



Communication of Research Staff Concerns Raised During Clinical Research

Issue of Concern

- To maintain high research standards and insure that the interests of research subjects and their families are protected it is essential to insure a culture of openness and transparency in the conduct of clinical research at the Children's Hospital.

To meet these goals, all members of every clinical research enterprise, whether laboratory technician or research nurse or investigator, should always feel free to bring any concerns they might have regarding the recruitment of research subjects or the conduct of the research to the immediate attention of the principal investigator (PI) without fear of censure or retribution.

All clinical research investigators are responsible for promoting and encouraging open discussions with their research staff and collaborators regarding any concerns raised during the course of a clinical research protocol. Investigators are also obliged to share any substantiated concerns with either the Chairman of the Committee on Clinical Investigation (CCI) or with the CCI administrative staff.

A human subject protection program requires proactive, collaborative communication between principal investigators, their research staff, the IRB, and any other individual who shares a responsibility for the conduct of a clinical research protocol. Individuals working on a research protocol may observe situations that result in concern, but may become apprehensive about expressing this concern for fear of inadequacy, intimidation, or repercussions. This type of barrier must not exist and there is an expectation that it is every individual's responsibility to bring forth concerns. Individuals who bring forth concerns should be thanked and be rewarded for this activity, regardless of whether a concern is substantiated or not. Principal investigators hold the ultimate responsibility for promoting this type of atmosphere within their research team.

Investigator Responsibilities

Principal investigators have the responsibility to promote an open and communicative environment for all issues and concerns raised about the conduct of all clinical research activities.

To achieve an open environment, we ask that investigators incorporate the following responsibilities into their clinical research activities:

- Investigators should meet frequently with their research team for the purpose of reviewing the progress of the research, and to encourage the discussion of any concerns about the research in general or a specific research subject.
- Investigators should individually inform each member of the research team that it is the member's responsibility to speak up about any concern without fear of any recourse or repercussions.
- Investigators must take any concern raised seriously and fully investigate it. The investigator must report back to the individual who raised it. No concern should be dismissed.
- Investigators must not punish any individual who brings a concern to their attention.
- Investigators are responsible for reporting to the IRB any concerns raised that have resulted in findings regarding subject safety, compliance with the research protocol, informed consent violations, or integrity of the research data.

Ombudsperson

Realizing that members of the research team may not always feel comfortable about raising issues of concern to their supervisors, the Children's Hospital has implemented the following alternatives: Susan Kornetsky or Dr. Steve Colan , who have had extensive experience in issues of human subject protection, should be able to resolve most concerns quietly and discreetly (ext 5-7052 or pager 0617). In addition, Dr. Kenneth McIntosh has agreed to function in an advisory capacity for Susan Kornetsky and Dr. Steve Colan when the concerns are more complex and cannot be resolved simply and directly. If members of the research staff feel more comfortable doing so, or if their concern is of a more serious nature, they may contact Dr. McIntosh directly (56832, pager 1406)

Any questions or concerns about these responsibilities may be addressed to either [Susan Kornetsky](#), Director of Clinical Research Compliance, at ext 5-7052, or Dr. Steven Colan , Chairman of the Committee on Clinical Investigation, at ext 5-6429 or pager 1453.

Related Content

Document Attributes

Title	Communication of Research Staff Concerns Raised During Clinical Research		
Author	Susan Kornetsky	Dates Reviewed/ Revised	04/01/05 06/20/05
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