MEMORANDUM

Date: January 27, 2021
From: Jui Shah, PhD, Chief, Protection of Participants, Evaluation and Policy Branch, OPCRO, DAIDS, NIAID, NIH
To: Network Leadership and Operations Centers, DMID
CC: DAIDS, HANC
Subject: Revised DAIDS ClinicalTrials.gov Protocol Checklist

Background:

As required by the NIAID Clinical Terms of Award, all NIH-funded clinical trials must register and submit results information to Clinicaltrials.gov. For DAIDS-held IND studies, the responsibility to meet the ClinicalTrials.gov reporting requirements falls within DAIDS. For other studies (e.g., network non-IND, non-DAIDS held IND, non-network non-IND, etc.), the responsibility generally lies with the grantee institution, organization, and/or IND holder.

The current DAIDS ClinicalTrial.gov checklist (version date 20 November 2015) has been revised to fulfill requirements set forth by Section 801 of the Food and Drug Administration Amendments Act of 2007 (FDAAA 801) and the NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information. The revised checklist also aligns with the Final Rule for Clinical Trials Registration and Results Information Submission (42 CFR Part 11) which implemented a broader definition of "controlled" for determining the applicability of a clinical trial.

Outline of the Revisions:

The revised checklist implements the following modifications:

1. The checklist no longer defines "control" according to 21 CFR 314.126 which is a more specific assessment to determine adequacy of the study. This definition is no longer relevant for determining the applicability of a clinical trial.
2. The current checklist (version date 20 November 2015) is an interactive document where some portions of the form appear as necessary upon completing questions. The revised form is static – all users will see the ClinicalTrials.gov Results Reporting Required section and will need to complete the form based on the instructions and their responses to Questions 1 – 6.
3. The top section for identifying information includes requests for Contact Name and Contact Role.
4. Sections have been added for the NIH Policy on the Dissemination of NIH-Funded Clinical Trials Information and Sub-Study Results Submission.
5. The ClinicalTrials.gov Results Reporting section adds a field to identify the Sponsor.
6. The checklist more closely aligns with the Checklist for Evaluating Whether a Clinical Trial or Study is an Applicable Clinical Trial (ACT).
7. The checklist does not address International Committee of Medical Journal Editors (ICMJE) requirements.
8. Hyperlinks to references and tools have been included.

For complete information, please view the revised DAIDS ClinicalTrials.gov Protocol Checklist (https://rsc.niaid.nih.gov/networks-protocol-teams/clinicaltrialsgov-checklist).

References:

1. NIAID Clinical Terms of Award: https://www.niaid.nih.gov/grants-contracts/niaid-clinical-terms-award
2. Food and Drug Administration Amendments Act of 2007 (FDAAA): https://www.govinfo.gov/content/pkg/PLAW-110publ85/pdf/PLAW-110publ85.pdf#page=82
3. NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information: https://grants.nih.gov/grants/guide/notice-files/not-od-16-149.html
4. 42 CFR Part 11, Clinical Trials Registration and Results Information Submission: https://www.govinfo.gov/content/pkg/FR-2016-09-21/pdf/2016-22129.pdf