



Contemporary Issues for Protecting Patients in Cancer Research: Workshop Summary

*Sharyl J. Nass, Margie Patlak, National Cancer Policy Forum, Board on Health Care Services, Institute of
Medicine*

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In the nearly 40 years since implementation of federal regulations governing the protection of human participants in research, the number of clinical studies has grown exponentially. These studies have become more complex, with multisite trials now common, and there is increasing use of archived biospecimens and related data, including genomics data. In addition, growing emphasis on targeted cancer therapies requires greater collaboration and sharing of research data to ensure that rare patient subsets are adequately represented. Electronic records enable more extensive data collection and mining, but also raise concerns about the potential for inappropriate or unauthorized use of data, bringing patient protections into a new landscape. There are also long-standing concerns about the processes and forms used to obtain informed consent from patients participating in clinical studies. These changes and challenges raise new ethical and practical questions for the oversight of clinical studies, and for protecting patients and their health information in an efficient manner that does not compromise the progress of biomedical research.

Contemporary Issues for Protecting Patients in Cancer Research is the summary of a workshop convened by the National Cancer Policy Forum of the Institute of Medicine in February 2014 to explore contemporary issues in human subjects protections as they pertain to cancer research, with the goal of identifying potential relevant policy actions. Clinical researchers, government officials, members of Institutional Review Boards, and patient advocates met to discuss clinical cancer research and oversight. This report examines current regulatory provisions that may not adequately protect patients or may be hindering research, and discusses potential strategies and actions to address those challenges.



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