

Bioethics Commission Study Released

December 16, 2011

The Presidential Commission for the Study of Bioethical Issues has released its report "[Moral Science: Protecting Participants in Human Subjects Research](#)." The report was requested by President Obama to determine if current regulations adequately protect human subjects in federally funded research. The Commission determined that current regulations "generally appear" to protect participants from harm or unethical treatment, "as far as is feasible given limited resources," but that it cannot say if current regulations are optimal for protecting against avoidable harm and unethical treatment because some agencies have limited ability to identify basic information about all human subject research.

The Commission made several recommendations of actions to improve protections for human subjects which are of interest to FDA regulated entities that perform human trials. The Commission recommended, among other things, that the government:

1. develop a central, web-based portal for research from each federal agency to increase transparency
2. develop a systematic assessment of the effectiveness of human subject protections for future human studies
3. explore development of a national system of compensation or treatment for research-related injuries
4. clearly articulate ethical standards in regulatory provisions
5. revise the Common Rule to address the role of investigators as is done in FDA clinical research regulations and in international standards
6. develop rigorous bioethics and human subject research courses at all levels of post-secondary education
7. develop a process for evaluating foreign government and non-governmental organization standards for equivalency of protection for human subjects
8. develop a framework for community engagement
9. ensure research sites and researchers have the capacity to support protection of human subjects
10. evaluate responsiveness to local needs as a condition for research site selection
11. ensure ethical study design for control trials
12. support current federal reform efforts such as accounting for risk to human subjects when

determining level of research review, eliminating continuing review for certain low risk studies, reducing unnecessary institutional review in multi-site studies, making available standardized consent forms that are easily understood, requiring that all federal agency regulations are consistent with the Common Rule, and developing an adverse event reporting system compatible across all agencies