University of California, San Francisco
Helen Diller Family Comprehensive Cancer Center
Policy and Procedure

Policy for the Classification of Clinical Research Coordinators (CRCs) as Research Support Staff in Therapeutic Industry Trials Conducted at the HDFCCC

Purpose

The purpose of this policy is to define the role of the Clinical Research Coordinators (CRCs) as Research Support Staff (RSS), and not as Sub-Investigators, for all therapeutic Industry trials conducted in the Helen Diller Family Comprehensive Cancer Center (HDFCCC).

Background

Currently, Clinical Research Coordinators (CRCs) are listed as Research Support Staff (RSS) in the CHR application of all therapeutic Industry trials conducted in the HDFCCC. However, some Industry sponsors have recommended that CRCs be listed as Sub-Investigators on the FDA 1572 form. Additionally, as per the FDA Information Sheet Guidance for Sponsors, Clinical Investigators, and IRBs, Frequently Asked Questions – Statement of Investigator (Form FDA 1572) (current version), there is language on this guidance document to support this recommendation; however, the CRCs in the HDFCCC do not have the clinical expertise and training, as well as do not perform critical study functions that would be required for them to be listed as Sub-Investigators in these trials. Furthermore, as per the HDFCCC Policy for Obtaining Informed Consent of Potential Patients for Therapeutic Oncology Clinical Trials (current version), CRCs are not considered Key Study Personnel (KSP) for consenting patients in Industry trials, as this responsibility is to only be performed by the Principal Investigator or Sub-Investigator (i.e., physician or nurse practitioner).

References

- FDA Information Sheet Guidance for Sponsors, Clinical Investigators, and IRBs, Frequently Asked Questions – Statement of Investigator (Form FDA 1572) (current version).
- Policy for Obtaining Informed Consent of Potential Patients for Therapeutic Oncology Clinical Trials (current version).

Process

In general, there is a recent trend for some Industry sponsors to require that CRCs in the HDFCCC be listed as Sub-Investigators in their trials. The rationale from the sponsor for this requirement is that CRCs are performing critical study functions in these trials. Additionally, the FDA Information Sheet Guidance for Sponsors, Clinical Investigators, and IRBs, Frequently Asked Questions – Statement of Investigator (Form FDA 1572) (current version) supports, but does not mandate, this requirement. This FDA guidance document contains the following statements:

> *"The purpose of Section #6 is to capture information about individuals who, as part of an investigative team, will assist the investigator and make a direct and significant contribution to the data. The decision to list an individual in Section #6 depends on*

his/her level of responsibility (i.e., whether he/she is performing significant clinical investigation-related duties). In general, if an individual is directly involved in the performance of procedures required by the protocol, and the collection of data, that person should be listed on the 1572."

"The decision about whether to list a pharmacist or research coordinator on the 1572 is a matter of judgment, dependent upon the contribution that the individual makes to the study."

"Generally, a research coordinator has a greater role [than a research pharmacist] in performing critical study functions and making direct and significant contributions to the data. For example, a research coordinator often recruits subjects, collects and evaluates study data, and maintains study records. Therefore, the research coordinator should usually be listed in Section #6 of the 1572."

Although the CRCs in the HDFCCC are integral members of the study team, their function is more supportive of the Investigators and Sub-Investigators on the trial. It is the Investigators and Sub-Investigators who have the appropriate clinical training and experience as physicians or nurse practitioners to perform clinical investigation-related duties as well as all procedures required by the protocol, and make direct and significant contributions to the data as is required of a Sub-Investigator as per the FDA guidance document.

Additionally, the HDFCCC CRCs are not involved in the recruitment of subjects nor in the collection and evaluation of study data as is indicated as a rationale per this requirement for Sub-Investigators in this FDA guidance document. Additionally, the HDFCCC CRCs are not involved in the clinical care of the research participants, the performance of study procedures, and the evaluation of adverse events in the Industry trials, which are responsibilities of the Sub-Investigators.

Overall, while the HDFCCC CRCs are integral and important members of the research team in Industry trials, they do not perform critical study functions nor make direct and significant contributions to the data in the Industry trials; hence, the HDFCCC exercises its judgment by *not* listing CRCs as Sub-Investigators in therapeutic Industry trials conducted in the HDFCCC.

Alternate Procedures

There are no alternate procedures to this policy. FOR IRB POLICIES ALWAYS CHECK THE UCSF HRPP WEBSITE FOR FORMS AND GUIDANCE.

http://www.research.ucsf.edu/chr

Policy Approval

This policy document was approved by the following personnel on the following dates:

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