SWOG CANCER RESEARCH NETWORK

September 15, 2020

TO: ALL NATIONAL CLINICAL TRIALS NETWORK (NCTN) MEMBERS AND NCORP COMPONENTS AND SUBCOMPONENTS

FROM: SWOG Operations Office (E-mail: protocols@swog.org)

MEMORANDUM

IRB Review Requirements
(√) No review required

RE: 1572 and DoA Logs for BMT CTN Studies

MEMORANDUM – 1572 and DoA Logs for BMT CTN Studies

The purpose of this memorandum is to provide sites with the attached guidance information for BMT CTN studies.

For questions, please contact Iris Gersten at BMT CTN (igersten@emmes.com).

This memorandum serves to notify the NCI, CIRB, and SWOG Statistics and Data Management Center.

cc: PROTOCOL & INFORMATION OFFICE
Iris Gersten – BMT CTN

August 31, 2020

M E M O R A N D U M C T N - 1 7 7
via E-mail

TO: BMT CTN Core/Consortia and Affiliate Centers' PIs, Regulatory and Study Coordinators

FROM: Iris Gersten
BMT CTN DCC Project Director

SUBJECT: **Site Activation Requirements: Guidance for Completion of Statement of Investigator Form and Delegation of Authority Log for BMT CTN studies**

BMT CTN DCC experience has shown that one of the rate-limiting factors in time to site activation for BMT CTN protocols is the submission of required site essential documentation. The primary driver of this requirement is the number of staff members recorded on the site's protocol-specific Statement of Investigator (Form FDA 1572 for IND trials or Investigator Agreement for non-IND trials) and Delegation of Authority (DoA) Log. For each person listed on these forms, six or more documents must be provided such as medical license, signed and dated CV, Financial Disclosure Form, and training documentation for the specific protocol, GCP and HSP in addition to IATA, Global Trace and protocol-specific Advantage eClinical or Medidata Rave training for select coordinator(s).

The BMT CTN DCC recommends carefully reviewing FDA guidance so that only staff members making direct and significant contributions to the clinical study data are included on the study's Statement of the Investigator (Form FDA 1572 or Investigator Agreement) and DoA Log. This should not only reduce the burden on the site by lessening the number of documents to be submitted but also decrease the amount of time required for the DCC to review and process the documents. Both process improvements should contribute to a reduction in the time to site activation.

A review of FDA guidance[1] on the Form FDA 1572 and Delegation of Authority Log is provided below:

- The guidance on Investigator Responsibilities states that "The investigator should maintain a list of the appropriately qualified persons to whom significant trial-related duties have been delegated."
- While this guidance is specifically talking about the Form FDA 1572, note that the FDA is clear that persons who "provide ancillary or intermittent care but who do NOT make a direct and significant contribution to the clinical data, do not need to be listed individually." Due to the lack of an official log or further requirements outlined by the federal government, the format and content of the DoA Log, as well as supporting SOPs, is flexible. A good rule of thumb is to include any staff member that contributes to study-specific assessments or data entry outside of standard of care contributions. Those persons should be considered study staff and included on the DoA log.
    - For example, if the protocol states that the Chronic GVHD Provider Survey must be completed as part of direct patient examination by the PI, sub-I or other Clinician (e.g., physician's assistant,

nurse practitioner, or nurse), the clinician should be listed as he/she is responsible for conducting protocol-specific assessments that will contribute to study data.

- Hospital staff, including nurses, residents, or fellows and office staff who provide ancillary or intermittent care but who do not make a direct and significant contribution to study assessments, do not need to be listed individually. It is not necessary to include a person with only an occasional role in the conduct of the research; e.g., an on-call physician who temporarily dealt with a possible adverse effect or a temporary substitute for any research staff. In such cases, the event should be relayed to a study staff member who can review and countersign the medical records related to the study data.
- The decision about whether to list a pharmacist on the Statement of the Investigator is a matter of judgment and is dependent upon the contribution that the individual makes to the study. For example, a research pharmacist may prepare test articles and maintain drug accountability for many clinical studies that are ongoing concurrently at an institution. Because the pharmacist would not be making a direct and significant contribution to the data for a particular study, it would not be necessary to list the pharmacist as a sub-investigator in Section #6 of the 1572; however, the pharmacist would be listed on the DoA Log.
- Staff primarily responsible for the data entry and verification with monitors, performing specialized techniques or administering questionnaires to participants on a study should be on the DoA Log.
- It may be difficult to prospectively identify those individuals who might perform specified protocol procedures or collect clinical data as part of their clinic rotation. Specific names of the rotational staff do not have to be listed in Section #6 of the 1572.
- Staff that collect study data that aligns with what they would do in a normal job capacity, would NOT need to be on the DoA Log. For example, this includes staff who take vital signs anddraw blood samples. If they are also doing those things for a research participant and not doing anything substantially above and beyond their job duties, then they are really acting within their professional capacity and not a significant contributor to the study (from the perspective of the DoA Log, of course the work they do matters to data integrity, but in this case someone else appears to be responsible for that specific aspect).
- An individual deemed significant on one type of study and listed on that study's DoA Log might not be considered significant on another study (due to things like complexity of procedures, licensure requirements, survey or equipment administration expertise, etc.)

We sincerely appreciate you taking the time to review and streamline your staff listing in efforts for us to work together with the goal of improving the time to site activation of BMT CTN protocols. IF you have any questions, please do not hesitate to contact me at igersten@emmes.com.

[1]Information Sheet Guidance for Sponsors, Clinical Investigators, and IRBs Frequently Asked Questions – Statement of Investigator (Form FDA 572) U.S. Department of Health and Human Services Food and Drug Administration Office of Good Clinical Practice Center for Drug Evaluation and Research (CDER) Center for Biologics Evaluation and Research (CBER) May 2010 Procedural

cc. DCC: M. Horowitz, S. Devine, A. Mendizabal, I. Gersten, A. Foley
NHLBI: N. DiFronzo
NCI: L. Henderson