



## 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 Boston 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 retaliation.

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.

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. Despite the best efforts of all involved to ensure the adequate protection of human subjects, individuals working on a research protocol may observe an actual, apparent, or potential violation of Hospital policy. These individuals are expected to report the concern to his or her supervisor, the Principal Investigator, Hospital counsel, or to the Compliance Officer. The Hospital has established additional reporting arrangements set forth below.

### 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, investigators are expected to 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 retaliation.
- Investigators must take all concerns raised seriously and fully investigate the concerns. The investigator must report back to the individual who raised it. No concern should be dismissed without due consideration.

- Investigators must not retaliate against any individual making a report in good faith, or who cooperates in the investigation of any report. Retaliation is unlawful, violates Hospital policy and is prohibited.
- 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 or the Principal Investigator, the Boston Children’s Hospital has implemented the following additional alternatives: Susan Kornetsky or Dr. Tina Young Poussaint, who have had extensive experience in issues of human subject protection, should be able to resolve most concerns (ext 5-7053). In addition, Dr. Kenneth McIntosh has agreed to function in an advisory capacity for Susan Kornetsky and Dr. Tina Young Poussaint 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 (41229).

Any questions or concerns about these responsibilities may be addressed to either [Susan Kornetsky](#), Director of Clinical Research Compliance, at ext 5-7053, or Dr. Tina Young Poussaint, Chair of the Institutional Review Board, at ext 5-6450 or pager 0535.

## Related Content

The Boston Children’s Hospital Compliance Manual. [“Compliance Reporting and “whistleblower” Protections.”](#)

## Document Attributes

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