11-25-2013

Legal and Policy Environment for State-Based Biomedical Research

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Support for biomedical research and protection of human subjects in that research are primarily federal responsibilities. However, primacy does not necessarily mean exclusivity. Although sometimes overlooked, state laws play an important role either by extending the reach of human subjects protection beyond that afforded under federal law, addressing issues left open by federal regulation, or determining which types of research to encourage or prohibit.

I. Augmenting Protection of Human Subjects

Under the Common Rule, federally funded or conducted research must comply with regulations aimed at protecting human subjects. Similarly, researchers may submit research to the Food and Drug Administration (FDA) in support of an application for approval of a drug or device only if such research adhered to the protections for human subjects in FDA regulations. These parallel regulatory schemes include the following essential elements: (1) voluntary informed consent; (2) the provision of information enabling intelligent choice by potential subjects, free of coercion or undue influence; (3) review by an institutional review board (IRB), a group independent of the researchers; and (4) an IRB determination that the benefits potentially derived from the research justify the risks to research subjects.

Important gaps and limitations characterize this federal regulatory regime. Specifically, core protections in the Common Rule and FDA regulations, including additional regulatory protections for prisoners and children, do not extend to privately funded and conducted research not used in an application to the FDA. Additionally, these regulations do not afford a remedy to individuals who may have been harmed as a result of their participation in research. Also, some of the protections are just plain vague (such as an IRB’s duty to include “additional safeguards” for vulnerable subjects). Other issues are left unaddressed (for example, circumstances under which an individual incapable of giving informed consent may nonetheless become a research subject).

Federal regulations are modest in recognizing that state law may serve to fill in these gaps. The Common Rule is explicitly non-preemptive: the regulations do not affect state laws that “provide additional protections for human subjects” or that “require additional information . . . for informed consent to be legally effective.”

Similar language also appears in FDA regulations. Accordingly, preserving a state’s role in the protection of human subjects appropriately recognizes the state traditional police power.

Under the rubric of additional protections, four states - California, Maryland, New York, and Virginia - impose an informed consent requirement for all research, including privately funded research. Three of these states - Maryland, New York, and Virginia - require IRB review for all research. In addition, many state laws provide additional protections for vulnerable populations. At least five states prohibit using prison inmates for “medical, pharmaceutical, or cosmetic experiments,” although these individuals may participate in research that is “medically appropriate for a specific inmate.” Also, to protect nursing home residents, states frequently grant residents an explicit right to refuse to participate in experimental research or require that informed consent be obtained prior to a resident’s research participation.

II. Developing the Law of “Research Negligence”

State tort law potentially affords subjects a means of compensation for research harms. In comparison, federal regulations neither require compensation in the event of injury nor create a private right of action to seek compensation; they merely require disclosure about the extent of available compensation, which may be nothing. State common law fills this void by specifying a researcher’s duty to subjects and the circumstances under which a breach of this duty occurs.

In one respect, state research liability law is well-established, arising from ad hoc experimentation during the course of clinical care. As a New York court observed more than a century ago in Carpenter v. Blake, when standard therapy exists, “there should be no departure from it, unless the surgeon who does it is prepared to take the risk of establishing by his success the propriety and safety of his experiment.” Similar cases also highlighted this point: in the clinical setting, the patient is entitled to expect the skillful application of standard therapy. Consequently, the use of experimental treatment that harms the patient

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gives rise to negligence claims, unless the patient properly consented to the procedure.

More recent cases often focus on alleged deficiencies in the informed consent process. In equating the confidentiality of medical records or mandating the reporting of driven research related to stem cells” that is now hampered by “limited Regenerative Medicine, which will support “open-ended, investigator-denied federal funding under the policies of the Bush Administration. by using public funds to support the kind of embryonic stem-cell research to ban the research altogether. However, if a state’s public policy favors the California Court of Appeals held that the jury should have been allowed to consider all of the evidence, not just expert testimony, in deciding whether his physicians breached the standard of care.11 In particular, the jury should have considered the effect of federal and California informed consent requirements.12 Because the physician-investigators had agreed to comply with FDA regulations, the regulations themselves established the standard of care. The Court then held that the plaintiff had “presented sufficient evidence that his injury resulted from the kind of occurrence the statutes and regulations . . . were intended to prevent: participation in a clinical trial without the subject’s fully informed consent in writing, with a copy for the subject and under circumstances permitting a free and deliberate choice.”13 Under this analysis, failure to adhere to regulatory standards for informed consent amount to the tort of “research negligence.”

In Moore v. Regents of the University of California, the California Supreme Court suggests that some courts view informed consent as requiring disclosure not only of the protocol-related information specified in the Common Rule but also of any material economic incentives that affect the researcher.14 Moore, also arising in a clinical setting, held that a physician who used a patient’s surgically removed spleen to create a patented cell line should have disclosed his research and economic interests to the patient prior to removing the spleen.15

A research negligence claim might also arise if research procedures are carried out in a different manner than described in the informed consent document.16 In Grimes v. Kennedy, in controversial dicta, the Maryland Court of Appeals also laid the basis for claims that proxy consent (here, of a parent on behalf of a child), although permissible under the federal regulations, was deficient as a matter of state law and hence invalid.17

III. State Policy Decisions For or Against Research
If states deem that a particular type of research endeavor - human cloning, for example - is contrary to sound public policy, they are free to ban the research altogether. However, if a state’s public policy favors embryonic stem-cell research, which some scientists seek to pursue using cloning techniques, a ban on cloning can be drafted to exclude those techniques from the ban. Indeed, several states have gone even further by using public funds to support the kind of embryonic stem-cell research denied federal funding under the policies of the Bush Administration. For example, California has established a state-funded Institute for Regenerative Medicine, which will support “open-ended, investigator-driven research related to stem cells” that is now hampered by “limited federal support.”18

States may also facilitate research in more subtle ways. Laws protecting the confidentiality of medical records or mandating the reporting of certain diseases to a state registry, invariably allow access by researchers. Similarly, vital records laws typically have a broadly phrased research exception to their confidentiality requirements. For example, Illinois mandates the reporting of Reye’s Syndrome cases which allows individually identifiable data available for “health-related research” to researchers who agree not to redisclose the data.19 Also, public records laws, which always exempt individual health and other sensitive information from mandatory disclosure, usually allow researchers access to this information if they agree to protect the confidentiality of the records.

IV. Conclusion
In sum, current public policy on human subjects research is fractured. The federal regulatory scheme remains incomplete, and state laws vary significantly in their scope and content. This diversity, while an attractive aspect of federalism, has been criticized as inefficient and inconsistent with a research environment that increasingly involves multi-site collaborations. Nevertheless, in the absence of major federal initiatives, innovative public policy is more likely to originate from states.

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1 See 45 C.F.R. § 46.101(a) (2005).
3 See 45 C.F.R. § 46.111(b) (2005).
5 See 21 C.F.R. §§ 50.25(d), 56.103(c) (2001).
8 See 103 MARY. CODE REGS. § 180.07 (2007).
9 See 60 Barb. 488, 523 (N.Y. Sup. Ct. 1871).
12 See id. at 1314-15.
13 See id. at 1317-18.
14 See id. at 1309.
16 See id.
18 See id.