Responsible Conduct of Research: The Role of Clinicians in Research

National Institutes of Health / National Cancer Institute
Educational grant requirement

- What role do pharmacists and other clinicians play in health-related research?
- Considerations for participation in research
  - Pros and cons
  - Conflict of interest
  - Guiding principles for the conduct of ethical research

The Role that Clinicians Can Play in Health-Related Research

"If we want more evidence-based practice, we need more practice-based evidence."
– Dr. Lawrence W. Green, University of California San Francisco

- Significant gaps exist between science and practice
- Opportunities exist for all clinicians to contribute to health-related research

Practice-Based Research Networks (PBRNs)

- Teaming researchers with practicing clinicians, to maximize generalizability of research findings
- Answering community-based health care questions and translating research findings into practice
- Agency for Healthcare Research and Quality (AHRQ):
  - https://www.pbrn.ahrq.gov/
  - Events, registry, tools and resources

Practice-Based Research Networks (PBRNs)

- Medication Safety Research Network of Indiana (Rx-SafeNet)
- Minnesota Pharmacy PBRN
- PearlRx (University of Wisconsin)
- Rural Research Alliance of Community Pharmacies
- San Diego Pharmacist Resource and Research Network (SDPharmNet)
- ACCP PBRN [no longer active]

Pros of Clinician Participation in Research*

- Intellectual curiosity
- Enables clinicians to "give back"
- Innovation, advancement of care
- Direct contributions to clinical or translational science
- Benefits to patients, clinicians, and health systems
- Financial compensation
- Enhanced understanding and appreciation for research process

* Rahman et al. Advances in Medical Education and Practice 2011;2:85-93.

Cons of Clinician Participation in Research*

- Time and effort / IRB training
- Challenges with patient recruitment, complexities
- Duration of initiatives
- Resources/costs/infrastructure
- Culture of organization(s)
- Disruption to clinical practice
- Inadequate financial compensation

* Rahman et al. Advances in Medical Education and Practice 2011;2:85-93.

Conflict of Interest*

- "A set of circumstances that creates risk that a professional judgment or actions regarding a primary interest will be unduly influenced by a secondary interest."**
- Can impact the health and welfare of human subjects/patients in research
- Work with your institution to determine rules and regulations for compliance with management of COI

* Ghooi RB. Perspectives in Clinical Research 2015; 6(1):10-14.
** Lo B, et al. Conflict of Interest in Medical Research, Education, and Practice, 2009.

Seven Principles to Guide the Conduct of Ethical Research

1. Social and clinical value
2. Scientific validity
3. Fair selection of study participants
4. Favorable risk-benefit ratio for participants
5. Independent review
6. Informed consent
7. Respect for potential and enrolled participants

* NIH Clinical Center. https://www.nih.gov/health-information/nih-clinical-research-trials-you/guiding-principles-ethical-research.

Summary

- Abundant opportunities exist for clinicians, of all types, to contribute to health-related research
  - Find a PBRN in your area; clinical trials registries
  - Connect with academic institutions, health systems
  - Respond to surveys
- Consider the pros and cons of participation and COI
- Maintain fidelity to study procedures and ethical conduct

"Research is creating new knowledge."
– Neil Armstrong

1930 – 2012