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Authors

Gustavson, Allison

Drake, Cynthia

Lakin, Alison

et al.

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Conducting Clinical Research in Post-Acute and Long-Term Nursing Home Care Settings: Regulatory Challenges

Allison M. Gustavson, PT, DPT[1], **Cynthia Drake, MA**[2], **Alison Lakin, RN, LLB, LLM, PhD**[3], **Andrea E. Daddato, MS**[4], **Jason R. Falvey, PT, DPT, GCS**[1], **Warren Capell, MD**[5], **Hillary D. Lum, MD, PhD**[4,6], **Christine D. Jones, MD, MS**[7], **Kathleen T. Unroe, MD, MHA**[8], **Gail L. Towsley, PhD, NHA**[9], **Jennifer E. Stevens-Lapsley, MPT, PhD**[1,6], **Cari R. Levy, PhD, CMD**[10], **Rebecca S. Boxer, MD, MS**[4,6], **The PACRATS Investigators**[11]

[1]Physical Therapy Program, Department of Physical Medicine and Rehabilitation, University of Colorado, Aurora, CO, USA

[2]Colorado School of Public Health, University of Colorado, Aurora, CO, USA

[3]Colorado Multi-Institutional Review Board (COMIRB), University of Colorado School of Medicine, Aurora, CO, USA

[4]Division of Geriatric Medicine, Department of Medicine, University of Colorado, Aurora, CO, USA

[5]Department of Medicine, University of Colorado, Aurora, CO, USA

[6]Veterans Affairs Geriatric Research, Education and Clinical Center, Aurora, CO

[7]Division of Hospital Medicine, University of Colorado, Aurora, CO, USA

[8]Indiana University School of Medicine, Indianapolis, IN, USA

[9]University of Utah, College of Nursing, Salt Lake City, UT, USA

[10]Rocky Mountain Regional Medical Center, Aurora, CO, USA

[11]Program of Post-Acute and Long-Term Care, School of Medicine, University of Colorado, Aurora, CO, USA

Abstract

Despite multiple initiatives in post-acute and long-term nursing home care settings (NHs) to improve the quality of care while reducing healthcare costs, research in NHs can prove challenging. Extensive regulation for both research and NHs is designed to protect a highly vulnerable population but can be a deterrent to conducting research. This paper outlines regulatory challenges faced by NHs and researchers, such as protecting resident privacy as well as health

Corresponding Author: Rebecca S. Boxer, MD, MS, University of Colorado, 12631 E. 17th Ave, Rm 8111, Aurora CO, 80045 Office: (303) 724-1922, Rebecca.Boxer@ucdenver.edu.

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information and obtaining informed consent. The paper provides lessons learned to help form mutually-beneficial partnerships between researchers and NHs to conduct studies that grow and advance NH research initiatives and clinical care.

Brief Summary:

Research in nursing homes is challenging despite the need to improve cost-effective patient outcomes. This paper outlines regulatory challenges and lessons learned pertaining to resident privacy, health information, and consent.

Keywords

post-acute care; long-term care; research regulation; nursing homes

Introduction

Conducting research in nursing home care settings (NHs) is fraught with challenges due the regulatory oversight needed to ensure protection of a caregiver-dependent, frail population. However, research in NHs is needed to inform best practices, improve outcomes, and reduce costs--all of which align with the goals of the NH industry and researchers alike. “Nursing home” refers to certified skilled nursing facilities that provide post-acute and long-term care. Patients in NHs have different goals, needs, and payment sources depending on whether they require rehabilitation following a hospitalization versus long-term, custodial care.

Even when researchers and NH leaders have the best intentions for collaboration, confusion regarding the regulatory landscape can thwart research initiatives. The authors formed the Post-Acute Care Research and Team Science (PACRATS) group at the University of Colorado to collaborate and further advance NH research. This paper describes common challenges we faced, and solutions used in successfully conducted NH research. This paper is organized into three sections addressing regulatory challenges surrounding 1) NH engagement in research, 2) the security of health information, and 3) informed consent. Our aim is to expand upon previous literature that describes challenges to research in NHs[1–6] and provide lessons learned when navigating the regulatory aspects of NH research.

Regulatory Challenge: Determining NH Engagement in Research

An important initial step and key regulatory challenge to NH research is determining whether NHs will be “engaged” in the research. Engagement in research is an important term that is context-dependent. *Community engagment* in research is a process involving stakeholders to jointly address issues relevant to a community through participation in research.[7] *Community engagement* improves commitment from leadership and staff and promotes feasibility of research protocols. On the other hand, NHs are considered *engaged* in human subjects research from a regulatory definition when NH employees interact with subjects for research purposes or are involved in obtaining informed consent from residents.[8]

Regulatory “engagement” can create barriers to involving NH staff in a research project. Institutional Review Boards (IRBs) from institutions that voluntarily apply federal

regulations to all research may require extra regulatory steps for the NHs, such as requiring the NH to enter into a reliance agreement with the researcher's IRB,[9–11] and having the engaged NH employees undergo human subjects protections training. If so, such engagement may increase NH staff time, which is usually not protected for full engagement in the research process.[12] NHs "engaged" in research at a facility level may also have undue influence over NH staff who feel pressured to participate even when research is beyond their scope of work. Clear expectations and requirements for staff need to be outlined in advance, with open lines of communication between study and NH leaders, to allow for dialogue if staff members develop concerns about balancing patient care and research needs.

For researchers external to the NH system, defining the NH's engagement in research has implications for the study design (e.g., using NH employees or research personnel to administer an intervention), funding for time (e.g., funding for NHs to protect time for research or hiring additional research personnel), and future scalability of the research intervention (e.g., including NHs in the study design and evaluating implementation). Negotiating the best way to operationalize engagement in a research study between the NH and research team can be challenging to discuss without both parties having a clear understanding of the regulatory framework and participation expectations.

Regulatory Challenge: Protecting Security of Health Information

Research conducted in NHs requires access to sensitive protected health information (PHI), which entails a delicate balance between adhering to clinical privacy regulations while complying with distinctly different regulations related to human subject research. The two concurrent challenges pose significant issues for researchers regarding recruitment for both prospective and retrospective studies.[13] The Health Insurance Portability and Accountability Act (HIPAA)[9] protects a resident's privacy by requiring a resident's authorization for certain uses of his or her PHI that are unrelated to clinical care, such as research.[14] For some studies, the largest risk for the resident is disclosure of sensitive PHI such as psychiatric diagnoses or psychotropic medication use. Therefore, to ensure resident protection it is critical for the participant or surrogate to be informed of the PHI collected and how it will be protected.

HIPAA Privacy Rule Implications for NHs

NHs qualify as "covered entities" under the HIPAA Privacy Regulation,[15] and must remain in compliance with the Privacy Rule, which stipulates NHs may use or disclose PHI for research under specific conditions.[16] However, NHs may be reluctant to allow researchers to access PHI as penalties for HIPAA violations can be severe.[17] Consequently, NHs have established strict policies and procedures to protect the privacy of their residents' data, that may not consider the exceptions provided within the Privacy Rule to facilitate research. Fear of penalties is further exacerbated by the reality that NHs typically do not have their own Privacy Board or IRB to approve the use of these exceptions. The lack of an IRB or close ties with a research institution leaves NHs vulnerable without the infrastructure to systematically review research and determine whether it complies with privacy regulations.

Navigating HIPAA Privacy Rules in Research

Since research is not exempt from the HIPAA regulation, external researchers cannot directly access identifiable health information. This restriction creates barriers to examining research feasibility and recruitment. As such, researchers need residents' authorization prior to gaining access to PHI unless one of the following regulatory exceptions applies.[18]

Preparatory to Research Activities

Prior to conducting NH research, researchers need to determine feasibility. Under the HIPAA Privacy Rule, researchers may review data in medical records to characterize the population, evaluate proposed inclusion and exclusion criteria, and calculate sample size. The researcher must present the following justification to the NH in oral or written form:[19] use or disclosure is requested solely to review PHI as necessary to prepare a research protocol, and PHI will not be removed from the NH during review.[9] Since this preparatory process involves access to identifiable data, any data taken out of the NH must be de-identified or aggregate data.[9,19]

Research Recruitment

Research recruitment is the largest barrier created by HIPAA regulations. External researchers cannot directly approach NH residents, with whom they do not have a clinical relationship, without written authorization from these residents. This written authorization needs to be obtained by a NH employee who has a clinical connection to the resident, again raising the issue of NH resources. Relying on NH personnel who are detached from the research project and who have other clinical priorities can stunt recruitment. Given the barriers to adding NH personnel as *engaged* in research, investigators may consider adding key NH personnel as co-investigators on the research project, thereby avoiding the HIPAA access issues and increasing NH investment.

HIPAA Waiver of Authorization and Practicability

Though access to identifiable health information for research generally requires individual resident HIPAA authorization, the rule allows exceptions through a waiver of authorization (HIPAA waiver) approved by the Privacy Board or IRB.[9] A HIPAA waiver allows researchers to access PHI without first obtaining authorization. The HIPAA waiver increases the ability to recruit study participants by enhancing the timeliness, representativeness, and the impact of the research in a way that would not be feasible if prospective authorization was required. The waiver request must demonstrate minimal risk to resident privacy and present justification for how the research could not be practicably conducted without the waiver.[18] For example, it may not be practicable to have residents provide HIPAA authorization prior to prescreening for recruitment purposes or to gain consent from past or current residents for a retrospective chart review study. A HIPAA Waiver can only be granted by a Privacy Board or an IRB, which is problematic for NHs that do not have such a review board. Researchers usually have such a committee at their institutions that can grant a HIPAA Waiver for the NH, which requires transparent and collaborative communication between NH staff and NH Privacy Officer. The decision to grant a HIPAA waiver is

protocol-specific and solely the responsibility of the Privacy Board or IRB, with permission and understanding from the NH.

Challenge: Informed Consent

Attention to informed consent is an important ethical consideration in NH research to ensure resident protection. NH research involves an inherently vulnerable population who, due to sensory and cognitive impairments, depend on NH staff and are potentially vulnerable to coercion. Furthermore, the ability to understand the risks and benefits of participating in a research study can wax and wane due to impaired decision-making capacity from cognitive impairment or delirium common in NH populations.

Navigating Informed Consent During Research

Under the Code of Federal Regulations for Human Subjects Research (45 CFR 46) or "Common Rule," all human subjects must provide consent to research participation, unless consent can be waived.[9] Informed consent requires the potential participant be able to comprehend information and make an informed choice. The following sections outlines general guidelines to obtaining consent from residents in NHs and rules surrounding waivers of consent (Table 1).

Capacity for Informed Consent

For many residents in NHs, informed consent is complicated by diminished decision-making capacity or the inability to understand research purpose, risks and benefits, and one's role as a participant.[24] Routine cognitive tests do not reliably reflect consent capacity.[25,26] Of note, a large proportion of residents with cognitive impairment have not been declared incompetent.[27] Assessing a resident's ability to understand the research study and his or her specific involvement in the research may be more accurate.[28] One of the best methods for assessing capacity is to have a resident repeat back and explain key concepts about the research to the person conducting the consent process.[28] If potential subjects can verbalize that the activity is research, the reason for the research, risks and benefits, and whether they can leave the research, they are likely capable of making an informed decision.

Sensory limitations prevalent in the NH population, particularly hearing and visual loss, can be confused with or compound cognitive impairment. For cognitive and sensory impairment, working closely with NH staff helps to create an efficient plan to approach appropriate patients.[29] Additionally, to ensure capacity for informed consent is accurately assessed and not masked by sensory impairments, investigators can submit multimedia consent forms, such as audio consent for persons with visual impairments, to the IRB and work with the NH to secure a quiet room to obtain consent.

If the resident is unable to provide informed consent due to impaired decision-making capacity, the research study can be designed to allow for surrogate consent. Surrogate consent can include consent from a legally authorized representative (LAR), an individual or entity that is legally authorized to grant consent on behalf of the individual (Table 2).[29–31] Note that definitions of LAR vary by state.[32] In lieu of participants' ability to provide verbal informed consent, assent is a process for observing research participants' behaviors related

to willingness to participate in study activities.[33] At minimum, any indication of patient dissent to participate should be respected.

Waiver of Consent

In studies where obtaining individual informed consent is impracticable, a waiver of consent can be considered if the research does not pose more than minimal risk to the participants, the research does not adversely affect rights or the welfare of participants, and the research participants will be provided with any additional relevant information.[34] Research interventions involving testing different approaches to clinical care that fall under the NH's current scope of practices may be minimal risk. Often, pragmatic trials involve interventions with minimal risk that do not require consenting individual patients because consent happens at the NH level and not at the individual level.[20] Consider a study randomizing different NHs to use two different approaches to evaluate a specific condition. If the NH agrees to adopt one of the two approaches for research, individual residents would not be able to decline participation if the approaches were considered standard of care. Several studies in non-NH settings have argued that research processes embedded in routine healthcare activities and are minimal risk to the residents do not require informed consent.[21–23] Depending on the interventions studied, investigators may consider informing residents and families either during or after the study.

Addressing Regulatory Challenges: Lessons from the field

Regulatory challenges related to defining engagement in research, HIPAA, and informed consent make it difficult for researchers and NH partners to gain mutual understanding of the processes necessary to succeed in NH research. The work of the Post-Acute Care Research Team Science (PACRATS) group is presented here as an example of lessons learned in NH research. The highly collaborative partnership was developed to help all stakeholders better navigate regulatory challenges to provide more opportunities for high-quality, impactful NH research.[35] The PACRATS is a multi-disciplinary group with extensive research and clinical experience.[36] By identifying and convening the post-acute and long-term care stakeholders, the PACRATS group has facilitated community network of researchers and NHs, research studies, papers, grants, presentations, and dissemination strategies. The PACRATS group supports researchers in NHs by sharing strategies to navigate the regulatory challenges by enhancing transparency and synergy between researchers and NHs (Table 3). The following sections outline strategies shared, modified, and used by PACRATS investigators to alleviate regulatory challenges for research conducted in NHs.

Creating Transparency in Research Conducted in NHs

Transparency between NHs and researchers from the start of collaboration is critical to proactively addressing regulatory challenges and to promoting commitment and trust. An effective way to connect with NHs is to immediately involve national and local leadership, as well as direct-care staff, who possess the knowledge and skills to successfully move research-based initiatives forward. Robust leadership support is a known contributing factor to the success of quality improvement and research initiatives,[37,38] particularly in

unpredictable NH environments that face high staff turnover and frequent ownership changes.[37,39,40] Facilitating staff discussions regarding workflow and conducting an in-service regarding the research study are also important aspects to improve staff "buy-in."

Initial and ongoing conversations on a regular, pre-determined basis with NH partners should be carefully documented to create an audit trail of agreements to ensure transparency and understanding across both parties. Development of a Memorandum of Understanding or Research Data Agreement is often required and beneficial in creating well-documented agreements. Additionally, early conversations to anticipate and determine plans to address NH staff turnover and research personnel changes help to assure research continuity. Early conversations regarding the Privacy Board or IRB processes and research terminology can help alleviate NH concerns regarding protection of residents by allowing NH to ask questions and understand what it means to allow researchers to access NH data. A Research Data Agreement allows researchers to describe exactly how data will be accessed, obtained, shared, and used. Specifically, parties present clear documentation about what is considered proprietary information or sensitive data that may not be publicly known, such as NH staff turnover, which may draw scrutiny from payers or other facilities in the area.[41] Once the research has been approved by a Privacy Board or IRB, providing NHs with stamped documents and protocols further demonstrates transparency in the research process and trust that researchers are doing all possible to ensure resident protection. A Computer Use Agreement is often generated by the NH and is signed by each researcher who uses NH computers or accesses the electronic medical record remotely, often with read-only access. This agreement should also delineate that researchers access only the records of residents who are eligible (pre-screening) or actively participating in the research even if the software system cannot limit access. This is an important point of discussion between the researcher and the NH since most electronic medical record providers cannot offer user-access to only particular individuals.

Creating Synergistic Collaborations between Researchers and NHs

A synergistic relationship built on trust between researchers and NHs is of high value. Researchers often have well-established ideas but require clinical settings and clinician's insights to conduct the research. NHs are under regulatory scrutiny while providing quality resident care and balancing costs.[24] Working with NHs to identify mutually relevant deliverables and allow them to market a research partnership may improve a NH's competitiveness for payer contracts (e.g., Managed Care plans) and hospital preferred-provider status. For example, the Comprehensive Care for Joint Replacement model holds hospitals financially accountable for the cost and quality of care delivered over an episode of care, which may include a post-acute stay.[42] As a result, hospitals are looking for NH partners who demonstrate innovative and effective approaches to care (e.g., fewer re-hospitalizations, return to the community, and low costs). Collaboration with researchers creates market differentiation with partnered NHs, thus making them attractive to become preferred providers. Researchers benefit from use of the NH to conduct real-world research that can be translated faster into clinical care.

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Implications for Practice, Policy, and/or Research.

Research in NHs is challenging given the breadth of regulatory constraints, however NH research is greatly needed to improve resident outcomes and inform policy. Researchers can overcome challenges in defining NH engagement in research, protecting health information, and obtaining informed consent by building relationships with NHs using setting-specific safeguards. Furthermore, creating a multi-stakeholder coalition can increase interest in research by sharing strategies and working together to traverse regulatory issues specific to NHs. Partnerships between researchers and NHs have the potential to create a culture of research and adoption of evidence-based practices that extends beyond the length of a research study.

Table 1.

Capacity and Informed Consent for Residents in Nursing Homes

Terms	IRB Guidance	Practical Considerations and Lessons Learned
Issues of Capacity: Sensory Impairment and Decisionally-Challenged Persons		
Capacity: "Ability to understand information relevant to making an informed, voluntary decision to participate in research.[33]"		• Anticipate different multimedia consent forms needed based on target population characteristics before submitting to IRB • Consider using multimedia for consent (e.g., videos, interactive computer programs) • Partner with nursing home staff such as social workers, activity directors, and nurses to plan for approach and timing when recruiting patients participants[18] • Work with nursing home facility to prepare a quiet room for the consenting process • Allow for extra time to complete the consenting process • Assess capacity using the repeat-back method[18] • If capacity is diminished, request consent from a legally authorized surrogate[18] • Consider the research intervention as a new, but different, standard of care to qualify for a waiver of consent[22–24]
Sensory Impairment:	For residents with hearing impairment who can read and write the consent process is followed the same as for those residents without hearing impairment. Allow participants to read IRB approved documentation and sign consent forms.[34] For residents with visual impairment, use an audio recorded version of the consent form.[34] If able to do so, resident should sign and date the consent form (some states require minimal physical marking, such as an "X" but regulation varies by state), or a PI may request a waiver of consent. Participants are given a copy of the signed consent, as well as the Research Participants Bill of Rights, if required by the IRB.[34]	
Categories of Decisionally-Challenged Persons: Altered decisional capacity, incompetent to consent, or cognitively-impaired.		
Altered Decisional Capacity: An individual has decision-making capacity but is temporarily unable to due to external factors.[35]	A potential participant must be able to discuss the research protocol, remember it, weigh risks and benefits, and understand the consequences of participation. This ability can be altered by many external factors including high stress, medical illness, and limited time to learn and understand the protocol.	
Incompetence: Unable to be independent in handling one's own affairs. Also commonly called "incapacity"[35]	Of note: "All adults (including those with cognitive impairments) are presumed competent to consent unless legally judged to be incompetent."[36] To consent adults with proven incompetence, investigators must obtain informed consent from surrogate decision-makers (below).	
Cognitive Impairment (e.g. Dementia): A condition—psychiatric, developmental disorder, or impairment—preventing or diminishing one's ability to make reasonable and sound judgements. [35]	Even with a cognitive impairment, a resident may still have the capacity to consent. Capacity is defined as the ability to understand the protocol, the risks and benefits, one's role as a participant, and express their choice to participate.[37]	
Older Patients With Multiple Comorbid Diseases	Informed consent forms not only to legally protect investigators and their affiliated entities, but also to	

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Terms	IRB Guidance	Practical Considerations and Lessons Learned
	improve comprehension by older adults with multiple comorbid diseases.[38]	

Table 2.

Surrogate or Proxy Consent (terminology and restrictions vary by state)

Definition:	Recommendations for researchers:
Legally authorized representative (LAR): Per the Common Rule, an LAR is an individual or body authorized under applicable law to consent on behalf of a prospective subject to participate in the procedure(s) involved in the research. • In the case of diminished capacity in consenting a NH resident, researchers must gain consent from a legally authorized representative (LAR), with the assent from the participant. * • The LAR undergoes the same informed consent process, as would a potential participant. Examples of a LAR include a legal guardian, health care agents, surrogates.[31] The legal definitions of these terms vary by state, and many states do not have a statutory standard of for their definitions.[31]	• Gain knowledge of state regulations where research is conducted regarding who is considered the LAR • Assure you are speaking with the person who is the surrogate decision- maker • Inform nursing homes staff of your protections of residents who are decisionally-challenged • Engage informal and formal caregivers[31] • Consent in private with both parties present • Allow time for assent process

* Assent is the on-going, interactive conversation between researchers and residents, like consent, but with those patients and residents who have been determined unable to give informed consent.

Table 3.

Support for transparency in research and synergistic relationships between researchers and NH settings.

Research Transparency
• Create an audit trail of conversations and agreements
• Build and sign a Memorandum of Use or Research Data Agreement
• Develop plans to address research and NH staff turnover
• Prior to initial IRB submission discuss IRB process and terminology
• Identify NH concerns regarding sensitive data collection
• Provide the facility with drafts and approved IRB documents
Synergistic Relationship Between Researchers and NHs
• Provide NHs opportunities and information to market research relationships to highlight to payers and hospital systems their commitment to patient care
• Identify deliverables generated by research that may be valuable to facilities