The Reasonable Person: A Character of Interest in the New Common Rule

13 Jun 2018 by Jim Gearhart

Discussions about the revised Common Rule have brought a new character onto the research ethics stage. This upstart is not without controversy, but could prove influential once the new Common Rule comes into effect. The newcomer is known as "the reasonable person."

This is not to say that reasonable people do not already exist in research; this reasonable person is a fictional character, often created to act as a kind of role model in liability or malfeasance lawsuits. In these cases, the actions of the accused are compared to the imagined standards of the reasonable person to help determine whether to punish or exonerate. Merriam-Webster describes this role better than I can:

Reasonable Person

A fictional person with an ordinary degree of reason, prudence, care, foresight, or intelligence whose conduct, conclusion, or expectation in relation to a particular circumstance or fact is used as an objective standard by which to measure or determine something.

With the new Common Rule, this character will have a new task: to help determine what information a study participant needs from an informed consent process. Not everyone is convinced, however, that the reasonable person is right for the job.

As we have noted in other posts over the past months, the Department of Health & Human Services (HHS) and other federal agencies have approved extensive changes to the Common Rule, regulations that guide the ethical conduct of research involving human subjects. Many of the changes will focus on the important process of informed consent, which describes a research study to potential participants or those who have already agreed to participate. The reasonable person standard arrives alongside other Common Rule changes, such as new required elements of informed consent, a broad consent to allow future research on biological samples or data, and a new mandate to provide essential research information at the start of a consent form. In this collection of changes, the addition of the reasonable person standard intends to guide what goes into and what might stay out of the informed consent process.

A perennial challenge in preparing informed consent forms for participants is deciding how much information to include. One principle states that consent forms should be as concise and easily comprehended as possible, but medical studies can involve myriad procedures and extensive risk information that are difficult to summarize. To find the right balance of information and concision in informed consent, the new Common Rule will ask us to imagine the decision-making criteria of a reasonable person.

The Reasonable Person in Research

This new player, the reasonable person, appears twice in the revised Common Rule. Here:

45 CFR 46.116(a)(4) The prospective subject or the legally authorized representative must be provided with the information that a **reasonable person** would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.

And here:

45 CFR 46.116(d)(2) A general description of the types of research that may be conducted with the identifiable private information or identifiable biospecimens. This description must include sufficient information that a **reasonable person** would expect that the broad consent would permit the types of research conducted.

Unfortunately, this is all the drafters of the Common Rule have said about this potentially influential person, and that has left more than a few questions unanswered. During a February conference in San Diego, an attendee asked a representative of HHS's Office for Human Research Protections (OHRP) whether OHRP would issue any guidance about the reasonable person standard. The representative answered, "I'm sure we are." To date, however, none has appeared. In April, attorney Jeanne Velders and Dr. Johnathan Green discussed the reasonable person standard at the Association for the Accreditation of Human Research Protection Programs (AAHRPP) conference. There they posed a crucial question: Who in the research community determines what is reasonable? A slide from the presentation offered some candidates: study participants, principal investigators, research sponsors, institutional review boards, and regulatory authorities. No one has answered that question yet, either.

Opportunity or Hindrance?

A skeptical observer could argue that the abstract nature of an idealized, imagined person's thinking will add nothing but confusion to these discussions. Still, the reasonable person standard might offer an opportunity to influence conversations about informed consent. It could create a new context for debate, a place from which we can argue for excluding information that some might think necessary, or for including details others consider superfluous.
Another speaker at the AAHRPP conference, Dr. Jeremy Sugarman suggested that the reasonable person standard presents an opportunity for new, formative research into consenting. Ethicists and researchers can use the standard as a launching point for exploring what real people need and expect when making decisions about participation in research. If that happens, this newcomer in human subjects research, although fictitious, could prove truly influential