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Nota di contenuto	Session 1: Review of the Evidence -- Session 2: Risks and Harms -- Session 3: The Consent Process and Special Populations -- Session 4: Data Use and Sharing and Technological Advancements -- Session 5: Multisite and Multidisciplinary Studies -- Session 6: Purview and Roles of Institutional Review Boards -- Appendix A: Workshop Agenda -- Appendix B: Biographical Sketches of Speakers.
Sommario/riassunto	On July 26, 2011, the U.S. Department of Health and Human Services issued an advance notice of proposed rule-making (ANPRM) with the purpose of soliciting comments on how current regulations for protecting research participants could be modernized and revised ... on how to better protect human subjects who are involved in research, while facilitating valuable research and reducing burden, delay, and ambiguity for investigators. The current regulations governing human subjects research were developed years ago when research was

predominantly conducted at universities, colleges, and medical institutions, and each study generally took place at only a single site. Although the regulations have been amended over the years, they have not kept pace with the evolving human research enterprise, the proliferation of multi-site clinical trials and observational studies, the expansion of health services research, research in the social and behavioral sciences, and research involving databases, the Internet, and biological specimen repositories, and the use of advanced technologies, such as genomics ... [The summary] focuses on six broad topic areas: 1. Evidence on the functioning of the Common Rule and of institutional review boards (IRBs), to provide context for the proposed revisions. 2. The types and levels of risks and harms encountered in social and behavioral sciences, and issues related to the severity and probability of harm, because the ANPRM asks for input on calibration of levels of review to levels of risk. 3. The consent process and special populations, because new rules have been proposed to improve informed consent (e.g., standard consent form, consent for future uses of biospecimens, and re-consenting for further use of existing research data). 4. Issues related to the protection of research participants in studies that involve use of existing data and data sharing, because the ANPRM proposed applying standards for protecting the privacy of healthcare data to research data. 5. Multidisciplinary and multisite studies, because the ANPRM proposed a revision to the regulations that would allow multisite studies to be covered by a single IRB. 6. The purview and roles of IRBs, because the ANPRM included possible revisions to categories of research that could entail changes in IRB oversight. --