DEPARTMENT OF HEALTH & HUMAN SERVICES

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From: Catherine Yen, MD, MPH, FAAP, Chief, Protection of Participants, Evaluation and Policy Branch, OPCRO, DAIDS, NIAID, NIH

To: DAIDS, Network Leadership and Operations Centers, Principal Investigator(s), PPD

RE: Who to contact for ClinicalTrials.gov-related queries and requests regarding protocols for which DAIDS is the Responsible Party

BACKGROUND

This memo is being provided to clarify who to contact with ClinicalTrials.gov (CT.gov)-related queries and requests for updates to be made **after** a protocol has been registered to CT.gov with a National Clinical Trial (NCT) number assigned.

> *Please note that the Initial Registration of a protocol to CT.gov is completed by the PPD Regulatory Affairs Specialist Team and the process is outlined in the following memo: How to Initiate the ClinicalTrials.gov Initial Registration Process.*

PROCESS

When DAIDS is the Responsible Party, CT.gov-related queries, protocol specific questions related to CT.gov, and requests to update a CT.gov record can be directed to PPD by sending an email to naractgov.sm@ppd.com (PPD's ClinicalTrials.gov Shared Mailbox) with daids-trials@nih.gov in copy.

Emails requesting an update to a CT.gov record should contain the information outlined below:

- Email recipients: naractgov.sm@ppd.com **and** daids-trials@nih.gov
- Required title of email: DAIDS CRSS Record Query/Update Request: [*Insert Protocol Number*] (Example: DAIDS CRSS Record Request: X1234)
- Required attachments:
  - For a protocol amendment, the email **must contain as attachments**: A clean copy of the FDA approved, final amended protocol **and** a tracked changes version.

ADDITIONAL INFORMATION

Please see below a list of examples of CT.gov-related queries/requests that PPD **can** assist with. These items are important to communicate to PPD and/or usually require action by PPD to keep the CT.gov record up to date. Per the regulations, most items below need to be updated

within 30 calendar days of the change (for an amendment it is within 30 calendar days of the first IRB approval).

- CT.gov protocol registration queries
- To confirm when results have been entered and the record can be released for PRS review
    - Note: Please ensure DAIDS Medical Officers have reviewed the results before requesting PPD to release
- To update:
    - an anticipated study start date (i.e., the anticipated date the first subject will enroll onto the study)
    - a site status* (i.e., add a new site, remove a site/site dropped out, site is now enrolling/recruiting)
        - Note: For sites added, please include full site name, study coordinator's full name, phone number and email address
    - the Anticipated Study Completion Date/Primary Completion Date
- To report:
    - date actual Primary Completion Date* (PCD) is reached
    - date actual Study Completion Date* (SCD) is reached
    - total number of enrolled subjects once enrollment is complete
    - the first human subject/patient is enrolled* (providing date and at which site)
- To request:
    - a change in site study coordinator/PI/site contact information listed in the record
    - an updated Protocol or Letter of Amendment uploaded to the record; Protocol Amendments/Letters of Amendments
    - access to a record to make updates to the results section
    - additional keywords to be added to the study record

Please see below, examples of ClinicalTrials.gov-related queries/requests that PPD is **not** able to assist with.

- User account has been locked/password needs to be reset – Contact register@clinicaltrials.gov
- Specific system "how-to" questions surrounding results entry – Contact register@clinicaltrials.gov
- Queries/requests related to the Health and Human Services (HHS) Human Subjects System (HSS) – Contact your DAIDS Program Officer

Additional helpful references can be found on the DAIDS Regulatory Support Center (RSC) website: ClinicalTrials.gov | DAIDS Regulatory Support Center (RSC) (nih.gov).

**These items are also updated during the processing of the weekly reports by the PPD team.*