

***WHI Clinical Trial Working Group:
Updates***

May 4, 2017

WHI Annual Meeting

Columbus, Ohio

Earlier Work: 2011

- WHI convened a CT working group in 2011: Mark Espeland (Chair), Marcia Stefanick (Co-Chair), Garnet Anderson, Bob Brunner, Becky Jackson, Karen Johnson, Lew Kuller, JoAnn Manson, Jennifer Robinson & Cyndi Thomson
- Charge was to organize & coordinate the development of CT proposals
- Solicitation for proposals was broadly distributed
- Proposals were submitted and reviewed

Members & Charge

- Members: Garnet Anderson, Mark Espeland, Rebecca Jackson, Andrea LaCroix, JoAnn Manson, Sally Shumaker, Marcia Stefanick, & Jean Wactawski-Wende
- Charge:
 - Current WHI contract periods includes the development of new RCTs w/in WHI – group convened to accelerate this process
 - Seeking opportunities for smaller & more focused RCTs
 - Identify key scientific questions that will sustain the cohort and advance science
 - Further identify value of the WHI cohort going forward – how does WHI *uniquely* contribute to advancing science of older women's health and well-being
 - Identify process to develop promising RCTs and non-RCTs to move science forward

Opportunities & Challenges

- Opportunities:
 - Randomizing smaller, targeted cohort for efficiency and cost-effective designs
 - Potential for shorter duration of interventions
 - ID factors that enable women to live longer and live well into older years; resilience
 - WHI is a well-characterized population and offers the opportunity for more personalized designs of interventions to fit specific sub-population needs
 - New data/monitor innovations may eliminate/minimize need for F2F contact
- Challenges:
 - Geographic distribution – difficult (but not impossible) to bring women into clinic visits
 - Age; multiple-comorbidities
 - Only women
 - Managing multiple RCTs w/in the cohort

Next Steps

- WHI will distribute a formal solicitation to all scientists associated w/WHI for a request for RCT proposals
- Key components of proposals:
 - Brief review of science, specific aims, design
 - WHI will provide a firm deadline for submissions, review process & notifications
- Review process:
 - Committee will be convened to review/rank proposals
- Benefits to investigators for highly rated proposals:
 - Provide critical feedback from peers re: quality and ways to strengthen
 - Expertise in CT design & implementation
 - Actively link individuals w/others who have expertise needed & overlapping expertise