DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Institute of Allergy
and Infectious Diseases
Bethesda, Maryland 20892

**MEMORANDUM**

**Date:** August 7, 2020

**From:** Carol Worrell, M.D., Director, OPCRO, Division of AIDS (DAIDS)

**To:** NIAID/DAIDS HIV/AIDS Network Leadership, Operations Center Principal Investigator(s), Laboratory Center Principal Investigator, Statistical and Data Management Center (SDMC) Principal Investigator (PI), Data Management Center (DMC) Directors, Clinical Research Site (CRS) Leaders, Clinical Trials Unit (CTU) PIs, Office of HIV/AIDS Network Coordination (HANC)

**CC:** DAIDS MGX, DAIDS MOs, DAIDS OCSO, DAIDS OPCRO, DAIDS NLGPOs, DAIDS ClinTrials Group

**Subject:** Implementation of the new Electronic Information Systems (EIS) Policy

**N.B:** The implementation of the EIS policy will follow a unique pathway and differs from DAIDS' usual process.

Considering the current COVID-19 pandemic and taking into account the iminent re-competition of the HIV/AIDS Clinical Trials Networks, DAIDS will follow a phased implementation of this new policy that encompasses a large number of existing technical and regulatory requirements.

**Background**

The Division of AIDS is pleased to announce the new 'Electronic Information Systems' (EIS) Policy. This policy describes the requirements for electronic systems used in the conduct of NIAID DAIDS Network trials conducted by the HIV/AIDS Clinical Trials Networks.

DAIDS has worked closely with the stakeholders on the development of the EIS policy. In response to the comments received in December 2018, the policy has been extensively updated and will follow a unique implementation pathway described below.

The EIS policy applies to NIAID DAIDS Clinical Trial Network trials only. The roles,responsibilities and scope of the policy have been clarified, and the appendix has been updated to match the policy requirements. A checklist has been created to assist the end users of this policy in documenting compliance.

Electronic systems which fall under the scope of this policy are systems from which clinical trial data may be submitted to the US Food and Drug Administration (FDA), European Medicines Agency (EMA), South African Health Products Regulatory Authority (SAHPRA), or any other regulatory authority, and must meet applicable requirements such as the US 21 Code of Federal Regulations (CFR) Part 11.

In addition, the term "electronic system" applies to records in electronic form that are used to create, modify, maintain, archive, retrieve, or transmit clinical or other data which are required to be maintained for, or submitted to, the FDA, EMA or any other regulatory authority.

Please note that this policy is not limited to systems used for data/documentation in registrational trials but also includes data for all trials under any health authority oversight. Examples include required periodic (e.g. annual) study reports, end of study reports, final clinical study reports (CSR) and any essential documents necessary to reconstruct the trial.

**DAIDS' Implementation Plan**

DAIDS notes that this is a new, complex, and highly technical policy for which our collaborators will require additional information and training. To streamline policy implementation and minimize burden on our collaborators, DAIDS plans to conduct a phased rollout of this policy:

1. **Phase 1**: The Data Management Centers should be compliant with this policy by November 01, 2020.
2. **Phase 2**: Other collaborators, including but not limited to, clinical research sites and Network Leadership Operation Centers, should be compliant with this policy by December 01, 2021.

**Training on the EIS policy**

DAIDS, in collaboration with the DMCs, will provide the training to other collaborators on the EIS policy beginning in early 2021. These trainings will be focused towards the end-user implementation of the policy. Any logistical or operational issues with the implementation of this policy will be carefully reviewed and addressed in the context of meeting collaborators' needs and 21 CFR part 11 compliance.

While DAIDS expects compliance with 21 CFR part 11, comments regarding logistical and operational challenges will be considered in terms of policy modifications after the training.

Please refer to the FAQs posted on the DAIDS Clinical Research Policy website.

DAIDS looks forward to a successful implementation of this policy.

**Signed by:**

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| Carol Worrell, MD<br>Director, OPCRO | Carol J. Worrell -S | Digitally signed by Carol J. Worrell -S<br>Date: 2020.08.07 17:24:25 -04'00' |