

Recent National Academies report puts research participants' rights at risk, say law scholars

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In a [Policy Forum article](#) appearing in the Oct. 12 issue of *Science*, leading bioethics and legal scholars sound the alarm about a recent report from National Academies of Science, Engineering, and Medicine. The Academies' report on "[Returning Individual Research Results to Participants](#)" makes recommendations on how to share research results

and data with people who agree to participate in research studies and calls for problematic changes to federal law. This report proclaims its support for research participants' rights but, in reality, creates major new roadblocks to the return of data and results to participants and would roll back important privacy protections people have under current law, according to the analysis in the new *Science* article.

The article's authors, Susan M. Wolf and Barbara J. Evans, collaborated as part of the "LawSeqSM: Building a Sound Legal Foundation for Translating Genomics into Clinical Application" project funded by the National Human Genome Research Institute and National Cancer Institute of the National Institutes of Health. Wolf is the McKnight Presidential Professor of Law, Medicine & Public Policy; Faegre Baker Daniels Professor of Law; and Professor of Medicine at the University of Minnesota and is Chair of the University's Consortium on Law and Values in Health, Environment & the Life Sciences. Evans is the Mary Ann and Lawrence E. Faust Professor of Law, Professor of Electrical and Computer Engineering, and Director of the Center for Biotechnology & Law at the University of Houston.

"Researchers conducting imaging, environmental health, and genetics studies have offered participants their research findings for years," Wolf and Evans point out. Research participants value access to their results for a wide range of reasons, including protecting their health, and evaluating the privacy risks posed by circulation of their data. People value access to results even when the results are still under study and may be uncertain. Over the past 20 years, researchers have developed pathways for returning results in situations where the results raise clinical concerns, such as suggesting that the person may have a medical condition that needs clinical follow-up evaluation. These pathways are ethically sound and protect the participants' safety by ensuring compliance with necessary laws and regulations. Unfortunately, the Policy Forum article asserts, "the Academies' [report](#) rejects this widely

supported, legally sound approach" and instead recommends restrictions on access to research results and data.

Wolf and Evans write that, "Efforts to turn back the clock on return of results appear rooted in confusion about the law." The Academies' report incorporates incorrect statements about the federal CLIA legal framework, which aims to ensure the quality of laboratory tests conducted for health care purposes.

The report overstates the degree to which research laboratories can be regulated under the CLIA statute.

The Academies' report also conflicts with existing [federal privacy laws](#) that protect research participants' access to their own data. For more than 50 years, Congress has treated individual access to one's own data as an essential element of personal privacy protection, as seen in the Privacy Act that protects data stored in governmental databases, the HIPAA Privacy Rule that protects Americans' medical privacy, and the Genetic Information Nondiscrimination Act that expanded HIPAA's protections to genetic information. Only by seeing the personal data collected can an individual assess the privacy risks involved. Yet the Academies' report recommends that an individual's access to their data be restricted to the subset of data that meets certain quality standards. Wolf and Evans explain how this would undermine federal privacy protections, which recognize that [privacy](#) can be put at risk even by low-quality data and data that is wrongly attributed to a person.

Finally, the Policy Forum article criticizes the Academies' recommendation to load multiple decisions about return of results on Institutional Review Boards (IRBs). This would place "substantial new burdens on IRBs, despite extensive literature on the limits of IRB decision making." The report "maximizes the burden on IRBs by mischaracterizing existing consensus guidelines and suggesting that IRBs

start over."

Wolf and Evans conclude, "The Academies' report endorses the idea of participant access to results and data, but then builds daunting barriers. The report rejects established legal rights of access, two decades of consensus guidelines, and abundant data showing that participants benefit from access while incurring little risk. The report too often prefers paternalistic silence over partnership."

"True progress on return of results requires accepting participants' established rights of access and respecting the value that participants place on broad access to their [data](#) and results. The next step is not to build barriers but to promote transparency."

More information: Susan M. Wolf et al, Return of results and data to study participants, *Science* (2018). [DOI: 10.1126/science.aav0005](https://doi.org/10.1126/science.aav0005)

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