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Abstract: When State Laws Conflict: Choice of Law Challenges in Multi-Site Research

Precision medicine offers the promise of health advances through the combined study of individual variation in genes, environment, and lifestyle. Massive studies with millions of participants have become feasible due to declining cost of genome sequencing, widespread use of electronic health records, proliferation of wearable devices, and other technological advances. But the scale of these studies in terms of participants, data collected, and questions addressed, coupled with evolving information risks, also create new challenges.

Our previous research demonstrated that precision medicine research implicates numerous state laws that govern an array of topics—human subjects research, genetic testing, and both general and genetic privacy and discrimination to name a few—that are not preempted by federal law. These state laws can substantially alter participant rights and protections in precision medicine research. Thus, the choice of which state’s laws apply, and under what circumstances can have significant impact on research design and human subjects protections.

However, the traditional route for addressing choice of law issues—contractual agreement—is not available in the context of research and there has been little attention to the problem of accounting for and reconciling state laws in research oversight. The evolving research context, including the new federal requirements for single-IRB review, is likely to bring choice of law issues to rapid prominence.

In our NIH-funded exploratory research project, we conducted qualitative interviews with key informants regarding their experiences and opinions regarding choice of law questions in the research context. We also held workshops with choice of law experts and research law and ethics experts together to identify the factors, including the places associated with precision medicine research, characteristics of participant’ rights and protections, and elements of choice of law frameworks that are most crucial to account for in a future choice of law precision medicine research framework.

We will present the findings from both aims of our research and the implications of that research for future research and development of a framework for addressing choice of law questions in precision medicine research design and consent processes.