Advocate involvement in all stages of a large national clinical trial can be an asset to

I. Assistance with the IRB process:
DESCRIPTION: With examples of interventions have taken place without the vision and support of the I-SPY TRIAL PI laura Esserman. The project was brought to the UCSF breast SPORE advocate core (BSAC) to develop.

MRI. Measurement of tumor response to therapy and change in tumor size and biology using This trial provides the opportunity for the molecular characterization of tumors and the

Conclusions:
Survey data to better document their impact. Example 2: we will formally document the impact of educational/decision aid support during undergoing consent. We will refer to this as example 1. Further projects in this area were continued by CISN, a Non-profit organization founded by Ms. Devine. Example 2: CISN principals are currently working with the American College of Surgery Oncology Group

Description:
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EMERGING SOLUTIONS: ADVOCATE COLLABORATIVE MODEL

II. Development of educational materials for eligible trial participants:
B. Trial brochure: Explains core biopsies and MRIs. Pictures of each procedure is included to ease women’s fear of the unknown.

D. A standard treatment vs. study procedures flowchart: A comparison brochure was also developed because patients where having a difficult time understanding the difference between standard treatment and study expectations. The standard treatment information is presented before the line, printed on paper and slipped into a clear sheet protector. This flowchart is shown to the patient.

The I-SPY TRIAL collaboration was the first ever effort to incorporate an advocate component into an existing multi-site study. Leading the way in this effort was the study PI Laura Esserman from UCSF and the ACRIN PI, Nola Hytten also with UCSF.

This idea has been embraced by others and will serve as an example for how to better serve patients by forming collaborations between academic and patient advocates.

ACKNOWLEDGMENTS
Example 1: The advocate component for the I-SPY study would not be successful without the support and cooperation of the study PIs, the project manager, the advocates, the research nurses and the CRCs at each site. We would therefore like to acknowledge the following people:
– The lead study PIs - Laura Esserman and Nola Hytten
– The project manager - Meredith Buxton, originally Kathy Horing
– The CRCs - Lisa Carev, Anna Gomberg, Todd Buxton, Jen Torres, Jenny Crawford, Ann Amos, Jane Fey, Carolina Montalvo, Cathleen Cooper, Jen Torres, Jenny Crawford, Ann Amos, Jane Fey, Carolina Montalvo, Cathleen Cooper, Jen Torres
– The CRCs at each site
– The volunteer advocates - Robin Hachinski, Linda Kirti, Nori Corbin, Gayle Becker, Peggy Devine, Jo Ellen Loutree, Sue Lewis and Judy Mann
– The study nurses and CRCs - Jessica Gibbs, Neema Emerongo, Hillary Robb, Lauren Sherman, Nadine Shajrawi, Jani Holiday, Anna Tread, Lynne Shiner, Verna Kramer, Yol Aron, Jane Fay, Carolina Montalvo, Cathleen Cooper, Jen Torres, Jenny Crawford, Ann Amos, Jane Fey
– The CALGB data manager - Eleanor Leung; The ACRIN data managers - Sophie Sobe and Debi Halabi

We would especially like to thank and honor those women who have enrolled in this study.

Example 2: UCSF / ACOSOG / CISN Decision Aid Collaboration

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A newsletter was developed to remind participants in a 5 year long screening study to continue to have their yearly screen. This is a specific piece focused on improving retention in a multi-year screening study, these types of studies suffer from dropping retention which this continues the data.

SUMMARY
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