

## POSTER ABSTRACTS

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### Impact of Differential IRB Processes in a Multi-site Study

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**Background:** In multi-site studies, including the CRN, every participating site is obliged to obtain IRB approval for the conduct of a project. Variability in IRB review considerations, coupled with complex regulations that may also vary by institution, result in multiple, iterative reviews which can potentially compromise the consistency of study methodology. Reconciling this process, and meeting all IRBs' requirements is time- and resource-intensive, jeopardizing established study timelines and budget.

**Methods:** This study involved six CRN sites. Specific aims were to assess long-term outcomes and satisfaction with the decision to have a prophylactic mastectomy, among women who had undergone this procedure between 1980-1988. Data were collected via a 7-page cross-sectional survey. Materials reviewed by the IRB included the questionnaire, introductory letter, reminder letter, and script used for telephone reminders to participants to complete the survey. At five sites, an external survey firm handled data collection. Data on IRB processes included total time from initial submission to final approval, number of iterations of IRB review for each site, nature of review, and any unique stipulations.

**Results:** Multiple review cycles were necessary at all sites. Although three months were built into the original study timeline to accommodate an iterative review process, completing IRB review at all sites ultimately took twice that long. In this period, investigators tackled HIPAA regulations, requests from some IRBs to add a physician consent process, and a requirement by one IRB that the site notify prospective participants that the outside survey firm would be contacting them. Often, one IRB's stipulations necessitated repeated resubmissions of materials at other sites.

**Discussion:** In this minimal risk survey of women's outcomes and attitudes following prophylactic mastectomy, with no physical or behavioral intervention, numerous human subjects complexities were encountered, largely due to the multi-site nature of the study. This experience underscores the need to examine approaches that collaborative projects and IRBs could take to implement more efficient and standardized processes. The IRB is a fundamental aspect of scientific research. Yet uneven procedures and inconsistencies threaten the clarity, efficiency, and timeliness of many studies, resulting in a tension between researchers and the review boards.