TOPIC:

WHO CAN OBTAIN ACCESS TO RESEARCH DATA? PROTECTING RESEARCH DATA AGAINST COMPELLED DISCLOSURE

INTRODUCTION:

While publication and dissemination of research results is the norm and expectation in an academic environment, questions often arise about who can obtain access to the underlying research data. Researchers may receive requests (or demands) for their “raw” or unanalyzed data, including measurements, tables, figures, formulae, drawings, recordings, images, completed questionnaires, research notes, and interview transcripts. Recently, there have also been highly publicized (and potentially politically motivated) requests to researchers for a broad range of email messages related to their research, including requests filed with the University of Virginia [1] and the University of Wisconsin. [2]

Academic researchers typically share key data underlying published results with other researchers upon request after publication. In addition, they may be obligated (by contract or law) to make certain data from their sponsored research available to sponsors or others, or by agreements with journals to make available certain data underlying articles published in those journals.

Nonetheless, they may have good reasons to withhold raw data when access is demanded via subpoena, state or federal Freedom of Information Act (FOIA) request, or other means of compelled disclosure. Premature disclosure of data may negatively impact researchers’ ability to publish or patent the results of their work, including letting someone else “scoop” the results by publishing first, which can in turn negatively affect their careers. It could also lead to publication of preliminary and unverified data, which may be contrary to the public interest in the dissemination of good science. Even after publication, there may be good reasons to withhold certain data. For example, release of some data could breach promises of confidentiality made to research subjects and result in harm, not only to those research subjects but also to the scientific process itself, particularly if it discourages participation by subjects or dampens candid conversations with researchers. [3] Indeed, disclosures about controversial areas of research could place researchers at risk for threats and harassment. As research opponents or political groups with an “ax to grind” utilize tools like FOIA to obtain access to research records and scholarly communications, some see a growing threat to academic freedom itself. Finally, responding to a subpoena or other compelled disclosure method can be burdensome, costly, and disruptive to the researcher’s work, potentially harming both the researcher and the public.

This Note discusses the circumstances under which access to research data may be demanded or compelled, provides an overview of who can access research data, discusses relevant law, and provides practical pointers for protecting research data from compelled disclosure.

DISCUSSION:
I. Circumstances Under Which Access to Research Data May Be Compelled

A. REQUESTS MADE UNDER STATE AND FEDERAL PUBLIC RECORDS LAWS

1. State Public Records Acts (PRA)

State institutions may receive requests from members of the public, policymakers, reporters, or even other researchers asking for research data under the state’s public records law. Such laws typically require state agencies to provide access to their records unless an applicable exemption permits a record (or portions of the record) to be withheld. [4]

2. Federal Freedom of Information Act (FOIA)

   a. FOIA Generally

Only federal agencies are subject to the federal FOIA [5] which, like its state counterparts, requires agencies to provide requesting members of the public with access to agency records unless an exemption applies. However, FOIA is relevant to most universities, because a FOIA requestor may ask a federal agency for data that relates to research conducted by a researcher at a public or private university under a federal award. To the extent such data is in the possession of the agency (e.g., funded research proposals or final reports of research results), it is disclosable unless an exemption applies. Federal agencies may (and in some limited instances must) consult with awardees about such FOIA requests to determine whether any of the requested information should be withheld from release under one of the FOIA exemptions. [6]

   b. FOIA - Shelby Amendment.

Prior to 1999, FOIA applied only to records in the possession or control of a federal agency. [7] Since grantees typically do not provide raw data to federal agency sponsors, FOIA at that time generally could not be used to obtain such data. In 1998, Senator Richard Shelby introduced into an omnibus appropriations bill language that became known as the “Shelby Amendment,” directing the federal Office of Management and Budget (OMB) to amend OMB Circular A-110 (which governs administration of grants to universities, hospitals, and other nonprofit entities) to require all data produced under federally funded research awards to be made available under FOIA. [8]

After receiving numerous comments from researchers, academic institutions, and associations about the potential negative impact of the “Shelby Amendment” on research, OMB implemented it via a final rule published in 1999 that significantly narrowed its scope, requiring disclosure only for research data (a term defined to exclude preliminary analyses, drafts of scientific papers, peer reviews, or communications with colleagues) that relate to published research findings produced under a federal award and that were used by the federal government in developing an agency action that has the force and effect of law. When a federal agency receives a FOIA request for data meeting those criteria, OMB Circular A-110 C. _36(d)(1) now requires the agency to request the data from the award recipient (and requires the awardee to provide it). While it is important to know about this possible avenue of mandated disclosure, there is little evidence in the case law that it has thus far been used to mandate disclosure of raw data from federally funded researchers.

B. REQUESTS MADE THROUGH SUBPOENAS; LITIGATION DISCOVERY REQUESTS

Demands for research data may also come through a discovery request in litigation directly involving the researcher or, more commonly, a third party subpoena in litigation conducted by other parties. Such demands often arise in the context of a civil tort lawsuit where either side may rely on scientific
research findings to demonstrate that a product or environmental substance did or did not cause harm. [9] In such cases, a party may seek the raw data underlying the research findings to conduct its own analysis to counter the claims of the other side.

Demands may also come in connection with criminal investigations or proceedings, including grand juries and FBI investigations, where a subpoena or warrant may be issued. [10] One should be careful when responding to such subpoenas or investigation inquiries to avoid being misperceived as obstructing justice while protecting client interests. [11] In cases where a law enforcement agency seeks to speak to employees or students in connection with executing a search warrant or serving a subpoena, such employees or students should be advised that they have the right to consult with an attorney before consenting to any interview. A target of a criminal investigation may wish to have counsel present.

C. REQUESTS MADE THROUGH SPONSOR OR JOURNAL DATA ACCESS REQUIREMENTS

While requests for research data typically come in the context of records requests or subpoenas, there may also be data access obligations imposed in other circumstances pursuant to contract, statute, or regulation.

1. Sponsored Research: Sponsor Access

In the case of research sponsored by a federal agency grant or cooperative agreement, OMB Circular A-110 C. ___53 (2 C.F.R. 215) gives the awarding agency (and the Inspectors General and the U.S. Comptroller General) a right of “timely and unrestricted access” to data produced under the award. For federally-sponsored research contracts, the Federal Acquisition Regulations (FARs) reserve for the sponsoring agency a similar right of access to data produced under the contract. [12] Other sponsors may impose similar access requirements as a term and condition of the award; an awardee should always check the award document and the governing terms and conditions.

2. Sponsored Research: Data Sharing Requirements

Many federal sponsoring agencies, including NIH [13] and NSF, [14] have adopted data sharing requirements as a condition of their research awards. Increasingly, research grants from foundations and other non-profit sponsors have also included data sharing requirements. [15] Sponsor acceptance of the grantee’s data sharing plan typically is incorporated as a term and condition of the award. For requests for data produced under a sponsored award, it is important to know about any data sharing requirements applicable to the award, since those requirements may affect whether the institution or the researcher can successfully resist disclosure.

3. Journal Requirements

For published research, the journal in which an article is published may require, as a condition of publication, that the author make available certain data underlying the published study. For example, Nature specifies that as a condition of publication, “authors are required to make materials, data and associated protocols promptly available to readers without undue qualifications,” [16] and specifies that readers who encounter refusal by authors to comply may contact the journal, which may refer the matter to the author’s funding institution and/or publish a formal statement of correction stating that readers have been unable to obtain necessary materials to replicate the findings. Counsel should also be aware that some journals are moving beyond simple data disclosure requirements to seek ownership of data sets associated with the scholarly articles for which they already regularly demand copyright ownership. This is a significant concern since, as is covered below, institutions generally do not give faculty ownership rights to research data in the same way that faculty are afforded control over their scholarly publications. Clear advice to faculty to pay attention to
publication agreements so they do not give away what they do not own is important in this context.

II. Ownership of Research Records and Data

At the outset of any dispute about access will be a question about who owns the records or data, and when it is appropriate for the university to defend against demands for researcher data. This Note is not intended to provide a detailed discussion of ownership; however, following are some key questions counsel may consider when faced with an access dispute:

- **What does your institution’s policy say about ownership of or access to data?** Institutional policies (e.g., those regarding intellectual property, patents, or data access or stewardship) may address ownership of research data produced by employees, faculty or others who conduct research under the auspices of the institution (e.g., under a sponsored award). University policies typically specify that faculty own copyright to their creative works (e.g., journal articles). However, universities almost uniformly establish ownership rights to research data and research results to protect patent rights and to enable compliance with sponsored research mandates imposed by funders. Check your institution’s policies. The Council on Government Relations (COGR) provides excellent guidance on access to, sharing, and retention of research data and corresponding rights and responsibilities. [17]

- **Does the requested data relate to sponsored university research?** In general, when research data is produced under an extramural award to the institution, there is a good argument that the institution (as distinct from the researcher) has an ownership interest in the data. The institution, as grantee, has taken on legal obligations with respect to the work conducted under the award. The grantee’s ownership interest is supported by federal agency guidance including the NIH Grants Policy Statement, which specifies that “[i]n general, grantees own the data generated by or resulting from a grant-supported project.” [18] NSF also acknowledges grantees’ rights to their data. [19] In addition, under federal research misconduct regulations, institutions are responsible for taking action to ensure research integrity, which may include taking custody of or sequestering data in cases involving investigation of research misconduct, an obligation that necessitates the institution being able to control data produced under its federal awards. [20]

- **What is the relationship of the researcher to the institution?** Typically, the institution can assert an ownership interest in records and research data produced by staff researchers and faculty, who are employees of the institution. The strength of the argument that the institution has an interest in student generated data may depend on the particular circumstances surrounding the given project, including whether the research was subject to institutional oversight, review or approval (such as student research involving Institutional Review Board oversight) and the institutional interest in seeing promises of confidentiality upheld.

III. Arguments Against Compelled Disclosure

A. APPLICABILITY OF A PRA OR FOIA EXEMPTION

When a demand comes in the form of a PRA or FOIA request, one question to consider is whether to argue that some of the requested material is not a covered public agency record. While it may be
possible to argue that certain communications among scholars are purely personal or otherwise were not prepared in connection with transacting the public’s business, broad use of this line of argument has a number of potential downsides. In addition to the challenges of persuading a court that records in the possession of a public institution are not public records, there may be instances in which an institution itself has a compelling interest in obtaining access to such communications, so an institution may want to be cautious about arguing that scholarly communications are not University records.

Explore whether there is a specific exemption that can be used to withhold some or all of the requested data. Some state public records laws (e.g., New Jersey, Utah, Ohio, Virginia, and Indiana) contain specific exemptions applicable to research data. For additional citations and discussion of state records law exemptions for research, see the University of Virginia’s brief in American Tradition Institute v. UVA, as well as the recent excellent two-part NACUA outline on “Research Data Sharing, Security, and Preservation,” by Heidi Henning and Madelyn Wessel.

Even if your state records law does not contain a specific exemption for research records, explore using other exemptions, such as the general public interest “balancing test” exemption in California’s public records law that allows a record to be withheld if the public interest in not disclosing clearly outweighs the public interest served by disclosure. A public interest balancing approach is commonly used by courts even when there is no explicit balancing test exemption in a particular records statute.

Under the federal FOIA, the exemptions most commonly used to protect sensitive research information from compelled disclosure are Exemption 4 (pertaining to confidential business information, including trade secrets) and Exemption 6 (which applies to information the disclosure of which would constitute a clearly unwarranted invasion of privacy).

B. RESEARCHER’S PRIVILEGE/ACADEMIC FREEDOM/FIRST AMENDMENT

One argument to make is that compelled disclosure of research data would impinge on First Amendment rights and chill the pursuit of scholarly research by (1) eroding the trust subjects place in researchers to keep their information confidential (making it more difficult to find willing research subjects); (2) dissuading scientists from pursuing controversial topics; (3) impinging on a researcher’s ability to publish; and (4) forcing a researcher to make public data that are still tentative and that have not yet been tested or subject to scientific peer review. Though there is some case law supporting a limited researcher’s or scholar’s privilege (akin to a reporter’s privilege) based on academic freedom or First Amendment grounds, courts have been skeptical of such assertions. Even where courts have favorably considered elements of the academic freedom and First Amendment arguments in rejecting efforts to compel disclosure of research data, they typically have done so not by basing their rulings on a formal researcher’s privilege, but rather by weighing those interests as part of a balancing test approach.

C. BALANCE OF INTERESTS

This is the approach most commonly used by courts, both in cases involving public records requests and in cases involving subpoenas or discovery requests. Courts will consider the requestor’s and the public’s interest in disclosure versus the researcher’s and the public’s interest in withholding. Arguments useful in setting up a balancing test analysis arguing against compelled disclosure include:

- Excessive burden on the researcher, including time away from research, time reviewing and compiling requested data, and time and difficulty in redacting
personal identifying information to protect subject confidentiality;

- Harm from premature release of unpublished data, including the researcher’s inability to publish or patent, the possibility of being “scooped,” resulting effects on the researcher’s career, and harm to the public’s interest in the dissemination of good science;

- Potential for threats or harassment;

- Academic freedom and First Amendment concerns that affect both the researcher’s and the public’s interests;

- Lack of probative value of the requested data;

- Availability of the requested data from other sources;

- Harm to participants who were promised confidentiality and the related institutional and public interests of encouraging future research participation.

Factors that may make a difference in applying a balancing test include:

- **Unpublished v. published.** Once results of a research study have been published or publicized, courts tend to be less sympathetic to arguments for withholding underlying data, since the public has an interest in knowing whether the data supports the published results. By contrast, courts are more likely to protect data relating to unpublished research, since academic freedom interests are more pronounced and it is easier to demonstrate harm to that researcher from premature disclosure. [34]

- **Civil vs. criminal proceedings.** Courts have been less sympathetic to protecting research data when the requested data relates to a criminal proceeding, given the public’s strong interest in solving crimes. A recent example is the decision in *U.S. v. Moloney*, 685 F.3d 1 (1st Cir. 2012), where the appellate court upheld an order that required Boston College researchers to produce many unpublished interview materials subpoenaed by the U.S. Department of Justice (acting on behalf of the British government, which considered the material relevant to an unsolved abduction and murder). The court dismissed concerns that university research would be less effective if researchers and participants were subject to subpoenas, stating that “[t]he choice to investigate criminal activity belongs to the government and is not subject to veto by academic researchers. [35]”

- **Promises of Confidentiality.** Research data may be more likely to be protected when researchers promise confidentiality to research subjects. For example, federal law protects individually identifiable information from compelled disclosure in cases where a researcher obtained, in advance, a Certificate of Confidentiality (COC) from the National Institutes of Health. [36] Although not fully tested in court, COCs allow a principal investigator and others who have access to research records to refuse to disclose identifying participant information in any federal, state or local civil, criminal, administrative, legislative or other proceeding. One of the requirements for obtaining a COC is a promise of confidentiality to the subjects. As noted below, however, researchers should be cautious about offering subjects
absolute promises of confidentiality, which they may not be able to uphold, since researchers cannot contract away statutory or constitutional obligations. [37]

IV. Preparing for and Responding to Attempts to Compel Disclosure

There are a number of practical steps researchers and institutions can take to prepare for and respond to attempts to compel disclosure. [38] Following is a brief summary of key steps.

A. PLAN IN ADVANCE

Encourage researchers to consider privacy and confidentiality concerns at the outset. The following steps may mitigate problems connected to responding to data requests and/or bolster arguments against compelled disclosure:

● Consider whether the project can be conducted without obtaining or retaining personally identifiable data, and/or create de-identified datasets.

● If personally identifiable data is needed, create a record at the outset of a project documenting why it is critical to promise subject confidentiality. Combined with documented institutional research board (IRB) recommendations, such records can help counter arguments that the need for confidentiality is merely a pretense created for the purpose of resisting a data demand.

● Seek a Certificate of Confidentiality before research commences, if the research is eligible.

● Think carefully about the circumstances and form of any confidentiality assurances to be provided to subjects. First, consider whether the assurance is necessary (to obtain the needed data or subject participation, and/or to protect the subject). Courts may be less inclined to grant protection from disclosure if there is not a good argument that the confidentiality assurance was needed. Second, use caution before offering absolute promises of confidentiality to research subjects, since a court order could interfere with the ability to honor such promises. Rather, consider telling subjects and interviewees that confidentiality will be maintained “to the fullest extent permitted by law.” [39]

● When submitting information to a federal agency, follow any established procedures for identifying or marking any confidential information. This can both flag for the agency the potential need to consult with the institution or researcher in the event there is a FOIA request for the data, and can bolster the argument for later invoking one of the available FOIA exemptions (particularly Exemption 4, which protects confidential business information, including trade secrets, from disclosure, and Exemption 6, which permits an agency to withhold information about individuals in personnel, medical and similar files when disclosure “would constitute a clearly unwarranted invasion of personal privacy”). [40]

● Encourage faculty to use reasonable records management practices (e.g., consider which records are necessary or useful to retain, and for how long); establish and follow record retention/disposition schedules that provide for regular review and, where appropriate, destruction of records that are no longer needed.
B. AFTER DEMAND FOR DATA IS RECEIVED

Once a demand for research data is received, in addition to exploring the substantive arguments for withholding (as discussed above in Section III), there are practical steps university counsel can take to protect, as best as possible, such data. While options are more limited for dealing with burdensome or invasive public records requests, litigation procedures are available for inappropriate discovery demands.

- Notify research partners (and confidential sources) that may also have an interest in protecting the data.

- Send written objections. Whether by formal pleading or informal letter, you should put your objections in writing, so as to have a clear record for any future court proceeding.

- Negotiate with opposing counsel. You can try to negotiate with opposing counsel to narrow the scope of the data to be produced, or to produce what is not confidential or burdensome. Offering to redact sensitive data also can help.

- File a motion to quash. If negotiations are fruitless, then consider filing a motion to quash the offending civil or criminal subpoena. Courts have discretion to quash such a subpoena when, for instance, that subpoena unduly burdens researchers, harms academic freedom, coerces unretained researchers into serving as unwilling expert witnesses, or requires disclosure of trade secret or confidential research, development or commercial information. Many of the arguments raised earlier, especially the balancing test, can be used here.

- Seek a protective order. If efforts to resist production of research data in litigation are unsuccessful, explore seeking a protective order requiring that it be used only for purposes of that particular litigation, that it cannot be disclosed to the public, and so on.

CONCLUSION:

It is important for researchers and university legal counsel to be aware of the various ways that disclosure of research data may be compelled, and the steps that can be taken to protect confidential research data both in advance of a demand for disclosure and after such a demand is received. Although courts have been largely skeptical of the existence of a broad researcher’s or scholar’s privilege, and although there are limited public records act exemptions that apply specifically to research, there are a number of arguments that can be successfully deployed to protect confidential research data.

FOOTNOTES

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