Considering Subjects' Rights

Susan J. Fetzer, PhD, RN

ONE OF THE LONGEST RUNNING research studies involving patients was begun in 1932 in Tuskegee, Alabama. The study was stopped abruptly in 1972 when it was revealed that the patients with syphilis were not given the opportunity to make informed decisions about taking part in the study. The discovery led to the National Research Act of 1974, which requires independent oversight of any research study involving humans. All nursing research is subject to the oversight often designated as the Human Subjects Review Board, Institutional Review Board, or just IRB. Internationally, the human subjects review may be conducted by an Ethics Committee. Most acute care hospitals host an IRB, composed of at least five members, including a nonscientific member and a public member. Many facilities include at least one nurse on an IRB.

The main purpose of the IRB is to protect five important patient rights (Table 1) by reviewing the research proposal before implementation. The IRB focuses on the research proposal's provision of subject informed consent, procedures for selecting subjects, and confidentiality. After review and vote, the IRB informs the researcher of their decision. A study is prohibited if the risks to subjects outweigh the benefits.

The IRB review takes one of three forms: exempt, expedited, or full review. *Exempt* studies are studies presenting no more than minimal risk or harm and no procedures for which written consent would normally be required. For example, a questionnaire is used to collect opinion data from nonvulnerable adults. In these studies, there is no identifiable data requested. The requirement for a formal written informed consent document can be waived by the IRB for exempt studies. In this issue of JoPAN, the study by Wagner et al[1] investigated the routine infection process in the postanesthesia care unit. As there was no risk to subjects, the authors reported that the study was deemed exempt by the IRB.

A study that poses minimal risk may also be reviewed by *expedited* IRB procedures. In this category, minimal risk refers to the probability and magnitude of harm that is no greater than during the performance of routine physical examination. For example, a study involving phlebotomy for a blood sample may undergo expedited review by the IRB. Both exempt and expedited studies only require review by the IRB chairperson and one other IRB member. Tian et al[2] in this issue of JoPAN conducted an observational study. The researchers indicated that they sought a review by the Hospital Ethics Committee; however, there was no indication that consent was obtained. Although the study posed little risk, the reader should be assured that the IRB waived subject consent. Finch et al[3] also conducted a low-risk descriptive study but clearly indicate that IRB approval was obtained as well as written informed consent.

Studies that can pose greater than minimal risk undergo *full* IRB review. Each IRB member reviews the study proposal to determine if patient benefits outweigh patient risks and if subject rights will be protected. Two studies in this JoPAN issue were candidates for a full board review. Zou et al[4] conducted an experimental randomized controlled trial of tramadol for sufentanil-induced cough. Their article indicated Ethics Committee review, but only that consents were obtained. The type of consent was not noted. Hajini et al[5] underwent full board review in their study of children; written consent was obtained from parents. Studies involving vulnerable groups, such as children, pregnant women, and prisoners, always undergo full board review. During the deliberations of a full IRB review, the primary research investigator is invited to answer any questions.

Susan J. Fetzer, PhD, RN, Southern New Hampshire Medical Center, Nashua, NH.

Conflict of interest: None to report.

Address correspondence to Susan J. Fetzer, 59 Stonehenge Drive, Henniker, NH 03242; e-mail address: sfetzer@unh.edu.

1089-9472/$36.00

https://doi.org/10.1016/j.jopan.2019.08.004

Table 1. Rights of Patients in a Research Study

1. Right to freedom from discomfort and injury
2. Right to privacy
3. Right to dignity
4. Right to anonymity and confidentiality
5. Right to self-determination

Table 2. Evaluating Human Protection in Research Reports

1. Is the problem significant?
2. Is the design scientifically or theoretically based?
3. Are subjects ethically selected?
4. Is their evidence that consent was written, voluntary, and informed?
5. Is their evidence of subject deception?
6. Were subjects under high stress requested to attend?
7. Is there any way to identify subjects in the report?
8. Is there evidence that an IRB was consulted?

IRB, institutional review board.

When reading research reports, the researcher must include one or two sentences that the study was reviewed, the group reviewing the study, and the type of review. Most professional journals require similar sentences before publication acceptance. This information informs the reader that ethical standards were addressed. However, the reader is still bound to evaluate risks, benefits, and informed consent when reviewing the article (Table 2).

When research studies are being conducted in the perianesthesia areas, the nurse has the right and responsibility to verify that the study has been approved by an IRB and the right to know the purpose of the research study. The researcher should provide, if asked, the name of the reviewing IRB. If the nurse believes patient's rights as a research subject have been violated by the research study procedures, the nurse has an ethical obligation to inform the IRB. Simple awareness that the patient is in a research study is not sufficient to provide patient advocacy.

References

1. Wagoner M, Snyder S, McCarty M, et al. Routine disinfection of mobile communication devices in the postanesthesia care unit. *J Perianesth Nurs*. 2019;34:1176-1180.
2. Tian C, Yu Y, Mao J, Davidson PM. Perceived discomfort, pain and nonpain symptoms in a postanesthesia care unit: an observational study. *J Perianesth Nurs*. 2019;34:1032-1039.
3. Finch C, Parkosewich JA, Perrone D, Weidman KH, Furino L. Incidence, timing, and factors associated with postoperative nausea and vomiting in the ambulatory surgery setting. *J Perianesth Nurs*. 2019;34:1146-1155.
4. Zou Y, Ling Y, Kong G, et al. Effect of tramadol pretreatment on sufentanil-induced cough. *J Perianesth Nurs*. 2019;34:1181-1186.
5. Hajdini H, Steurer LM, Balakas K, Ercole PM. A randomized controlled trial to compare pain medications in children undergoing strabismus surgery. *J Perianesth Nurs*. 2019;34:1196-1204.