Mobile Research Applications and State Research Laws

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Introduction

This article assesses the protections provided by state research laws for participants in mobile application (mobile app) mediated health research conducted by independent scientists, citizen scientists, and patient researchers. Prior scholarship in this area focuses on the lack of application of: (1) federal regulations governing research conducted or funded by one of sixteen signatory federal departments and agencies (the Common Rule);[1] and (2) separate federal regulations promulgated by the Food and Drug Administration applicable to research conducted in anticipation of a submission to the FDA for approval of a drug or medical device.[2] This article builds on this prior scholarship by carefully examining state research laws and suggesting ways in which these laws could be improved to better protect participants of mobile app-mediated research conducted by independent scientists, citizen scientists, and patient researchers.

As discussed in more detail below, a number of states have enacted laws that govern non-federally funded research. Some of these laws apply to all research involving human participants, deferring to the Common Rule's definitions of research and human subject. Other laws apply only to certain types of researchers (e.g., physician researchers), certain types of research participants (e.g., hospital inpatients and outpatients), certain types of research interventions (e.g., physical or physiological interventions), or research conducted in certain facilities (e.g., hospitals and other state-licensed health care facilities).

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In terms of their substantive protections, some of these laws defer to the requirements set forth in the Common Rule, whereas others establish state-specific, research-related obligations, including detailed human research review committee requirements, enumerated approval-of-research criteria, and explicit consent-to-research language. Still other laws contain modest consent-to-research provisions. As currently written, some of these laws would apply to mobile app-mediated health research conducted by independent scientists, citizen scientists, and patient researchers. Other laws would require amendment to address the unregulated mobile research space. Taken together, these laws suggest the capacity of states to enact research-specific laws designed to protect the health, safety, and welfare of individuals who participate in federally-unregulated research.

Maryland

Enacted in 2002, the Maryland research law requires "a person conducting human subject research to comply with federal regulations on the protection of human subjects."[3] The Maryland law regulates "all research using a human subject," regardless of whether such research is federally funded,[4] and prohibits "a person" from "conduct[ing] research using a human subject unless the person conducts the research in accordance with the federal regulations on the protection of human subjects."[5] The law authorizes the Maryland Attorney General to seek injunctive and other relief to prevent the conduct of human subject research in violation of the Common Rule.[6]

The Maryland law is desirable in the context of mobile app-mediated research due to its unrestricted use of the word "person." The Maryland law applies to all researchers, including traditional scientists,

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independent scientists, citizen scientists, and patient researchers, as well as any other person who conducts research.[7] Other state research laws discussed below only apply to certain researchers, such as researchers who are licensed physicians or researchers who conduct research in licensed health care facilities.

A second desirable feature of the Maryland law is its definition of "federal regulations on the protection of human subjects." The definition specifically references "Title 45, Part 46 of the Code of Federal Regulations [the Common Rule], and any subsequent revision of those regulations."[8] The Maryland law anticipates the possible revision of the Common Rule and expresses a clear desire for Maryland research to be conducted in accordance with the most current version of the Common Rule. If other states enacted laws like the Maryland law (or if the Maryland law were used as a model for a Uniform State Research Law), research regulation would be uniform among all fifty states and interpretation of such laws would be consistent with the Common Rule, greatly easing implementation, compliance, and enforcement efforts.

The Maryland law is desirable in the context of mobile app-mediated research due to its unrestricted use of the word "person." The Maryland law applies to all researchers, including traditional scientists, independent scientists, citizen scientists, and patient researchers, as well as any other person who conducts research. Other state research laws discussed below only apply to certain researchers, such as researchers who are licensed physicians or researchers who conduct research in licensed health care facilities.

Virginia

The Virginia research law, enacted in 1979,[9] has been amended several times. Currently, it regulates "human research," defined as a "systematic investigation, including research development, testing and evaluation, utilizing human subjects, that is designed to develop or contribute to generalized knowledge."[10] Like the Maryland law, the Virginia law is not limited in application to federally-funded research.[11] Instead, it applies to any human research conducted by the State of Virginia and any political subdivision thereof, as well as "any facility, program, or organization owned or operated by … any person, firm, corporation, association, or other legal entity."[12] As written, the Virginia law would apply to research programs owned or operated by independent scientists, citizen scientists, and patient researchers.

Unlike the Maryland law, which defers to the Common Rule, the Virginia law establishes its own unique research regulations, including detailed requirements for the formation of human research review committees,[13] criteria for review committee approval of research,[14] and mandatory informed-consent-to-research statements.[15] If other states followed Virginia and established their own unique research protections, the result could be a patchwork of state laws. Compliance with this patchwork would prove difficult for mobile app-mediated researchers who collect data from study participants who reside in a variety of states.

The Virginia law does, however, appear to have contemplated that independent scientists might be involved in the conduct of human research and considered how best these independent researchers might be brought into the fold: "Every person engaged in the conduct of human research or proposing to conduct human research shall affiliate himself with an institution or agency having a research review committee, and the human research which he conducts or proposes to conduct shall be subject to review and approval by such committee in the manner set forth in [the Virginia law]."[16] The Virginia law also mandates that review committees assess "whether the persons proposing to conduct the particular human research are appropriately competent and qualified."[17] These provisions, in theory, respond to the quality concerns associated with independent researchers and citizen scientists.[18]

New York

Enacted in 1975, the New York research law establishes a policy of protecting state residents against "pain, suffering or injury resulting from human research conducted without their knowledge or consent."[19] To this end, the New York law regulates "human research" involving "human subjects" to the extent such research is not subject to the federal Common Rule.[20] The New

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York law broadly defines "human subjects" to include "any individual who may be exposed to the possibility of injury, including physical, psychological or social injury, as a consequence of participation as a subject in any research ... "[21]

At first glance, the New York law would appear to protect mobile research participants who could be psychologically or socially injured by privacy and security breaches involving research data. However, human subjects are only protected by the New York law if they participate in "human research," defined narrowly as those investigations that involve physical or psychological intervention by the researcher on the body of the subject.[22] The New York law thus does not protect participants of mobile app-mediated informational research. If "human subjects" are involved in "human research," however, the New York law contains detailed requirements relating to the formation of human research review committees,[23] specific criteria for review committee approval of research,[24] and explicit informed-consent-to-research obligations.[25]

A desirable feature of the New York law, like the Virginia law, is that it appears to have contemplated that independent scientists might be involved in the conduct of human research: "Each person engaged in the conduct of human research or proposing to conduct human research shall affiliate himself with an institution or agency having a human research review committee, and such human research as he conducts or proposes to conduct shall be subject to review by such committee in the manner set forth in [the New York law]."[26] The New York law also requires review committees to determine "that the persons proposed to conduct the particular medical research are appropriately competent and qualified,"[27] thus potentially responding to quality concerns associated with citizen science and other forms of unregulated research.[28]

California

Signed into law in 1978, the California Protection of Human Subjects in Medical Experimentation Act (California law) recognizes that "medical experimentation on human subjects is vital for the benefit of mankind, however such experimentation shall be undertaken with due respect to the preciousness of human life and the right of individuals to determine what is done to their own bodies."[29] To this end, the California law establishes a detailed "bill of rights"[30] as well as a series of explicit informed consent requirements[31] designed to benefit subjects of medical experiments.[32]

However, the California law only applies to "medical experiments," narrowly defined to include the "severance or penetration or damaging" of tissues of a human subject as well as the use of certain drugs, devices, and substances. The California law thus would not apply to many mobile app-mediated research projects due to the research participants' lack of physical involvement. That said, some internet-mediated research studies have involved participants' ingestion of drugs, such as lithium,[33] and these types of studies might be captured by the California law.

Illinois

The Illinois law, "An Act Concerning Certain Rights of Medical Patients," was enacted in 1979. As currently written, the Illinois law requires physician researchers who conduct research programs or experimental procedures involving hospital inpatients and outpatients to provide those patients with an "explanation of the nature and possible consequences of [the] research or experiment before the research or experiment is conducted" as well as the opportunity to consent, or refuse to consent, to research participation.[34] The Illinois law further specifies that no physician shall conduct a research program or an experimental procedure without the prior informed consent to research of the patient.[35]

Regulations implementing the Illinois law define a "research program" as an "organized activity intended to establish new medical or scientific information, involving medical, surgical, manipulative, or psychiatric diagnosis or treatment of human subjects who are inpatients or outpatients of a hospital and who are subjects at risk."[36] The regulations further define "experimental procedures" as "the use of medical, surgical, manipulative, or psychiatric procedures, drugs, or devices for purposes of diagnosis or treatment of human subjects who are inpatients or outpatients of a hospital and who are subjects at risk."[37] As a result of these limited definitions, the Illinois law would not apply to mobile app-mediated research studies conducted by non-physician researchers and/or involving non-hospital patients.

Florida

Enacted in 1991, the "Florida Patient's Bill of Rights and Responsibilities" was intended to "promote the interests and well-being of the patients of health care providers and health care facilities and to promote better communication between the patient and the health care provider."[38] To this end, and among many other requirements, the Florida law establishes certain notification and consent requirements applicable to experimental research.[39] In particular, the Florida law provides: "a patient has the right to know if medical treatment is for purposes of experimental research and to consent prior to participation in such experimental research."[40]

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The Florida law, however, only applies to patients of health care providers and health care facilities.[41] The Florida law thus would not apply to mobile app-mediated research studies conducted by non-health care providers who work outside traditional, bricks-and-mortar health care facilities.

Wisconsin

A final, illustrative state research law, enacted in Wisconsin in 1976, establishes a right of patients not to be subjected to experimental research without informed consent and the duty of researchers to conduct research in accordance with the Common Rule.[42] However, the Wisconsin law only protects "patients," defined as certain individuals with mental illness, developmental disabilities, alcoholism, or drug dependency who receive treatment for such conditions in certain licensed health care facilities.[43] Because mobile app-mediated research can involve participants who do not have mental illness and/or who do not receive mental health care in a licensed health care facility, the Wisconsin law does not adequately respond to the ethical and legal concerns associated with mobile app-mediated health research.

Conclusion

Due to a lack of federal funding or a lack of contemplated submission to the FDA for approval of a drug or medical device, not all mobile app-mediated health research involving human participants will be subject to federal regulation. This article has examined state regulation of research involving human participants, focusing on the applicability of such regulation to research projects conducted by independent scientists, citizen scientists, and patient researchers. As currently written, the Maryland and Virginia laws would require all mobile app-mediated researchers to comply with the Common Rule and state law requirements that are similar to the Common Rule, respectively. Other states laws would require amendment to apply to the mobile app-mediated health research space.

States that do not currently regulate all non-federally funded research should consider enacting a comprehensive law (or amending existing laws) to regulate all research conducted in the state. These states should review the Maryland research law, which contains a broad definition of "person" performing research and expressly applies the most recent version of the Common Rule. To promote uniformity in state laws, organizations that draft and advocate for the adoption of uniform or model state laws, such as the Uniform Law Commission (ULC), should initiate efforts to draft a Uniform State Research Law.

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Note

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1. The current list of 16 Common Rule Departments and Agencies and their regulations are as follows: Department of Homeland Security, 6 C.F.R. Pt. 46; Department of Agriculture, 7 C.F.R. Pt. 1c; Department of Energy, 10 C.F.R. Pt. 745; National Aeronautics and Space Administration, 14 C.F.R. Pt. 1230; Department of Commerce, 15 C.F.R. Pt. 27; Social Security Administration, 20 C.F.R. Pt. 431; Agency for International Development, 22 C.F.R. Pt. 225; Department of Housing and Urban Development, 24 C.F.R. Pt. 60; Department of Labor, 29 C.F.R. Pt. 21; Department of Defense, 32 C.F.R. Pt. 219; Department of Education, 34 C.F.R. Pt. 97; Department of Veterans Affairs, 38 C.F.R. Pt. 16; Environmental Protection Agency, 40 C.F.R. Pt. 26; Department of Health and Human Services, 45 C.F.R. Pt. 46; National Science Foundation, 45 C.F.R. Pt. 690; Department of Transportation, 49 C.F.R. Pt. 11.
2. 21 C.F.R. Pt. 50. See Food and Drug Administration, Protection of Human Subjects; Informed Consent, 46 Fed. Reg. 8942 (1981).
3. An Act Concerning Human Subject Research, Ch. 552, H.B. 917, 2002 (Reg. Sess.), May 16, 2002.
4. Md. Code Ann., Health-Gen. § 13-2002(b).
5. *Id.* § 13-2002(a).
6. *Id.* § 13-2004(a).
7. *Id.* § 13-2002(a).
8. *Id.* § 13-2001(b)(1) (italicized emphasis added).
9. Virginia Acts 1979, ch. 38, § 37.1-234.
10. Va. Code Ann. § 32.1-162.16.
11. *See* Va. Code Ann. § 32.1-162.20 (2018) ("Human research which is subject to policies and regulations for the protection of human subjects promulgated by any agency of the federal government shall be exempt from the provisions of this chapter."); *id.* § 32.1-162.18 (exempting other categories of research from state regulation).
12. *Id.* § (defining institution or agency).
13. *Id.* § 32.1-162.19(A).
14. *Id.* § 32.1-162.19(B).
15. *Id.* §§ 32.1-162.18(A) and 32.1-162.19(B).
16. *Id.* § 32.1-162.19(D).
17. *Id.* § 32.1-162.19(B).
18. For a further discussion, see M.A. Rothstein et al., "Unregulated Health Research Using Mobile Devices: Ethical Considerations and Policy Recommendations," *Journal of Law, Medicine & Ethics* 48, no. 1, Suppl. 1) (2020): 196-226 (Part I-D, Quality Issues).
19. N.Y. L.1975, c. 450, § 1, currently codified at N.Y. Pub. Health § 2440 et seq.
20. N.Y. Pub. Health § 2445 ("The provisions of this article shall not apply to the conduct of human research which is subject to, and which is in compliance with, policies and regulations promulgated by any agency of the federal government for the protection of human subjects.").
21. *Id.* § 2441(1).
22. *Id.* § 2441(2) ("'Human research' means any medical experiments, research, or scientific or psychological investigation ... which involves physical or psychological intervention by the researcher upon the body of the subject and which is

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not required for the purposes of obtaining information for the diagnosis, prevention, or treatment of disease or the assessment of medical condition for the direct benefit of the subject.").
23. *Id.* § 2444(1).
24. *Id.* § 2444(2).
25. *Id.* § 2442.
26. *Id.* § 2444(3). *See also id.* § 2441(6) (defining researchers to include not only individuals licensed to diagnose and treat patients but also "any other person deemed appropriately competent and qualified by a human research review committee [under the New York law].").
27. *Id.* § 2444(2).
28. *See supra* note 18.
29. Cal. Stats. 1978, ch. 360, p. 1077, § 1 (1978), currently codified at Cal. Health & Safety Code §§ 24170-24179.5.
30. Cal. Health & Safety Code § 24172.
31. *Id.* §§ 24173, 24175.
32. *Id.* § 24176.
33. *See* Paul Wicks et al., "Accelerated Clinical Discovery Using Self-Reported Patient Data Collected Online and a Patient-Matching Algorithm," *Nature Biotechnology* 29, no. 5 (2011): 411-416 (analyzing data reported on a website by patient researchers with ALS who experimented with lithium carbonate).
34. 410 Ill. Comp. Stat. § 50/3.1(a).
35. *Id.* § 50/3.1(b).
36. 7 Ill. Admin. Code § 250.130(b)(1)(B).
37. *Id.* § 250.130(b)(1)(A).
38. The Florida Patient's Bill of Rights and Responsibilities, Fla. S.B. No. 292, Chapter 91–127 (May 28, 1991).
39. Fla. Stat. § 381.026(4)(e).
40. *Id.*
41. *Id.* § 381.026(4) ("Each health care provider or facility shall …").
42. Wis. Stat. § 51.61(1)(a)(j).
43. *Id.* § 51.61(1).

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