DIVISION OF AIDS (DAIDS) CLINICAL RESEARCH POLICY ARCHIVE

TABLE OF CONTENTS

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

Number	Title	Date Archived
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
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

TABLE OF CONTENTS

Laboratory and Specimens Management

---Laboratory and Specimens Management – Other Documents

TABLE OF CONTENTS

Pharmacy and Study Products Management

Protocol and Informed Consent Development

TABLE OF CONTENTS

Site Implementation and Operations

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

DIVISION OF AIDS (DAIDS) CLINICAL RESEARCH POLICY ARCHIVE

TABLE OF CONTENTS

---Human Subjects Protection (HSP) and Good Clinical Practice (GCP) Training Requirements

---Protocol Registration Policy

---Protocol Registration Policy – Other Documents

---Requirements for Source Documentation

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

TABLE OF CONTENTS

---Requirements for On-Site Monitoring

---Clinical Research Event Reporting and Safety Monitoring

TABLE OF CONTENTS