The Hastings Center and AAAS hold a Capitol Hill briefing on the changing landscape of clinical trials

Increased commercialization and gaps in oversight as research expands raise concern about conflicts of interest and potential harm

(Washington, DC) As medical research has become a $90 billion dollar enterprise, record numbers of people are being recruited for research. More trials are being outsourced to private companies and conducted in doctors’ offices rather than in academic medical settings. Financial conflicts are a growing concern. Rare, but high profile, deaths have sparked questions about the adequacy of human research protections.

These are some of the issues addressed at a Capitol Hill briefing on May 2, co-sponsored by the American Association for the Advancement of Science and The Hastings Center.

The conclusions: Federal regulations for protecting human subjects have not kept pace with changes in the clinical trials landscape, leaving significant gaps in ethical oversight. More data about clinical trials, a less fragmented ethical review system, and updated regulations that cover new technologies such as stem cells are needed.

Karen Maschke, PhD, Associate for Ethics and Science Policy at The Hastings Center and Editor of IRB: Ethics & Human Research, gave an overview of the problem. She said that federal regulations do not cover many clinical trials funded by industry, as well as trials involving stem cells and other new technologies. Compounding the problem are gaps in basic data, such as the number of institutional review boards (IRBs), which are mandated by federal regulations to oversee the ethics of clinical trials, and the decisions they make. While there is disagreement about where to draw the line on regulating human research, Maschke said, a promising first step would be a requirement that all IRB decisions be published, thereby helping IRB members share insights into how to handle specific ethical issues.
Ivor Pritchard, PhD, Acting Director of the Office for Human Research Protections (OHRP), outlined specific regulatory problems. When the federal regulations were written 30 years ago, he said, “the typical model of research was a study that took place at a single medical institution” and would be reviewed by that institution’s own IRB. Today, with trials increasingly being held at 100 or more sites, he said, many IRBs are involved and coordination among them may be difficult.

The growing number of U.S. trials conducted in foreign countries poses additional challenges—multiple rules governing human research protections, as well as the increased risk for exploitation. “It’s cheaper to conduct trials abroad,” he said. “But we need to make sure we don’t create situations where we are exploiting people in other cultures in order to benefit Americans.”

Christine Grady, PhD, Head of the Section on Human Subjects Research, Department of Bioethics, National Institutes of Health, and a Fellow of The Hastings Center, proposed some solutions. First of all, more data is needed on what trials are being conducted and who the human subjects are. “We can’t understand the quality of protections until we know whom we’re trying to protect,” she said. She also called for training on research ethics for private doctors doing research and the creation of a new entity for human research protections that would put all research under one monitoring system.

Alan Leshner, PhD, CEO of AAAS and former Head of the National Institute on Drug Abuse at the National Institutes of Health, who moderated the panel, raised another issue related to the changing landscape: the untold number of trial results that go unpublished and the implications for the safety of human subjects as well as medical practice.

The briefing was the second in collaboration between the AAAS and The Hastings Center to reach out to media and policymakers to promote informed dialogue on important issues in medicine, science, and bioethics. The Hastings Center has established a Washington, DC office at AAAS.

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