
**American Pharmacists Association
House of Delegates – March 18-21, 2022**

NEW BUSINESS

(To be submitted and introduced by Delegates only)

Introduced by: Matt Kirchoff, USPHS Delegate; Juliette Taylor, USPHS Alternate Delegate
(Name)

Feb. 4, 2022
Date

United States Public Health Service Commissioned Corps
(Organization)

Subject: Supporting the Integration of Pharmacists into the Clinical Research Workforce

Motion: Adopt the following two policy statements:

1. APhA supports the integration of pharmacists as clinical research team members in all forms of clinical research, including but not limited to healthcare outcomes research, pre-marketing clinical trials, and post-marketing studies.
2. APhA encourages pharmacists and student pharmacists to build clinical research enterprise knowledge and specialized skills.

Background:

Clinical trials for new medicines and devices regulated by the US Food and Drug Administration (FDA) or other regional regulatory bodies involve rigorous and highly regulated processes to provide adequate safety and efficacy data for regulatory approval and post-marketing monitoring. It is estimated that over 34,000 clinical trials are being conducted at any given time in the United States.¹ The execution of these trials requires a highly trained workforce with a variety of skills in addition to a general healthcare background.

While the American Pharmacists Association Academy Of Pharmaceutical Research And Science provides an avenue to support pharmacist researchers, there does not appear to be an existing community for pharmacists engaged in the broader clinical research enterprise. Traditionally, many jobs within the clinical research enterprise have often recruited for and been filled by nurses. Examples of these jobs include clinical research coordinators, clinical research associates, operations managers, logistics managers, compliance managers, regulatory managers, and a variety of other related and similar positions. These jobs include many entry-level positions which provide additional skills development, opportunities for advancement, an interesting and varied career, and the opportunity to travel both domestically and internationally. Settings for these positions include academic institutions, hospitals, clinics, dedicated study sites, clinical research organizations, life science companies, government entities such as National Institutes of Health or Centers for Disease Control and Prevention, Food and Drug Administration, and others. The current policy statement urges the sponsors of drug research to permit pharmacists to serve as principal investigators; however, there are many other roles that pharmacists may be well-suited to serve.

Over the past decade business cost-saving practices, technological advancements, regulatory changes, and increased patient access to remote or mail-order pharmacy has generally reduced the number of pharmacist job openings relative to the overall new pharmacist graduation rate. Clinical research professionals have steadily increased during this time, with a recent report finding a 9.3% compound annual growth in monthly job postings across all clinical research positions from 2016 to 2019.¹ The average salary for clinical trial specialists was reported to be \$100,224.¹

References:

1. Association of Clinical Research Professionals (ACRP). *An Assessment of the Adequacy of the Clinical Research Workforce*. 2020.

Current APhA Policy & Bylaws:

In the current policy handbook, sections that pertain to this motion include: Internships/Externships and Residencies p 49, Pharmaceutical Care p 91, Facility Design and Face-to-Face Communication p. 106, Research p 148, 149.

2013, 2008

Pharmacy Practice-Based Research Networks

1. APhA supports establishment of pharmacy practice-based research networks (PBRNs) to strengthen the evidence base in support of pharmacists' patient care services.
2. APhA encourages collaborations among stakeholders to determine the minimal infrastructure and resources needed to develop and implement local, regional, and nationwide networks for performing pharmacy practice-based research.
3. APhA encourages pharmacy residency programs to actively participate in pharmacy practice-based research network (PBRNs).

(JAPhA. NS48(4):471; July/August 2008) (JAPhA. 53(4):366; July/August 2013) (Reviewed 2018)

1989

Pharmacists as Principal Investigators in Clinical Drug Research

1. APhA urges the sponsors of drug research to permit pharmacists to serve as principal investigators.
2. APhA encourages state and federal agencies to eliminate regulatory and policy obstacles that prohibit pharmacists from being investigators, including principal investigators, in drug research or sponsors of Investigational New Drug Applications, Investigational Device Evaluations, and Animal Investigational New Drug Applications.

(Am Pharm. NS29(7):465; July 1989) (Reviewed 2005) (Reviewed 2009) (Reviewed 2014) (Reviewed 2019)

****Phone numbers will only be used by the New Business Review Committee in case there are questions for the delegate who submitted the New Business Item Content.**

New Business Items are due to the Speaker of the House by **February 16, 2022** (30 days prior to the start of the first House session). Consideration of urgent items can be presented with a suspension of the House Rules at the session where New Business will be acted upon. Please submit New Business Items to the Speaker of the House via email at hod@aphanet.org.