

## INTRODUCTION

We thank the reviewers for their strong support for this application and insightful concerns. We have endeavored to respond fully. (Note: Changes to the original text are indicated with margin brackets.)

- *Inadequate justification for only English and Spanish speakers.* We now include Cantonese speakers and have added collaborators, staff, and translation/adaptation procedures to accommodate this change.
- *Question the feasibility of completing baseline assessment by phone in proposed time frame/concern about participant burden./What is the rationale for selecting the primary outcome variables?/ Measuring change in anxiety is not well-justified.* We prioritize outcomes that will best ascertain the non-inferiority of remote counseling, that are most readily answerable by low literacy respondents over the phone, and that allow us to limit respondent burden. There are many options and little consensus regarding measures of genetic counseling although change in knowledge (8-10 items) is fundamental. The most widely assessed psychological factors are the Impact of Events Scale<sup>56,57</sup> (cancer specific distress, 15 items) and Decisional Conflict<sup>58,62</sup> (10 items). Both were used by Schwartz<sup>7</sup> and Kinney,<sup>8</sup> the only other major trials on this topic, and have been validated in multiple populations. On these bases, we have selected our primary outcomes as knowledge and cancer-specific distress. Our measurement strategy is described in detail (section c.)xii.). These measures are part of a streamlined baseline phone call (sections c)vii. and viii.) which will be limited to 30 minutes.
- *Need alternative in case 90% follow-up rate not reached. Concerns over power assumptions.* We need 540 patients to complete the final survey. As the expanded Table 2. shows, our assumptions are conservative when viewed next to the recruitment and completion rates from our recent studies with diverse low-income participants. We have ample room to increase the proportion of patients invited to enroll among the 1345 individuals who will be eligible for genetic counseling. In addition, options for further increasing our numbers include extension of the intervention through the first quarter of year 5, and recruitment in the primary care clinics of our collaborating hospitals.
- *The key informant interviews are underdeveloped and not well integrated.* We have deleted these interviews.
- *There is some evidence that genetic counseling for breast cancer is “oversold”.* The value of genetic counseling and negative consequences of genetic testing without counseling are documented.<sup>92-96</sup> This value is magnified for patients of low literacy and limited English. Importantly, as the field moves from genetics to genomics, the issues for patients and providers will become “exponentially more complex.”<sup>90,91</sup> Access to and quality of communication for those less educated should be an urgent priority as precision medicine continues to evolve with the threat of leaving large segments of the population further behind.
- *Video or telephone could be better, does the analysis allow for that?* People randomized to phone counseling may be more likely to complete counseling (video counseling requires a clinic visit), but it seems unlikely that their response to counseling would be better compared with in person; those preferring a particular mode will be assigned to that mode. If, however, video or telephone turns out to be superior to in-person counseling for a particular outcome, this will be demonstrated by the confidence interval for the difference in means between video or telephone and in-person being entirely above zero (or below zero, if lower values are better).
- *For an R01 of this size, a second geographic location would strengthen external validity.* While going outside the state could enhance external validity, the reviewers note the complexity of the study as proposed. We are confident that findings from this ethnically diverse sample in three very different counties and hospitals will be of great value to most safety net settings where distance and a shortage of genetics counselors are barriers.
- *Gender distribution not justified.* We will include male breast cancer patients.
- *A dissemination plan is needed.* See Dissemination, section c).xx.
- *Resource Sharing Plans: Unacceptable.* See Resource Sharing Plan.
- *Will patients be receptive to invasion of privacy/does expected counseling rate assume knowledge of recording?* Participants will be informed of recording during recruitment and can refuse at any point. In Dr. Joseph’s current study of counseling in two public hospitals, only 10% of 172 patients have refused recording.
- *The overall impact is lessened by not including follow-up beyond the first genetic counseling session.* Most patients will have only one appointment. (This was 100% in Schwartz’ study, and 84% in our prior R01.) All participants will have one thing in common: the first session. Our design allows us to compare knowledge, distress, etc. based on that one comparable experience. Any subsequent encounters will be highly variable including possible mode switching and testing/not testing. We will track receipt of testing, and our qualitative inquiry with a subset of patients will allow us to explore subsequent counseling scenarios in depth.