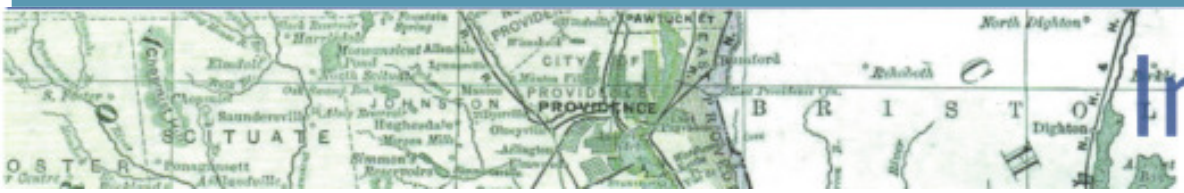
2011-1

Distinguishing the Ethics of Clinical Research and Clinical Care

Rashelle B. Hayes
University of Massachusetts Medical School



Ethics Corner

Distinguishing the Ethics of Clinical Research and Clinical Care

Clinical research is vital to clinical care. These days, more research is conducted by clinicians in more organizations and across many disciplines. Thus, at some point in a career, a clinician will undoubtedly work with researchers or may hold dual roles as both clinician and research investigator. While this can create enormous opportunities for advances in healthcare, often this can potentially allow for ethical concerns to surface. These ethical concerns may stem from a limited understanding of how clinical research differs from clinical care. Additionally, roles and obligations of a clinician versus clinician-researcher may unintentionally blur in research settings. Clarifying these differences for the clinician-researcher as well as for the patient may help to reduce ethical concerns when conducting research.

So, what are the differences? In clinical care, the primary goal is to promote the well-being of the individual patient. That is, treatment and assessment is tailored to the individual. Ethically, the potential benefits of therapeutic care prescribed to the patient must outweigh the risks posed to them. On the other hand, the goals of clinical research are to produce generalizable scientific knowledge that will improve clinical care for future patients and for society. Thus, in clinical research an individual patient receives treatment based on the scientific design of a research protocol and not on individualized care. The care is standardized and may not be the most optimal care that a patient could receive. In fact, nontherapeutic procedures that are part of a study protocol, may pose some risk to patients without providing individual benefits. However, federal regulations allow institutional review boards to only approve clinical research that minimizes risks, maximizes potential benefits, and presents the value of advanced knowledge for society that outweighs the risks.

These separate goals suggest distinct roles for the clinician and clinical-researcher. Clinician-researchers duties are protective, not fiduciary. Clinician-researchers are obligated to protect patient-participants from harm and exploitation in the course of conducting research. They must protect patient-participants from facing unnecessary risks to answering the research question and protect them from any exploitation of any vulnerabilities due to health, age, income, or other factors. Further, clinician-researchers must protect the autonomy of patient-participants by providing accurate and easy to understand information about the research aims, procedures, risks and benefits, and treatment alternatives.

Ethical concerns surface when the clinician-researcher believes he or she should fulfill a therapeutic obligation to the patient-participant, thereby changing their role and relationship with the patient-participant. For example, they may not recruit particular patients due to a belief that the individual will not benefit from the research, or they may change an aspect of the research protocol (e.g. reduce the number of assessment follow-ups) to benefit an individual patient. Although it can be argued that these behaviors were done for the patient-participant's best interests, they still violate research ethics. Emanuel and colleagues (2000) offer an in-depth discussion of the requirements that are necessary and sufficient to make clinical research ethical. These requirements are the following: value, scientific validity, fair subject selection, favorable risk-benefit ratio, independent review, informed consent, and respect for enrolled subjects.

Unfortunately, when clinician-researchers continue to blur their role as clinician and clinician-researcher, the research participant is also affected. Often patients believe that their clinician will always act with their best interests in mind. They may fail to comprehend that the purpose of research is not to promote their individual welfare. This tendency to view research as a form of medical care contributes to the therapeutic misconception (Appelbaum, 2002). Tendencies for clinician-researchers to single out any patient-participant further contributes to the therapeutic misconception, which ultimately threatens informed consent and risks exploitation. Thus, clinician-researchers have an obligation to be honest with patient-participants about the risks of research that do not promote the patient-participant's welfare. Altogether, an understanding of research ethics includes knowledge that the duties of the clinician and clinician-researcher intersect, but clearly are not identical.

Submitted by Rashelle B. Hayes, PhD
RIPA Ethics Committee

References
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Emanuel, E.J., Wendler, D., & Grady, C. (2000). What makes clinical research ethical? JAMA, 283, 2701-2711

Got a question about ethics in your professional work, whether clinical or research? Contact the RIPA Ethics Committee for assistance from a committee of your fellow psychologists. Contact Jack Hutson at 732-2900 or jhutson@ripsych.org to find the Ethics on-call member.