Institutional Review Board Policies and Procedures Manual

SECTION 15: SPONSORED PROGRAMS' ROLE IN HUMAN RESEARCH PROTECTION

15.1 SPONSORED PROGRAMS' ROLE IN HUMAN RESEARCH PROTECTION

A. Study Agreements Include Protection for Research Participants

The Institution has and follows written policies and procedures setting forth the ethical standards and practices of the Human Research Protection Program. Relevant policies and procedures are made available to Sponsors, Researchers, Research Staff, research participants, and the Institutional Review Board, as appropriate. In sponsored research, the Institution addresses the protection of research participants by:

i. Including in their standard contract templates a provision that the sponsor acknowledges and understands that the Institution's Human Research Protection Program is applicable to all human participant research.

ii. Asking for the inclusion of such a provision in any proposed contract that does not use their standard templates

Additionally, the IRB will review the proposed consent form and delete any provision that requires a participant to waive or appear to waive any legal rights (i.e., exculpatory provisions).

B. Provision Addressing Medical Care for Participants

The Institution has a written agreement with the Sponsor that addresses medical care for research participants with a research-related injury, when appropriate. In sponsored research, medical care for participants is addressed by:

i. Including in its standard contract template a provision that the sponsor provides for the cost of diagnosis, care and treatment of any undesirable side effects, adverse reactions, illness or injury to a participant, when the directly related to the study and absent negligence on the part of the Institution.

ii. Asking for the inclusion of such a provision in any proposed contract that does not use the Institution's standard template

   a. Including the substance of any such provision in the consent form.

iii. Including a statement in the consent form that participants do not waive any liability rights for personal injury by signing the consent form

C. Communication from Sponsors Affecting IRB Oversight

In studies where Sponsors conduct research site monitoring visits or conduct monitoring activities remotely, the Institution has a written agreement with the Sponsor that the Sponsor promptly (no longer than 30 days) reports to the Institution findings that could affect the safety of participants or influence the conduct of the study.

In sponsored research contracts, the Institution addresses communication with sponsors regarding information and findings relating to the protocol obtained by the sponsor which could affect the safety of participants or influence the conduct of the study. This is accomplished by:

i. Including in standard contract templates a provision that the sponsor will notify the Director of Sponsored Programs or the IRB of:

a. Any audit or visit findings that could affect the safety of subjects or their willingness to continue participation, indicate a protocol violation may have occurred, influence the conduct of the study, diminish the integrity of the study data, or alter the IRB's approval to continue the study.

Asking for the inclusion of such a provision in any proposed contract that does not use their standard template.

D. Data and Safety Monitoring (DSM) in sponsor agreements

When the Sponsor has the responsibility to conduct data and safety monitoring, the Institution has a written agreement with the Sponsor that addresses provisions for monitoring the data to ensure the safety of participants and for providing data and safety monitoring reports to the Institution.

For sponsored research, agreements specify that, as appropriate:

i. Provisions are made for monitoring study data which could affect the safety of participants;

ii. The results of this monitoring are reported to the researcher (PI/PD) so that:

   a. Routine monitoring reports will be submitted to as part of Continuing Review applications to the IRB, and

   b. Urgent reports are submitted according to the guidelines specified in this same guidance.

E. Publication of Research Results

Before initiating research, the Organization has a written agreement with the Sponsor about plans for disseminating findings from the research and the roles that Researchers and Sponsors will play in the publication or disclosure of results.

The Institution requires that provisions for fair and reasonable ownership of data and research results be included in its sponsored research agreements.

i. Including in its standard contract templates a provision that provides the investigator with a right to publish the research results.

ii. Revising any provision in any proposed contract that limits an investigator's right to publish research results

F. Communicating Study Results to Participants

When participant safety could be directly affected by study results after the study has ended, the Institution has a written agreement with the Sponsor that the Researcher or the Institution will be notified of the results in order to consider informing participants.

For sponsored research, Lurie Children's address communication with sponsors regarding the impact of research results on participant health and safety by:

i. Including in their standard contract templates a provision that the sponsor will develop a plan of communication with the Protocol Director that is acceptable to the IRB when new findings or results of the protocol might impact the willingness of

subjects to continue to participate in the protocol or directly affect their current or future safety or medical care.