their proxies will be obtained. Regulations require consent by research participants or their legal representative except when four specific conditions are met, including "a life-threatening situation necessitating the use of the test article." 21 C.F.R. § 50.23.

A number of states, such as California and New York, have enacted legislation similar to the HHS regulations. See Cal. Penal Code §§ 2670–2678 (West 2012); N.Y. Pub. Health Law §§ 2440–2446 (McKinney 2013). Like the HHS regulations, both New York and California require participant's informed consent. Unlike the HHS regulations, both the California and New York statutes cover all medical research conducted within the state, not just research in institutions receiving state funding. Neither the California nor the New York statutes explicitly cover behavioral research (unlike the HHS regulations, which cover all human-participant research but do explicitly exempt several categories of behavioral research including surveys, educational testing, and observation of public behavior. 45 C.F.R. § 46.101(b)).

Neither federal nor most state regulations provide specific remedies for individuals injured while participating in research. HHS does deny funding to institutions with whom an offending researcher is affiliated, while California imposes criminal penalties and fines on medical researchers who fail to obtain participants' informed consent. Cal. Health & Safety Code § 24176 (West 2012). A private legal remedy may nevertheless be available to an injured participant under state tort law or conceivably under one of the federal civil rights statutes. See *Grimes v. Kennedy Krieger Inst., Inc.*, 782 A.2d 807 (Md. Ct. App. 2001). The scope of the Federal Civil Rights laws and their impact on the mental health treatment field is discussed in Chapter Three, supra.

QUESTIONS AND COMMENTS

1. *Disclosure under HIPAA of PHI obtained in a research context.* A research institution is only subject to the Health Insurance Portability and Accountability Act (HIPAA) privacy rules if it is a covered entity. (HIPAA privacy provisions and the definition of "covered entity" are discussed in detail in Chapter Five, infra.) However, if the research facility is also involved in treatment and meets HIPAA's covered entity criteria it must comply with these privacy rules. This means that it can transfer personal health information (PHI) to another covered entity without a patient's authorization, but transfer of PHI to a non-covered entity requires the research participant's authorization. As a practical matter, however, such authorization will generally be obtained before admitting an individual into the research program. Such pre-admission authorization is permitted by HIPAA privacy rules (45 CFR § 164.508(b)(4)(i)), discussed in greater detail in Chapter Five, infra.

2. *International standards.* An important contributing factor to the movement for reform—both in the U.S. and in other countries—was the

disclosure of human rights abuses carried out under the guise of scientific and medical experimentation by Nazi scientists and physicians during World War II. See Marian F. Ratnoff & Justin C. Smith, *Human Laboratory Animals: Martyrs for Medicine*, 36 Ford. L. Rev. 673, 679 (1968). The World Medical Association has been at the forefront of efforts to develop international standards for the control of human experimentation. One result of these efforts is the Helsinki Declaration, the sixth revision of which was issued in 2008, which sets out ethical principles regarding human experimentation. See Jon R. Waltz & Fred E. Inbau, *Medical Jurisprudence* 381–83 (1971); Edmund Pellegrino, *The Nazi Doctors and Nuremberg: Some Moral Lessons Revisited*, 127 Annals Internal Med. 307 (1997); Joseph E. Persico, *Nuremberg: Infamy on Trial* (1994).

The Tuskegee study and other abuses that stimulated the movement towards greater regulation of research involving human participants are discussed in Nathan Hershey and Robert D. Miller, *Human Experimentation and the Law* 153–56 (1976); see also Giselle Corbie–Smith, *The Continuing Legacy of the Tuskegee Syphilis Study: Considerations for Clinical Investigation*, 317 Am. J. Med. Sci. 5 (1999).

3. *HHS regulations.* The HHS regulations under the National Research Act delegate to each institution's IRB the power to prospectively review all consent forms and procedures. But the regulations do not indicate to what degree IRB representatives should monitor or intervene in the consent process to insure that research participants are truly informed. Some commentators have argued IRBs concentrate too heavily on the review and revision of consent forms, suggesting that participants might receive better protection if IRB representatives more frequently intervened in the consent process itself. See John A. Robertson, *Taking Consent Seriously: IRB Intervention in the Consent Process*, 4 IRB: A Rev. of Hum. Subject Res. 1 (1982) (citing a study by Gray (1975) in which 40% of participants signing consent forms did not know they were involved in research). See also James Flory & Ezekiel Emanuel, *Interventions to Improve Research Participants' Understanding in Informed Consent for Research: A Systematic Review*, 292 JAMA 1593 (2004) (concluding "investing additional effort in forms is . . . unlikely to have a large effect on understanding" and that "adding an extra meeting with a qualified person is the most reliable approach to improving understanding," while noting "lower educational attainment, mental illness, and perhaps advanced age are associated with lower understanding").

4. *Definition of "risk of harm."* Under the HHS regulations, determinations of the likely risks to human participants should have a significant impact on whether the IRB will approve proposed research. Accordingly, the definition of risk of harm will be pertinent to a court's determination of whether a researcher acted negligently. Neither state nor federal regulations, however, adequately define risk of harm. Under the HHS regulations "minimal risk" means "that the probability and magnitude of harm or discomfort anticipated in the research are not greater . . . than those ordinarily encountered in daily life or during the performance of routine