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Ramifications of the Freedom of Information Act (FOIA) as a Modality to Obtain Research Data

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Scientists who conduct medical research funded by federal grants or contracts are increasingly 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. The research community has expressed concern over the potential for disclosure legislation like the FOIA to threaten research privacy. While, disclosure exemptions maintain research privacy, other unanticipated threats may pose greater concerns for the research community.

The extent and scope of healthcare confidentiality has long been the subject of debate [1]. While the obligation of confidentiality is integral to professional ethical codes of conduct and is safeguarded under federal laws such as the Health Insurance Portability and Accountability Act (HIPPA), it has never been regarded as absolute. Health care confidentiality can be outweighed by public interest in disclosure. Ever since public access to federal agency documents has been facilitated by disclosure legislation such as the FIOA, new concerns have been raised about the sanctity of medical research material.

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 [2]. The Act initially took aim at material stored within federal agencies. It was first applied to medical research data stored outside 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.

Concerns have been raised across the disciplinary spectrum that the FOIA would compel disclosure of sensitive research material from researchers funded by federal agencies. Specifically, concerns centered on the potential ramifications of the Shelby Amendment and the reach contemplated in its language. However, many of those concerns were tempered when the OMB published its proposed changes to Circular A-10, which offered access to much fewer kinds of information than first contemplated in the original Amendment.

However, the full affect of the FOIA's potential was neither anticipated nor covered by the OMB's language revisions. 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. It means 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 [4].

The FOIA has been instrumental in facilitating access to medical and research data in the possession of governmental agencies the access of which disclosed important safety data about pharmaceuticals and medical procedures. For instance, through the FOIA, researchers were able to determine which patients with emphysema would benefit from lung volume reduction surgery by accessing the follow-up data of the National Emphysema Treatment Trial (NETT) [5]. Others, clarified the risks of vertebroplasty and kyphoplasty by accessing complication data held by the Food and Drug Administration. Accessing this data helped quantify the risk of hypotension related to the acrylic (polymethylmethacrylate) bone cement used during these procedures as well as the risk of pedicle fracture and cord compression with kyphoplasty [6].

Despite concerns across the disciplinary spectrum that disclosure legislation would offend research integrity by compromising confidentiality, disclosure exemptions have been effective in maintaining that integrity. However, other ramifications of disclosure legislation, such as the FOIA's impact on Bayh-Dole Act protections for universities, may pose a greater concern over the time.

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