NEXT STEPs
Advancing Nursing Home Care Through Research

Institutional Review Board Considerations for Investigators Planning to Conduct Nursing Home Research

Background

Institutional Review Board (IRB) review is required for all nursing home (NH) research that is designed to produce generalizable knowledge in a systematic manner under 45 Code of Federal Regulations (CFR) Part 46.[1] The goal of IRB review is to ensure participants' rights are protected and that the research is conducted in a way that holds the ethical principles of respect for persons, beneficence, and justice.[2] The IRB is responsible for determining whether the research is human subjects research and what level of review is required based on an assessment of risks to participants. Quality assurance projects that are designed to improve internal clinical care or services and are not intended to produce generalizable knowledge for use outside of the specific NH or group of NHs participating in the project do not require IRB review. The purpose of this resource is to assist NH researchers in proactively addressing common IRB concerns related to NH research to streamline the review experience and enhance collaboration.

Communicating with the Nursing Home about IRB Review

Researchers are encouraged to share information about the IRB review process and IRB approval with NH partners. Even if the NH does not have an IRB, NHs may have their own requirements or preferences for protocol review and other matters; it is advisable to confer with NH partners early and provide regular updates. NHs should be provided with a copy of the IRB approval documentation and protocols. Where permitted by the IRB, consent forms and participant-facing materials may need to align with NH preferences or policies; investigators should discuss these considerations early with NH partners.

Building Relationships with the IRB

IRBs and IRB members can vary in their interpretation of federal regulations and understanding of the NH context. Investigators are encouraged to proactively communicate with the IRB in advance of submitting proposals to confer on the planned submission and establish a relationship with IRB staff. These discussions provide an opportunity to talk through potential concerns, solve problems collaboratively, and avert delays related to misunderstandings of both the proposed science and the NH environment. Moreover, proactive conversations with the IRB can help build confidence in the investigator's familiarity with the environment, expertise, and sensitivity to the NH population. These conversations should happen well in advance whenever possible to allow time for an iterative review process. Researchers are also encouraged to talk with institutional colleagues who conduct similar research as they may be able to provide helpful insights, template language, and successful strategies for navigating common decision points.[3]

Engagement in Research

An important factor that is considered during IRB review of NH research is whether a NH is "engaged" in research. In this document, "engagement in research" refers specifically to the regulatory definition used by the Office for Human Research Protections (OHRP), not to informal collaboration or partnership. It centers on whether or not NH staff are actively involved in the research on behalf of the research team.[4,5] Regulatory engagement determines whether an institution must meet additional federal requirements (e.g. reliance agreements, training, and assurances) and is a key factor in IRB review of nursing home (NH) research.

Engagement comes with additional regulatory requirements for NHs that may be burdensome, so avoiding engagement is preferable to lessen NH work associated with partnering with a researcher. Relying on NH staff for research activities may also create additional challenges. Staff may not have sufficient paid time for the required training or for research activities such as conducting assessments, and IRBs may be concerned that research could detract from routine care, increasing the risk of harm to other residents. Moreover, staff may feel pressured to agree to support the study or engage in research activities. IRB review and approval may be delayed as well if a NH is engaged in research. Therefore, **researchers should clearly specify in the IRB protocol whether the NH involvement in the study meets the OHRP definition of "engaged in research," and why/why not.** Table 1 outlines ways in which NH staff may be involved in research and whether that activity does or does not meet the criteria for engagement.

Table 1. Criteria for Assessing Whether a NH is Engaged in Research.

NH is Engaged in Research	NH is Not Engaged in Research
• NH staff obtain informed consent • NH staff interact or intervene with participants for research purposes (e.g., data collection, intervention delivery) • NH staff obtain identifiable private information about residents for research	• NH allows researchers in the building to use space to interact with participants • NH staff message residents, family, and staff to share that the NH will be partnering with a researcher • NH staff inform potential participants about a study or seek permission from potential participants for investigators to contact them • NH staff share identifiable information or data consistent with the "preparatory to research" exception under the Health Insurance Portability and Accountability Act HIPAA as long as the information does not leave the NH or under a partial waiver of authorization. See Before a Study Begins: A Roadmap to Regulatory Requirements for Developing Research in Nursing Homes for more information.[6] • NH staff share identifiable information or data to researchers to be used off-site with direct HIPAA authorization from the resident and/or legal proxy or a full waiver of authorization • NH staff collect clinical data as part of routine care that are later used by the research study (e.g., vital signs, MDS data)

Note: This table is intended to provide general guidance. The final determination of whether a nursing home is engaged in research is made by the reviewing IRB based on the totality of study activities.

Determining the IRB of Record and Whether a Federal Wide Assurance (FWA) is Needed

When a NH is "engaged" in research, an IRB of record and an approved Federal Wide Assurance (FWA) form is required.[7] Most NHs do not have their own IRB. If a NH is engaged in research, it must identify an external IRB of record that will review the research and file a FWA with the Office for Human Research Protections (OHRP). The FWA includes an assurance that the NH will follow required protections for human subjects including giving NH staff engaged in research time to complete human subjects protections training required by the IRB of record. Researchers will likely need to support NHs in completing these requirements as this process will likely be unfamiliar to most NHs. Additionally, the FWA will require identifying who is authorized to sign on behalf of the NH as the Signatory Official.

Some NHs have their own IRB or are part of a health system with an IRB that can review the study. If the NH is engaged in research, the NH IRB will need to sign an "IRB authorization agreement" in which they agree to defer to the investigator's IRB or a Central IRB.[8] The investigator's IRB should provide the form to support this deferral. Less commonly, a NH may engage or be covered by a Central IRB, which can serve as the IRB of record for multisite trials and replaces the need for local review.

Once the IRB of record is identified, it assumes responsibility for oversight of the project. This oversight includes the ability to approve a HIPAA waiver of authorization for the use or disclosure of protected health information for research purposes without individual authorization.[9]

Research Risks and NH Residents as a Vulnerable Population

Under Federal IRB Regulations, vulnerable research populations include NH residents with impaired decision-making capacity due to dementia, mental illness, trauma, or intellectual disabilities.[10] IRBs are required to more closely scrutinize research that involves vulnerable populations. Investigators must provide a justification to support the inclusion of NH residents who may be vulnerable to coercion or undue influence. This justification should demonstrate that participant selection is equitable and scientifically appropriate. One important consideration in assessing whether the inclusion of NH residents is appropriate is whether they are likely to benefit from the proposed research, particularly if the study is determined to have more than minimal risks that are greater than the risks associated with daily life. If NH residents involved in the study are unlikely to benefit, the study can have no more than minimal risk and must have the potential to produce meaningful scientific information. IRBs will also review the informed consent plan and data safety monitoring plan carefully to ensure appropriate processes to protect vulnerable subjects.

Preparing for IRB Review of NH Research

In developing the IRB protocol, there are special considerations and best practices for NH research. In addition to carefully considering whether or not the research requires NH engagement, researchers are encouraged to address common IRB concerns and knowledge gaps about NH research throughout the protocol, as described in Table 2.

Table 2. IRB Protocol Elements, Descriptions, and Best Practices for NH Research

IRB Protocol Element	Description	Best Practices to Include in NH Research Protocols
Study Overview	Background, rationale, and specific objectives/aims	• Why enrolling NH participants is appropriate for the clinical question versus other populations
Study Population	Inclusion and exclusion criteria, number of planned participants, and how they will be recruited	• Who is considered a research subject (resident, family, staff) • Whether or not subjects with cognitive impairment are eligible and why • Scientifically justify any exclusion criteria (including age cut-offs and how you will ensure those of advanced age will not be identifiable)
Study Design and Methodology	Detailed description of the study design, procedures (what participants will be asked to do), setting, and statistical analysis	• Briefly describe NH setting, level(s) of care provided, population • Whether or not the NH meets the definition of "engaged" in research • Choice of randomization unit (resident, unit, NH), procedures to reduce contamination bias if applicable • Clearly describe aspects of the protocol that are considered research vs. routine NH care • Clearly distinguish research data collection from data routinely collected in clinical care • Explain plans for controlling the clustering of residents or staff within NHs
Ethical Considerations	Risks & benefits: Potential risks and how they are minimized; benefits to participants or society	• Any impact on staff, disruption in care, risks if data confidentiality is breached • Define potential adverse events (AEs, monitoring procedures, and process for assessing study related versus expected (e.g., related to hospitalizations and deaths) • Plan for identifying and sharing reports of AEs and other material required by the IRB
	Informed consent: consent process, any waivers (see Informed Consent guidance for more information)	• Accessibility and content of the informed consent form • Validated capacity assessment tool (if applicable) and frequency of capacity assessment • Consent verification processes • Vision and hearing accommodations • Surrogate and remote consent process • Assent from people living with dementia and how this will be determined

		● Justification for a waiver of documentation of informed consent or a waiver of consent if applicable ● Examples of any potentially sensitive questions
	Privacy & confidentiality: How participant data/samples are stored, de-identified, shared, and protected	● Private space (e.g., away from roommates) for interactions with and about residents ● Locked storage and transport for paper data sources, samples ● Security precautions for electronic data
	Special protections	● Staff participant confidentiality procedures, if applicable ● Handling of observed or reported abuse or neglect
Data Collection and Management	How data are collected, stored, secured, shared, and destroyed	● Plans to modify data collection approaches if needed to support residents' physical, cognitive, sensory, or emotional needs or break into multiple sessions if resident is fatigued ● Data Use and Transfer agreements executed with NH ● Adherence to HIPAA Privacy Rules surrounding the use of electronic health records
Compensation and Costs	Details on payments to participants, study-related costs, and handling of research-related injuries	● Participant and NH-level incentives ● Explore alternative reimbursement options (e.g., depositing money directly into residents' NH spending account)
Sharing Findings	Plan for if, when and how study results will be communicated	● Communication with NH staff and medical providers ● Approach to sharing results with participants
Appendices	Recruitment materials, questionnaires, interview guides, consent forms, investigator training certificates	● Participant and NH-level materials

Funded by U24AG087939, NIA

REFERENCES

1. United States Department of Health and Human Services 45 CFR 46: Protection of Human Subjects. 2026. eCFR :: 45 CFR Part 46 -- Protection of Human Subjects

2. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. *The Belmont Report: National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research*. 1979. https://www.hhs.gov/ohrp/sites/default/files/the-belmont-report-508c_FINAL.pdf

3. Cartwright JC, Hickman SE, Nelson CA, Knafl KA. Investigators' successful strategies for working with Institutional Review Boards. *Res Nurs Health*. Oct 2013;36(5):478-86. doi:10.1002/nur.21553

4. Office for Human Research Protections (US). Engagement of Institutions in Human Subjects Research. 2008. https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-engagement-of-institutions/index.html

5. Secretary's Advisory Committee on Human Research Protections (US). A New Interpretation of the “Engaged in Research” Standard. 2022. https://www.hhs.gov/ohrp/sachrp-committee/recommendations/attachment-d-july-25-2022-letter/index.html

6. Next Steps Network. *Before a Study Begins: A Roadmap to Regulatory Requirements for Developing Research in Nursing Homes*. https://nextstepsnetwork.org/resource/before-a-study-begins-a-roadmap-to-regulatory-requirements-for-developing-research-in-nursing-homes/

7. Office for Human Research Protections (US). Federalwide Assurance (FWA) for the Protection of Human Subjects. 2026. https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/forms/fwa-form-2017/index.html

8. Office for Human Research Protections (US). Institutional Review Board (IRB) Authorization Agreement. 2017. https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/forms/irb-authorization-agreement/index.html

9. United States Department of Health and Human Services 45 CFR § 164.512(i)(1)(i)(A): Uses and disclosures for research purposes. 2026. eCFR :: 45 CFR 164.512 -- Uses and disclosures for which an authorization or opportunity to agree or object is not required.

10. United States Department of Health and Human Services 45 CFR 46.111(b) Criteria for IRB approval of research. 2026. https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-C/part-164/subpart-E/section-164.512