14/2019
TEMP-A15-OPC-001.00	Delegation of Duties (DOD) Log Template	03/14/2019
NA	DOD Template (Staff Information Additional Lines Fillable)	NA
NA	DOD Template (Research Related Duties Additional Lines Fillable)	NA
NA	DOD Template (Investigator Additional Lines Fillable)	NA
WI-A15-OPC-001.00	Delegation of Duties Log Instructions	03/14/2019
POL-A15-OPC-003.00	Protocol Registration Policy	03/01/2019
NA	Protocol Registration Algorithm	NA
MAN-A15-OPC-001.00	Protocol Registration Manual	03/01/2019
DWD-POL-CL-007.02	Enrolling Children (including Adolescents) in Clinical Research: Clinical Research Site Requirements	11/02/2015
DWD-POL-CL-03.03	Human Subjects Protection (HSP) and Good Clinical Practice (GCP) Training Requirements	03/16/2015
DWD-POL-CL-04.00	Requirements for Source Documentation in DAIDS Funded and/or Sponsored Clinical Trials	02/05/2007
DWD-POL-CL-04.00A1	Appendix 1 - Source Documentation Requirements	12/20/2006
DWD-POL-CL-05.00	Requirements for Manual of Operational Procedures (MOP)	02/05/2007
DWD-POL-CL-05.00A1	Appendix 1 - Required Site SOPs	12/20/2006
DWD-POL-CL-05.00A2	Appendix 2 - Sample Table of Contents	12/20/2006
DWD-POL-SM-01.02	Requirements for On-Site Monitoring	08/07/2015
POL-A28-OCS-001.00	Requirements for Clinical Quality Management Plans (CQMP) Policy	07/05/2019

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APP-A28-OCS-001.00	Appendix 1 - Clinical Quality Management Plan (CQMP): Participant CHART Review Tool	07/05/2019
APP-A28-OCS-002.00	Appendix 2 - Clinical Quality Management Plan (CQMP): Protocol Regulatory File Review Tool	07/05/2019
APP-A28-OCS-003.01	Appendix 3 - Clinical Research Site (CRS) Quality Assurance (QA) Summary Report	04/02/2020
NA	Appendix 3 - Clinical Research Site (CRS) Quality Assurance (QA) Summary Report Section IV Additional Lines	NA
NA	Guidelines for Preparation of the Bi-annual Quality Assurance (QA) Summary Report Required per DAIDS CQMP Policy	02/19/2020
DWD-POL-CL-006.02	Storage and Retention of Clinical Research Records	07/11/2016
NA	Appendix 1 - Record Retention Flow Chart	NA
CL-201.01A	Appendix 2 - TEXT ONLY-Record Retention Flow Chart	05/09/2009
POL-A15-OPC-013.00	Electronic Information Systems Policy	08/21/2020
APP-A15-OPC-005.00	Requirements for using Electronic Information Systems in Clinical Research	08/21/2020
APP-A15-OPC-006.00	Electronic Information System Evaluation Checklist	08/21/2020
WA23_20200630	EIS Policy FAQ	08/21/2020
NA	Electronic Information Systems Implementation Memo	08/21/2020