

HUMAN RESEARCH PROTECTION PROGRAM

Announcements

October 7, 2011

The success of our clinical research program depends on many factors. One of the most important of these is generating a favorable opinion of the research process from our participants. Baystate recently participated in a multi-institutional Clinical and Translational Science Award (CTSA)-sponsored study designed to assess participant satisfaction with the research process. This was a survey-based study which correlated elements such as the coordination of care, information & education, informed consent, trust, and respect for patient preferences with the participants' overall perception of the research experience. 15 centers participated representing a broad geographic mix. The majority of the hospitals that participated in the survey were major academic programs with large research programs.

Here at Baystate, 192 surveys were sent to individuals who participated in clinical research projects between 2008-2010 in five active clinical research areas representing a good mix of NIH, industry, and investigator-initiated clinical research projects. 133 (70%) surveys were returned. We were pleased to rate within the norm of participating institutions on several factors, however, opportunities for improvement were clearly present. We were particularly struck by the fact that Baystate had the lowest overall rating on the overarching question of "Would you recommend joining a research study?" and in the category of questions evaluating the informed consent process. Like other centers, our participants overwhelmingly expressed a desire to receive a summary of a study's results, while only 14% of our participants reported that they actually did. As compared to other centers, a larger proportion of our participants reported that they joined the study to find out more about their disease and to help others. Our participants were less influenced by the potential to earn money or gain access to free healthcare.

While we begin the critical work of assessing our current practices and developing action plans, we ask you to examine your own practices and implement changes that could positively influence the experience of participants in your studies. Even small changes, like those suggested below, can have a big impact.

Finally, we encourage you to get involved in developing solutions. Please contact [Glenn Markenson](#), [Karen Christianson](#), [Bob Baevsky](#), [Matt Richardson](#), or any of the HRPP/IRB staff with your thoughts and ideas or simply to share information on current practices and challenges. If you are interested in the detailed survey results, please contact [Glenn Markenson](#) or [Karen Christianson](#).

Small Strategies to help participants feel valued:

- Birthday and holiday cards
- Magnets and wallet cards with contact information
- Newsletters
- Welcome folders prefilled with critical pieces of information – consent copy, bill of rights, contact information, do's and don'ts, appt schedule, parking directions, etc.
- Expressing thanks regularly
- Sharing results

Small Strategies to Improve Understanding / Consent:

Supplements to consent forms such as flow diagrams

Training in Research Consent – mentoring, observing

Allotting sufficient time to allow for meaningful dialogue

Private, quiet environment

Team Approach – discussion by investigator with follow up by research coordinator or vice-versa

“Teaching back” for consent

Use of Consent Assessment tools such as the [ICEFT](#)

Ongoing consent, revisit key elements, encourage questions – *remember we talked about..., now that you've been doing this for a while do you have any questions about...*