Consenting Adults – an innovative informed consent workshop

The Problem

Many clinicians at BIDMC participate in both clinical care and research.

- Previously, education on the informed consent process was provided separately for researchers and for clinicians.
- The process of informed consent can be similar in both domains.
- We developed a pilot informed consent workshop to see if educating clinicians and researchers on one method of performing consents would be of value, as indicated by attendance at the workshop.

  Some of the regulations and requirements re: consenting patients/subjects can be difficult to understand. We developed a case format that included aspects of clinical consent and research consenting to see if this would allow the audience to understand the regulations and requirements more easily.
- BIDMC is committed to an informed consent process that is more patient-centered and respectful of cultural and linguistic characteristics.

Aim/Goal

To develop an educational program for members of the BIDMC community that would teach clinicians and researchers alike how to perform the informed consent process more comfortably and effectively while also making it more patient-centered.

The Team

Margo Coletti, MLS – IS/Knowledge Services
Catherine Mahoney, JD – Office of General Counsel
Dan DeHainaut, S.B. – Committee on Clinical Investigations (IRB)
Angela Lavoie, RN – Human Subjects Protection Office
Nancy J. Brown, RN – Human Subjects Protection Office
Michael D'Egidio – Human Subjects Protection Office
K. Babu Krishnamurthy, MD – Human Subjects Protection Office
Ediss Gandelman, MBA—Community Benefits
Shari Gomez, MBA—Interpreter Services
Stephen O'Neill, LICSW, BCD, JD - Ethics Support Service

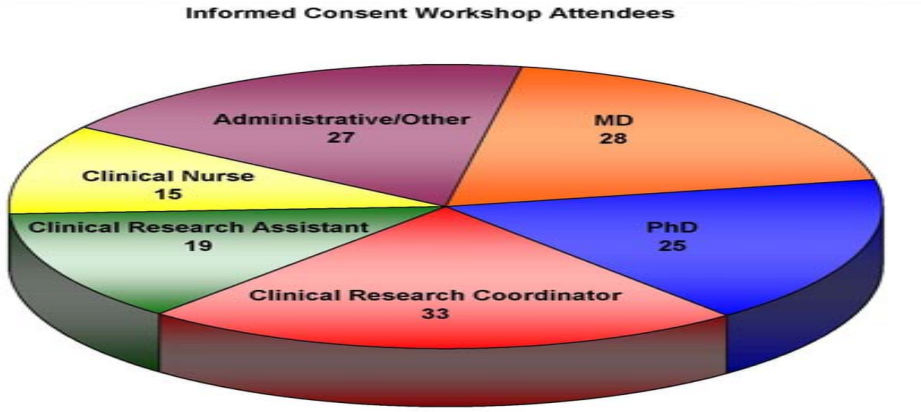
The Interventions

- ***Ongoing meetings with the workshop team to review evaluations, discuss and revise program content.***
- ***Incorporation of a case example into the presentations. Addition of pretest questions to assess the learning needs of the audience.***

The Interventions *(continued)*

- ***Obtained approval for nursing and physician continuing education credits.***
- ***Continuation of quarterly workshops.***
- ***Development of a research consent observation process.***

The Results/Progress to Date



Lessons Learned

Since the beginning of this program one year ago, many clinicians and investigators have attended the workshop, thereby confirming our expectation that caregivers and researchers are eager to obtain education and guidance on proper consenting practices. Following workshops, our office (the HSPO) has been asked to provide additional, focused education on consenting practices to different groups around BIDMC. We continue to promote the use of interpreter services and use of the translated "short form" consent form for research consents.

Next Steps/What Should Happen Next

- Perform additional research consent observations to provide feedback to research teams re: best practices.
- Advertise the workshops on the Human Subject Protection Program website
- Complete an in-development on-line resource tool-kit to include information on health literacy, a thesaurus of plain language medical terms, interpreter services and translation sources.
- Explore opportunities at BIDMC for clinical informed consent process observations.

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

For More Information Contact
K. Babu Krishnamurthy, M.D.
bkrishna@bidmc.harvard.edu