

Network News

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Expert Perspective

IRB Issues in QI Research

Research is defined in the Code of Federal Regulations (CFR) as systematic investigation, including research development, testing and evaluation, designed to contribute to generalizable knowledge. Oversight of this definition is assigned to the Office for Human Research Protection (OHRP). OHRP provides leadership in the protection of the rights, welfare, and wellbeing of subjects involved in research conducted or supported by the U.S. Department of Health and Human Services (HHS).



“The challenge for us and regulatory boards is to ask the key questions when we examine our studies to determine whether we go to IRB.”

CHRISTINE A. GOESCHEL, SCD, MPA, MPS, RN, FAAN, DIRECTOR OF STRATEGIC DEVELOPMENT AND RESEARCH INITIATIVES AT THE JOHNS HOPKINS ARMSTRONG INSTITUTE FOR PATIENT SAFETY AND QUALITY

“It is crucially important to understand this purpose statement of OHRP’s

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National Leaders Set to Speak at Summit



This year marks the third Improvement Science Summit hosted by the Improvement Science Research Network in San Antonio, TX. A new, exciting change this year involves the combination of the *Summer Institute on Evidence-Based Practice*, hosted by the Academic Center for Evidence-Based Practice, and the *Improvement Science Summit* to form the *Summer Institutes on Evidence-Based Quality Improvement*. The Summit is a sharply focused research methods conference that brings together practice and academic leaders in improvement science to forge partnerships in pursuit of healthcare quality improvement.

National nursing education leader and ISRN Steering Council member Patricia Benner, RN, PhD, FAAN, will kick off the third Improvement Science Summit with a keynote focused on how improvement science can help guide the transformation of the U.S. healthcare

system. Following Dr. Benner are a number of national leaders in research methodologies including Michael L. Parchman, MD, MPH, FAAFP, Director of the MacColl Center for Healthcare Innovations; Jack Needleman, PhD, FAAN, ISRN Steering Council member and Associate Director of the UCLA Patient

Safety Institute; Kieron Dey, statistical expert on orthogonal design; and John Øvretveit, BSc (Hons), MPhil, PhD, CPsychol, CSci, MIHM, international improvement intervention evaluator and ISRN Steering Council member.

Speakers will discuss factors that contribute to success in conducting national multi-site improvement studies. Stephen C. Hines, PhD, Vice President for Research at the American Hospital Association will discuss the importance of multi-site quality improvement research for determining scalability and spread of successful improvement interventions. Panelists from the first ISRN Network Study will share findings and lessons they learned in conducting the 15-site project on frontline engagement and quality improvement. This panel will also include the Network PIs and members of the research collaborative who will

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Expert Perspective

authority but also to understand that for studies that transcend the bounds of this authority, we may need to go beyond OHRP for guidance” says Christine A. Goeschel, ScD, MPA, MPS, RN, FAAN, Director of Patient Safety and Quality Initiatives and Manager of Operations at The Johns Hopkins University Quality and Safety Research Group. The interpretation of the CFR’s definition is one of the challenges that affect regulatory boards in determining whether what we do, as improvement science researchers, is subject to Institutional Review Board (IRB) review. Dr. Goeschel continues; “The challenge for us and regulatory boards is to ask the key questions when we examine our studies to determine whether we go to IRB.”

IRB Checklist

If you check any of the boxes below, then your study will require IRB review.

- Does the activity involve research? (45 CFR 46.102(d))
- Does the research activity involve human subjects? (45 CFR 46.102(f))
- Does the human subjects research qualify for an exemption? (45 CFR 46.101(b))
- Is the non-exempt human subjects research conducted or supported by HHS or otherwise covered by applicable FWA approved by OHRP?

Dr. Goeschel’s recent ISRN web seminar on this topic entitled “Quality Improvement vs. Research: Regulatory Issues in Improvement Science” adds further detail to this important issue. To view this and other ISRN presentations, visit www.ISRN.net/events. 

National Leaders Set to Speak at Summit

Featured Speakers



PATRICIA BENNER, RN, PHD, FAAN
KEYNOTE: Improvement Science and the Future of Healthcare Transformation



MICHAEL L. PARCHMAN, MD, MPH, FAFAP
How Complexity Science Can Inform a Reflective Process: MAP/RAP in Action



JACK NEEDLEMAN, PHD, FAAN
Stepped-Wedge Design: From Principle to Clinical Practice

share their experiences with the process and procedures that made their collaboration successful. Dr. Needleman will summarize the panel by discussing implications of this landmark study on future frontline research. The program will describe the next frontier for ISRN Network Studies. Presentations will outline the next Network Studies and invite collaboration for investigating (a) Team Performance and (b) Coordination and Transitions of Care.

An exciting Student Program has been added. Students from all healthcare disciplines and across all educational levels will have special sessions designed specifically around their interests. The Student Program includes: meeting with experts in the field of Improvement Science in a roundtable format to discuss topics pertinent to improvement science education and student poster presentations moderated by experts in the field. All Summit attendees are encouraged to attend the poster discussion session.

The 2012 Improvement Science Summit will carry forward the successes of Summits

past. For an overview with detailed descriptions of each session and to register, visit www.ISRN.net and download the program brochure.

The cost for the 2012 Improvement Science Summit will be \$310 for professionals. For students, the registration rates are highly subsidized at \$180 which also includes membership to the ISRN. Continuing Education (CE) credits are granted for nursing; other health professionals may request CE credits from their own accrediting bodies.

Visit www.ISRN.net for up-to-date information on the Summit and to register for the conference. 



Research Resources: IRB Issues in QI Research

To learn more about IRB Issues in QI Research, consult the following references:

- Protection of Human Subjects, 46 C. F. R. pt. 46 (2005). Retrieved from <http://ohsr.od.nih.gov/guidelines/45cfr46.html>
- Kass, N., Pronovost, P.J., Sugarman, J., Goeschel, C.A., Lubomski, L.H. & Faden, R. (2008). Controversy and quality improvement: Lingering questions about ethics, oversight, and patient safety research. *Joint Commission Journal on Quality and Patient Safety Forum*, 34(6),349-353.
- Borrer, K.C. (2007 July 19). Human research protections under federal-wide assurances FWA-5752, FWA-287, AND FWA-3834 [letter]. Rockville, MD: Office for Human Research Protections. Retrieved from http://www.hhs.gov/ohrp/detrm_lettrs/YR07/jul07d.pdf. 

Coordination and Transitions of Care

“A high level of hospital readmissions has not improved much over the past five years and a study investigating safer care transitions will address a huge need in the clinical setting.”

VIVIAN LOW, MPH,BSN, RN-BC, MANAGER, CARDIOVASCULAR PULMONARY WELLNESS CENTER EL CAMINO HOSPITAL, ISRN STEERING COUNCIL MEMBER

The rising incidence of preventable adverse events has become a national concern spurring initiatives to improve care coordination. The Centers for Medicare and Medicaid Services have set a goal to decrease preventable hospital readmissions by 20% through their Partnership for Patients initiative. In response to this national momentum, the fourth ISRN landmark network study will focus on coordination and transitions of care.

The movement of patients from one healthcare provider or setting to another is a complex process that can involve hospitals, ambulatory clinics, home care agencies, community service providers, and rehabilitation centers. Healthcare delivery teams that span distance, facilities, and disciplines increase the opportunity for errors to occur due to fragmentation and a lack of collaboration. For example, poor coordination between providers can foster poor communication that results in medication errors or early readmission. Thus, a study focusing on care transitions and care coordination is a high priority for the ISRN and has the support of the Network’s stakeholders.

Vivian Low, MPH, BSN, RN-BC, Manager,

Cardiovascular Pulmonary Wellness Center El Camino Hospital, and ISRN Steering Council Member, stated that transitions of care is an important topic to address for its relevance to Magnet Accreditation and professional practice models of patient care that show accountability across the continuum. The rise of initiatives to decrease hospital readmissions and promote safer hand-offs in patient care is a reflection of the evidence-based work that is ongoing. “A high level of hospital readmissions has not improved much over the past five years and a study investigating safer care transitions will address a huge need in the clinical setting,” said Low.

The ISRN has begun to formulate and develop the investigative team. A Principal Investigator (PI) will be chosen to lead the team on this important topic in improvement science. The PI will leverage ISRN members and resources to develop a research question on coordination and transitions of care. “We have an aggressive timeline to develop this fourth network study,” says Darpan Patel, PhD, Clinical Research Project Manager for the ISRN. “The ISRN will discuss details on the Coordination and Transitions of Care Network Study at the Improvement Science Summit.” Dr. Patel added.

The three other ISRN Priorities have been reviewed in previous *Network News*.

To track the development of this network study, visit www.ISRN.net and engage by attending the Improvement Science Summit in July. 🌟



Team science is growing because of the need to address complex issues related to the quality of healthcare delivery. Evidence shows that investigative teams produce stronger evidence than single Principal Investigators (PIs). Transdisciplinary collaboratives are particularly relevant in the ISRN given that both scientists and clinicians play key roles in improvement research. Responding to this growing trend, the Improvement Science Research Network has developed a guide for *Building Successful Research Collaboratives for Healthcare Improvement*. This evidence-based guide is a resource for those interested in team-based improvement research. The guide describes the factors that lead to successful collaboratives, with guidance on overcoming potential barriers.

The guide *Building Successful Research Collaboratives for Healthcare Improvement* will be available for purchase at the Improvement Science Summit from July 17-18, 2012 and online at www.ISRN.net beginning August 1st. A brief excerpt of the guide can be found on the ISRN website at www.ISRN.net. 🌟

Research Priorities

To focus and speed the work of testing improvement strategies, national consensus on Research Priorities was set. Priorities were based on environmental scans, literature reviews, major health care organizations’ priorities, and a survey of stakeholders. The Research Priorities reflect consensus on the most important and urgent gaps in improvement knowledge, according to clinical and academic scholars, leaders, and change agents in acute health care settings. The priorities inform decisions about the scope and dissemination of the work of the Improvement Science Research Network. “By adding a Network Study on improving Coordination of Care, the ISRN is fulfilling a commitment to produce the priority knowledge to improve and transform healthcare.” says Kathleen R. Stevens, RN, EdD, MSN, ANEF, FAAN, and ISRN Director.

To learn more about the ISRN Research Priorities visit www.ISRN.net/research 🌟

A Virtual Collaboratory for Student Research and Improvement Projects

Increasingly, today's students are expected to engage in improvement studies as part of their master's or doctoral programs. Such studies may require support and resources not readily available to the student. Challenges related to design, implementation, data collection, analysis, and interpretation of results can act as barriers in improvement studies. The ISRN provides key resources to aid student research through a unique infrastructure that supports transdisciplinary and virtual collaboration across multiple sites. This infrastructure includes the ISRN Coordinating Center, a virtual collaboratory, and the ISRN nationally developed stakeholder research priorities. Students can take advantage of these resources to increase the feasibility and impact of their research.

The ISRN Coordinating Center can assist students with coordination, communication, and implementation of quality improvement studies across multiple hospitals. Support services available from the Coordinating Center include: consultation on research design, development of a protocol implementation kit to assure high fidelity of project implementation across multiple sites, database creation and management, regulatory compliance guidance, technical support, operational oversight, assistance with data analysis/interpretation, and dissemination of research findings.

In tandem with the Coordinating Center, the ISRN also provides students with a

virtual collaboratory, or center without walls, that allows a team of scientists and academic-practice partners to work together regardless of physical location. The collaboratory fosters the formation of investigative teams allowing students to identify mentors and address complex problems that would otherwise be difficult to accomplish as a single researcher.

Finally, the ISRN Research Priorities provide a framework to help students identify topics for their research projects. These Research Priorities create a research agenda consisting of four broad categories that highlight the most important and urgent gaps in improvement knowledge as identified by clinical and academic scholars, leaders, and change agents in acute healthcare settings. Priority topics include: coordination and transitions of care, high performing clinical systems, microsystems approaches to improvement, evidence-based quality improvement and best practice, and learning organizations and culture of quality and safety. Using these priorities, students can conduct high impact studies at a national landmark level to advance the field of improvement science and ultimately improve patient outcomes.

If you are interested in joining the ISRN as a student member and would like to use this exciting national laboratory for your research project, please contact us at ImprovementScienceResearch@isrn.net. The ISRN science team is eager to facilitate student research! 🌟

Eileen Breslin, PhD, RN, FAAN, elected President-Elect of AACN



We are excited to announce that Eileen Breslin, PhD, RN, FAAN, Dean of the School of Nursing at the University of Texas Health Science Center San Antonio, has been elected as the president-elect of the American Association of Colleges of Nursing (AACN), the premiere association for nurses involved in academia. Dean Breslin assumed her new role March 27, 2012 at the conclusion of the association's annual meeting in Washington, D.C. Dean Breslin has been a catalyst in the successes of the Improvement Science Research Network and the Academic Center for Evidence-Based

Practice within the School of Nursing at the UT Health Science Center at San Antonio. We are energized to have Dean Breslin in this leadership position with AACN. 🌟

Web Events Update

Case Study: "Improving Our Work IS Our Work"

Wednesday, August 29, 2012

2:00 pm EST

Join us for this webinar as we explore case studies in *Improving Our Work IS Our Work: Creating a Climate for Improvement*. This webinar builds on a previous webinar presented by Cathy Rick, RN, NEA-BC, FACHE and Roxanne Rusch, RN, BSN, MPA.

Systems Engineering Impact on Healthcare Delivery

Wednesday, November 14, 2012

2:00 pm EST

The need for dramatic improvement in the healthcare delivery system is critical. In 2011, the Agency for Healthcare Research and Quality published the report "Industrial and Systems Engineering and Health Care: Critical Areas of Research" which articulated a vision for an ideal healthcare delivery system utilizing systems engineering principles. Join the ISRN for this web event to explore the impact of systems engineering on healthcare delivery.

For details, registration, and past events, visit the ISRN web site www.ISRN.net/events 🌟



KATHLEEN R. STEVENS, RN,
EdD, MSN, ANEF, FAAN, ISRN
PRINCIPAL INVESTIGATOR

Note FROM THE DIRECTOR

Call for Member-Led Network Studies

Each *Network News* gives me the opportunity to announce the next ‘big thing’ at ISRN: Our next major milestone is to take on the first Member-Led Network Study!

The ISRN is up and running, ready for MEMBERS to use it as a “laboratory,” a test bed for conducting landmark studies. Together, we have built a collaboratory in which large, rigorous studies can be conducted. Major milestones over the 2-year building phase were achieved through your encouragement and guidance in development of the Network cyber infrastructure, operating procedures, and ISRN website features such as the eReading Room and eLearning Room. A major milestone was achieved in September 2011: We began to “test fly” a research project—the STAR-2 project on Frontline Engagement in Quality Improvement—to see how well our laboratory worked. And, it did! And, it does.

As the Network PI for the first study, I can proudly say that the ISRN performed amazingly well. Your study can enjoy the same success as reflected in the first Network Study: a highly collaborative investigative team of over 30 members across 14 hospital sites was convened; web seminars launched the study; the complete protocol implementation kit was developed to guide high-fidelity in implementing the master research plan; and collected data from over 6,000 shifts. The implementation of the study was smooth. Attesting to the deft guidance from the ISRN Coordinating Center, all 14 sites gained IRB approvals quickly! Study reports will be given at the 2012 Improvement Science Summit...less than a year after the study was launched.

I am happy to say that the ISRN is ready for YOUR research. Launch your own multi-site improvement study to answer your most urgent research questions! The ISRN is eager to help you fast track your study.

For more information and next steps visit us at www.ISRN.net. 🌟

ISRN Member Spotlight



HEATHER TUBBS COOLEY, PHD, RN, ASSISTANT PROFESSOR AND NURSE SCIENTIST, DEPARTMENT OF PATIENT SERVICES (CINCINNATI CHILDREN’S HOSPITAL MEDICAL CENTER), QUALITY SCHOLAR, JAMES M. ANDERSON CENTER FOR HEALTH SYSTEMS EXCELLENCE (CINCINNATI CHILDREN’S HOSPITAL MEDICAL CENTER), ASSISTANT PROFESSOR OF CLINICAL NURSING, UNIVERSITY OF CINCINNATI COLLEGE OF NURSING

“My experience with STAR-2 is invaluable because of what I am learning,” says Heather Tubbs Cooley, STAR-2 Site PI. Dr. Tubbs Cooley joined the ISRN because of the research opportunities that are available to members. “The STAR-2 Study has been very interesting for me in a number of ways. The first is being a site PI. Almost everything that I have done previous to this study was secondary data analysis, so this is the first time I am enrolling human subjects into a research study. Also, I currently don’t work clinically at Cincinnati Children’s Hospital, so STAR-2 has reinforced the importance of having collaborative relationships with managers and clinicians. It is critical to have those personal relationships to understand what is occurring at the front lines of care delivery.” Dr. Tubbs Cooley is currently in her second year of a post-doctoral fellowship at Cincinnati Children’s Hospital Medical Center called the Quality Scholars Program in Healthcare Transformation, which focuses on improvement science methodology and implementation. “My research focuses on the interactions between the organization of nursing care within hospitals and the real-time delivery of patient care, both of which likely influence patient outcomes. The Quality Scholars Program has enabled me to incorporate a systems-level intervention focus into my work, which I previously did not have the skills to do.” 🌟



SONYA R. OSBORNE RN, PHD, MRCNA MACORN, SENIOR LECTURER, SCHOOL OF NURSING, FACULTY OF HEALTH, QUEENSLAND UNIVERSITY OF TECHNOLOGY, AUSTRALIA
Sonya R. Osborne joined the ISRN

Coordinating Center for six weeks as an international visiting scholar. “The advantage to me, as a researcher in the early stages of my post-doctoral career, is that I was immersed in a nationally funded research

center that focuses on evidence-based practice and the science of improving patient outcomes. It was advantageous to be immersed in the workings of ACE to understand the development and support of the ISRN. The experiential approach to learning about the ISRN helps to enhance my knowledge and skills in the area of developing successful research collaborations.”

“My clinical specialty is perioperative nursing and my research interests include evidence-based practice and the efficiency and effectiveness of translating and implementing best evidence into practice,” says Dr. Osborne. “I want to develop a research program where evidence-based practice is integrated into and sustained in perioperative nursing practice and I think where these intersect strongly is in the area of patient safety and improving patient outcomes. Improvement Science is the natural extension of this program...”

As a part of her experience at the ISRN, Dr. Osborne was actively involved in a number of operational aspects of the center. Dr. Osborne contributed to the development of a learning module about Team Science and Research Collaboration, compiled resources for the Compendium of Research Instruments, and added to the annotated bibliography database in the eReading Room. 🌟

Med Errors Landmark Study Gets IRB Approval

The second ISRN Network Study, *The Impact of Cognitive Load, Interruptions, and Distractions on Procedural Failures and Medication Administration Errors* protocol received IRB approval in February and will launch at this year's Improvement Science Summit in July. The ISRN Coordinating Center is working closely with the two study PIs, Lily Thomas, PhD, RN and Patricia Donohue-Porter, PhD, RN, to develop the Protocol Implementation Kit. "I am excited about this study, specifically for the opportunity to understand how factors such as cognitive load and an interruption driven work environment culminate in errors; this will also enable us to create multi-prong interventions effective in preventing medication administration errors," said Lily Thomas PhD, RN, Vice President, System Nursing Research at North Shore Long Island Jewish Health System, Network Study PI, and ISRN Steering Council member.

According to the Institute of Medicine, medication errors are among the most common medical errors occurring in hospitals, harming at least 1.5 million people every year. Thus, there is a need for rigorous scientific studies on medication errors. This national, multisite study

addresses this need by investigating the complexity of nursing workload and its effects on the delivery of care. The first phase of this study begins with a descriptive-correlational phase to identify and describe the relationship between interruptions, distractions, and the medication administration process. Results from this study will lead to the development of a generalizable intervention that will help prevent medication errors across the national healthcare system.

"This Network Study attests to the power of the ISRN to conduct improvement research. It contains all the 'right stuff': Co-PIs representing academic-practice scientific partnership, alignment with ISRN priorities, and a rigorous study to produce conclusive results." says Dr. Kathleen R. Stevens, RN, EdD, MSN, ANEF, FAAN, and ISRN Director. A meeting of the Med Errors research collaborative members will be held at the Improvement Science Summit.

To learn more about this collaborative or inquire about future studies contact the ISRN at: ImprovementScienceResearch@isrn.net or 210-567-1480. 🌟

How to get Involved

Become a member of the ISRN, the first national collaboration of clinical and academic leaders devoted to accelerating improvement science in a systems context across multiple hospital sites. Benefits include the following:

- Opportunities to participate in multisite collaborations on patient safety and quality improvement research initiatives;
- Access to members-only ISRN online resources;
- Leverage of a national test bed for evaluating improvement strategies;
- Training resources such as IRB training;
- Expert guidance in conducting research;
- Technology infrastructure for participating in multisite studies;
- Access to the ISRN web portal, which provides secure communication, storage, and sharing of documents and data;
- A technical support system that provides access to expert guidance in conducting research and using statistics; and
- Recognition as an ISRN member and use of the ISRN logo on presentations and publications.

To become a member of the ISRN visit: www.ISRN.net and click on "Join Us." 🌟

JOIN US

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Network News

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