Protection of Human Subjects

Description
Maintaining constant improvement in the emergency care system requires extensive research conducted with patients seeking treatment in emergency care settings. Emergency care researchers are responsible for protecting the rights and safety of patients who become human subjects in the context of research. This responsibility can be fulfilled by researchers through the exercise of respect for persons, beneficence, and justice. Respect for persons is demonstrated by recognizing the rights of individuals to decline participation in research with no adverse consequences to themselves. Additionally, people with limited decision-making capacity are entitled to protection from unauthorized research participation. Researchers demonstrate beneficence by implementing research that causes no harm, maximizes potential benefits, and minimizes risks. Justice is implemented through the even-handed treatment of research subjects and by not targeting research to a vulnerable population that is not anticipated to benefit from the results.

Vulnerable populations include pregnant women, human fetuses, neonates, prisoners, and children. Depending on where the research is conducted, vulnerable populations may also include students; employees; racial, religious, or ethnic minorities; the economically or educationally disadvantaged; and those with physical, sensory, or mental disabilities. Despite the best efforts of researchers to epitomize ethical conduct in their work, some vulnerable populations may feel they are required to participate in research. Individuals may believe they do not have the right to decline research participation or fear that nonparticipation means they will be denied services to which they otherwise would be entitled (e.g., emergency healthcare, employment). They may also experience a phenomenon known as therapeutic misconception, which occurs when patients who are asked to participate in research do not recognize the difference between clinical care and a clinical trial. These patients may believe that declining research participation is akin to declining clinical care.

Research subjects have the right to be informed of the actual or potential risks in any research endeavor and to refuse to participate or withdraw from research without penalty. Nurses act as advocates to ensure that patients’ rights and safety are protected during the consent process and the conduct of the research. This is a legal, ethical, and professional responsibility of nurses.

ENA Position
It is the position of the Emergency Nurses Association that:

1. It is essential for emergency nurses to be knowledgeable of the tenets relating to the protection of human subjects.
2. Emergency nurse researchers and others conducting studies in the emergency setting adhere to U.S. Department of Health and Human Services and Federal Drug Administration regulations for the protection of human subjects in research.
3. The rights of research subjects are protected during the informed consent process and during and after the conduct of the study. These include 1) the right to voluntary participation and withdrawal without loss of future benefits and 2) the right to anonymity, confidentiality, and privacy.
4. All research proposals undergo scientific and institutional peer review to ensure quality research and the protection of research subjects’ rights and safety.
5. Medical and Social/Behavioral Institutional Review Boards are interprofessional and include nurses as both scientists and clinicians.
Many advances in healthcare are the result of research. For example, research in the 1940s contributed to today’s emergency nursing practices for the care of people with high-altitude injuries, hypothermia, or seawater inhalation. While these research findings have strong clinical significance, the experiments were conducted by Nazi scientists on prisoners at the Dachau concentration camp without the research subjects’ permission. These unethical experiments, revealed at the subsequent trial of the Nazi scientists, led to the establishment of the Nuremberg Code, which focuses on informed consent. After many years of discussion, the World Medical Association subsequently approved the Declaration of Helsinki in 1964, which has evolved over time, with the seventh version being approved by the World Medical Association in 2013. The Declaration addresses multiple aspects of the protection of human subjects: general principles; risks, burdens, and benefits; vulnerable groups and individuals; scientific requirements and research protocols; research ethics committees; privacy and confidentiality; informed consent; use of placebos; post-trial revisions; research registration; publication and dissemination of results; and the use of unproven interventions in clinical practice.

Concurrent with the research at Dachau, violations of human subjects’ rights were occurring in the United States. For example, the Syphilis Study at Tuskegee involved the enrollment, without informed consent, of African-American men, some with syphilis. Long after effective treatment for syphilis became available, it was withheld from the research subjects with the disease. The study began in the 1930s and continued until 1972 when its details were revealed in a news story. In 1979, following an investigation, the United States Department of Health and Human Services published the Belmont Report, which established:

- boundaries between practice and research;
- basic ethical principles of respect for people, beneficence, and justice;
- application of the informed consent process in research;
- assessment of risks and benefits; and
- subject selection process

Along with the Belmont Report, policies now regulate the qualifications of investigators as well as the review, approval, conduct, and emergency use of drugs, biologics, and medical devices in research on human subjects. "Emergency research” is an exception to the informed consent investigation process. Such research investigations “involve human subjects who have a life-threatening medical condition that necessitates urgent intervention (for which available treatments are unproven or unsatisfactory), and who, because of their condition (e.g., traumatic brain injury) cannot provide informed consent. The research must have the prospect of direct benefit to the patient and must involve an investigational product that, to be effective, must be administered before informed consent from the subject or the subject’s legally authorized representative can be obtained and in which there is no reasonable way to identify prospectively individuals likely to become eligible for participation.”

Emergency research are responsible for advocating on behalf of their patients by informing the physician scientist initiating the emergency research once a patient or representative is capable of being informed of the research in which the patient is participating.

Despite U.S. federal regulations, however, violations persist. In 2012, DuBois, Anderson, and Chibnall surveyed U.S. medical schools and comprehensive doctoral institutions; 129 institutions responded. Over a two-year period, the researchers found the majority of institutions indicated multiple violations in the conduct of research on human subjects. These included violations of consent and privacy regulations, misconduct, conflicts of interest, and fraud. Even in the Veterans Administration healthcare system, 15% of researchers participating in the research process in 2010 self-reported being pressured to disregard the regulations and practices of ethical research. The persistence of violations today necessitates continued vigilance to ensure the protection of human subjects.
Position Statement

Resources


Collaborative Institutional Training Initiative (CITI) at the University of Miami: https://www.citiprogram.org/


Food and Drug Administration’s Information Sheet Guidance Documents: http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/GuidancesInformationSheetsandNotices/ucm113709.htm


References


Authors

Authored and Reviewed by the Position Statement Committee

Diane Gurney, MS, RN, CEN, FAEN, Chair
Katie Bush, MA, RN, SANE-A
Gordon Lee Gillespie, PhD, DNP, RN, CEN, CPEN, CNE, PHCNS-BC, FAEN
Robin Walsh, MS, BSN, RN
E. Marie Wilson, MPA, RN

ENA 2015 Board of Directors Liaison

Sally Snow, BSN, RN, CPEN, FAEN

ENA Staff Liaisons

Dale Wallerich, MBA, BSN, RN

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