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New report says individual research results should be shared with participants more often

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When conducting research involving the testing of human biospecimens, investigators and their institutions should routinely consider whether and how to return individual research results on a study-specific basis through an informed decision-making process, says a new report from the National Academies of Sciences, Engineering, and Medicine. Decisions on whether to return individual research results will vary depending on the characteristics of the research, the nature of the results, and the interests of participants.

The undertaking of biomedical research with human participants—from exploratory, basic science inquiries to clinical trials using well-validated tests—often includes development of laboratory test results associated with an individual research participant. Recent changes to federal regulations have promoted transparency and allowed individuals greater access to these results; however, regulations are not consistent, the report says. For example, the Centers for Medicare & Medicaid Services (CMS) prohibits the return of results from laboratories that are not certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), but in some circumstances the Health Insurance Portability and Accountability Act of 1996 (HIPAA) may require the return of results requested by a participant, regardless of whether they were generated in a CLIA-certified laboratory. CLIA requirements ensure the quality and integrity of data, accurate reconstruction of test validation and test performance, and the comparability of test results

regardless of performance location.

"There is a long-standing tension in biomedical research arising from a conflict in core values—the desire to respect the interests of research participants by communicating results versus the responsibility to protect participants from uncertain, perhaps poorly validated information," said Jeffrey Botkin, associate vice president for research and professor of pediatrics at University of Utah and chair of the study committee that wrote the report. "In weighing the complex and competing considerations, we recommend a transition away from firm rules embodied in current CLIA and HIPAA regulations toward a process-oriented approach favoring communication of results while seeking to enhance the quality of results emerging from research laboratories. Our hope is that this report will provide a road map toward better and more collaborative and transparent research practices that will benefit participants, investigators, and society more broadly."

The justification for returning results becomes stronger as both the potential value of the result to participants and the feasibility of return increase, the report says. To harmonize relevant regulations, regulators and policymakers should revise them in a way that respects the interests of research participants in obtaining individual research results and balances the competing considerations of safety, quality, and burdens on the research enterprise. For example, CMS should revise CLIA regulations to allow for the return of results from non-CLIA certified laboratories when results are requested under the HIPAA access right and also when an institutional review board process determines it is permissible.

Establishing laboratory processes to give all stakeholders confidence in the validity of the individual research results is critical to ensuring the accuracy of information provided to research participants as well as the quality of the science. Currently, there is no accepted quality

management system (QMS) for research laboratories that could serve as an alternative to CLIA certification. The committee recommended that the National Institutes of Health lead an effort with other relevant federal agencies, nongovernmental organizations, and patient and community groups to develop a QMS with external accountability for non-CLIA certified research laboratories testing human biospecimens.

To minimize the burden for research laboratories with constrained resources to put such a QMS in place, sponsors, funding agencies, and research institutions should facilitate access to resources and support training and the development of the necessary laboratory infrastructure. The initial training, cost, and time commitment will likely be significant, but the value added will be considerable for both participants and science, the report says.

Furthermore, the use of effective communication strategies can minimize the risk of misinterpretation or over-interpretation of research results. In the consent process, investigators should communicate clearly to research participants whether, under what circumstances, and how investigators will offer and return research results. When individual results are communicated to participants, investigators should facilitate understanding of the meaning and limitations of results by, for example, ensuring there is a clear take-away message, explaining the level of uncertainty, and providing mechanisms for the participants to obtain additional information and guidance for follow-up consultation, when appropriate.

The report also includes recommendations for investigators to engage community groups and advocacy organizations to make sure participant needs and values are incorporated into decisions about returning individual results, regardless of participant social or economic status, and for research sponsors to require planning for the return of individual results in funding applications.

More information: www.nap.edu/catalog/25094/retu … s-guidance-for-a-new