THE NIH'S GENOMIC DATA SHARING POLICY AND THE FIRST AMENDMENT

Adam Candeub [*]

Genome-wide association studies (GWAS) use DNA statistical analyses to examine the relationship between genotypic differences and phenotypic traits. Revolutionizing genetics, these studies have discovered more than 50,000 associations of genome-wide significance between genetic variants and common diseases and traits. GWAS also have transformed the study of physical anthropology, establishing the relatedness of modern and proto-humans and other primates as well as modern humans' ancient migration patterns.

The NIH's 2014 Genomic Data Sharing Policy (GDSP) governs collecting, storing, and accessing the databases upon which most GWAS research in this country relies. Many data repositories refuse access to those who pursue what the NIH categorizes as "stigmatizing" or "sensitive" research.

The GDSP does not comply with the Administrative Procedure Act (APA). The policy's "sensitive" and "stigmatizing" standard lacks any statutory basis and is perforce arbitrary and capricious.

And even assuming that the GDSP is consistent with administrative law, the policy is best viewed as a condition to obtain a government benefit or as a viewpoint-based restriction of generally available government information. So characterized, the GDSP violates the First Amendment.

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[*] Professor of Law, Michigan State University (candeub@msu.edu). I thank Jonathan Adler, Ashutosh Bhagwat, and Eugene Volokh for important suggestions and critiques that improved the paper. In particular, I thank Jane Bambauer for her input as well as organizing the symposium and, above all, Barbara Evans for her superb comments and research suggestions. Errors are mine.

Introduction

Genome-wide association studies (GWAS) allow scientists to analyze statistically those parts of the human genome that differ among human individuals and among species—and then associate detected genotypic differences with specific phenotypes. These studies have revolutionized numerous research areas over the last decade, both within and beyond the hard sciences. Scientists have identified more than 50,000 associations of genome-wide significance between genetic variants and common diseases and traits.[1] These associations allow estimations of disease risk, improve pharmacological development by identifying new drug targets and disease biomarkers as well as allowing personalized medicine through optimization of therapies based on genotype.

[1] *See* Vivian Tam et al., *Benefits and Limitations of Genome-Wide Association Studies*, 20 NATURE REVIEWS GENETICS 467 (2019).

Beyond their biomedical use, GWAS have transformed genetics more generally. Researchers have identified areas in the genome that drive differences in height and weight[2] and other physical characteristics such as eye color.[3] The genetic bases of schizophrenia as well as psychological traits, such as personality, have been established, leading to new insights about the nature of mental illness.[4] GWAS have also affected areas outside of the hard sciences. They have transformed the study of physical anthropology by establishing the relatedness of protohuman species such as Neanderthals and Denisovans to modern humans. And they have helped establish human migration patterns in ancient history.[5]

The National Institutes of Health (NIH) hosts many genomic and phenotypic data repositories on which most GWAS research in this country relies, as these repositories were collected pursuant to various grants and programs administered by the NIH's constituent institutes. The NIH's 2014 Genomic Data Sharing Policy (GDSP)[6] governs the rules for collecting, storing, and accessing all of these repositories. Some repositories store open-access or unrestricted-access genomic data and consequently require no special credentials for downloading their data.

On the other hand, other repositories, notably the Database of Genotypes and Phenotypes (dbGaP), limit access to "credentialed" users. Many data repositories refuse credentials to those who pursue what the NIH categorizes as "stigmatizing" or "sensitive" research. In addition, the recent 2018 update of NIH policies restricts access to all summary data submitted to the NIH under the GDSP that a private researcher tags as potentially "stigmatizing" or "sensitive."

The credentialing approval process, in turn, is highly bureaucratic, operating under an obscure legal basis with diffuse authority and accountability. Recently,

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[2] *See* Loic Yengo et al., *Meta-Analysis of Genome-Wide Association Studies for Height and Body Mass Index in ~700000 Individuals of European Ancestry,* 27 HUM. MOLECULAR GENETICS 3641 (2018).

[3] *See* Mark Simcoe et al., *Genome-Wide Association Study in Almost 195,000 Individuals Identifies 50 Previously Unidentified Genetic Loci for Eye Color*, SCI. ADVANCES, Mar. 10, 2021, https://doi.org/10.1126/sciadv.abd1239.

[4] *See* ROBERT PLOMIN, BLUEPRINT: HOW DNA MAKES US WHO WE ARE (2018).

[5] *See* DAVID REICH, WHO WE ARE AND HOW WE GOT HERE: ANCIENT DNA AND THE NEW SCIENCE OF THE HUMAN PAST (2018).

[6] Final NIH Genomic Data Sharing Policy, 79 Fed. Reg. 51,345 (Aug. 28, 2014) [hereinafter *2014 Final NIH Genomic Data Sharing Policy*].

prominent behavioral geneticists James Lee[7] and Stuart Ritchie[8] have drawn attention to a practice among NIH data access committees (DACs) to block research they deem to be "sensitive" or "stigmatizing."

This article examines legal objections to the NIH's current credentialing practice. First, the NIH's data access restrictions do not comply with the Administrative Procedure Act (APA). It is not clear that the GDSP complies with the NIH's underlying statutory authority even if it was promulgated appropriately outside of notice-and-comment rulemaking. Its vague standards may render all decisions made under its authority "arbitrary and capricious," and therefore violative of the APA. Perhaps most egregiously, the 2018 update to the GDSP requires that the agency provide automatic ratification of submitting institutions' designation of particular summary datasets as "sensitive" or "stigmatizing" without *any* NIH deliberation or review.[9] This not only violates the APA's arbitrary and capricious standard but also flouts legal limits on agency delegation of statutory authority to third parties.

According to Lee and Ritchie, the NIH has deemed as stigmatizing those studies looking at the genetic bases for traits such as intelligence, education, and health outcomes. It is essential, however, to realize that the NIH blocks studies that are *not* part of the "ultra-controversial parts" of this research area, i.e., "inquiries into race or sex differences."[10] Rather, as Ritchie explains, the NIH blocked his research on using GWAS summary statistics to study the relationship of Alzheimer's disease to declining mental functioning and intelligence, and has categorized as "potentially sensitive behavioral traits . . . [such as] alcohol or drug addiction."[11] The NIH will also reject proposals to use its Genetic Epidemiology Research on Adult Health and

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[7] James Lee, *Don't Even Go There: The National Institutes of Health Now Blocks Access to an Important Database If It Thinks a Scientist's Research May Enter "Forbidden" Territory*, CITY J., Oct. 19, 2022, https://www.city-journal.org/article/dont-even-go-there.

[8] Stuart Ritchie, *The NIH's Misguided Genetics Data Policy*: *Banning Scientists from Using Data to Research Certain Topics is a Bad Move for All Sorts of Reasons*, SCI. FICTIONS, Oct. 25, 2022, https://stuartritchie.substack.com/p/nih-genetics/.

[9] National Institutes of Health, Update to NIH Management of Genomic Summary Results Access, Notice No. NOT-OD-19-023 (Nov. 1, 2018) [hereinafter *2018 Update*], https://grants.nih.gov/grants/guide/notice-files/NOT-OD-19-023.html.

[10] Ritchie, *supra* note 8.

[11] *Id.*

Aging (GERA) dataset if the proposed research investigates numerous demographic and behavioral variables, including Body Mass Index, or BMI, a common proxy for obesity.[12]

But even assuming that the GDSP is consistent with applicable administrative law, the NIH's restrictions to data access—which are speech restrictions[13]—must still satisfy First Amendment scrutiny. The First Amendment analysis is not straightforward, primarily because it is not clear how to characterize the GDSP. Research studies dependent on the NIH data could, themselves, be characterized as government speech. If so, the First Amendment would not apply. Conversely, the GDSP could be viewed as a prior restraint, and if so, the First Amendment would render it unlawful almost automatically.

More likely, a court will view the GDSP as a condition to obtain a government benefit or, even more likely, a viewpoint-based restriction of generally available government information. As discussed below, the best reading of precedent suggests that the GDSP is unlawful under these characterizations. And the "sensitive" and "stigmatizing" designations are likely unconstitutionally vague.

I. GWAS RESEARCH

Determining the relationship between genome and phenotype is arguably genetic research's fundamental goal. Primates have around 25,000 genes. (A gene is a particular part of the DNA strand associated with the production of a particular amino acid chain or protein.) But, differences in genes are not the only driver of phenotypic differences among either individuals or species. Rather, the mechanism of turning genes on and off ("gene expression") drives much of this phenotypic difference. Gene expression is typically driven by parts of the DNA that are not associated with particular genes. Thus, while DNA ultimately determines gene expression, its complexity renders misguided any attempt to account for phenotypic difference simply by comparing genes.

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[12] National Institutes of Health, Data Use Certification Agreement (Dec. 15, 2023) at 11, *available at* https://tinyurl.com/mtj3r39e.

[13] The GDSP could be characterized as an indirect restriction on the creation of speech, akin to bans on recording public officials in public places or restricting the activities of tattoo parlors. *See* Ashutosh Bhagwat, *Producing Speech*, 56 WM. & MARY L. REV. 1029 (2015) (advocating for First Amendment protection for conduct associated with producing speech). The GDSP punishes speech that is stigmatizing, as well as restricting its production.

To correlate genotypic difference with phenotypic difference, researchers have turned, therefore, to genome-wide association studies (GWAS). These approaches compare large sequences of DNA. GWAS often use single-nucleotide polymorphism (SNP) genotyping. SNPs are single base pairs (single "rungs" in the DNA molecule's double helix) that differ among individuals' DNA within the same species. There are around ten million SNPs in the human genome, occurring roughly once every 300 base pairs. Although these variations constitute less than 1% of the genome, the differences appear to cause the lion's share of the genetic variation between individuals. GWAS typically correlate the differences between these "landmark" SNPs with a particular trait.

GWAS leverage the decreasing cost of obtaining entire human genetic sequences (all 3.2 billion single nucleotide pairs) combined with the increasing statistical power present in large study populations. They require large datasets to detect statistically significant differences among the huge number of SNP sites. Further, it seems as if many of the traits researchers are interested in—ranging from diabetes susceptibility to eye color—result from the interactions of many SNPs. Each particular genomic difference correlates with marginal differences in phenotype, with significant differences emerging as cumulative effects of these tiny differences. This research depends, therefore, on ever larger datasets to refine its correlations.

Some have pointed out that GWAS have been a disappointment in developing clinical interventions because this process is so difficult—and perhaps intractable.[14] In a similar vein, some have voiced disappointment that GWAS analysis has only shown relatively small correlations between identifiable genomic differences and specific phenotypes which by themselves cannot explain much about why a particular trait or disorder develops. "Although many recent findings from well powered GWAS have been replicated in independent data sets, the genes identified have pinned down few if any underlying causal mechanisms. Therefore, a key issue is whether or not the genes implicated by GWAS form a coherent story on their own and thus could in principle lead to insight into the biological mechanisms underlying the trait or disorder."[15]

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[14] Eddie Cano-Gamez & Gosia Trynka, *From GWAS to Function: Using Functional Genomics to Identify the Mechanisms Underlying Complex Diseases*, 11 FRONTIERS IN GENETICS 424 (2020).

[15] Mark A. Reimers et al., *The Coherence Problem: Finding Meaning in GWAS Complexity*, 49 BEHAV. GENETICS, 187 (2019).

Arguably, whether GWAS will succeed is a big data question. Further analysis with ever larger datasets will reveal whether GWAS results become more robust—or show diminishing correlations between genomic and phenotypic difference as datasets grow larger. At the point that correlations fail to become more robust with larger datasets, research interest will likely begin to cool. It does not appear, however, that we are anywhere near that point. As discussed in the Introduction, GWAS continue to offer researchers in a variety of different fields fertile grounds for advancement—and that continuing research depends upon building and accessing bigger datasets.

II. THE NIH'S CONTROL OF ACCESS TO GENETIC DATA REPOSITORIES

GWAS data can raise, of course, considerable privacy concerns, as there are risks that anonymized genetic data can be re-identified. Thus, since the launching of these databases, the NIH has developed data-sharing policies, primarily for the purpose of protecting subjects' genetic data. In 2007, the NIH issued a Policy for Sharing Data Generated through NIH-supported Genome Wide Association Studies (2007 GWAS Policy) and launched the Database of Genotypes and Phenotypes (dbGaP).[16] In 2014, the 2007 GWAS Policy was subsumed under the NIH Genomic Data Sharing Policy (GDSP), which applies to all large-scale genomic data generated from NIH-funded research.[17] The GDSP was updated in 2019.[18]

Under the original 2007 GWAS Policy, access to "stigmatizing" research was controlled, but in a highly discretionary manner. The Policy defined stigmatizing data as "highly sensitive because they may suggest the existence either of individually identifiable or socially undesirable traits . . . . Tools for analysis of genomic data increasingly are able to make inferences about some individual traits . . . and behaviors with social stigma. In recognition of these risks, the NIH policy includes steps to protect the interests and privacy concerns of individuals, families and identifiable groups who participate in GWAS research."[19]

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[16] Policy for Sharing of Data Obtained in NIH Supported or Conducted Genome-Wide Association Studies (GWAS), 72 Fed. Reg. 49,290–02 (Aug. 28, 2007) [hereinafter *2007 Policy*].

[17] 2014 Final NIH Genomic Data Sharing Policy, *supra* note 6.

[18] *2018 Update*, *supra* note 9.

[19] *2007 Policy*, *supra* note at 16, at 49,292.

But the 2007 GWAS Policy did not quite outlaw stigmatizing research. Rather, it simply stated that "The NIH Data Access Committees (DACs) will approve access only for research uses that are consistent with an individual's consent as defined by the submitting institution. In addition, in the event that requests raise questions or concerns related to privacy and confidentiality, risks to populations or groups, or other relevant topics, the DACs will consult with other experts as appropriate."[20] Again, written in a vague way, the policy appeared to grant DACs complete discretion to make "stigmatizing" determinations. And, there are apparently many within the genetics and medical research fields who believe such rules warranted, if not necessary.[21]

The 2014 NIH Genomic Data Sharing (GDS) Policy is more precise in outlining applicable processes.[22] Its basic parameters are described graphically below:[23]

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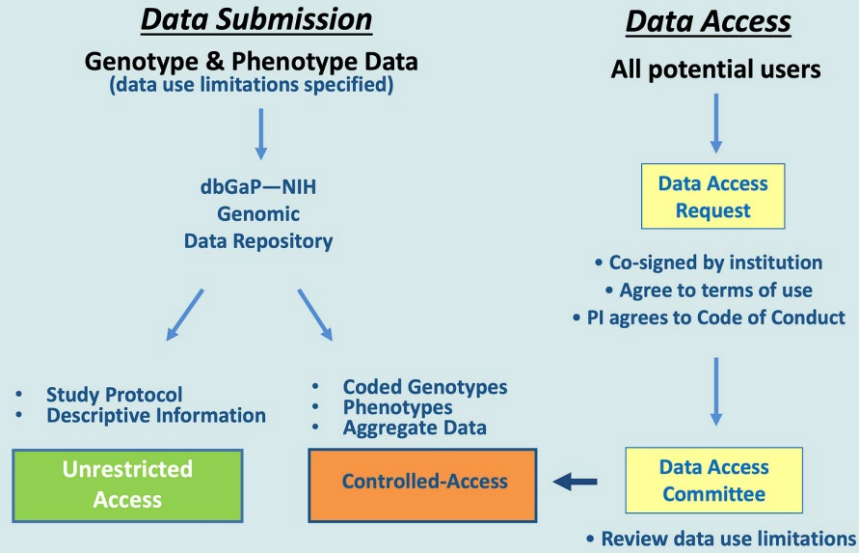
[20] *Id.* at 49,291.

[21] *See, e.g.,* Diane E. Hoffmann et al., *Are Changes to the Common Rule Necessary to Address Evolving Areas of Research? A Case Study Focusing on the Human Microbiome Project*, 41 J.L. MED. & ETHICS 454, 465 (2013) ("A major criticism of the HGP was its failure to address group harm and group stigma. IRBs do not generally address group stigma at all because it is not within their jurisdiction to do so. However, there is an NIH policy on 'Genome-Wide Association Studies' (GWAS) that asks 'institutions submitting GWAS datasets to certify that an Institutional Review Board (IRB) . . . has considered [risks to identifiable groups] . . . .' The policy goes on to say that 'in the event that requests raise questions or concerns related to privacy and confidentiality, risks to populations or groups, . . . the DACs [NIH Data Access Committees] will consult with other experts as appropriate.' Outside of this statement there are no other agency policies or guidance documents on group harm related to genetics research."); Amy L. McGuire et. al., *Importance of Participant-Centricity and Trust for a Sustainable Medical Information Commons*, 47 J.L. MED. & ETHICS 12, 14 (2019) ("Risks of discrimination and stigmatization are of special concern to individuals and groups who have already experienced significant social disadvantage and are especially vulnerable to harm from impersonal, non-transparent algorithmic decision-making drawing on big data. Concern may also be heightened for particular areas of genomic and other health-related information, such as information about potential genomic contributors to drug or substance abuse, propensity for criminal behavior, and intelligence or impulsivity, as well as particular kinds of research uses, such as studies that stratify by social or ancestry groups.").

[22] National Institutes of Health, *How to Request and Access Datasets from dbGaP,* SCI. DATA SHARING, https://sharing.nih.gov/accessing-data/accessing-genomic-data/how-to-request-and-access-datasets-from-dbgap.

[23] This graphic is from an NIH Powerpoint, "NIH's Genomic Data Sharing Policy," *available* at https://tinyurl.com/wfcw4a3t.



A potential user must be at "a level equivalent to a tenure-track professor, or a senior scientist with responsibilities (which may include laboratory or research program administration and oversight)."[24] He must submit a request, with institutional sign-off and agree to the NIH's conditions in its Genomic Data User Code of Conduct that limits researchers to "[u]se datasets only for the research project described in the approved Data Access Request for each dataset."[25] Then, the request must be approved by the committee that controls access to the particular data resources. There are eighteen such committees—each of which controls access to one or more NIH data resources. [26]

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[24] National Institutes of Health, *Accessing Genomic Data*, NAT'L CANCER INST. CTR. FOR BIOMEDICAL INFORMATICS & INFO. TECH., https://datascience.cancer.gov/data-sharing/genomic-data-sharing/genomic-data.

[25] National Institutes of Health, Genomic Data User Code of Conduct (June 11, 2019), https://sharing.nih.gov/sites/default/files/flmngr/Genomic_Data_User_Code_of_Conduct.pdf.

[26] Central DAC (CDAC); Kids First DAC (KFDAC); National Cancer Institute (NCI); Joint Addiction, Aging, and Mental Health (JAAMH); National Eye Institute (NEI); National Heart, Lung, and Blood Institute (NHLBI); National Human Genome Research Institute (NHGRI); National Institute of Allergy and Infectious Diseases (NIAID); National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS); Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD); National Institute on Deafness and Other Communication Disorders (NIDCD); National Institute of Dental and Craniofacial Research (NIDCR); National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK): National Institute of Environmental Health Sciences (NIEHS); National Institute of General Medical Sciences (NIGMS), National

Interestingly, the NIH Genomic Data Sharing Policy (GDSP) omits the stigmatization language included in the 2007 version.[27] Individual DACs appear to have the option of including these requirements as an appendix to their Data Use Certification Agreement, which all researchers are required to sign.[28] This document has an appendix specifically intended to set forth "Data Use Limitations" or "DULs." And many DACs apparently include stigmatization restrictions there.[29]

James Lee describes how this procedure works.[30] He points to the Framingham Heart Study (FHS), a well-known study that was established in 1948 to study risk factors for cardiovascular disease and that includes a database useful for GWAS.[31] The National Heart, Lung, and Blood Institute names the DAC for the FHS. Its Data Use Certification agreement does indeed include Data Use Limitations restricting research in stigmatizing topics.[32] Interestingly, these were added sometime between 2011 and 2019, as a version from 2011 does not have this clause, and does not mention anything about so-called "stigmatizing" research. Perhaps the change was made in light of the 2014 policy.[33]

And the NIH continues to enforce the stigmatizing topics restriction in new ways. The NIH updated the GDSP in 2019 to loosen some rules concerning public access to non-sensitive data, specifically, Genomic Summary Results (GSR) that could not be de-anonymized and re-identified with particular individuals. None-

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Institute of Neurological Disorders and Stroke (NINDS): National Institute of Nursing Research (NINR), and National Center for Advancing Translational Sciences (NCATS). *See* National Institutes of Health, *Using Genomic Data Responsibly,* SCIENTIFIC DATA SHARING, https://sharing.nih.gov/accessing-data/accessing-genomic-data/using-genomic-data-responsibly.

[27] National Institutes of Health, NIH Genomic Data Sharing Policy, Notice No. NOT-OD-14-124 (Aug. 27, 2014), https://grants.nih.gov/grants/guide/notice-files/not-od-14-124.html.

[28] National Institutes of Health, Data Use Certification Agreement (Mar. 19, 2019), https://sharing.nih.gov/sites/default/files/flmngr/Universal_DUC_01102023.pdf.

[29] *See supra* note 12 (citing to a Data Use Certification Agreement with an example DUL)

[30] *See supra* note 7.

[31] *About the Framingham Heart Study,* FRAMINGHAM HEART STUDY (last accessed Jun. 23, 2023), https://www.framinghamheartstudy.org/fhs-about.

[32] NATIONAL INSTITUTES OF HEALTH, *supra* note 28.

[33] Framingham Heart Study (FHS) Data Use Certification Agreement (May 24, 2011) (on file with author).

theless, controlled access was maintained for GSR that were "sensitive" and involved "potentially stigmatizing traits."[34] Disturbingly, from an administrative law perspective, as elaborated below, the NIH relies entirely on the "sensitive" designation made by the institution submitting the data without performing its own review.[35]

The NIH also makes clear that violation of the GDSP is punishable. Anyone who violates its terms, including using research for a matter not approved by a DAC, faces enforcement provisions under 59 C.F.R. § 74.62. This regulation, which governs NIH grant-making, prescribes enforcement actions including withholding of further awards or taking "any other remedies that may be legally available."[36]

III. The "Sensitive" and "Potentially Stigmatizing" Designation and the APA

The NIH did not use administrative rulemaking, i.e., formal or informal rulemaking under Section 556 or 553 of the APA, to set forth its "sensitive" and "potentially stigmatizing" database access limitations. Rather, the NIH set them forth in a policy statement, the GDSP. Unlike rules promulgated through administrative rulemaking, which are binding regulations with the force of law that can be challenged immediately in court by anyone with standing, policy statements are "guidance" that do not bind agency action. Rather, the GDSP acts more like a very strong suggestion.

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[34] 2018 Update, *supra* note 9 ("Institutions submitting genomic data to NIH-designated data repositories under the NIH GDS Policy would be expected to notify NIH of any studies for which there are particular sensitivities, such as studies including potentially stigmatizing traits, or with identifiable or isolated study populations. These studies would then be designated as 'sensitive', and access to GSR from such datasets would remain under controlled-access.").

[35] National Institutes of Health, *Designating Scientific Data for Controlled Access,* SCIENTIFIC DATA SHARING (last visited Jun. 23, 2023), https://sharing.nih.gov/data-management-and-sharing-policy/protecting-participant-privacy-when-sharing-scientific-data/designating-scientific-data-for-controlled-access.

[36] Uniform Administrative Requirements for Awards and Subawards to Institutions of Higher Education, Hospitals, Other Nonprofit Organizations, and Commercial Organizations; and Certain Grants and Agreements with States, Local Governments and Indian Tribal Governments, 59 Fed. Reg. 43,760 (Aug. 25, 1994), as amended at 62 Fed. Reg. 38,218 (July 17, 1997).

The NIH's decision to promulgate its rules as a policy, not via administrative rulemaking, can itself be challenged—at least in theory.[37] If a policy functions as a rule, i.e., it "(1) 'impose[s] any rights and obligations' and does not (2) 'genuinely leave[] the agency and its decision-makers free to exercise discretion,'"[38] then the NIH cannot evade review by labeling its rule a "policy." Challenges to agency decisions to proceed by policymaking, as opposed to rulemaking, must show that the guidelines eliminate agency discretion—which is generally a high bar.

Indeed, the GDSP seems to have buried and obscured its decision-making process to provide at least the appearance of continued discretion and, therefore, make the policy appear to be unlike agency rulemaking. The GDSP omits the stigmatization language included in the 2007 version.[39] Individual DACs appear to have the option of including these requirements as an appendix to their Data Use Certification Agreement which all researchers are required to sign.[40] And, as noted above,[41] many DACs apparently include stigmatization restrictions there. In this way, the NIH tries to hide that it, in fact, even has an official policy on stigmatizing research applicable to all its institutes. Rather, the NIH likely would claim that bans on sensitive and stigmatizing research emerge from individual decisions by each DAC exercising its own discretion.

A more likely course, therefore, to challenge the policy is for a researcher who has had a request refused to challenge the agency decision to refuse access. Under the APA, 47 U.S.C. § 706(2)(A), an agency action will be overturned if a court deems it "arbitrary and capricious." Courts have explained the arbitrary and capricious standard as considering whether "the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evi-

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[37] The policy does not fall under the APA's exemption for matters "relating to agency management or personnel or to public property, loans, grants, benefits, or contracts," 5 U.S.C. § 553, because the policy governs the rights of non-grantees and non-beneficiaries who seek access to information the NIH has acquired already and assembled for the entire research community.

[38] Texas v. United States, 809 F.3d 134, 171 (5th Cir. 2015) (cleaned up).

[39] National Institutes of Health, *supra* note 27.

[40] National Institutes of Health, *supra* note 28.

[41] *See supra* note 12.

dence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise."[42] Review under the "arbitrary and capricious" standard is narrow, and courts give deference to an agency's construction of a statutory provision it is charged with administering.[43]

The question is, therefore, whether a DAC's invocation of "sensitive" and "potentially stigmatizing" limitations to database access relies upon the factors and goals that Congress set forth in creating the NIH and its constitutive institutes. The NIH and its institutes are not typical agencies in that they are not explicitly regulatory. Rather, they are conduits for grantmaking. Their stated statutory aims are simply the pursuit and advancement of scientific and medical knowledge.[44] For example, the general purpose of the National Cancer Institute "is the conduct and support of research, training, health information dissemination, and other programs with respect to the cause, diagnosis, prevention, and treatment of cancer, rehabilitation from cancer, and the continuing care of cancer patients and the families of cancer patients."

The "stigmatizing" and "sensitive" prohibitions lack any specific statutory basis. The NIH's access decisions that rely on these concerns, therefore, are arbitrary and capricious because they include factors that go beyond its congressional mandate. In creating the NIH, Congress wanted to promote all forms of scientific advancement and did not give the NIH the discretion to limit that advancement to those ends which it considers "inclusive" or "unprovocative" as opposed to "stigmatizing" or "sensitive." And numerous courts have set aside agency decisions in grantmaking processes when the agencies have relied on conditions extraneous to statutory conditions or not rationally related to congressional goals.[45]

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[42] Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983).

[43] Am. Fed'n of Gov't Emps. v. Fed. Lab. Rels. Auth., 204 F.3d 1272, 1274–75 (9th Cir. 2000).

[44] 42 U.S.C. §§ 285, 285a–t.

[45] People for Ethical Treatment of Animals, Inc. v. Tabak, 662 F. Supp. 3d 581, 593 (D. Md. 2023) (quoting Balt. Gas & Elec. Co. v. NRDC, 462 U.S. 87, 104 (1983)) ("These [statutory and regulatory] factors [in the Public Health Service Act] provide concrete metrics by which the Court may evaluate whether NIH's grantmaking process as to the five challenged grants was arbitrary and capricious. . . . 'To survive challenge at the motion to dismiss stage, the Complaint must make plausible that NIH's funding decisions fell outside the "bounds of reasoned decisionmaking."'"); State *ex rel.* Becerra v. Sessions, 284 F. Supp. 3d 1015, 1032 (N.D. Cal. 2018) ("The State argues that the identification of Section 1373 as an 'applicable law' for the Byrne JAG Program grant is arbitrary

On the other hand, as discussed in the context of the First Amendment and, in particular, the *Finley* case discussed below, courts often are more lenient to agencies in the grant-making process, reluctant to second guess highly discretionary and often highly professionalized judgments.[46] But it should be pointed out that the NIH is *not* awarding or managing research grants when it creates access terms to its databases that its DACs implement. It is functioning more as a librarian of a government-funded library. When the NIH acts as a grantor, it may be appropriate for it to consider particular moral perspectives—or at least courts should defer to its choices concerning the general direction of research it wishes to support. The arbitrary and capricious standard would leave latitude for the broadest scope of directions in research, and courts should defer to an agency's choice among these myriad directions.

But when the NIH acts as a librarian entrusted with publicly funded materials, it should have little to no role in prescribing the scope or direction of research, absent a clear congressional mandate. When the NIH, through its constitutive institutes, makes grants, an activity that administrative law governs, Congress has provided guidance.[47] On the other hand, when dealing with non-grantees or non-beneficiaries when managing a publicly accessible depository, the only applicable congressional mandate is to advance scientific research. *Qua* librarian, the NIH cannot refuse legitimate scientific proposals on the basis of vague moral standards and satisfy the "arbitrary and capricious" test of the APA.

Finally, as mentioned in the Introduction, the recent 2018 update of NIH policies requires all data submitted that is tagged potentially "stigmatizing" by the submitting institution to be considered sensitive, with access to the data summaries only upon approval through a credentialing process.[48] (Normally, summaries

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and capricious in violation of the APA. It contends that the federal government has failed to identify a good reason for the policy change as required by the APA.").

[46] A-G-E Corp. v. United States *ex rel.* Off. of Mgmt. & Budget, 968 F.2d 650, 654 (8th Cir. 1992) ("Unless plaintiffs can point to a specific constitutional or statutory constraint that is violated by the Common Rule, we think it clear that the courts may not interfere with the manner in which DOI carries out its grant administration responsibilities.").

[47] Chapter 64, Using Procurement Contracts and Grant and Cooperative Agreements, 31 U.S.C. § 6301 et seq., is the large and complex area of law that governs grantmaking by federal entities.

[48] 2018 Update, *supra* note 9 ("Institutions submitting genomic data to NIH-designated data repositories under the NIH GDS Policy would be expected to notify NIH of any studies for which there are particular sensitivities, such as studies including potentially stigmatizing traits, or with

would be available without credentialing.) Thus, the NIH relies entirely on the "sensitive" designation made by the institution submitting the data without performing its own review.[49]

In general, "[d]elegations by federal agencies to private parties are . . . valid so long as the federal agency or official retains final reviewing authority."[50] But the process set forth by the 2018 Update provides for no review or input by the NIH. To the contrary, the NIH rejected such a role for itself in the notice implementing the update:

> [A] minority of respondents (all self-identified as scientific researchers) pointed out potential concerns about limiting access to GSR from "sensitive" studies. A key concern among these comments was that it could diminish the benefit achieved through the use of GSR, because GSR from only a subset of studies would be broadly available. . . . NIH has considered all of the comments received, and this GDS Policy access update will retain the ability to designate certain studies as "sensitive" or "stigmatizing" for the purposes of GSR access. GSR from studies so designated will be accessible only through controlled-access and remain subject to any data use limitations attached to the corresponding individual-level data.
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> Of the respondents who disagreed about who had the appropriate authority to make the "sensitive" designation, half commented in favor of institutional designation, and half opposed it or suggested additional considerations. Those who opposed institutional designation advocated for input or additional oversight from a separate, independent body, or the NIH, either to ensure adequate protection, or to ensure that the "sensitive" classification was used appropriately and consistently.
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> In this update to GSR access procedures, NIH has retained the original proposal to have the submitting institutions for every incoming and already submitted study determine if a dataset should be designated as "sensitive" and the GSR made accessible only through submission of a standard data access request for the full study dataset. This process is consistent with other responsibilities of submitting institutions prior to NIH accepting any dataset for distribution through NIH-designated data repositories (e.g., the delineation of any Data Use Limitations for future research use).[51]

In "outsourcing" the decision to restrict data, the NIH gives non-governmental actors with no employment relationship with the federal government power to

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identifiable or isolated study populations. These studies would then be designated as 'sensitive', and access to GSR from such datasets would remain under controlled-access.").

[49] National Institutes of Health, *supra* note 35.

[50] Nat'l Park & Conservation Ass'n v. Stanton, 54 F. Supp. 2d 7, 19 (D.D.C. 1999).

[51] 2018 Update, *supra* note 9.

limit everyone else's ability to conduct scientific research. The NIH exceeds the bounds of permissible administrative delegation to private individuals and organizations—without any agency review—by delegating the power to decide who can access information the Government controls.

IV. The "Sensitive" and "Potentially Stigmatizing" Designation and the First Amendment

Typically, when government provides a resource for research, whether a GWAS database, a library, or a telescope, it does not limit what can be said, thought, or concluded from information derived from that resource. The strangeness of the GDSP's "sensitive" and "potentially stigmatizing" limitations—which provide a general research tool and then prohibit certain lines of inquiry—renders it difficult to place it in established lines of First Amendment precedent.

First, unlike the family planning programs in *Rust v. Sullivan*,[52] the government is not paying for a particular type of speech. "GWAS research speech" is not attributed to the government; it is attributed to those researchers conducting analyses.

Second, it does not seem to be a system of prior restraint, as the government does not review GWAS research before it is published.

Third, the "stigmatizing" and "sensitive" limitations are unconstitutionally vague.

Fourth, one could characterize the "stigmatizing" and "sensitive" limitations that the DACs place on their Data Utilizations Limitations ("DULs") as a condition of funding if one were to view GWAS databases as a sort of in-kind government subsidy. Similarly, one could view them as a conditioned governmental legal benefit. Under these characterizations, the stigmatization prohibitions likely fail. There is an established line of conditioned subsidy cases, but as the Supreme Court itself admits, the precedent is not clear. A good argument can be made, however, that under *Agency for International Development v. Alliance for Open Society International, Inc.*,[53] the stigmatization prohibition is so unrelated, indeed contrary, to the underlying purpose of government support of research, *i.e.,* the advancement of

[52] 500 U.S. 173 (1991).

[53] 570 U.S. 205, 210 (2013).

knowledge, that the condition fails. Similarly, under *Matal v. Tam*[54] and *Iancu v. Brunetti*,[55] viewpoint-based conditions on the grant of a government benefit fail when the condition involves prohibiting "disparaging" or "scandalous" speech, a close analog to the limitation on "stigmatizing" uses.

Last, the best fit—although not perfect—is probably the cases dealing with access to government records. Those cases deal largely with access to voting records or tax information, not government-funded resources designed for scientific research. But these cases show a judicial distrust of viewpoint discriminatory access, and that distrust logically applies to scientific research as well as voting or tax information.

A. Research Based on GWAS Studies Is Not Government Speech

When government pays for specific types of medical programs as in *Rust*, or requires certain types of speech as part of government employment,[56] the government is speaking through a sort of agent. The agent has no First Amendment rights; its speech is government speech.

If studies based on GWAS depositories are government speech, there is no First Amendment issue. "The Free Speech Clause restricts government regulation of private speech; it does not regulate government speech."[57] The difficulty is that the line between government and private speech can be hard to draw. Unfortunately, "[n]o clear standard has yet been enunciated in our circuit or by the Supreme Court for determining when the government is 'speaking' and thus able to draw viewpoint-based distinctions, and when it is regulating private speech and thus unable to do so."[58]

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[54] 582 U.S. 218, 235–36 (2017).

[55] 139 S. Ct. 2294, 2296 (2019).

[56] Garcetti v. Ceballos, 547 U.S. 410, 421 (2006) ("We hold that when public employees make statements pursuant to their official duties, the employees are not speaking as citizens for First Amendment purposes, and the Constitution does not insulate their communications from employer discipline.").

[57] Pleasant Grove City, Utah v. Summum, 555 U.S. 460, 467 (2009).

[58] Sons of Confederate Veterans, Inc. *ex rel.* Griffin v. Comm'r of Virginia Dep't of Motor Vehicles, 288 F.3d 610, 618 (4th Cir. 2002). The lower courts have developed several other tests that look to (1) the central "purpose" of the program in which the speech in question occurs; (2) the degree of "editorial control" exercised by the government or private entities over the content of the

But even though the standard is blurry, studies based on GWAS studies are almost certainly not government speech. The Supreme Court has provided guidance on what constitutes government speech, beginning with *Rust v. Sullivan*.[59] There, the Supreme Court upheld the federal government's prohibition on doctors in a federal health and family planning program counseling or providing other information regarding abortion. Because the government explicitly decided to fund one type of health program—programs not including discussion of abortion—the government was making choices about counseling, and thus, the programs were its own speech. While the discussion in *Rust* analyzes the issue in terms of conditions on receipt of government grants, the Court later described *Rust* as involving government speech.[60]

The *Rust* rule stands for the proposition that when government pays for a certain type of speech, the speech is the government's, and its funding decision thus stands immune from First Amendment scrutiny. The Court reaffirmed the *Rust* rule in *Johanns v. Livestock Marketing Ass'n*.[61] There, it determined that a beef promotion campaign is government speech where the "message set out in the beef promotions is from beginning to end the message established by the Federal Government" and "the Secretary [of Agriculture] exercises final approval authority over every word used in every promotional campaign."[62]

Conversely, in *Legal Services Corp. v. Velazquez*,[63] the Court struck down on First Amendment grounds government restrictions placed on lawyers receiving Legal Service Corporation funds. The restrictions prohibited lawyers receiving this funding from engaging in efforts to amend or otherwise challenge the validity of existing welfare laws. The Court ruled, among other things, that because the federal legal service program for indigents was "designed to facilitate private speech, not

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speech; (3) the identity of the "literal speaker"; and (4) whether the government or the private entity bears the "ultimate responsibility" for the content of the speech. *Id.*

[59] 500 U.S. at 194.

[60] Legal Servs. Corp. v. Velazquez, 531 U.S. 533, 541 (2001) (stating that while "[t]he Court in *Rust* did not place explicit reliance on the rationale that the counseling activities of the doctors . . . amounted to governmental speech[,] when interpreting the holding in later cases, . . . we have explained *Rust* on this understanding.").

[61] 544 U.S. 550 (2005).

[62] *Id.* at 560–61.

[63] *Velazquez*, 531 U.S. at 533–35.

to promote a governmental message," the government speech doctrine does not apply.[64]

Likewise, in *Matal v. Tam*,[65] the Court ruled that trademarks, though registered by the government, do not constitute government speech. The Court so ruled because "the Federal Government does not dream up these marks, and it does not edit marks submitted for registration."[66] The same is true for research based on GWAS studies—government does not design or conduct them, nor does it edit or approve them.

Without going much further into precedent, GWAS research based on NIH databases isn't government speech because it doesn't communicate a government message; as a resource for research, the databases are meant to facilitate private speech. No one would attribute a peer-reviewed GWAS article to the NIH.

B. Prior Restraint

"Any system of prior restraints of expression comes to this Court bearing a heavy presumption against its constitutional validity."[67] The problem for First Amendment jurisprudence is that the definition of prior restraint is far from clear. In a classic description of the First Amendment's purpose, Justice Story states:

> It is plain, then, that the language of [the First A]mendment imports no more than that every man shall have a right to speak, write, and print his opinions upon any subject whatsoever, without any prior restraint. . . . It is plain that Blackstone taught that under the common law liberty of the press means simply the absence of restraint upon publication in advance as distinguished from liability, civil or criminal, for libelous or improper matter so published.[68]

While agreeing with Justice Story in recognizing that the term originally referred to the English system of licensing printing presses,[69] the Supreme Court has avoided

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[64] *Id.* at 534.

[65] 582 U.S. at 235–36.

[66] *Id.* at 235.

[67] Bantam Books, Inc. v. Sullivan, 372 U.S. 58, 70 (1963).

[68] Near v. Minnesota *ex rel.* Olson, 283 U.S. 697, 733, 735 (1931), *citing* STORY ON THE CONSTITUTION § 1880.

[69] *Id.*; *see also* LAWRENCE TRIBE, AMERICAN CONSTITUTIONAL LAW § 12-34, at 1039 (2d ed. 1988)("At a minimum the First Amendment was adopted to prevent the federal government— and later the state governments through the Fourteenth Amendment—from instituting a general system

expounding a complete definition of prior restraint. Rather, "neither the Supreme Court nor the lower federal courts thus far have developed such a definition."[70]

But, of course, the Court has ruled in many cases that certain government restrictions are prior restraints. The Court has defined prior restraints to include everything from judicial injunctions and systems of administrative pre-publication preclearance to a state tax on newspapers based on their circulation and the refusal by a city to rent its municipal theater for a production of the musical "Hair."[71] In *Shuttlesworth v. City of Birmingham*,[72] the Court ruled that a requirement to obtain a city license to parade, under a process that afforded great discretion to the city, constituted a prior restraint. The Court stated, "the prior restraint of a license, without narrow, objective, and definite standards to guide the licensing authority, is unconstitutional."[73] In *Joseph Burstyn, Inc. v. Wilson*,[74] the Court reviewed a New York licensing regime that required the Board of Regents to assure that a film was not sacrilegious before it could be viewed and distributed. The Court reasoned that "New York requires that permission to communicate ideas be obtained in advance from state officials who judge the content of the words and pictures sought to be communicated. This Court recognized many years ago that such a previous restraint is a form of infringement upon freedom of expression to be especially condemned."

It is not clear that the GDSP is a system of prior restraint. On one hand, it does aim to subject a large swathe of expression to scrutiny. It creates a bureaucratic process to ensure that certain types of information are never disseminated, very much like the old printing press licensing system in England in the sixteenth and seventeenth centuries.[75] On the other hand, the system is not really *prior*. Completed research papers do not have to be submitted to DACs for approval, the way that, for

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of prior restraint on speech or press similar to that employed in England and the Colonies in the seventeenth and eighteenth centuries, i.e., licensing of the press and censorship of expression.").

[70] Marin Scordato, *Distinction Without A Difference: A Reappraisal of the Doctrine of Prior Restraint*, 68 N.C. L. REV. 1, 6 (1989).

[71] *Id.* at 7.

[72] 394 U.S. 147 (1969).

[73] *Id.* at 150–51.

[74] 343 U.S. 495, 503 (1952).

[75] HARVEY L. ZUCKMAN ET AL., MASS COMMUNICATIONS LAW IN A NUTSHELL 28 (3d ed. 1988) ("When the first amendment was approved by the First Congress, it was undoubtedly intended to

instance, movies had to be submitted to the New York Board of Regents for approval in *Joseph Burstyn*. Given the nebulous parameters of the doctrine, other approaches should be examined.

C. Vagueness

The "vagueness" doctrine under the First Amendment stems from the Fourteenth Amendment, which prohibits statutes that fail to give adequate notice to a reasonable person of the nature of prohibited conduct or that give government officials too much discretion in enforcement.[76] The doctrine has a specific application to laws that have chilling effects on the exercise of First Amendment freedoms. Courts will strike down a law on vagueness grounds if it discourages or threatens people from exercising First Amendment rights.[77] "Uncertain meanings inevitably lead citizens to 'steer far wider of the unlawful zone' . . . than if the boundaries of the forbidden areas were clearly marked.'"[78]

Following the Due Process standard set forth in a criminal case, *City of Chicago v. Morales*, the First Amendment vagueness rule in the administrative context states that "[a] vague rule 'denies due process by imposing standards of conduct so indeterminate that it is impossible to ascertain just what will result in sanctions.'"[79] "In reviewing regulations for vagueness, [the court] must decide only whether the regulation 'delineated its reach in words of common understanding.'"[80]

Under the GDSP, DACs may impose requirements forbidding "sensitive" and "stigmatizing" research in their DULs. Precisely what these terms mean is far from clear—leaving aside the real and definable problem of de-anonymizing. As discussed above,[81] these terms have been defined in circular ways. Indeed, the Depart-

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prevent government's imposition of any system of prior restraints similar to the English licensing system under which nothing could be printed without the approval of the state or church authorities. On one point adherents of all schools of thought appear to agree.").

[76] City of Chicago v. Morales, 527 U.S. 41 (1999); United States v. Williams, 553 U.S. 285 (2008).

[77] 600 Marshall Ent. Concepts, LLC v. City of Memphis, 705 F.3d 576, 586 (6th Cir. 2013).

[78] Grayned v. City of Rockford, 408 U.S. 104, 108 (1972).

[79] Timpinaro v. SEC, 2 F.3d 453, 460 (D.C. Cir.1993) (quoting Hastings v. Jud. Conf. of the U.S., 829 F.2d 91, 105 (D.C. Cir.1987)).

[80] Throckmorton v. Nat'l Transp. Safety Bd., 963 F.2d 441, 444 (D.C. Cir.1992).

[81] *2007 Policy*, *supra* note at 16, at 49,292.

ment of Health and Human Services, of which the NIH is a part, has in other contexts rejected "sensitivity" as a meaningful term to justify limiting the use of consumer-directed genetic testing.[82]

Under current practice, DULs prohibit researchers from pursuing lines of research that a DAC might find "sensitive" or "stigmatizing." And, as mentioned above, each DAC can define these terms in their DULs in whatever way it wishes.[83] The GDSP punishes violations of DULs, so, faced with having to sign the DUL to conduct research, a scientist might refrain from proposing certain types of research—or fail to publish research after a permission has been granted, perhaps after making unexpected or unintentional discoveries that could be seen as "stigmatizing." In either case, the GDSP's vagueness chills lawful speech—even speech that a DAC might find acceptable.

The vagueness analysis is particularly powerful if one views scientific inquiry as a process—and not just the speech of researchers—deserving full First Amendment protection. There are numerous prominent advocates for that position.[84] Indeed, it has been convincingly argued that speech *about* the human genome, itself, deserves First Amendment protection in the context of interpretation of polygenic risk scores, a process which the Federal Drug Administration has claimed jurisdiction over.[85]

Last, *Finley v. NEA* would suggest that in government grant-making contexts, courts should be more tolerant of vague statutory and regulatory terms given the

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[82] Department of Health & Human Services, Centers for Medicare & Medicaid Services, 42 CFR Part 493, Final Rule, 79 Fed. Reg. 7290, 7296 (Feb. 6, 2014) ("With a very limited exception, covered entities may not deny an individual access to his or her health information based on the information's sensitive nature or potential for causing distress to the individual.").

[83] *See supra* note 12.

[84] Lori B. Andrews, *Is There a Right to Clone? Constitutional Challenges to Bans on Human Cloning*, 11 HARV. J.L. & TECH. 643, 661 (1998); Natalie Ram, *Science as Speech*, 102 IOWA L. REV. 1187, 1198 (2017) (arguing that scientific experimentation produces knowledge that is the basis for speech and that, therefore, "the First Amendment must also be concerned with the production of ideas and information"); Richard Delgado & David R. Millen, *God, Galileo, and Government: Toward Constitutional Protection for Scientific Inquiry*, 53 WASH. L. REV. 349, 394–99 (1978); June Coleman, *Comment, Playing God or Playing Scientist: A Constitutional Analysis of Laws Banning Embryological Procedures*, 27 PAC. L.J. 1331, 1367–68 (1996).

[85] Barbara J. Evans, *The First Amendment Right to Speak About the Human Genome*, 16 U. PA. J. CONST. L. 549 (2014).

inevitably open-ended nature of the award process. In *Finley*, the Court upheld a statutory requirement found in Section 954(d)(1) of the National Foundation on the Arts and the Humanities Act of 1965, admonishing the National Endowment of Arts to take "decency and respect" in consideration when making award decisions.

The Court conceded that "[t]he terms of the [statute's challenged] provision are undeniably opaque, and if they appeared in a criminal statute or regulatory scheme, they could raise substantial vagueness concerns."[86] But the Court rejected the vagueness argument because "although the First Amendment certainly has application in the subsidy context, we note that the Government may allocate competitive funding according to criteria that would be impermissible were direct regulation of speech or a criminal penalty at stake. So long as legislation does not infringe on other constitutionally protected rights, Congress has wide latitude to set spending priorities." The Court continued that "[i]n the context of selective subsidies, it is not always feasible for Congress to legislate with clarity. Indeed, if this statute is unconstitutionally vague, then so too are all Government programs awarding scholarships and grants on the basis of subjective criteria such as 'excellence.'"[87]

But with the GDSP, the distinction, mentioned above,[88] between funding specific research and operating a database has particular force. When conducting or funding research, the NIH should have the discretion not to fund what it believes to be insensitive or stigmatizing research. Congress should be able to provide the NIH with such broad discretion without running afoul of the First Amendment. In contrast, when the NIH is acting as curator of federally funded, general purpose databases, the permissive *Finley* standard does not apply.

D. Unconstitutional Conditions

Constitutional law does not clearly identify the point at which the Constitution prohibits government's conditioning some grant or benefit—whether it be financial support, access to information, or some legal preferment—on the grantee's

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[86] Nat'l Endowment for the Arts v. Finley, 524 U.S. 569, 587–88 (1998).

[87] *Id.* at 589.

[88] *See supra* note 47 and accompanying text.

surrender of his free speech rights.[89] While case law presents this question often, ranging from government's power to limit employees' speech rights in exchange for continued employment[90] to limitations on the scope of legal representation in exchange for federal legal aid support,[91] most commenters believe that the Court has not come up with a consistent framework for deciding these questions.

Theory aside, there seem to be two highly relevant lines of precedent which would likely control a legal challenge to the NIH's GDSP: (1) the Court's cases on speech conditions for receipt of program funding or subsidies and those conditions' relationship to program scope and (2) its cases on the provision of non-monetary legal privileges, particularly intellectual property rights, under viewpoint discriminatory standards. These precedents suggest that the NIH's GDSP is unconstitutional.

1. Government funding or subsidy and program scope

One could describe the NIH's GDSP as a form of government funding or subsidy. The database reflects an "in-kind" payment to or financial support for researchers. There is established Court precedent on speech-limiting conditions attached to government subsidies. "[W]hen the Government appropriates public funds to establish a program it is entitled to define the limits of that program."[92] This principle would suggest that the GDSP is constitutional. The government has set up a program to facilitate GWAS, but only those GWAS that are not stigmatizing may receive "funding" through it. [93]

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[89] *See* PHILIP HAMBURGER, PURCHASING SUBMISSION: CONDITIONS, POWER, AND FREEDOM (2021).

[90] *Garcetti*, 547 U.S. at 421.

[91] *Velazquez*, 500 U.S. at 194.

[92] *Rust*, 500 U.S. at 194.

[93] And the Court has ruled that the government can condition receipt of federal funds upon forfeiting constitutional rights so that the only recourse is to decline the funds. *See, e.g.,* United States v. Am. Library Assn., Inc., 539 U.S. 194, 212 (2003) (plurality opinion) (rejecting a claim by public libraries that conditioning funds for Internet access on the libraries' installing filtering software violated their First Amendment rights, explaining that "[t]o the extent that libraries wish to offer unfiltered access, they are free to do so without federal assistance").

But the Court has recognized two important limits to that principle, suggesting that the GDSP is not constitutional. First, the Court distinguishes "between conditions that define the limits of the government spending program—those that specify the activities Congress wants to subsidize—and conditions that seek to leverage funding to regulate speech outside the contours of the program itself."[94] For instance, in *FCC v. League of Women Voters*, the Court struck down a condition on federal financial assistance to noncommercial broadcast television and radio stations that prohibited all editorializing, including with private funds.[95] The condition "barred [even a station that received a de minimis amount of funds] absolutely from all editorializing."[96] The law provided no way for a station to limit its use of federal funds to noneditorializing activities, as was allowed for limits on non-profit, tax exempt organizations' lobbying activity.[97] The prohibition thus went beyond ensuring that federal funds not be used to subsidize "public broadcasting station editorials," and instead leveraged the federal funding to regulate the stations' speech outside the scope of the program.[98]

Second, "Congress cannot recast a condition on funding as a mere definition of its program in every case, lest the First Amendment be reduced to a simple semantic exercise."[99] In *Agency for International Development*, the federal government required groups, as a condition for receipt of funding under the United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act, to adopt an official position against prostitution. The Court ruled that this affirmation went beyond the scope of the program. The distinction between conditions that define the federal program and those that reach outside it is not always self-evident. But, it was the funding requirement's forced avowal of a position on a political issue in all circumstances that swayed the Court: "A recipient cannot avow the belief dictated by the Policy Requirement when spending Leadership Act funds, and then turn

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[94] *Agency for Int'l Dev.*, 570 U.S. at 206 (and at 214–15).

[95] 468 U.S. 364, 399–401 (1984).

[96] *Id.* at 400.

[97] *Id.* (citations omitted).

[98] *Id.* at 399 (internal quotation marks omitted).

[99] *Velazquez*, 531 U.S. at 547.

around and assert a contrary belief, or claim neutrality, when participating in activities on its own time and dime."[100]

Here, the GDSP seems to violate *Agency for International Development's* holding because all users of GWAS databases must agree, at least implicitly, with the government's judgment about what constitutes stigmatizing research. Rather than condition involvement in a government program that produces government speech, GWAS prohibitions affects a user's ability to pursue "activities on its own time and dime." After all, the government qua database librarian is not paying for the research of people who use the database.

This conclusion is reinforced by *Matal v. Tam*, which involved limitations on the issuance of trademarks to proposed marks that were deemed "disparaging." The Court unanimously struck down the requirement but did so in two four-Justice opinions. (Justice Gorsuch did not take part in the decision.) The lead opinion, discussed below, distinguished non-monetary from monetary benefits in its constitutional analysis.

In a concurrence that the other half of the Court endorsed, the viewpoint discrimination that the restriction on "disparaging" marks invited was seen as not integral to the government program—and reached beyond it. The Court reasoned that "[t]he central purpose of trademark registration is to facilitate source identification. . . . Registered trademarks do so by means of a wide diversity of words, symbols, and messages. Whether a mark is disparaging bears no plausible relation to that goal. While defining the purpose and scope of a federal program for these purposes can be complex, our cases are clear that viewpoint discrimination is not permitted where, as here, the Government expends funds to encourage a diversity of views from private speakers."[101]

If "disparaging" bears no plausible relationship to the goal of trademark registration, preventing stigmatizing information from being created cannot bear a plausible relationship to the goal of scientific research. Its goal is truth, which exists independently of people's reaction to it.

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[100] *Agency for Int'l Dev.*, 570 U.S. at 218.

[101] *Matal*, 582 U.S. at 253 (Kennedy, J., concurring in part and concurring in the judgment) (cleaned up).

2. Government provision of non-monetary benefits and government viewpoint discrimination

As mentioned above, *Matal* presents a similar issue to the GDSP. In *Matal* the government conditioned its grant of trademark registration on the mark not being "disparaging"; in the GDSP, access is provided only to research that is not "stigmatizing." The *Matal* four-Justice lead opinion concluded that a trademark registration was not a subsidy. Distinguishing *Rust,* the lead opinion reasoned that "just about every government service requires the expenditure of government funds. This is true of services that benefit everyone, like police and fire protection, as well as services that are utilized by only some, *e.g.*, the adjudication of private lawsuits and the use of public parks and highways. Trademark registration is not the only government registration scheme."[102] Distinguishing the direct financial support in *Rust* and *Finley*, the *Matal* plurality ruled that "valuable non-monetary benefits" cannot be offered on terms that require surrender of constitutional rights.[103] Under that rule, the GDSP would be unconstitutional.

The other four Justices did not reach the question of unconstitutional conditions, but the Court recognized in a later case, *Iancu v. Brunetti*,[104] that both *Matal* opinions agreed that the USPTO non-disparaging requirement was unconstitutionally viewpoint based. In *Iancu*, the Court addressed another statutory basis for denying trademark protection: the proposed mark's being "immoral or scandalous." The Court struck down this restriction as well. The Court reasoned that "if a trademark registration bar is viewpoint based, it is unconstitutional," and that "the 'immoral or scandalous' bar similarly [to the disparaging mark bar in *Matal*] discriminates on the basis of viewpoint and so collides with this Court's First Amendment doctrine."[105]

The GDSP's limitations on "stigmatizing" and "sensitive" research appear to be just as viewpoint-based as the prohibitions on registering "disparaging" and "immoral or scandalous" trademarks. Thus, if access to a database is viewed as a government non-monetary benefit like a trademark, the GDSP is viewpoint discriminatory and unconstitutional.

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[102] *Id.* at 241.

[103] *Id.* at 240.

[104] 139 S. Ct. at 2298–99.

[105] *Id.* at 2296.

E. Viewpoint Discriminatory Access to Information in Government's Control

The Supreme Court has ruled that the First Amendment does not "guarantee the public a right of access to information generated or controlled by government."[106] If we characterize the GDSP *not* as a restriction on speech, but as a simple restriction on access to information, then the Policy does not implicate the First Amendment.

But *viewpoint-discriminatory* access to government records does present constitutional problems, as does viewpoint discrimination in other government programs or preferments.[107] In *Los Angeles Police Department v. United Reporting Publ'g Corp.*, [108] the Court decided whether a California statue could deny access, consistent with the Constitution, to a firm that planned to use a list of arrestee names for commercial purposes but also grant access to noncommercial users, namely the press.[109] "Although the Court resolved the case on standing grounds," all nine Justices recognized that "no obligation to release the names of arrested individuals existed, and at least six thought viewpoint-based discriminatory access restrictions would be invalid."[110] Justice Ginsberg, in a concurrence, states the problem: "[I]f States were required to choose between keeping proprietary information to themselves and making it available without limits, States might well choose the former option. In that event, disallowing selective disclosure would lead not to more speech overall but to more secrecy and less speech. As noted above, this consideration could not justify limited disclosures that discriminated on the basis of viewpoint or some other proscribed criterion."[111]

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[106] Houchins v. KQED, Inc., 438 U.S. 1, 16 (1978) (Stewart, J., concurring in the judgment); Pell v. Procunier, 417 U.S. 817, 833 (1974) ("The First Amendment does not guarantee . . . special access to information not available to the public generally.").

[107] Board of Comm'rs, Wabaunsee Cty. v. Umbehr, 518 U.S. 668 (1996) (the First Amendment shields city independent contractors from ending at-will government contracts in retaliation for their exercise of freedom of speech).

[108] 528 U.S. 32, 43–44 (1999).

[109] Note, *Viewpoint Discrimination and Media Access to Government Officials*, 120 HARV. L. REV. 1019, 1021 (2007).

[110] *Id.*

[111] *Los Angeles Police Dep't*, 528 U.S. at 43–44.

To be sure, virtually all the important access to government records cases involved press access to government records or general public access to court records.[112] In both situations, the records at issue are created as a necessary administrative function of government. In contrast, the GWAS depositories result from specific, highly discretionary government research programs, a difference that might suggest greater government control. That distinction, however, does not exist in the precedent and is difficult to make on normative grounds. Records are records. If the government provides them generally, it cannot limit the provision to those with approved viewpoints.

Conclusion

GWAS data depositories are like Galileo's telescope viewing the moons of Jupiter. Both tools allow researchers a first glimpse into key relationships in the natural world. And both tools were the product of significant government support.[113] While, of course, the NIH has threatened no one with an auto-da-fé, the GDSP's aim to cut off entire lines of research is, indeed, reminiscent of the Church's inquisition of Galileo. The Church viewed the heliocentric theory as "sensitive" or even "stigmatizing" to its ideology of divinely created humanity—which should be the center of His creation, not stashed away on a peripheral celestial body. The Church therefore banned Galileo's *Dialogue Concerning the Two Chief World Systems*, which argued that the existence of Jupiter's moons supported a heliocentric Coper-

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[112] Cohen v. Cowles Media Co., 501 U.S. 663 (1991); Pell v. Procunier, 417 U.S. 817, 833 (1974); Saxbe v. Washington Post Co., 417 U.S. 843 (1974); *see generally* Barry P. McDonald, *The First Amendment and the Free Flow of Information: Towards A Realistic Right to Gather Information in the Information Age*, 65 OHIO ST. L.J. 249, 275–76 (2004).

[113] Galileo's telescopes appear to have been developed with significant government financial support. He presented one of the first that he had made to the Doge of Venice and, in return, received a big raise and life tenure at the University of Padua. The Venetian government later contracted Galileo to produce 10 more telescopes but in secret. Richard S. Westfall, *Science and Patronage: Galileo and the Telescope* 76 ISIS 1, 16–18 (1985). Galileo arguably developed telescope technology under a Renaissance version of grantmaking under Chapter 64 of Title 31 of the U.S. Code. Indeed, given that his high-quality telescopes had one practical application—military operations—the telescope was an early example of scientific research aiding national defense. Mario Biagioli, *Replication or Monopoly? The Economies of Invention and Discovery in Galileo's Observations of 1610*, 13 SCI. IN CONTEXT 277, 308 n.34 (2000).

nican system. In the same way, GWAS has the potential to disrupt widely held ideological beliefs about human nature as a blank slate that environment predominantly determines.

First Amendment and constitutional law aside, the GDSP presents a fundamental question about how our society views government support of scientific inquiry. Should our government only allow speech that supports one world view and set of moral priors? A liberal society should support the search for truth, regardless of how uncomfortable and unsettling that truth turns out to be.