Urgently Needed: Policies on Access to Data by Erstwhile Collaborators

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Not all conflicts that arise in the course of biomedical research involve scientific misconduct. Some are disputes over authorship or access to data, often arising in the context of the dissolution of a research team (*1*). Many of these conflicts could be avoided (or at least resolved) by developing institutional policies and federal regulatory standards to guide academic scientists and administrators.

Court Cases

There are few judicial opinions about the right of collaborating scientists to publish or further develop their research data independently. The U.S. Court of Appeals for the Second Circuit was confronted in 1987 with a disagreement over the right of one member of a team to revise an article based on jointly developed information without the permission of his collaborators (*2*). Appeals to university administrators had failed to resolve the matter, and the revised article was published, listing the original author last (*3*). Weinstein (who wanted to remain first author) sued his two coauthors and the university for deprivation of property without due process. He also sued two other members of the faculty, the college dean, and the trustees. The court ruled that under copyright law, each of several coauthors of a joint work is entitled to revise, and publish independently, an article describing that work (*4*). That is why copyright law is generally not helpful in analyzing or resolving disputes of this kind. The court also made clear its displeasure over having to deal with the problem at all and characterized the litigation as a form of private warfare over academic politics (*5*).

More recently, the National Institutes of Health (NIH) successfully sued a former intramural scientist for trespass or "conversion" of tangible property—namely, a cell line. "Trespass" is defined as "an intentional use or intermeddling with [property] in possession of another," whereas "conversion" is "an intentional exercise of dominion or control over [property] which ... seriously interferes with the right of another to control it" (*6*). The cell line in question was developed at (and thereby owned by) NIH, and the principal investigator's access to it was blocked by sabotage (destruction of the cell line). The court's reasoning would apply as well to the use of other means to deprive a principal investigator of access to materials he or she had developed. The court not only awarded NIH the cost of personnel and supplies to re-create the cell line, it also awarded punitive damages because the defendant's actions "not only delayed a vitally important research project; they were obviously calculated to diminish the reputation of the entire laboratory involved with the project" (*7*).

Juries have awarded more sizable sums. A Michigan jury in 1993 awarded over $1 million to a postdoctoral fellow who complained that her faculty adviser misappropriated her data, used it to obtain a National Science Foundation grant, and then retaliated against her when she complained about it (*8*). That case was based primarily on a state Whistleblower's Protection Act (*9*). In May of this year, a federal jury in Baltimore, Maryland, heard a dispute over access to—and permissible use of—clinical data that had been collected over a period of 20 years by the University of Alabama, Birmingham (*10*). A former visiting graduate student, who had been granted access to the data, argued that no one else should be permitted to use the university's database for epidemiologic studies so long as she continued to analyze the data she had derived from it. In a surprising verdict, the jury awarded nearly $2 million against the university and several members of its faculty. The university and its faculty are appealing (*11*).

University Policies

The dean of the School of Basic Health Sciences at Virginia Commonwealth University (VCU) urged universities in 1991 to develop policies that "(i) clarify ownership of scientific data; (ii) assign responsibility for the preservation of original data; (iii) develop a system to catalog or inventory data; (iv) delegate authority to permit removal or destruction of data; and (v) provide for continuing access to original data after an investigator leaves the institution" (*12*). Unfortunately, VCU did not heed this advice and thus had no relevant policies when a dispute arose in 1992 between two members of its faculty.

The dispute involved publication of genetic linkage data developed in a collaborative study of schizophrenia (*13*). The dispute was not only about the right to publish; it involved more fundamentally a departing scientist's right of access to data he developed in research for which he was the principal investigator on an NIH grant. In 1993, I represented the geneticist, Scott Diehl, in related scientific misconduct proceedings brought by his erstwhile collaborators. An inquiry panel dismissed the misconduct charges, noting that the dispute really was a dispute over control of data (*14*). University proposals to resolve the authorship dispute consistently included the astonishing demand that Diehl relinquish all claims to the DNA, immortalized cell lines, and computerized genetic linkage information that he and his colleagues developed from clinical specimens, collected in Ireland from schizophrenics and their families (who were identified and clinically evaluated by VCU psychiatrists and Irish collaborators) (*15*).

A year ago, in responding to these proposals, the NIH legal adviser wrote to the university's general counsel:

> Your proposal not to afford Dr. Diehl access to the biological samples that were developed under his direction and that he renounce any claims to such materials is totally unacceptable. I cannot imagine what basis can be advanced in equity or in law for such a mean-spirited proposal. Dr. Diehl is entitled to complete access to the DNA samples and to a copy of each cell line developed under his direction (*16*, p. 2).

The impasse demonstrates the difficulties of resolving such conflicts in the absence of established policies.

Other universities have established exemplary policies on such matters. Estelle Fishbein (general counsel of Johns Hopkins University) urged academic institutions in 1991 to make clear that, although the university "owns" the data developed under a federal grant, departing scientists have a right to take copies of their data with them when they leave and, to the extent that the data are not susceptible to photocopying, should have reasonable access to the data that they leave behind (*17*). Such a policy had been adopted by Harvard University Faculty of Medicine in 1988 and was later adopted by the University of Michigan and Johns Hopkins University, among others (*18*). In 1992, the National Academy of Sciences recommended that research institutions establish guidelines for data management that include provisions on "availability of data to scientific collaborators or supervisors" (*19*). As an example of good practice, the Academy endorsed the Harvard policy described above (*19*).

Federal Policies

Since 1990, NIH guidelines for intramural research have directed that

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Research data and supporting materials, such as unique reagents, belong to the National Institutes of Health, and should be maintained in the Laboratory in which they were developed. Departing investigators may take copies of notebooks or other material for further work (*20*, p. 8).

A 1994 revision added that

> Under special circumstances, such as when required for continuation of research, departing investigators may take primary data or unique reagents with them, if adequate arrangements for their safekeeping and availability to others are documented by the appropriate [NIH] official (*21*, p. 7).

The NIH guidelines also make clear that "[d]ata management, including the decision to publish, is the responsibility of the principal investigator" (*21*, p. 7). On the basis of an introduction describing the guidelines as "patterns of scientific practice that have been developed over many years and are followed by the vast majority of scientists" (*21*, p. 3), it is fair to say that NIH views the right of access by scientists, especially principal investigators, to their primary data and biological materials as well established in the scientific community.

Grant administration policies of the Public Health Service (PHS) (of which NIH is a component part) make clear that at least after publication, primary data and unique materials (such as DNA, cell lines, and genetic mapping information) developed with PHS funds should be made "readily available for research purposes to the scientific community" (*22*).

The Department of Health and Human Services (HHS) Office of Research Integrity (ORI) apparently prefers not to become involved in disputes among former colleagues who independently use "jointly developed concepts, methods, descriptive language, or other product of the joint effort" (*23*). Believing that "the collaborative history often supports a presumption that the products of the collaboration may be used by any of the former collaborators," ORI typically refers such cases to the funding agencies and grantee institutions for resolution (*23*). On the other hand, ORI has reviewed and accepted a university finding of scientific misconduct against a graduate student who sequestered research data and biological materials for 15 months, denying the principal investigator and collaborating scientists access (*24*).

Finally, the Commission on Research Integrity has decided to incorporate into a proposed new definition of scientific misconduct the following example of "interference."

> An investigator or reviewer shall not intentionally and without authorization take or sequester or materially damage any research-related property of another, including without limitation the apparatus, reagents, biological materials, writings, data, hardware, software, or any other substance or device used or produced in the conduct of research (*25*, p. 5).

Implementating this recommendation in PHS regulations would force recipients of NIH grants and contracts to treat interference with a researcher's access to data as misconduct. As with research involving human subjects, the HHS approach likely would be adopted by other federal agencies and, in time, could form the basis of a uniform, government-wide policy (*26*).

Conclusions

The public interest requires that data and materials developed with federal support be available to any scientist who wishes to extend the research after it has been published. When a collaborative team splits up, each member of the team should have continuing access to the data and biological materials with which he or she had been working, unless all parties agreed to some other arrangement at the outset. These principles should be added to federal regulations and enforced as a condition of receiving research support.

If the PHS, which is the largest benefactor of biological research in this country, would establish and enforce clear guidelines for all research it supports, other federal agencies likely would follow its example, as would most academic and research institutions. One model might be the one established by the National Institute of Mental Health (NIMH) for creating a genetics data set for Alzheimer's disease through cooperative agreements. Data and genetic materials that are collected are stored in centers operating under NIMH contracts and are available to "experienced, qualified investigators who are conducting research on Alzheimer's disease and are associated with a recognized biomedical research facility" (*27*). Investigators receiving the data and biological materials may not transfer them to anyone outside their direct supervision without written permission from NIMH (*27*).

I urge the Public Health Service to develop regulations as soon as possible. Too much time, effort, and other resources are being wasted on preventable disputes.

REFERENCES AND NOTES

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2. *Weinstein v. University of Illinois*, 811 F. 2d 1091 (7th Cir. 1987).
3. D. J. Belsheim, R. A. Hutchinson, M. M. Weinstein, *Am. J. Pharm. Educ.* **50**, 139 (1986).
4. *Weinstein v. University of Illinois*, 811 F. 2d at 1092, 1095.
5. *Ibid.* at 1096.
6. *U.S. v. Arora*, 860 F. Supp. 1091, 1097 (D. Md. 1994).
7. *Ibid.* at 1101.
8. C. Anderson, *Science* **262**, 23 (1993); *Phinney v. Perlmutter*, No. 90-689 NZ (Washternay Cty. Cir. Ct., 16 September 1993). (Opinion and Order Upholding Judgment.)
9. *Phinney v. Perlmutter* at 6.
10. G. Taubes, *Science* **268**, 1125 (1995).
11. While this paper was under consideration by *Science*, I was asked to represent the University in the appeal.
12. S. G. Bradley, *ASM News* **57**, 60 (1991).
13. E. Marshall, *Science* **268**, 792 (1995). Two research teams, one led by psychiatrist Kenneth Kendler, and the other by geneticist Scott Diehl, collaborated (from 1988 to 1993) on genetic linkage studies of schizophrenia. When their relationship soured, Diehl and some of his team relocated but were denied access to their data and biological materials. Kendler hired a new geneticist and, in August 1994, distributed an extraordinary "letter" to competitors in genetic linkage "following up unpublished linkage results obtained by Scott Diehl (while at MCV [Medical College of Virginia] in 1992–1993)." Kendler thus published Diehl's finding without his knowledge, consent, or participation and misstated the extent of his involvement in the research. Although Kendler *et al.* claim to have replicated Diehl's work, they merely confirmed the result of his 5-year search for a genetic marker for schizophrenia (an accomplishment akin to "finding" a needle in a haystack after someone has shown you where it is).
14. "Report of the panel of inquiry into allegations of scientific misconduct against Scott R. Diehl" (Medical College of Virginia, Virginia Commonwealth University, 31 August 1993), p. 9.
15. Diehl's team also conducted molecular genetic assays and statistical analyses. They made all of their data available to Kendler and his collaborators and offered them coauthorship on the 1995 paper.
16. Letter from Robert B. Lanman, NIH legal adviser, to David L. Ross, Esquire, general counsel and special assistant attorney general, Virginia Commonwealth University, 25 March 1994, p. 2.
17. E. Fishbein, *Acad. Med.* **66**, 129 (1991).
18. *Responsible Science: Ensuring the Integrity of the Research Process* (National Academy of Sciences, Washington, DC, 1993), vol. II, pp. 127–128 (Harvard), p. 134 (Johns Hopkins), p. 173 (MIT), p. 204 (Dana-Farber Cancer Institute), pp. 207–208 (Brain Tumor Research Center, University of California, San Francisco).
19. *Ibid.* (National Academy of Sciences, Washington, DC, 1992), vol. 1, pp. 138–139.
20. *Guidelines for the Conduct of Research at the National Institutes of Health* (National Institutes of Health, Bethesda, MD, 21 March 1990).
21. *Ibid.* (Revision 1994).
22. Public Health Service Grants Policy Statement (1990), pp. 8–24.
23. Department of Health and Human Services, Office of Research Integrity, Annual Report, 1994 (published April 1995), p. 28.
24. *Ibid.*, p. 15.
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26. See Office of Science and Technology Policy, Executive Office of the President, "Federal policy for the protection of human subjects: Notices and rules," 56 *Fed. Reg.* 28002 (18 June 1991) and implementing regulations of 15 departments and agencies at *ibid.*, 28003–28032.
27. "Availability of the NIMH Alzheimer's disease genetics dataset," *NIH Guide to Grants and Contracts*, vol. 24, no. 23 (23 June 1995) (electronic version, notice number 1).