PRIVACY AND AGENCY ARE CRITICAL TO A FLOURISHING BIOMEDICAL RESEARCH ENTERPRISE: MISCONCEPTIONS ABOUT THE ROLE OF CLIA.

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INTRODUCTION

The Clinical Laboratory Improvement Amendments'[1] status of a lab that generates research data is regularly perceived to interfere with the ability of individuals to access data about themselves for a variety of reasons, including to advance research as an active participant who seeks to contribute to the research process in ways that go beyond serving solely as a source of tissue or data for others to use. A recent experience that Professor Jason Bobe had is illustrative:

> I had just embarked on a new research effort to identify protective factors for disease among individuals that lack typical signs and symptoms despite exposure to known risk factors. The first case to emerge was a remarkable individual in his seventies with no coronary artery calcification despite severe elevation of his LDL cholesterol levels at least since initial diagnosis of familial hypercholesterolemia as a teenager. His personal experience of escaping the worst of a disease that would, he had been told, severely shorten his life animated our research collaboration to discover the factors that protected him, and any other similar individuals we could engage.
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> We collected his medical records and summarized his unique health circumstances in a published case report.[2] During the process of collecting his medical history, the participant reported that he had already had his genome sequenced as part of another research study and that he would happily contribute the data to this effort, however, his previous request for access to his genome sequence data had been denied by the researcher leading that study. He was told it was "not possible" to provide him access to his data. Shortly thereafter, I bumped into the researcher at a scientific

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1. Pub. L. No. 100-578, 102 Stat. 2903 (1988) (codified as amended at 42 U.S.C. § 263a (2012)).

2. K.W. Johnson et al., *A 72-Year-Old Patient with Longstanding, Untreated Familial Hypercholesterolemia but no Coronary Artery Calcification: A Case Report*, CUREUS, Apr. 9, 2018, at 1.

> conference and explained the unique case we might have in common. The researcher recognized the case and offered to share the data with me. I followed up several times, with no response. The third email generated a response: "I appreciate your persistence. I'll respond when ready." Many months later I followed up again. The researcher wished me luck but reported that the person responsible for that work had moved on from his lab and he did not have the bandwidth to provide a copy of the data.

Professors Barbara Evans and Susan Wolf (E&W) have made a compelling case that, contrary to conventional wisdom, the Clinical Laboratory Improvement Amendments of 1988 (CLIA) do not prohibit the return of research results from a non-CLIA lab when that return is done for any reason other than "for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings" (clinical purposes).[3] As a result of this analysis, two pearls of conventional wisdom that have impeded efforts to engage, respect, and honor the civil rights of research participants logically fall. First, CLIA does not conflict with a research participant's right under the Health Insurance Portability and Accountability Act (HIPAA)[4] Privacy Rule[5] to receive a copy of her research results that are contained in the designated record set (DRS). To the contrary, with very limited exceptions, HIPAA-covered entities are *required* by law to provide, upon request, access to individual research results held in the DRS, even when those results were produced in a non-CLIA lab.[6] Second, in all other cases—i.e., all cases except when a research participant requests her individual results in the DRS held by a HIPAA-covered entity (a legal right under HIPAA)[7] or when a lab or researcher returns non-CLIA results for clinical purposes (a legal prohibition under CLIA)[8]—federal law permits, but does not require, the return of (or access to) individual research results (legal permissibility).[9]

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3. Barbara J. Evans & Susan M. Wolf, *A Faustian Bargain that Undermines Research Participants' Privacy Rights and Return of Results*, 71 FLA. L. REV. 1281, 1310–11 (2019).

4. Pub. L. No. 104-191, 110 Stat. 1936 (1996) (codified as amended in scattered sections of 18, 26, 29, and 42 U.S.C. (2012)).

5. *See* 45 C.F.R. §§ 160.013, 164.524 (2019).

6. 45 C.F.R. § 164.524.

7. *Id.*

8. NAT'L ACADS. OF SCIS., ENG'G, & MED., RETURNING INDIVIDUAL RESEARCH RESULTS TO PARTICIPANTS: GUIDANCE FOR A NEW RESEARCH PARADIGM 28 (Jeffrey R. Botkin et al. eds., 2018) [hereinafter RETURNING RESULTS].

9. *See* Evans & Wolf, *supra* note 3, at 1331; *see also infra* Table 1.

Although, as E&W explain, the legislative purpose of the HIPAA access right is to enable people to manage the privacy risks associated with data about them held in the DRS,[10] like other rights (e.g., the Freedom of Information Act),[11] an individual need not be subjectively motivated by the concerns that animated legislators (here, privacy concerns) when requesting their research results; they may have some other purpose in mind—or no particular purpose at all—and HIPAA nevertheless requires that they be given access.[12] For example, breast cancer patients leveraged the HIPAA access right to pry their data from a company's proprietary database, so the data could be shared broadly, not so they could ensure their own privacy.[13] Moreover, even when HIPAA does not apply and therefore there is no legal obligation to honor a participant's request for data access or other results, CLIA is no barrier. Researchers may provide a research participant access to their uninterpreted data or individual results, so long as they do so for any reason other than the clinical purpose quoted above.

Table 1. Under U.S. federal law, when may, when must, and when must not individual research data or results be returned or made available to participants?

Scenario	Lab	HIPAA Covered Entity?	Lab or researcher's purpose in returning individual research results or providing access	Legal obligation or permission
1	CLIA labs[§]	HIPAA Covered Entity	Return "for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the heath of, human beings."	*Legally Permissible*[*]
2			Granting participant's request (for any reason) to access results in the DRS	*Legally obligatory under HIPAA*
3			Return for any other purpose[¶]	*Legally Permissible*[*]
4		Non-HIPAA Covered Entity	Return "for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the heath of, human beings."	*Legally Permissible*[*]
5			Granting participant's request (for any reason) to access results in the DRS	*Legally Permissible*[*]
6			Return for any other purpose[¶]	*Legally Permissible*[*]

10. *See* Evans & Wolf, *supra* note 3, at 1300.

11. Pub. L. No. 114-185, 130 Stat. 538 (2016) (codified as amended at 5 U.S.C. § 552 (2016)).

12. 45 C.F.R. § 164.524.

13. Ellie Kincaid, *Data Pirates: Patients and Scientist Battle to Liberate Genetic Testing Results*, FORBES (Jan. 17, 2019, 9:00 AM), https://www.forbes.com/sites/elliekincaid/2019/01/17/data-pirates-patients-and-scientist-battle-to-liberate-genetic-testing-results/ [https://perma.cc/V968-4WCE].

7	All other labs	HIPAA Covered Entity	Return "for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the heath of, human beings."	*Legally prohibited under CLIA*
8			Granting participant's request (for any reason) to access results in the DRS	*Legally obligatory under HIPAA*
9			Return for any other purpose[¶]	*Legally Permissible*[*]
10		Non-HIPAA Covered Entity	Return "for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the heath of, human beings."	*Legally prohibited under CLIA*
11			Granting participant's request (for any reason) to access results in the DRS	*Legally Permissible*[*]
12			Return for any other purpose[¶]	*Legally Permissible*[*]

[§] Includes certain labs in New York and Washington that meet state regulatory requirements at lease as strict as CLIA and have therefore been determined by CMS to be "exempt"
[¶] Including, but not limited to: altering participant that they might want to see clinical testing; enabling participant to make privacy-relevant choices; demonstrating respect for or gratitude to participant.
[*] This analysis of U.S. federal law assumes no state or local laws (statutory, regulatory, or judicial) forbidding or requiring returning return or access.

Here, we elaborate on one reason why research participants might wish to access their data for privacy-related reasons as intended by HIPAA. We then discuss several non-privacy related reasons why research participants might wish to receive, and researchers might want to provide, individual-level data or results.

I. ACCESS ENABLES PRIVACY

What if, by example, the investigators of a research study claimed in the informed consent that genetic data is not identifiable and also notified prospective participants that, as part of this study, research data, including genomic data, would be shared broadly at some point in the future?[14] Suppose a participant believes the assessment of the research investigators that their personal data was not identifiable and enrolls in the study. They receive the annual study newsletter stating that cutting-edge DNA sequencing was recently completed for all participants enrolled to-date and that, over the next year, researchers plan to analyze the data, prepare manuscripts for publication, and begin the process of depositing data into a public database. At this point, the participant decides to revisit the privacy implications of their prior informed consent through consultation with a trusted third party. After all, this seems like the perfect time, and with actual data in hand, the assessment is far less hypothetical. So, they request access to their uninterpreted genetic data. Several years pass, and a vibrant new economy takes shape that is fueled

14. While this is a hypothetical example, underestimation of the identifiability of genetic data were not infrequent in early genomic research studies, like the Human Genome Project and the HapMap Project.

by advances in machine-learning software and biotechnology. A dynamic marketplace emerges composed of a potent mixture of online genetic ancestry services, hyperconnected social platforms, and nearly ubiquitous access to computational tools. The landscape is so transformed that this participant wants to, again, revisit their prior decision-making around broadly sharing their biological data generated in the study. Again, they request access to their uninterpreted genetic data, so that they may consult a trusted third party about the privacy implications of their continued participation in research involving the broad dissemination of their personal data. Are these two requests for data access reasonable? Yes. Are the research investigators able to honor the participant's request and provide them access to their individual-level, uninterpreted genomic data? The Centers for Medicare & Medicaid Services (CMS),[15] and now the National Academies of Sciences, Engineering, and Medicine (NASEM),[16] would say no, unless the laboratory that performed analyses of the specimens met clinical standards under CLIA, even though, at no time, was the purpose of the laboratory analysis or the purpose of the data access request related to the "diagnosis, prevention, or treatment of disease."[17]

By analogy, imagine if you were audited by the IRS, and you were unable to access your own financial records. Instead, you were assigned an accountant by the IRS to advise you on the particulars of your case. We think most would prefer to have access to their own records and the freedom to hire an independent accountant, should a circumstance arise where this access became important. Regrettably, and with few exceptions, this is similar to the situation research participants regularly face today.

For example, the Broad Institute of Harvard and MIT, one of the most prestigious research organizations in the United States and one of the largest producers of human genome data globally, recently celebrated that in a single year, they had sequenced the genomes of enough people to fill Fenway Park in Boston, Massachusetts.[18] In an exchange on social media, one commentator asked how many of these genomes were available to

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15. *See Research Testing and Clinical Laboratory Improvement Amendments of 1988 (CLIA) Regulations*, CTRS. MEDICARE & MEDICAID SERVS., https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/Research-Testing-and-CLIA.pdf [https://perma.cc/35VA-4SYS].

16. *See* RETURNING RESULTS, *supra* note 8, at 52.

17. 42 U.S.C. § 263a(a) (2012).

18. *See generally* Lauren Solomon, *Broad Institute Sequences its 100,000th Whole Human Genome on National DNA Day*, BROAD INST. (Apr. 25, 2018), https://www.broadinstitute.org/news/broad-institute-sequences-its-100000th-whole-human-genome-national-dna-day [https://perma.cc/7KX8-ANEN] ("[T]he Broad Institute of MIT and Harvard sequenced its 100,000th whole human genome, adding to a global total that is approaching one million.").

the research participants that submitted specimens for analysis[19] and a Broad-affiliated scientist responded, "Approximately zero, per both consent and explicit CMS guidance forbidding return of non-CLIA data to participants."[20] Additionally, at a recent event sponsored by the National Cancer Institute entitled "Symposium on Personal Control of Genomic Data for Research,"[21] another Broad-affiliated scientist stated her position on the current difficulty of practicing participant-centered science: "If I could give the research-grade data back to patients easily, I'd do it yesterday. Give. It. Back!"[22]

Today, participant access to their own research data is the exception, not the rule. To be sure, with ingenuity and dogged effort, some research participants find ways to claw back their agency and liberate their personal data from research silos to use for their own purposes. For example, Steven Keating temporarily changed his affiliation at MIT while a PhD candidate in order to access his own brain tumor DNA as a researcher, after he was previously denied access as a research participant because the data was generated in a non-CLIA lab.[23] He often joked about the bizarre reality that his roommate, a Broad-affiliated scientist, had access to his genetic data, but he was forbidden.[24] Why must advocates for research, people who already are, in many ways, among the societal fringe due to their enthusiasm for and active participation in biomedical research studies, be required to suffer through episodes of regulatory gamesmanship like this in order to access their own data? As E&W observe, the answer provided in the NASEM report is because a right of access by participants is inconvenient for researchers.[25] While E&W

19. Mad Prime Ball (@madprime), TWITTER (Jan. 4, 2017, 4:29 PM), https://twitter.com/madprime/status/816758387262287872 [https://perma.cc/X72R-EA6R].

20. Daniel MacArthur (@dgmacarthur), TWITTER (Jan. 4, 2017, 10:00 PM), https://twitter.com/dgmacarthur/status/816841870051569665 [https://perma.cc/2Y9J-TYDC].

21. *See* Ctr. for Biomed. Informatics & Info. Tech, *Symposium on Personal Control of Genomic Data for Research*, NAT'L CANCER INST. (Sept. 26, 2019) https://datascience.cancer.gov/news-events/events/symposium-personal-control-genomic-data-research [https://perma.cc/XF72-SLCQ].

22. CBTTC (@CBTTC), Twitter (Sept. 26, 2019, 10:02 AM), https://twitter.com/CBTTC/status/1177221899870490627?s=20 [https://perma.cc/8FAU-Z6J5] (The Children's Brain Tumor Tissue Consortium; quoting Corrie Painter).

23. Mary Beth Gallagher, *Celebrating a Curious Mind: Steven Keating 1988-2019*, MIT NEWS (July 22, 2019), http://news.mit.edu/2019/celebrating-curious-mind-steven-keating-0722 [https://perma.cc/S2ZH-2ZAL].

24. Sarah Gray (@SGrayDC), TWITTER (July 30, 2019, 4:20 PM), https://twitter.com/sgraydc/status/1156298419931103232?s=12 [https://perma.cc/PRR5-URDJ].

25. Evans & Wolf, *supra* note 3, at 1286–87 ("The Report stresses that funds for biomedical research 'are precious and require careful and responsible stewardship,' so that letting participants have data access 'necessarily requires the diversion of some research resources from the primary goal of the research.' In short, honoring people's right to see their own results and data generated during research is inconvenient.") (footnotes omitted).

make the case that inconvenience to researchers is not sufficient grounds for prohibiting participant access to their data, Professor Evans also previously argued that many laboratories are ill-prepared to do so even if they are obligated.[26]

II. RESEARCH WITHOUT PRIVACY

If we truly want to live in the confines of a research enterprise that does not fully respect the individual privacy of research participants, one solution would be to propose that human research selectively recruit individuals with fewer significant interests in personal privacy. Obviously, this does not make any sense if the strength of the research enterprise, and the equitable generation of translational outcomes, hinge upon the ability to attract research participants representative of the general population.[27] However, in the void of privacy that the NASEM recommendations would deepen, perhaps this approach should be re-considered.

The Harvard Personal Genome Project (PGP) and its affiliated international sites is one example of what such a model would look like, both in terms of the informed consent process and the protocols surrounding data management. The PGP was founded in the lab of technologist George Church at Harvard Medical School, where new high-throughput techniques and inventions are conceived, prototyped, and evaluated.[28] Many of these methods and tools, like those that underlie next generation DNA sequencing, have drastically improved our ability to inspect how humans are put together, molecule by molecule, and how our bodily components interact with each other and the environment to

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26. Barbara J. Evans et al., *Regulatory Changes Raise Troubling Questions for Genomic Testing*, 16 GENETICS MED. 799, 802 (2014).

27. A core value of the All of Us research program is transparency. *About*, NAT'L INSTS. HEALTH, https://allofus.nih.gov/about [https://perma.cc/7VQ2-36CZ]. They are among the few research studies in the United States that have made a commitment, from the outset, that they would provide participants with access to their uninterpreted genomic data upon request. Adrian Thorogood et al., *APPLaUD: Access for Patients and Participants to Individual Level Interpreted Genomic Data*, 12 HUM. GENOMICS 1, 3 (2018). In their marketing materials, they state "What is the promise to participants? The ability and choice to access your own data." *The All of Us Research Program Genome Centers*, NAT'L INSTS. HEALTH, https://allofus.nih.gov/sites/default/files/genome_centers_webinar.pdf [https://perma.cc/5T5A-7XLS]. One other large, nationally funded research study more begrudgingly provides access. On their website, Genomics England states: "If you would like a copy of your whole genome sequence we can show you this on our screens in our London offices," which shows an incomprehensible image on a computer screen. While honoring the spirit of access, they clearly are trying to deter requests for access. *See Participant Data Requests Under the GDPR and Data Protection Act 2018*, GENOMICS ENG., https://www.genomicsengland.co.uk/the-100000-genomes-project/data/participant-data-requests/ [https://perma.cc/Z333-9A8V].

28. *The PGP is Not a Traditional Research Study*, HARV. PERS. GENOME PROJECT, https://pgp.med.harvard.edu/about [https://perma.cc/3JPM-5BMX].

produce human traits.[29] Critical assessment and improvement of these tools, through research on human samples, is essential so that they may be compared to competing technologies and refined for future clinical uses.[30] A significant portion of biomedical research regularly deploys cutting edge technologies and methods that are not yet clinically licensed, so the narrow context of the Church Lab, while unique in many ways, is applicable to biomedical research more generally.[31]

The PGP practices a form of research governance, called "open consent", that takes the view that genomic secrecy is impossible to guarantee in the context of a research study that aims to generate and broadly share integrated genomic and trait data while also obtaining valid informed consent.[32] To mitigate the risks of enrolling individuals that are not well-informed, either about the conceivable potential consequences of broad sharing or that some potential consequences are unknown, the research team implemented several features in the research protocol that were novel at the time.[33] For example, prior to enrollment, individuals are required to demonstrate informedness by correctly answering all questions in a quiz about the study.[34] After specimens are collected and genome sequencing is completed, individuals are provided with a privacy ripcord, of sorts, that they may pull during a limited period prior to dissemination of the data, should their reflections about risks or any personal circumstances change in the gap between the time they enroll and the present.[35] During this period, participants are provided access to their uninterpreted genomic data and a "preliminary research report" with summary information.[36] They are invited to proceed with data dissemination or withdraw themselves and their data from the study.[37]

The strength of the informed consent in the PGP was recognized by the National Institutes for Science and Technology (NIST) by their selection of the Harvard study to supply well-consented specimens for

29. *See id.*

30. *See id.*

31. Professors George M. Church (GMC) and Jason R. Bobe (JRB) co-authored the informed consent and protocols, and GMC, JRB, and Professor Michelle N. Meyer (MM) worked for several years on the implementation and operation of the Harvard PGP and Global Network of Personal Genome Projects. *See* Madeleine P. Ball et al., *Harvard Personal Genome Project: Lessons From Participatory Public Research*, 6 GENOME MED. 1, 6 (2014).

32. *See* George M. Church, Editorial, *The Personal Genome Project*, MOLECULAR SYS. BIOLOGY, Dec. 13, 2005, at 2 (discussing the potential psychological trauma and loss of public trust that can occur from broadly distributed PGP genome and phenome data); Jeantine E. Lunshof et al., *From Genetic Privacy to Open Consent*, 9 NATURE REVIEWS GENETICS 406, 408 (2008).

33. Ball et al., *supra* note 31, at 2.

34. *Id.*

35. *Id.* at 3.

36. *Consent Form*, HARV. PERS. GENOME PROJECT 6, https://my.pgp-hms.org/static/PGP_Consent_Approved03242009.pdf [https://perma.cc/6EUM-D5GS].

37. *Id.*

the creation of human genetic reference standards as part of their "Genome in a Bottle" program.[38] The end result is the public availability of extremely high quality genomes of individuals whose DNA sequences have so far been analyzed using twelve different sequencing technologies.[39] Aliquots of their DNA are also publicly available.[40] Anticipated users of these reference materials are DNA sequencing facilities and clinical laboratory accreditation organizations that aim to evaluate the performance and reproducibility of laboratory sequencing operations. These users now have a "genetic meter stick" that may be deployed to help measure the quality and accuracy of genetic sequencing operations. If we accept the recommendations of the NASEM report, then we also would need to accept a reality where efforts like the PGP—that develop and use cutting edge technology in concert with the development and use of innovative governance practices—are abandoned or delayed.

III. ACCESS ENABLES AGENCY

Beyond privacy, access to research data enables participants to take action in many important ways. At the most basic level, they may inspect their own data and create a back-up copy for future uses. Subsequently, they may share the data with any cause they care about, including contributing their individual-level data to other research studies that may not have been conceived of at the time the data was initially generated. They might also choose to deposit their data in a repository with governance that is far different from the original study where it was generated, such as one with fewer restrictions on data access or one with a data access committee that incorporates participant choice on secondary uses of data (or many other possibilities). They could take their data to a hands-on workshop at a local community lab and explore their interests in genetic ancestry, or many other topics. They could band together with other people with common interests in research related to a specific health condition affecting themselves or loved ones, form their own data cooperative,[41] and recruit investigators to collaborate on specific research aims prioritized by the group. Some may even use their own to data as a

38. *See* Justin M. Zook, et al., *Extensive Sequencing of Seven Human Genomes to Characterize Benchmark Reference Materials*, SCI. DATA (2016), https://www.nature.com/articles/sdata201625 [https://perma.cc/F9KJ-SU2G] ("The Genome in a Bottle Consortium . . . is creating reference materials and data for human genome sequencing, as well as methods for genome comparison and benchmarking.").

39. *Id.*

40. *Id.*

41. Stephanie Wankowicz et al., *Patient-driven Efforts to Liberate Clinical Cancer Genomic Data*, OSF PREPRINTS (Nov. 18, 2018), https://osf.io/gupvq/ [https://perma.cc/3L8R-2AQG].

starting point for leading their own research inquiries.[42]

People's capacity to contribute to research in ways that exceed tokenism, what Arnstein called the "ladder of participation,"[43] has grown considerably but is fundamentally limited by whether an individual has equal access to their data. A modern adaptation of Arnstein's ladder of participation, using the language of today, would have four rungs.[44] The first rung of this ladder is for the "human subject" where research is done *to you*.[45] The second rung is for the "participant" where research is done *for you*.[46] The third is for the partner where research is done *with you*.[47] The fourth is for the citizen scientist where research is done *by you*. Access to individual level data, including laboratory data generated in a non-CLIA lab, is a key enabling factor for individuals to climb higher on the ladder of participation.

CONCLUSION

Individual access to data is essential to a flourishing biomedical research enterprise that respects the privacy rights and agency of people that volunteer for research, regardless of whether they are subjects or participants, or aspire to be partners or citizen scientists. Regrettably, the NASEM report does very little in the way of securing this future for everyone.

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42. *See* Laura B. Mader et al., *Inverting the Patient Involvement Paradigm: Defining Patient Led Research*, RES. INVOLVEMENT & ENGAGEMENT (2018), https://researchinvolvement.biomedcentral.com/articles/10.1186/s40900-018-0104-4 [https://perma.cc/HPU7-24UE] (proposing a novel model that allows patients and the public not only to propose research questions, but design, initiate, and deliver their own research).

43. Sherry R. Arnstein, *A Ladder of Citizen Participation*, 35 J. AM. PLANNING ASSOC. 216, 217 (1969).

44. *See* Marie Ennis-O'Connor, *Patient Engagement in Research: From Rhetoric to Reality*, LINKEDIN (March 25, 2019), https://www.linkedin.com/pulse/patient-engagement-research-from-rhetoric-reality-ennis-o-connor/ [https://perma.cc/LR9N-XHC9].

45. *See* Elisa A. Hurley, *From the Director: Why We Need to Keep the Term "Research Subject" in Our Research Ethics Vocabulary*, AMPERSAND (Feb. 22, 2019) https://blog.primr.org/research-subject-vs-research-participant/ [https://perma.cc/96QD-TPBD].

46. *See id.*

47. We need not look far for examples of individuals that, against all odds, climbed the ladder of participation and took advantage of the amazing scientific capacity we've created in the United States, to search for answers that may one day solve health issues affecting themselves, a loved one, or a community member through research. People like Matt Might, Sharon Terry, Hugh Rienhoff, Steven Keating, Stephen Crohn, Dana Lewis, to name only a few.