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MEMORANDUM

DATE: August 21, 2017

FROM: Linda Ehler, R.N., M.N., Nurse Consultant, Protection of Participants, Evaluation, and Policy Branch (ProPEP), Office for Policy in Clinical Research Operations (OPCRO), Division of AIDS (DAIDS), National Institute of Allergy and Infectious Diseases (NIAID), on behalf of the DAIDS Audit Preparedness Working Group

TO: Clinical Trials Unit (CTU) Principal Investigators
Clinical Research Site (CRS) Leaders
Clinical Trials Unit Coordinators
Clinical Research Site Coordinators
HIV/AIDS Network Leadership and Operations Centers

CC: Carol Worrell, M.D., Director, OPCRO, DAIDS
Manizhe Payton, M.P.H., Director, Office of Clinical Site Oversight (OCSO), DAIDS
Mary Anne Luzar, Ph.D., Chief, Regulatory Affairs Branch, OPCRO, DAIDS
Judith Brooks, R.N, M.S, Chief, ProPEP, OPCRO, DAIDS
Karen Reese, M.S., Acting Chief, Monitoring Operations Branch (MOB), OCSO, DAIDS

SUBJECT: New DAIDS Requirements: Informed Consent Process

Background

Recently, several DAIDS sites had a routine International Conference on Harmonization (ICH)/Good Clinical Practice (GCP) inspection by the European Medicines Agency (EMA). Findings from this inspection revealed issues related to the informed consent processes, specifically the delegation of the responsibility for obtaining informed consent, signatures on the informed consent document, and the participation of the physician during consent. To address these findings, DAIDS established the Audit Preparedness Working Group to review relevant regulations, guidance, and best practices. This group was tasked with determining informed consent process requirements for all DAIDS networks that would ensure their compliance with the U.S. regulations as well as with the ICH E6 GCP informed consent standards. This memo outlines new DAIDS requirements related to the informed consent process.

DAIDS Regulatory and Document Review and Decision

Based on our review of relevant documents, DAIDS has determined that the task/responsibility of obtaining informed consent may be delegated to staff "qualified" by education, training, experience, and knowledge of the trial, as long as this practice is permitted per local laws, regulations, and institutional policies. However, overall responsibility for the conduct of a given trial at the site, including delegated tasks, remains with the Investigator of Record (IoR). Additionally, the CRS Leader has ultimate responsibility for the conduct of all studies at the site.

SITE ACTIONS – Effective November 1, 2017

1) All active DAIDS network sites must develop and implement an informed consent process Standard Operating Procedure (SOP) by November 1, 2017. This SOP must include information about applicable local laws, regulations, and institutional policies pertaining to the informed consent process, and must address vulnerable populations such as children and those who are illiterate.

2) IoRs must ensure by November 1, 2017, that staff performing delegated tasks, including informed consent, are "qualified" by education, experience, training, and knowledge of the trial, as determined by the IoR. Training documentation must support the delegated task/responsibility, be completed prior to performing the task, and the staff member needs to be listed on the Delegation of Duties Log (DL) prior to performing the task.

3) All DAIDS sites must have a study-specific Delegation of Duties Log (DL) which includes the task/responsibility of obtaining informed consent for ALL studies that are still enrolling participants to a given study at their site as of November 1, 2017. Study-specific DLs will also be required for ALL new studies, i.e. all DAIDS-approved version 1.0 studies, initiated on or after November 1, 2017, prior to enrolling participants to these studies at the site. NOTE – Study-specific DLs are not required for on-going studies that are no longer enrolling participants to a given study at their site on or after 11/1/2017 (e.g. "closed to accrual" status or later, de-registered, etc.).

4) CTU PIs/CRS Leaders need to verify informed consent Quality Assurance (QA)/Quality Control (QC) checks are part of the site's overall Quality Management Plan (QMP), as already required by the DAIDS Requirements for Clinical Quality Management Plans policy (https://www.niaid.nih.gov/sites/default/files/qmppolicy.pdf).

5) As per DAIDS policy outlined in the Protocol Registration Manual, site personnel who have more than minimal involvement with the conduct of the research should be listed on the FDA Form 1572/DAIDS IoR Form. Sites should include listing staff who perform informed consent on these forms.

How will these DAIDS informed consent process requirements be verified at the site?

1) Requirements will be verified by the site's OCSO Program Officer (PO) by December 1, 2017.

2) Requirements will also be verified by the DAIDS contracted monitors at the site's next monitoring visit, starting 1st quarter 2018.

OCSO Program Officers will be contacting their sites with details regarding these requirements. Sites should contact their Program Officer for any related questions.