Multi Site Research When A Children's Investigator Oversees an Operations, Coordinating or Statistical Center

Policy

When an operations, statistical or coordinating center for a multi-site human subjects research project is to be based at Children's, both the leadership and staff of the center and Children's as an institution will be engaged in this research according to OHRP guidance. To satisfy the responsibilities of an operations or coordinating or statistical center, where activities at Children's involve no interaction or intervention with subjects, the IRB will not review each collaborative protocol. However, the IRB will determine and document that the operations or coordinating center has sufficient mechanisms in place to ensure that

(i) management, data analysis, and data safety and monitoring (DSM) systems are adequate, given the nature of the research involved;
(ii) sample protocols and informed consent documents are developed and distributed to each collaborating institution;
(iii) each collaborating institution holds an applicable OHRP-approved Assurance of compliance with the HHS regulations for the protection of human subjects
(iv) each protocol is reviewed and approved by the IRB at the collaborating institution(s) prior to the enrollment of subjects;
(v) any substantive modification by the collaborating institution(s) of sample consent information related to risks or alternative procedures is appropriately justified; and
(vi) informed consent is obtained from each subject in compliance with HHS regulations or that appropriate waivers of alterations are considered and approved. when applicable.

The IRB will initially receive from the operations, statistical or coordinating center lead investigator an IRB protocol submission containing documentation of how the center will ensure that the above six activities will be performed appropriately, and a listing of active sites. At the time of initial review, the IRB will assess the procedures for prompt dissemination of protocol information to all participating sites. Assessment of protocol information includes unanticipated problems involving risks to participants, protocol modifications and interim findings. At the time of each periodic continuing review, the investigator will provide the IRB with

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updated information about each of these items, including the six items noted above.

Document Attributes

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