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Ethical Issues: Ethical Research

In academic medicine we are ruled by many masters—the need to see patients, the expectations of teaching, the desire (and expectation) to advance our careers through scholarship and research, and the ever present specter created by a never ending stream of committee/staff/faculty meetings, the agendas of which seem to have a life of their own. For those choosing academic life as a practicing physician, in order to compete and to advance, one must develop a strong resume, which requires a commitment to good scholarship as well as good doctoring—this means creating, writing about, and teaching the service oriented knowledge and skills that encourage evidence based medicine. Doing research, and doing it well, is challenging in a competitive academic environment where funding for health services research is scarce and expectations are high--its often tempting to push hard and cut corners.

Ethical research is more than “just” ensuring informed consent. In addition clinical and scientific investigations should provide added value in the enhancement of health and knowledge (not just state the obvious); incorporate fair selection procedures by equitably distributing risks, benefits, and access to research; minimize risk exposure and maximize the potential for benefit; offer independent and unbiased review of the research; and ensure ongoing respect for research subjects relating to privacy, the opportunity to withdraw, and the security of being protected from harm.ⁱ

In addition, the ethical researcher should minimize conflicts of interest. AcademyHealth has just released a report offering ethical guidelines for managing conflicts of interest in health services research.ⁱⁱ The primary interest of health services researchers is to generate and disseminate valid and reliable research that informs policy and practice. To remain credible, research integrity must be ensured in the process. Conflict of interests occur when secondary interests—such as teaching, administration, political advocacy, financial, or avocational pursuits—distort judgment regarding the primary interest.

AcademyHealth convened an Ethical Guidelines Committee comprised of individuals from a wide range of organizations and disciplines to provide practical guidance to individuals and organizations that often struggle with the potential for conflicts of interest in health services research and health policy analysis.

The Committee identified five characteristics that distinguish conflicts of interest in health services researchers:

1. The predominant financial conflict is less likely to be related to personal financial interests (as in clinical research) than to the financial viability of future research possibilities.

2. Research findings are frequently relevant to political, legal, and regulatory proceedings—which may make it difficult to distinguish between the researchers’ investigative and advocacy roles.
3. Because of the limited feasibility of randomized controlled trials in health services research, such research often relies on study designs and data sources that are less straightforward than those in basic and clinical research studies.
4. A substantial share of research funding comes from corporate, foundation, or public sponsors with direct financial, programmatic, or institutional interests in the outcomes.
5. Researchers are employed by many types of institutions (academic, private, government, etc.), and each institution has its own interests, procedures, and perceptions of what constitutes a conflict.

AcademyHealth developed guidelines addressing the initiation of, conduction of and reporting of research based on three key values: preserving and enhancing the integrity of health services research; maintaining consistency with other ethical values of health-related research; and adhering to ethical guidelines of other intersecting fields.

In developing these guidelines, the intent was to assist researchers, administrators, and organizations in managing conflicts of interest and preserving the ethical values described above. The AcademyHealth report is a good read and a helpful first step in creating a shared understanding of best practice strategies in order to ensure that conflicts of interest do not arise in the initiation, design, conducting, or dissemination of health services research.

¹ Emanuel E, Wendler D, and Grady C. What Makes Clinical Research Ethical?*JAMA*.2000;283:2701-2711
¹ <http://www.academyhealth.org/ethics/summary.htm>

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