

Informed Consent in the Changing Landscape of Research

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The current tenets of informed consent have evolved since the 1940s. The guidelines and mechanisms to ensure respect for persons, beneficence, and justice within today's sophisticated and vastly evolving research studies warrant revisiting. The following is an overview of future discussions that will examine how informed consent really is within various research scenarios.

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The history of informed consent dates back as early as the 16th century (Selek, 2010). The current tenets of informed consent pertaining to the ethical conduct of research on human participants predominately stems from the 1947 Nuremberg Code (National Institutes of Health, 2016), which was created following the Nuremberg trials at the end of World War II. The unethical conduct of research on human participants during the Holocaust, coupled with experiments (e.g., the Tuskegee syphilis study), prompted a more formalized structure for ensuring the well-being and autonomy of human participants in research studies. The World Medical Association (2013) created the Declaration of Geneva in 1948 (Fischer, 2006), followed by the Declaration of Helsinki in 1964, to apply ethical principles to medical research involving human participants (Fischer, 2006; Rickham, 1964). A decade later, on July 12, 1974, the National Research Act was signed into law (U.S. Department of Health and Human Services [HHS], 1979). Through this act, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research was formed and charged with developing guidelines for the conduct of biomedical and behavioral research. The guidelines were established in the Belmont Report (HHS, 1979; U.S. Department of Health, Education, and Welfare, 1979), which continues to

be periodically updated. The Belmont Report describes the general principles of respect for persons, beneficence, and justice, and it outlines the process of obtaining informed consent to ensure that these principles are followed (HHS, 1979). In 1998, an informed consent checklist was instituted (HHS, 1998). Although clearly outlined, defined, and described in consent forms, it is beneficial to revisit how informed participants are when they enter research studies, particularly for patients undergoing treatment for cancer. This article will provide an overview of several areas for consideration.

Clinical Trials as Treatment Options

Entering a clinical trial is voluntary. The individual signing the consent must have the capability to sign in addition to having a full understanding of the requirements, risks, and benefits of the trial (Abhyankar, Velikova, Summers, & Bekker, 2016). However, fear could overshadow the decision-making process. For example, when undergoing treatment for cancer, some patients may learn that no single protocol will guarantee cure; therefore, having options for new pharmaceutical therapies in varying phases of testing can be intriguing. In cases in which standard therapy can only offer the hope of a few years of survival, entering a clinical trial for a new therapeutic may give

the illusion of a possible “miracle cure.” In this common scenario, the patient’s focus may be on the dangling carrot of potential cure, not the process, risks, and consequences of the research study. For patients who meet the inclusion criteria for multiple trials, the information can be overwhelming in trying to determine which will provide the best chance for survival.

Challenges in Health Literacy

With emerging investigative methods like genomics, proteomics, metabolomics, transcriptomics, and pharmacogenomics, many healthcare providers are unable to clearly describe the details of an “omics”-centric investigation (Burke & Clarke, 2016). Patients are often targeted for research studies to investigate various pathways of disease and treatments through the omics lens. The area of health literacy, particularly in the world of omics, is substantially lacking (Burke & Clarke, 2016).

Creating and Using Big Datasets

The push for fast answers to research questions to reduce the burden of cancer includes advancements in data science for large-scale investigations of pre-collected data (Kaiser & Couzin-Frankel, 2016). Many large datasets from genomic analyses, long-term longitudinal studies, and pooled resources create the possibility of answering salient questions quickly. These types of datasets include data from studies in which patients have given written consent and agreed to have their data used in multiple analyses.

Aside from these large studies, another venue for investigations is in the creation of new fast datasets by abstracting patient variables from medical records. The benefits are tremendous. The ability to answer certain research questions

that can better inform prospective studies is preferable over the time and resources it would take to answer the initial questions by enrolling patients and collecting the data. However, the impracticality of identifying patient medical records, contacting patients, and requesting permission to use their information as part of a deidentified pool has prompted institutional review boards to grant exempt status for such studies, allowing researchers to obtain data without consent. Although the congregate is deidentified, the first point of contact with the medical record identifies each patient. In general, patients are likely unaware that entering the healthcare system may place their information into a study. Similarly, deidentified data from insurance carriers are also often used in large-scale, population-based investigations. Some institutions, particularly those known for research or affiliated with a strong research-based academic center, may have a notation about using information as part of the consent to receive health care. The patients’ actual notice and understanding of this is unclear. In addition, the push for patients to be more actively involved as research partners may lead to an informed consent paradigm shift (Ashley, 2015). The concept of broad consent for answering multiple and ongoing research questions may play a major role in reforming the consent content and process.

Surveys

Obtaining current information from patients through surveys can provide relatively fast, informative data that ideally can be used to expedite the improvement of patient care. Informed consent for surveys varies. Often, a written consent precedes the patient being handed a paper-based survey. However, online surveys sent via emails with

links bypass this process under the logic that an individual who chooses to answer the survey is consenting to do so. Many cancer centers also use tablet devices given to patients in the waiting room to report real-time symptoms and distress that can be immediately addressed by the clinician. Because of time constraints that seem to limit clinicians from asking the same questions directly to the patients, the tablet point-of-care survey has shown to improve management and outcomes (Bennett, Jensen, & Basch, 2012). However, that method requires resources to support the technology. Such technology has been successfully used to guide patient treatment decision making (Berry et al., 2013). Three routes exist for this type of information gathering: (a) direct point-of-care information for healthcare management, (b) purposeful data collection for research investigations, and (c) real-time patient management and investigations to inform future practice. Again, questions arise pertaining to the level of patient awareness regarding the information being used for research purposes when the primary intent of the tool is not based in research. In addition, answers that are true for the patient may not be an option on a Likert-type survey, but the patient is forced to select an answer (or sometimes leave it blank). Although multiple methods exist for statistically addressing these survey limitations, the downstream effect of translating this type of research into practice can bring into question how evidence-based the practice really is.

Conclusion

Current protocols for the protection of human participants have certainly prevented the ability to repeat the horrific events in the history of biomedical research.

However, revisiting informed consent from the current lens of a fast-paced, highly sophisticated research agenda is greatly needed.

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Research Ethics addresses issues of ethics in writing for academic purposes. The column strives to address common problems found in research. Materials or inquiries should be directed to Associate Editor Marilyn J. Hammer, PhD, DC, RN, at marilyn.hammer@nyu.edu.