CCI Process for Determining IRB Review Requirements

The Problem

Academic healthcare institutions are routinely involved in activities such as quality improvement, education and training, all of which involve human participants. It is not always clear whether these activities meet the definition of *human subject research* requiring some level of IRB review and oversight to ensure appropriate protections for research participants and compliance with federal regulations. Subjecting non-*human subject research* activities to the routine CCI process can increase costs to the institution by inappropriately applying resources of the project team and the IRB staff and delaying program implementation. Scarce resources are diverted from the goals integral to the patient care missions of the institution – promoting continuous quality improvement, high quality research, and protecting the welfare of participants in those activities.

Aim/Goal

Pursuant to obtaining accreditation of BIDMC's Human Research Protection Program, members of the AAHRPP working group formalized policy and procedures that would provide a a review process by the Committee on Clinical Investigations (CCI) for activities for which the question of human subject research is often ambiguous. The goal was to create a simple process for submission that would engage the human research subject protections provided by the IRB and significantly reduce response turnaround time.

The Team

Mary Williams, RN, MS; Anna Johansson, PhD, with support and input from members of the AAHRPP working group – Randy Mason, MBA, Julianne Chun, JD, Andi Hernandez; CCI Chair/Vice Chairs; CCI Staff; QI and Medical Education leadership.

The Interventions

- Create simple form designed to assess whether the proposed project meet criteria for two key regulatory definitions - *human subject* and *research.*
- Create process for Project Leaders/Principal Investigators to submit requests for determinations via email; determinations returned via email within 48 hrs providing documentation for regulatory records, support for grant submissions, or submissions to academic journals.
- Form and process beta tested Oct-Dec 2008, with formal implementation in mid-December 2008

Progress to Date

Twenty two (22) submissions to date, 16 received post formal implementation:

Lessons Learned

***Human Subject* Definition Not Met**	***Research* Definition Not Met**	***Human Subject Research* - Exempt**	***Human Subject Research* - Expedited**
3 – receipt of anonymized tissue samples or data; definition of *research* applies, but not definition of *human subject*	15 – routine quality improvement and/or education to improve local process – definition of *human subject* applies, but not definition of *research*	1 – met both definitions; conforms to an **exempt** human subject research category defined by the federal regulations	3 – met both definitions; conforms to an **expedited** human subject research category defined by the federal regulations

- Education – opportunity to improve understanding of the role of the IRB and ethical considerations that apply to all human participants, whether or not human subject research.
- Compliance and efficiency – reduces the time spent completing a CCI research application and time spent by CCI staff and reviewers when not human subject research (48 hrs versus a minimum of 10 days); improved compliance when human subject research regulations DO apply.
- Opens communication between the CCI and the broader BIDMC community.

Next Steps

Continue to refine the 'instrument' to facilitate accurate determinations of proposed project activities. Develop further metrics to assess effectiveness.

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

For More Information Contact
Mary Williams, RN, MS, Director of IRB Operations
Anna Johansson, PhD, Instructor in Medicine,
Vice Chair, Committee on Clinical Investigations