Research Ethics Rounds

The Problem

The Human Subjects Protection Office receives calls from patients participating in research who are having problems or concerns. Additionally, the office performs quality assurance audits on research projects as directed by the Institutional Review Board. As such, we have observed that issues and problems can arise during the progress of a clinical research study that existing written regulations and policies do not provide guidance for.

- We wanted to develop a forum to encourage members of the research community to discuss these issues and problems in a safe and confidential manner so that workable solutions could be derived. No existing opportunity for this type of discussion was in place at the time.

The Team

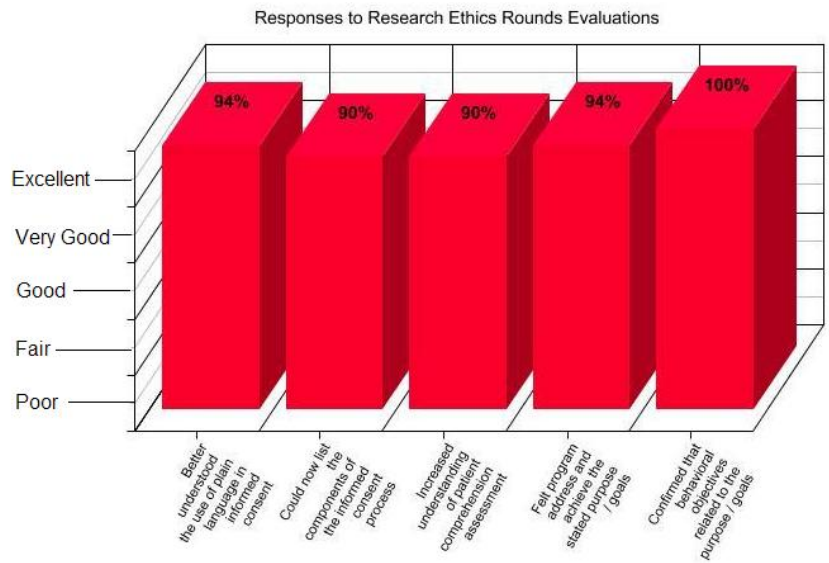
- Nancy J. Brown, RN – HSPO
- Wendy McHugh, RN, MS – Ethics Support Services
- Angela Lavoie, RN – HSPO
- Michael D'Egidio - HSPO
- Kaarkuzhali Babu Krishnamurthy, MD – HSPO, Ethics Liaison

The Interventions

- We met with members of the Ethics Support Service to identify a staff member who could facilitate our discussions.
- We have set up a monthly meeting time on the third Thursday of each month from 12-1 p.m.
- We have advertised the program in research e-mail listings, on the BIDMC portal, via the Ethics Advisory Committee, and at existing research seminars.
- We encourage members of the BIDMC research community to present specific cases or situations that have occurred within their research studies, with the ensuing discussion facilitated by Wendy McHugh.
- Examples of cases discussed include: Presentation of a geriatric medicine research project, and the challenges of planning for ethical recruitment and consenting procedures, including capacity assessment, for a particularly vulnerable population; Differences in HIV reporting requirements for research subjects vs. clinical care patients.

The Results/Progress to Date

For confidentiality reasons we do not maintain an attendance record, we collect an evaluation sheet after each discussion, with results as follows:



Lessons Learned

- Members of the research community at BIDMC have embraced this venue as an opportunity to discuss the dilemmas and challenges that can occur when attempting to carry out clinical research in a reasonable, practical, and ethical manner.
- Many attendees viewed the opportunity as thought-provoking and useful in daily practice.
- Through facilitated group discussion, we have achieved a forum to give practitioners and researchers new strategies to use in an ongoing way to better manage ethical problems.

Next Steps/What Should Happen Next

We will attempt to increase attendance at our monthly sessions by increasing our advertising, encouraging existing attendees to continue participation, and promoting the "bring a friend" concept. We will focus on encouraging other members of the BIDMC clinical community to join our discussion group. This would include employees within Interpreter Services and members of the Institutional Review Board.

Beth Israel Deaconess Medical Center | A teaching hospital of Harvard Medical School | The Silverman Institute For Healthcare Quality and Safety

For More Information Contact
Babu Krishnamurthy, MD, Director, HSPO
bkrishna@bidmc.harvard.edu