Nurse research and the institutional review board

Learn how the IRB process works to ensure participant safety and quality research.

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WHEN you participate in research, you have the opportunity to create new knowledge and evidence to inform patient care and nursing practice. And you're likely to interact with an institutional review board (IRB) or work on an IRB-approved project as a principal investigator, co-investigator, subinvestigator, research assistant, or team member. Whatever your role, understanding human subject protections is an important step in the research process.

Mandates published in the Code of Federal Regulations (CFR) and enforced by the U.S. Office for Human Research Protections (OHRP) guide IRB functions, board composition, membership qualifications, and the IRB role in protecting human subjects. You'll also want to know what kinds of projects generally require IRB review, how to complete an application, and what you may expect after submission. And don't forget to familiarize yourself with your organization's specific IRB protocols and procedures.

IRB responsibility

IRBs are responsible for confirming that research protocols are developed in accordance with federal regulations based on Protection of Human Subjects (Common Rule) guidelines. Respect for individuals, beneficence, and justice are the regulation's guiding ethical principles. The 1991 Common Rule (codified in separate regulations by 15 federal departments and agencies) outlines basic IRB provisions, informed consent, and compliance assurances.

The primary purpose of an IRB is to ensure that the rights, welfare, and well-being of people participating in research activities are protected in accordance with federal regulations. This is achieved in part by delineating IRB committee composition, including the number, backgrounds, and characteristics of members.

Regulations require that at least five members from different disciplines and backgrounds review the research activities commonly conducted by the institution. For example, nurse representation is needed if nurses within the organization commonly conduct studies involving human subjects. At a minimum, a convened IRB meeting must include five voting members, and those members must be diverse on a number of attributes, including gender, race, ethnicity, and profession. In addition, most members should be scientists with sufficient expertise to judge design safeguards across several content areas. At least one member must have a nonscientific background, and at least one must be from the community and not affiliated with the organization (for example, former patients, business owners, or clergy).

Protecting research subject identity

Gathering personal data for the purposes of research can put human subjects at risk of being identified. The following data are considered personal identifiers:

- names (including names and signatures on consent forms)
- Social Security number
- phone and fax numbers
- geographic information more specific than state
- dates (other than year) directly related to an individual, including birth date, admission date, discharge date, death date
- email, website, and IP addresses
- medical record numbers
- account numbers
- health plan beneficiary numbers
- certificate/license numbers
- device (for example, implanted medical device) identifiers and serial numbers
- biometric identifiers, including finger and voice prints
- full-face photographic images and any comparable images
- any other unique identifying number, characteristic, or code.

These data sources also can place subjects at risk of identification:

- medical discharge records from the past 6 months
- specimens (tissues, blood, serum, surgical discards, etc.)
- data directly from a health plan, healthcare clearinghouse, or healthcare provider
- data already collected for administrative purposes
- student records
- dental records.

Source: U.S. Department of Health and Human Resources. Protecting personal health information in research: Understanding the HIPAA privacy rule. privacyruleandresearch.nih.gov/pdf/HIPAA_Privacy_Rule_Booklet.pdf

What is research?

The IRB is tasked with reviewing research studies to protect participants, but determining what qualifies as research according to the Federal Regulation standards can be difficult. According to the OHRP, research is "a systematic investigation, designed to develop or contribute to generalizable knowledge." The intent to develop generalizable knowledge is what makes research distinct from quality improvement projects, which typically focus on making localized process improvements (for example, on a unit or in a hospital or clinic). Research that will require IRB review includes pilot studies with human subjects and studies with human subjects that use medical or other devices (apps, drugs, food, supplements). In addition, if identifiable subject information is used, an IRB review will be required. Research that doesn't need IRB review includes activities intended only for quality improvement and data collected only for internal departmental or administrative purposes.

Determining whether research involves human subjects also is defined by the federal guidelines and depends on many factors, including the type of interaction, the type of data collected, and the subject population. (See *Protecting research subject identity*.) For example, a plan for the confidentiality of the data must be evident for respondents when a survey asks about sensitive or volatile topics. Using pre-existing data with identifiers that have been collected for another purpose is likely to require IRB review and approval before use, particularly data containing personal identifiers.

Participant risk

Study applications are evaluated on the participants' potential psychological, social, economic, physical, and legal risks and the measures that are taken to mitigate them. Federal regulations define minimal risk as "the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests." Both the probability and magnitude of possible harm can vary from minimal to significant.

Informed consent

The following informed consent approval criteria and considerations are derived from the Code of Federal Regulations 46.111.

Approval criteria	Considerations
Risks are minimized	• Procedures consistent with sound design • Procedures are already being performed on subjects for diagnostic or treatment purposes
Risks are reasonable in relation to anticipated benefits	• Anticipated benefit to subjects vs. importance of knowledge expected to result from research
Equitable selection of subjects	• Risk burdens and benefits distributed fairly • No population being exploited or excluded from participation
Additional safeguards are in place to avoid coercion or undue influence	• Research involving vulnerable populations (impaired decision-making capacity, economically or educationally disadvantaged)
Informed consent will be sought and documented	• Must contain required elements* • Written at 6th- to 8th-grade reading level • Doesn't include language that waives or appears to waive any of the subject's legal rights or releases or appears to release those conducting the research from liability for negligence
Provisions to protect subject privacy and maintain data confidentiality	• Minimize personal identifiers • Use other unique identifiers • Data storage and protection
Provisions for monitoring collected data to ensure subject safety	• Depending on the complexity and risks of the study, these provisions may range from the principal investigator monitoring subject data for safety concerns to a sponsor-based data and safety board/committee

*Additional details about informed consent are available at hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html.

Although removing all risk from research participation is impossible, IRBs work to balance the rights of individual subjects with developing knowledge to further society as a whole. The IRB is responsible for confirming that research protocols meet federal guidelines and that they're written in accordance with the Common Rule. IRBs seek to ensure that study designs maximize benefits while minimizing potential harm and that those who agree to participate in research do so voluntarily with a full understanding of participation expectations and risks. (See *Informed consent*.) Healthcare providers conducting research must describe the voluntary nature of participation and the absence of coercion (for example, excessive cash payments or expensive gifts) in the IRB application regardless of the population being recruited.

IRB application: What to expect

The following elements are typically included in an institutional review board (IRB) application. Note that application requirements will depend on the individual organization.

- Purpose
- Background
- Resources available to conduct research
- Study design
  - recruiting plan
  - inclusion/exclusion criteria
  - step-by-step procedures
  - data management
- Data monitoring plan to ensure subject safety
- Subject risks
- Potential benefits and importance of knowledge gained
- Provisions to protect subject privacy
- Provisions to maintain data confidentiality
- Consent process
- Additional protections for vulnerable populations.

IRB process

Before your research can begin, you'll need to develop a timeline that includes application completion and IRB review.

Timeline and application

As you develop a timeline for your study, familiarize yourself with your institution's IRB application process and schedule any required additional approvals (for example, from a nurse manager or nursing shared gover-

IRB application: Additional documents

In addition to the institutional review board (IRB) application, you'll likely need to attach the following documents, although requirements will depend on the individual organization.

Documents submitted with the IRB application	Comments
Human subject protection training certification	• Required for principal investigator, co-principal investigator, and others listed on the application
Conflict of interest disclosure	• Management plan required if conflict exists
Protocol	• Should provide background and rationale for the study, state objectives, describe design and methods, discuss statistical considerations, detail organization of a clinical research project
Grant proposal	• Funding source information
Consent form Child assent Health Insurance Portability and Accountability Act of 1996 (HIPAA) authorization	• Required for all research unless a waiver has been requested and granted • Justification for waiver of consent and/or waiver of written consent document
Recruitment materials	• Flyers • Posters • Print media • Audio/video • Online content • Scripts • Letters and emails to subjects
Data collection forms and questionnaires/surveys	• Interview scripts/questions • Focus group guide • Observation guide • Cognitive assessment tool
Other supporting documents	• Letters of support • Other IRB approvals • Data transfer agreements • Certificates of confidentiality • Translation certification • Device form

nance council). Allow time for you and any co-investigators to complete and document human ethics training as required by your organization. Based on the data that you're collecting, consider the level at which your project might be reviewed. If your study is scheduled for a full board review, adhere to all deadlines, especially if your timeline is short. (See *IRB review categories*.)

Submitting a complete and detailed application is essential to preventing unnecessary delays. Be specific, avoid using acronyms, define all terms, and detail all procedures. (See *IRB application: What to expect*.)

Complete any additional sections required by your institution (if an item doesn't apply to your study, don't leave it blank, note that it's not applicable) and attach any necessary documents. (See *IRB application: Additional documents*.) Although the timeframe from protocol submission to decision may vary depending on your organization and the study's complexity, allow 1 to 3 months for IRB review.

IRB review

Typically, the review process of exempt or expedited protocols is more rapid than those requiring a full board review. Protocols requiring full board review typically pose more than a minimal risk to subjects (for example, interventional clinical trials), involve a vulnerable population (for example, children), use deception (for example, telling subjects that they'll engage in a cooperative task with other subjects when in fact they're interacting with study personnel), or collect potentially sensitive information (for example, about illegal activities).

When full board review is required, the application and supporting documents are placed on the board agenda and distributed to all committee members. A primary and secondary reviewer are assigned to examine the documents in accor-

IRB review categories

Institutional review board (IRB) reviews are usually categorized as exempt, expedited, and full board, although categories can vary depending on the individual organization.

Category	Description	Example
Exempt	• Minimal risk • Doesn't meet the criteria for research and is exempt from formal IRB review	Research using pre-existing de-identified data or public information
Expedited	• Minimal risk • Expedited reviews are not "quicker" or conducted with less rigor, but fewer reviewers are required for approval	Minimal risk behavioral research using cognitive tests, focus groups, surveys, or program evaluations where data are recorded anonymously
Full board	• Greater than minimal risk • Vulnerable population • Studies that use deception • Studies where sensitive information is collected	Clinical trials, survey where illegal activities may be disclosed, a study involving prisoners

Sources: American Nurses Association 2019 and Department of Health, Education, and Welfare 1979

10 tips for IRB success

Follow these tips to help expedite the institutional review board (IRB) process for your research project.

1. Identify which IRB is used by your organization (local, central, commercial) and review the guidance accordingly.
   - **Local IRBs** are "in-house" committees or those near your organization. They're frequently within or affiliated with a university or hospital.
   - **Central IRBs** provide review and oversight for all sites participating in a multi-site study, such as a network or consortium.
   - **Commercial IRBs** are professional, independent entities with organization affiliation.
2. Obtain IRB meeting and submission dates.
3. Ensure all team members complete human subject protection training.
4. Clearly describe the procedures that are performed as part of standard clinical care and those performed solely for research purposes.
5. Spell out acronyms and define scientific and clinical terminology.
6. Use current approved templates or formats for all documents.
7. Include well-defined inclusion and exclusion criteria.
8. Respond promptly and completely to requests for information during the review process.
9. Provide all supporting documents along with the application.
10. Ask someone knowledgeable about IRB processes to review your application.

dance with federal guidelines. At the meeting, the reviewers present relevant study details, including the purpose, participants, and procedures. The board members discuss the risks and benefits of the study and its alignment with federal guidelines to ensure all criteria for approval have been met. Any regulatory findings are confirmed, a recommendation is made, and a final vote taken.

The possible disposition of a study application includes approval with or without stipulations, deferral, or disapproval. Approval with conditions or stipulations requires that investigators make specified changes to the research protocols and/or informed consent documents, submit clarifications, or provide additional documents. Remember that research can't begin until the IRB has given full unconditional approval.

Be prepared

Before you begin, seek the advice of someone who's familiar with the IRB application process at your organization and ask him or her to proofread your application and provide feedback. If your attendance is required at a full board meeting, rehearse your presentation and request an experienced colleague accompany you to the meeting.

The IRB process may seem arduous, but it's necessary to ensure participant safety and successful research that benefits healthcare providers, patients, and the community. (See *10 tips for IRB success.*) ★

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