

Using the Freedom of Information Act (FOIA) to Compel Research Data Disclosure

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Scientists that conduct medical research funded by federal grants or contracts have recently been subjected to Freedom of Information Act (FOIA) requests for their research material. The Act compels federal agencies to provide copies of nonexempt documents in their possession upon request. While agency held research material is routinely accessed through the FOIA, privately held research material can also be requested under provisions of the Shelby Amendment. The research community should understand their obligations to disclose under the FOIA and the ramifications of disclosure legislation on scientific research.

The FOIA was passed and signed in 1966, and established a basis for public inspection of non-sensitive governmental records to enhance public awareness and participation in federal agency decisions [1]. The extensive records maintained by federal granting agencies relating to scientific studies can be requested through the FOIA, though funding agencies use varying interpretations of available exemptions to justify protecting much of this information (Table 1). Relevant documents include administrative records such as budget oversight and inspector general reports, grant proposals, and both interim and final reports of research. More recently, the National Institutes of Health (NIH), National Science Foundation (NSF), and other scientific granting agencies have assembled searchable, on-line databases of their catalogued documents, including abstracts. This facilitates public access, obviating the need to acquire information through FOIA procedures in many cases, and streamlining FOIA processes for both requesters and responders.

According to the rules and policies of various governmental agencies presented with FOIA requests, researchers may receive pre-disclosure notifications offering them the opportunity to redact responsive materials if there are concerns regarding personal privacy of subjects or investigators, or if they contain trade secrets. Receipt of this notification is what some scientists now refer to as being "FOIA'd". It does not involve providing additional data to requesters, but simply reviewing the materials that the agency considers responsive to the request, and not legally exempt from disclosure. Importantly, most granting agencies do redact material prior to sending the pre-disclosure notification. For example, NIH does not disclose personal data such as salaries and percent effort in grant proposals, nor the identities of investigators other than the principal Investigator (PI).

Several aspects of the FOIA make it an effective disclosure vehicle. First, anyone can request any public records under the Act. The purpose of the request and the identity of the requestor do not affect the requestor's entitlement to the records. Second, under the FOIA, it may be possible to obtain and make public information about nongovernmental entities if relevant documents from or about these entities are in the control or possession of a federal agency. For instance, the Project on Government Oversight (POGO) has used the FOIA to create a database of federal corporate contractor misconduct by tabulating agency data on private contractors with histories of misconduct, including contract fraud and environmental, ethics, or labor violations [2].

According to federal compliance data (www.foia.gov), FOIA requests to the NSF have incrementally increased each of the past

several years, while requests to the NIH and the Food and Drug Administration (FDA) have remained relatively stable. Despite suggestions that reviewing others' research material through the FOIA would confer competitive advantages on those who accessed them, there is no evidence of significant harm accruing to the scientific community as a result of FOIA disclosures. A notable exception involves the use of agency databases and traditional FOIA procedures by animal rights groups to identify research programs involving animal subjects in order to disrupt their work.

The FOIA was first applied to medical research data that were stored outside of federal agencies in the 1990s, after the U.S. Environmental Protection Agency (EPA) updated its clean air standards. The longitudinal health and mortality data that informed the standards were compiled and archived by Harvard University, which refused attempts by Congressional opponents of the new standards to access the raw data [3]. In response, Congress passed the Shelby Amendment to the Office of Management and Budget (OMB) appropriation for 1999 (Public Law 105-277). This legislation required revision of OMB Circular A-110, which governs the administration of grants to universities, hospitals, and other nonprofit organizations. Under the Amendment, the OMB was directed to require that all data produced by federally-funded research be made available to the public if requested through the FOIA.

After three cycles of public comment and revision, a new paragraph (d) was added to Circular A-110. It states that *research data relating to published research findings produced under an award and that were used by the Federal Government in developing an agency action that has the force and effect of law* must be supplied by the award recipient to the funding agency when needed to respond to a FOIA request. In addition to providing that FOIA requesters could be required to reimburse both the agencies and the researchers for costs associated with their responses, the new language also defined terms such as *research data*, *published*, and other concepts that would delineate applicability of the Amendment to disclosure of privately held scientific and medical research data.

Requests to disclose agency held documents far outnumber efforts to disclose privately held research material. Summary statistics tabulated annually by federal agencies on FOIA requests indicate over six hundred thousand requests were made under the Act in 2011, an increase of almost 8 percent from the previous year [4]. There is also

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1	Documents "related solely to the internal personnel rules and practices of an agency"
2	Documents "specifically exempted from disclosure by statute" other than FOIA, but only if the other statute's disclosure prohibition is absolute
3	Documents which would reveal "[t]rade secrets and commercial or financial information obtained from a person and privileged or confidential"
4	Documents which are "inter-agency or intra-agency memorandum or letters" which would be privileged in civil litigation
5	Documents which are "personnel and medical and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy"
6	Documents which are "records or information compiled for law enforcement purposes"
7	Documents which are related to specified reports prepared by, on behalf of, or for the use of agencies which regulate financial institutions
8	Documents which would reveal oil well data
9	National defense or foreign policy information properly classified pursuant an Executive Order

Table 1: FOIA exemptions.

great variability in what material is being requested, and the amount of public attention those requests attract. While grant material makes up the vast majority of FOIA requests aimed at federal agencies, raw research data seems to be the target of requests to access privately held data under the Shelby Amendment. Not surprisingly, requests to view federal grant material tend to fly under the public radar. However, attempts to access private data has attracted significant public attention; e.g. the highly publicized demands by the American Trade Institute for climate change research records from the University of Virginia that were purportedly used by the current administration in policy development.

What should research scientists know about the FOIA? First, the overwhelming majority of disclosure requests received by scientists come in the form of pre disclosure notifications sent by federal agencies offering the opportunity to redact prior to releasing agency held material. Much less frequently, scientists may receive disclosure requests for their privately held data, as a result of the Shelby Amendment, though extensive protections are afforded by the OMB language.

Second, judicial interpretation of the FOIA's language may affect how scientists and universities conduct research business. For instance, some courts have established that a publicly accessible record meets

the legal threshold of a "printed publication". Individuals attempting to block a patent award have since used the Patent Act's statutory bar for "printed publications" by referencing the FOIA's public access to research grant proposals. What this means is that the FOIA could circumvent Bayh-Dole Act (37CFR401) provisions designed to afford institutions an opportunity to patent, license, and derive financial support from intellectual property developed through federal research funding [5].

The use of the FOIA represents a paradigm shift in how scientists access their colleagues' research material. Universities should provide expert legal guidance to their research communities on how to respond to pre disclosure notifications, and to the legally more complex Shelby Amendment requests for privately held research material.

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