Journal of Pediatric Nursing 68 (2023) 18–23

Contents lists available at ScienceDirect

Journal of Pediatric Nursing

journal homepage: www.pediatricnursing.org

Variability in qualifications for principal investigator status in research studies by nurses: A call for clarification

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ARTICLE INFO

Article history:
Received 26 February 2022
Revised 8 August 2022
Accepted 10 August 2022

Keywords:
Clinical research
Investigator
Guidelines
Nurse scientist

ABSTRACT

Purpose: To describe existing guidance for qualifications of principal investigator s (PI s) of human subjects research and explore how they are operationalized for pediatric nurse scientists and clinical nurses in children's hospitals.

Design and methods: After reviewing federal regulations, accreditation guidelines, and the literature, a convenience sample of members of the National Pediatric Nurse Scientist Collaborative (NPNSC). Participants completed a 33-item survey that included questions about Institutional Review Board (IRB), guidelines, and policies for PI status at their affiliated children's hospitals.

Results: The survey was electronically disseminated to 179 members of NPNSC through the Collaborative's listserv. Of the 39 members who responded, 90% hold a PhD and 80% practice in a free-standing children's hospital, nearly all of which (93%) are recognized as Magnet® hospitals. While the majority of respondents indicated that nurse scientists and other nurses were allowed to be PIs of research studies, educational requirements for PI status varied, with 3% requiring a PhD, 15% a baccalaureate degree, and 10% a graduate degree. 54% of respondents reported there was no degree requirement for PI status; however15% reported that even doctorally prepared nurse scientists cannot serve as PIs of research studies at their affiliated children"s hospitals.

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https://doi.org/10.1016/j.pedn.2022.08.009

Conclusions: The survey identified substantial variability in requirements for PI status and potential barriers to pediatric nurses conducting independent research as PIs at children's hospitals.
Practice implications: Operationalizing existing guidance will expand inclusion of nurse scientist expertise in human subjects research.

Introduction

Nurses play a key role in the transformation of healthcare in the United States. The COVID-19 pandemic, perhaps the most profound natural experiment of our time, revealed gross inequities in health and access to healthcare. An expert committee recently published evidence-based recommendations focused on strengthening and protecting the nursing workforce with the larger goal of facilitating a critical role for nurses in promoting a future healthcare system rooted in health equity at all levels (National Academies of Science, Engineering, and Medicine, 2021). Removal of practice and research barriers in parallel with federal, state, and institutional support, are central to achieving these goals. Nurses have the knowledge, skills, and training to dismantle health disparities, promote health equity, and develop innovative models of care that prioritize health, well-being, and disease prevention. Improving healthcare depends on the ability of nurses to generate new knowledge through research. Unfortunately, barriers in some institutions limit nurses' scope of practice, including opportunities to conduct research.

Principal investigators (PIs) conducting investigator-led studies have multiple responsibilities, including evidence review and synthesis, articulating the research question, establishing the research process, identifying appropriate methods, engaging co-investigators and important stakeholders, and protecting human subjects. The PI takes full responsibility and provides oversight for all aspects of the study, maintaining adherence to the IRB approved protocol, and most importantly, ensuring the rights, safety, and welfare of all study participants (Marzinsky & Smith-Miller, 2019). While these responsibilities are common to all PIs, nurses functioning as PIs, regardless of formal education, often take an additional step in the research-to-practice process by identifying how study findings may improve patient outcomes or change nursing practice.

The purpose of this paper is to describe 1) existing federal regulations and accreditation guidance for the PI, 2) literature on research oversight for nurse-led research. 3) Magnet® requirements for clinical nurses' role in human subjects research. In addition, this paper reports the results of a brief survey conducted of members of the National Pediatric Nurse Scientist Collaborative (NPNSC) to gather information on the rules, guidelines, and policies for PI status affecting nurses at children's hospitals across the country. The overall goal of this paper is to begin a discussion about the role and qualifications of nurses to serve as PIs in human subjects research as defined by individual institutions and institutional review boards (IRBs).

Federal regulations and accreditation guidance on principal investigator qualifications

Guidance related to PI qualifications from the Department of Health and Human Services (DHHS), the U.S. Food and Drug Administration (FDA), and the Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP) is limited (Table 1). To ensure adequate protection of human subjects, researchers are required to complete relevant training, such as the Collaborative Institutional Training Initiative certification (Collaborative Institutional Training Initiative Program, 2022), Human Research Protection Training offered by the Office for Human Research Protections (OHRP), and other institution-specific training. Additional nursing, scientific, and/or medical training may be required to conduct research studies in hospital settings; however, many institutions do not specify required components of that training (American Association of Colleges of Nursing, 2019).

The FDA's Guidance for Industry Investigator Responsibilities, rooted in protecting the rights, safety, and welfare of human study subjects, requires that study sponsors select investigators qualified by training, experience, and licensure to investigate new drugs and medical devices

Table 1
U.S. federal agency definitions, qualifications, and guidance for principal investigators (PI) conducting human subjects research studies.

Agency	Document	PI Definition and/or Qualifications	Guidance
U.S. Department of Health and Human Services	The Code of Federal Regulations Title 45: Public Welfare Part 46: Protection of Human Subjects (US Department of Health and Human Services 2021,45 CFR 46)	None	• Provides IRB authority to determine what research may be conducted at an institution within its defined constraints and those set by other institutional and federal requirements • IRB ensures appropriate resources to conduct a study • IRB determines required PI credentials
U.S. Food and Drug Administration	• Code of Federal Regulations Title 21 Chapter 1 Subchapter A Part 50: Protection of Human Rights (US Department of Health and Human Services 2021, 21CFR50.3) • Code of Federal Regulations Title 21 Chapter 1 Subchapter D: Drugs for Human Use Part 312: New Drugs: Definitions and Interpretations (US Department of Health and Human Services, 2021, 21CFR312.3)	• An individual who conducts a clinical investigation • In a team of investigators, this person is the responsible team leader	• Study sponsors select only investigators qualified by training and experience to investigate the new drugs and medical devices • Investigator responsibilities include ensuring that any individual to whom a task is delegated is qualified by education, training, and experience (and state licensure where relevant) to perform the delegated task • Medical or dental decisions and care are the responsibility of a qualified physician (or dentist) • Non-physician investigators (not qualified to provide medical care) ensure appropriate provision for necessary medical care
Association for the Accreditation of Human Research Protection Programs, Inc.	AAHRPP Tip Sheets (AAHRPP, 2022)	None	• Institutions provide education to ensure investigators and research staff are knowledgeable (no specific topics or number of hours required per year)

(U.S. Food and Drug Administration, 2009). Thus, a nurse with appropriate research training, experience, licensing, and resources would be considered by the FDA to be qualified to conduct studies that investigate new drugs and medical devices. Investigator responsibilities include ensuring that tasks are delegated to individuals qualified by education, training, experience, and state licensure (where relevant) to perform the research task (US Department of Health and Human Services 21CFR312.3, 2022).

Magnet® designation

In addition to federal regulations and accreditation guidance, the American Nurses Credentialing Center (ANCC) Magnet Recognition Program® requires: 1) at least one nurse employed by the healthcare institution to be a member of their IRB and 2) clinical nurses (who provide >51% of their time in direct clinical care) need to have a knowledge and understanding of the applicant organization's study to be able to disseminate to internal and external audiences. The Magnet® Recognition Program is a component of national hospital metrics, such as *U.S. News and World Report's* Best Hospitals and Best Children's Hospitals rankings, because Magnet® designation is tied to high-quality clinical care. Magnet® designation is also linked to research led by nurses who provide direct patient care (Olmsted, Powell, Murphy, Bell, Silver, et al., 2021a; Olmsted, Powell, Murphy, Bell, Stanley, et al., 2021b); this research informs evidence-based practice changes with in Magnet® designated institutions (ANCC, 2021).

As of June 2022, 9.4% of hospitals in the U.S. had obtained Magnet® designation (American Nurses Credentialing Center, 2022), which is often attributed to having expert nurses and nurse leadership with advanced degree preparation (PhD-prepared nurse scientists & Doctors of Nursing Practice (DNP). These nurses maintain individual programs of research in addition to translating existing research, informing evidence-based practice (EBP), and supporting nurses and interprofessional teams in conducting research. While >80% of nurses in Magnet® designated hospitals must have a baccalaureate degree, the ANCC Magnet Recognition Program® does not specify an educational requirement for nurses who are PIs, site-PIs, or Co-PIs of studies.

Literature review of research oversight for nurse-led research

It is clear there are significant disparities in institutional requirements for PI status due to interpretation of the federal guidelines and implementation of the Magnet® standards. In 2004, Larson and colleagues reviewed IRB processes in 68 U.S. hospitals, mainly on the east coast. They found that 33.8% of IRBs required the PI to be employed by the hospital, but only 26.5% required some form of human subjects research training (Larson et al., 2004).

McLaughlin et al. (2013) investigated IRB policies and requirements for nurse-led research in 160 U.S. Magnet® and non-Magnet® designated hospitals. Overall, 87.1% of hospitals had no policy describing minimum qualifications for nurses to serve as PIs. In hospitals that did have a policy, the minimum educational requirement ranged from a Baccalaureate to a doctoral degree. Among non-Magnet® designated hospitals, 21.57% had a policy describing minimum PI qualifications, compared to 8.65% of Magnet®-designated hospitals. Furthermore, 37.5% of non-Magnet® designated hospitals did not allow nurses to sign the IRB application as PI; the same was true in 20.59% of Magnet® designated hospitals. These findings were corroborated in a survey of 181 nurse leaders across 67 Magnet® designated hospitals (Pintz et al., 2018); in that survey, 61.2% of respondents indicated that a nurse could “always” serve as PI of a research study, but only 59.1% indicated that a nurse could “always” assume full responsibilities for their study as PI.

McKee et al. (2017) conducted focus groups as part of an intervention to build research capacity among clinical nurses in a U.S. hospital affiliated with an academic institution. While restrictions on PI status for nurses were not identified as a barrier to nurse-led research, nurses perceived that the qualifications to conduct research were a barrier. These findings conflict with those of the McLaughlin et al. (2013) survey, which found that research mentors were available to guide clinical nurses in their research role in most hospitals (82.91%), and more so in Magnet® (98.1%) than non-Magnet® (52.83%) designated hospitals. This is an important finding because 25.35% of the respondents in the McLaughlin et al. (2013) survey also indicated that if a nurse did not meet minimum qualifications for PI status, a designee or mentor was required to play a significant role in the study. However, respondents also indicated that novice nurse PIs were required to complete research education prior to conducting research in <25% of both Magnet® and non-Magnet® designated hospitals (McLaughlin et al., 2013).

Magnet® designation and nursing research committees (NRCs) present in many hospitals affect the operationalization of nursing research studies, which have increased in volume and complexity (Grady & Edgerly, 2009). In a qualitative study of 26 Magnet® designated hospitals, best practices related to IRBs included having nurses on the hospitals' IRB and obtaining pre-review and approval of nursing research by NRCs (Day et al., 2017). NRCs provide infrastructure for mentoring and supporting nurses through the research process within the context of hospital-based collaborative governance structures. Internal institutional review and approval processes of nurse-led research also vary across hospitals. The roles of NRCs also vary by hospital, with some requiring NRC scientific review and approval for nurse-led research studies while other NRCs function in an advisory role. NRCs with advisory roles may conduct scientific reviews, host nursing research conferences, and provide education, sponsorship, mentoring, tracking, reporting, resource monitoring, and workflow solutions to support nurse PIs and interprofessional collaborations with clinical and academic partners.

Among hospitals surveyed, McLaughlin et al. (2013) found that most had an NRC (65.19%) or interprofessional research committee (31.01%). The role of the NRC was to review nurse-led research studies in 42.86% of hospitals and approve studies in 35.86%; interprofessional research committees were found to review in 22.45% of hospitals and approve in 17.24%. Most nurse-led studies required peer review and approval by one or more leaders, mentors, or committees before IRB submission. Both research mentors (23.81%) and Directors of Nursing Research (21.77%) filled this role. No committee review or approval was required in 16.33% and 26.97% of hospitals, respectively. Most hospitals required the nurse PI to give regular or intermittent progress reports to a mentor or committee. Overall, Magnet® designated hospitals (82.86%) were more likely than non-Magnet® designated hospitals (31.01%) to have an NRC and require nurse-led research study review and approval. In addition to specific educational requirements, various processes, structures, and check points were also in place to ensure nurses were adequately qualified to lead research studies.

Differences in the review process for nurse-led research studies were also evident in a survey of 181 nurse leaders across 67 Magnet®-designated hospitals (Pintz et al., 2018). Leaders reported that most NRCs or interprofessional research committees reviewed nursing research proposals before IRB submission either often (19.7%) or always (42.5%). However, whether committee approval of nursing research proposals was required before IRB submission varied widely: 37.3% of committees were not required to approve proposals, while 38.1% always approved them.

Results from a survey of pediatric nurse scientists

The NPNSC (https://www.npnsc.org) is a support network for pediatric nurse scientists from children's hospitals and schools of nursing across the U.S. The mission of the NPNSC is to inspire and support nurse-led research, integrate evidence-based healthcare delivery, foster knowledge development, and advance nursing science through integrative collaboration to improve pediatric health. The NPNSC, largely

comprised of PhD-prepared nurse scientists, maintains a listserv, meets monthly through video conference calls, and sponsors an annual educational and networking conference to provide a forum for communication among members.

Recent formal and informal discussions among NPNSC members revealed varying requirements for nurses to be recognized as a PI on research projects in their children's hospitals. To obtain further clarification, a brief investigator-developed survey on the roles and expectations of nurse PIs at their affiliated children's hospitals was distributed to NPNSC members. The IRB at Stanford University determined that this research does not meet the definition of human subjects research per federal regulations and guidelines and was therefore exempt from IRB review.

Surveys were distributed through the NPNSC listserv ($n = 179$) and were returned by 39 NPNSC members associated with children's hospitals nationwide (22% response rate), with 90% ($n = 35$) reporting their highest degree as a PhD and 10% ($n = 4$) as a DNP. Almost all survey respondents reported that their associated children's hospital is Magnet® designated (95%; $n = 37$) and affiliated with a college or school of medicine (77%; $n = 30$) and/or nursing (33%; $n = 13$). Respondents reported that their primary appointment was at the children's hospital (59%; $n = 23$), school of nursing (18%; $n = 7$), or both (23%; $n = 9$). Respondents also reported a range of 0–20 full time effort (FTE) nurse scientists affiliated with their hospitals, with an average of 2.4 FTEs.

Titles for pediatric nurse scientists with a primary appointment in academia ranged from Assistant Professor to Professor. Titles of those with appointments in hospitals included Nurse Scientist, Director of Nursing Research, Director of Research and Evidence-Based Practice, Director of Research and Professional Practice, Pediatric Complex Care Nurse Scientist, and Manager of Research & Outcomes. When asked to define the role and duties of a nurse scientist in a children's hospital, one comprehensive description included the following activities:

- Conduct research to support the mission of Nursing and Patient Care Services, the Department of Nursing Research, and the Children's Hospital.
- Direct, develop, and advise healthcare teams to create and implement EBP to promote quality patient care.
- Administer nursing research policies and procedures to ensure compliance with federal, state, local, and institutional regulations.

Almost all respondents stated that their associated children's hospital allowed nurse scientists (95%; n = 37) and nurses not identified as nurse scientists (i.e., clinical nurses and/or those with a master's degree; 82%; $n = 32$) to serve as PIs on research studies. The level of education required for PI status varied, with 54% ($n = 21$) of respondents stating that their hospital does not have a degree requirement. Other respondents (18%; $n = 7$) were not sure if there was a degree requirement, while 15% ($n = 6$) indicated a requirement for at least a baccalaureate degree (BSN), 10% ($n = 4$) a graduate degree, and only 3% ($n = 1$) a PhD. Respondents from hospitals that prohibit BSN or Master's-prepared nurses from acting as PIs indicated that MD, PhD, PharmD, or another clinical doctorate degree was required for PI status.

The survey revealed that some children's hospitals' IRBs may not require a certain level of education for PI status but do require that IRB applications from nurses include other personnel on the application. While 49% ($n = 19$) reported no restrictions on nurses serving as PIs on IRB applications, 33% ($n = 13$) of the respondents reported that their affiliatedchildren's hospital IRB requires that all BSN or MS-prepared nurses have the hospital's nurse scientist, a PhD mentor, or an MD mentor on the application. Importantly, several others reported that the university IRBs affiliated with their Children's hospital (15%; n = 6) require that even doctorally prepared nurse scientists have an MD or PhD faculty mentor on the IRB application, although the role of these additional individuals on the proposed studies is not clear. One respondent stated the children's hospital IRB with which they are affiliated only allows individuals who hold an academic appointment in their affiliated college of medicine to serve as PI on research studies.

Almost all respondents (97%; $n = 38$) reported that nurses are allowed to serve on the IRB and 44% ($n = 17$) of respondents had served or are serving on their IRBs. A wide range of nursing degree requirements to serve on the IRB were reported, from BSN to PhD. Several respondents (28%; $n = 11$) were not sure of nursing degree requirements to serve on the IRB affiliated with their children's hospital.

In addition to the IRB, more than half of respondents (54%; $n = 21$) reported that nurse scientists are required to have approval from an NRC for their research studies. These 21 respondents reported that an NRC is required to review and/or approve IRB applications from nurse scientists and other nurses either before IRB submission (86%; 18/21) or concurrent with submission (14%; 3/21). Others reported that their children's hospitals have an NRC only for research led by non-doctorally prepared nurses (18%; 7/39).

Discussion

Nurses with a Doctor of Philosophy (PhD) degree serve essential roles as nurse scientists. As PIs of research studies, these highly qualified nurses are positioned to partner with clinical nurses and multidisciplinary teams to improve the health and well-being of individuals, communities, and populations. Importantly, consistent with the aforementioned DHHS, FDA, and AHHRP guidance and Magnet® standards, clinical nurses educated at the baccalaureate degree level or higher may be qualified to be PIs on research studies provided the appropriate training, support, and mentoring are available.

An expert committee strongly recommended empowering nurses to lead systemic change to achieve health equity (National Academies of Science, Engineering, and Medicine, 2021). A key recommendation was to remove barriers that prevent nurses from reaching the full extent of their scope of practice. For nurse scientists, this means removal of barriers that prevent them from conducting research; however, results from our survey of NPNSC pediatric nurse scientists highlight restrictions that limit the ability of clinical nurses and nurse scientists to conduct research. Of particular concern is the finding that some institutions and IRBs deny nurses and nurse scientists PI status based solely on educational degree level or require supervision to conduct research to advance nursing science. A nurse scientist who developed the study and is responsible for study oversight should be recognized and take full accountability for the research as the PI on the study.

Our survey findings corroborate previously identified variability in the qualifications for a nurse to serve as PI of a research study (McLaughlin et al., 2013). While our survey revealed that nurses at most children's hospitals could serve as PI on a research study, the minimum education to serve in the PI role ranged from no requirement, to a graduate degree, or PhD. Most children's hospitals fulfilled the Magnet® requirement of nurse participation on their IRB.

A lack of accepted criteria for the qualifications and competencies for the PI role has likely contributed to high variability in how institutions and IRBs operationalize the PI role for nurse scientists, clinical nurses, and other researchers. For some survey respondents, oversight requirements specific to nurses in their institutions may hinder nurses' conduct of research and advancement of nursing knowledge. Further investigation of the impact of potential barriers to research led by nurses, including clinical nurses who provide direct patient care, as well as other healthcare professionals, is essential to generating new knowledge that can directly improve patient care.

In addition to limitations on PI status for nurses, our survey found that there are some additional requirements for nurse researchers. Most children's hospitals provided some supplementary oversight of nursing research, either in the form of an NRC or the requirement for a clinical nurse to have a nurse scientist or other doctorally prepared research mentor. Clinical and academic institutions typically require two types of approval for human subjects research, scientific review and

IRB approval. However, our respondents reported that many institutions require nurse-led studies to have an additional approval from an NRC. While NRC approval may be the only scientific peer review at some children's hospitals, for other hospitals, this is a third approval requirement beyond scientific and IRB approval. It is unclear if other disciplines require additional discipline-specific approval to conduct research. While scientific peer review is critical for research rigor, an additional required discipline-specific scientific review may present a significant barrier for nurses who spend the majority of their time providing direct patient care. Hospitals must recognize the substantial time required for clinical nurses and nurse scientists to obtain pre-IRB review and/or approval.

There were several limitations of the NPNSC survey, including the use of a convenience sample of NPNSC members who are predominantly affiliated with Magnet® designated children's hospitals. As reported in the survey results, hospitals with Magnet® designation are more likely to have an NRC that reviews and approves research proposals and are less likely to require an academic appointment for nurses to serve as PIs (McLaughlin et al., 2013). While developed by recognized experts in nursing science, the survey was created to provide a snapshot of what the NPNSC members were experiencing and was not extensively pilot tested or validated prior to its use. In addition, in a few cases, responses were provided by multiple nurse scientists affiliated with the same hospital, and some of these responses conflicted. Respondents were provided the option to remain anonymous and not identify their affiliated children's hospital, further investigation of these discrepancies was limited.

Recommendation

Given that federal regulations recommend PI qualifications be defined by investigators' education, training, and experience, interpretation of these regulations and other guidelines can be standardized. Interpretation should reflect individual hospital resources for safe human subjects' protections and rigorous scientific and clinical inquiry. IRBs should ensure that nurses are able to serve as PIs for research studies and that IRB policies are consistent with federal regulations and other interpreted guidelines. Hospitals that uniformly restrict PI status to physicians or faculty at academic affiliates are not following federal regulations; the resulting lack in nurse-led research studies is perpetuating knowledge gaps and contributing to inequities in health, access to healthcare, and healthcare outcomes.

Hospital-based NRCs should clarify the process for scientific review for nurse-led research and ensure that it is focused on the quality of the science. Given the challenges to PI status for nurses as addressed here, future work should focus on a national dialogue to develop standardized criteria for PI status within healthcare institutions and across IRBs (Table 2).

Table 2
Proposed questions for ongoing dialogue focused on nurses serving as PIs for human subjects research.

- What is the minimum training necessary to facilitate success as a PI?
- Should minimum training to act as a PI depend upon study design, i.e. different requirements for descriptive versus interventional research?
- Does education/degree sufficiently differentiate individuals adequately prepared to act as PI and those who are not?
- Are disparities present across healthcare disciplines as far as ability to act as PI, approval requirements, and access to research resources?
- Are systemic barriers present for nurses to conduct research in healthcare delivery settings?
- What institutional structures and processes promote nurses' conduct of research?
- In institutions that require a research mentor for nurses, to what extent does this requirement impact the quality and rigor of the research conducted? How do mentors contribute to the science and provide oversight?
- How do criteria defined by the Magnet® Recognition Program align with institutional practices and policies regarding nursing research in healthcare institutions?

Conclusion

The COVID-19 pandemic has highlighted the need to strengthen support for nurses to contribute to the health and well-being of the nation to a much wider audience. Removal of practice barriers for nursing is central to the transformation of healthcare in the U.S. This includes empowering all nurses to address research questions that have the potential to improve patient care. However, there remains a great deal of ambiguity around the research process in children's hospitals, including educational requirements for nurses to serve as PIs on research studies, barriers to nurses leading research in a PI role, and the need for additional NRC approval. Addressing these issues in a standardized fashion will ensure all patients benefit from robust nursing research and receive the best evidence-based care.

Declarations of interest

None.

CRediT authorship contribution statement

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Acknowledgments

The authors would like to thank the National Pediatric Nurse Scientist Collaborative (NPNSC) and its members who participated in and supported this work. Thank you to the editorial support by Stacey C. Tobin, PhD.

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