**Proposed Plan for Recruitment and Retention of Women and Minorities**

Proposed Study:

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| 1. **Describe the disease/condition of interest and summarize the evidence regarding potential differential treatment effect of your proposed intervention in underrepresented populations and women.**
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| **2) List your site selection criteria, and did you utilize site selection to ensure adequate representation.** |
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| **3) What is the investigator’s track record for recruiting and enrolling minorities and women into previous research? Do the sites selected have a track record of diverse recruitment?**  |
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| **4) Describe specific strategies that you will use to enhance recruitment and retention of under-represented minorities and women into your trial.**  |
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| **5) (FOR PHASE III TRIAL CONCEPTS) Describe the statistical analysis plan that will specifically address the NIH requirement for a valid statistical analysis by sex and under-represented minorities.** |
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