



National Institute  
on Aging



**RFA-AG-14-009**

**Clinical Trial of a Multifactorial Fall  
Injury Prevention Strategy in Older  
Persons (U01)**

National Institute on Aging

Patient-Centered Outcomes Research Institute (PCORI)

# Timelines

- **Earliest submission: October 13, 2013**
- Letter of Intent: October 13, 2013
- **Application: November 13, 2013 by 5PM local time of applicant organization**
- Scientific merit review: January 2014
- Advisory council review: February 2014
- Earliest start: March 2014

# Goal

- Randomized clinical trial of a multifactorial strategy for preventing serious fall-related injuries among non-institutionalized older persons.

# Important Considerations

## *Study Population*

- Excludes hospitalized and nursing home populations
- Includes significant and diverse patient populations, e.g., gender, race/ethnicity, SES, geography
- Rapid enrollment of a large sample

# Important Considerations

## *Investigative Team*

- Multidisciplinary team of investigators with diverse expertise
  - Trained clinicians: physicians, nurses, rehab therapists, pharmacists, etc.
  - Falls prevention experts
  - Researchers: health services, biostatistics, etc.
  - Patient/caregiver partners
- Attach letters of support from participating institutions to application

# Important Considerations

- One-year protocol development and refinement phase (March 2014-March 2015)
  - Tight timeline: training staff, piloting intervention and measures, measuring baseline fall/injury rates, estimating effect size, enrolling sample, finalizing agreements
- Definition and ascertainment of “serious fall-related injuries”
- Preliminary RCT findings to be reported in early 2017

# Responsiveness Criteria

## Application MUST Address All

- Designed to measure comparative effectiveness of the preventive strategy
- Use reliable outcome ascertainment to detect statistically significant change in rate of serious fall-related injuries
- No cost-effectiveness analysis
- Engagement of patients & stakeholders as partners in:
  - Formulating research questions and hypotheses
  - Defining essential study characteristics: interventions, participants, comparators, outcomes, measures
  - Monitoring study conduct/progress
  - Planning for dissemination of study results

# Scored Review Criteria

- Significance
- Patient-Centeredness
- Innovation
- Approach
- Patient and Stakeholder Engagement

# Scored Review Criteria

## ➤ *Significance*

- Whether the application addresses an important problem and if the aims of the project are achieved, will improvements in clinical practice likely lead to widespread improvements in outcomes that matter to patients?

# Scored Review Criteria

## ➤ *Patient-Centeredness*

- Whether the research questions and outcomes measurement are important to patients and caregivers?

## ➤ *Innovation*

- Whether the application utilizes novel theoretical concepts, approaches or methodologies, instrumentation, or interventions likely to improve care?

# Scored Review Criteria

## ➤ *Approach*

- Whether the study team and the study design are appropriate for achieving the study objectives.

## ➤ *Patient & Stakeholder Engagement*

- Whether the application demonstrates meaningful patient and stakeholder engagement throughout the project.

# Patient & Stakeholder Engagement

- **Patients** are individuals (or groups of individuals) who have experienced the aspects of the healthcare system to be studied.
  - Examples include individual (“real”) patients, patient-advocacy groups, and patient surrogates or caregivers for whom the results of the research will be relevant.

# Patient & Stakeholder Engagement

- **Stakeholders** are individuals or organizations that participate in the aspects of the healthcare system to be studied.
  - Examples include clinicians (e.g., physicians, nurses, pharmacists) and healthcare provider organizations, policy makers, purchasers, payers, and industries for which the results of the research will be relevant.

# Patient & Stakeholder *Engagement Standards*

PCORI funds research that includes meaningful involvement of patients and stakeholders as partners with researchers *throughout* the research process. Applications should describe:

- How patients and stakeholders were or will be identified and invited to participate in the research.
- The patients' and stakeholders' roles in helping the researchers to make decisions about formulating the study's questions, hypotheses and design; defining the study's participants, comparators, and outcomes; monitoring the study's conduct and progress; and disseminating the study's results.
- The format, media and frequency of interactions among patients, stakeholders and scientists.

# Additional Resources

- The PCORI seminar on "Promising Practices in Meaningful Engagement in the Conduct of Research" will be conducted on Sept. 19, 1-2 PM. Registration is through <http://pcori.org/events/promising-practices-of-meaningful-engagement-in-the-conduct-of-research/>
- Applicants may request assistance in finding patient and stakeholder research partners by sending an email message to PCORI's "Engagement mailbox" at [getinvolved@pcori.org](mailto:getinvolved@pcori.org)



Thank You!