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