

Conference Announcement and Call for Proposals:

The Future of Human Subjects Research Regulation

The Petrie-Flom Center for Health Law Policy, Biotechnology and Bioethics at Harvard Law School is pleased to announce plans for our annual conference, this year entitled: “The Future of Human Subjects Research Regulation” The one and a half day event will take place Friday, May 18 and Saturday May 19, 2012 at Harvard Law School in Cambridge, Massachusetts.

Conference Description

The U.S. Department of Health and Human Services recently released an Advanced Notice of Proposed Rulemaking (ANPRM), titled “Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators,” which proposes to substantially amend the Common Rule for the first time in twenty years. This development, as well as attention by the Presidential Commission for the Study of Bioethical Issues, suggests we are at a moment when the regulation of human subjects research is ripe for re-thinking. This conference is meant to gather leading experts from the U.S. and across the globe to assist in that endeavor.

We currently plan on having panels with papers on the following topics specifically covered by the ANPRM:

- Calibration of oversight based on risk level
- The regulation of multi-site clinical studies, including international sites
- Data security and information protection standards, as well as informational risks
- Unanticipated problems and adverse event reporting
- Which institutions and types of research should be regulated by the Common Rule, including exempt and excused categories
- Consent to biospecimen research
- IRB appeal mechanisms

We also hope to have papers and panels on the following topics *not* directly covered by the ANPRM:

- Biobanking
- Claims to the proceeds of research, and access to successful products

- Liability and compensation for study-related injuries
- Online research and solicitation of subjects
- Disclosure of results
- Payment and other benefits to subjects
- Community engagement
- Research involving special populations
- Gaps between US regulations and international ethical standards
- IRBs and Data Safety and Monitoring Boards
- The participatory turn in human subjects research (i.e., subjects as partners)
- Regulatory risk aversion, in general
- The appropriate relationship between ethical review and institutional Risk Management.
- IRBs and academic freedom
- The globalization of human subjects research, and research ethics.

This list is not meant to be exhaustive, and paper proposals related to the conference's general theme but not specifically listed above are welcome.

If you are interested in participating please reply to petrie-flom@law.harvard.edu as soon as possible, but not later than November 25, 2011, and include a brief, single-paragraph description of your proposal for presentation. Full abstracts will be due by January 6, 2012, and final submissions will be due after Spring Break, closer to the date of the event. The conference will pay travel expenses for those selected to present who must travel to Cambridge.

In the past we have successfully turned some conferences into edited volumes (one was published by Oxford University Press and a second is set to be published by Oxford soon). If such a volume arises out of this conference, authors will have the option (but are not required) to publish their paper with us.