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## Research and Applications

# Exploring public concerns for sharing and governance of personal health information: a focus group study

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### ABSTRACT

**Objective:** Researchers are increasingly collecting large amounts of deidentified data about individuals to address important health-related challenges and answer fundamental questions. Current US federal regulations permit researchers to use already collected and stored deidentified health-related data from a variety of sources without seeking consent from patients. The objective of this study was to investigate public views on the policies and processes institutions have in place for accessing, using, and sharing of data.

**Materials and Methods:** We conducted 5 focus groups with individuals living within a 20-mile radius of the local academic medical center. We also held a focus group with undergraduates at a local university.

**Results:** A total of 37 individuals participated, ages 18–76. Most participants were not surprised that researchers accessed and used deidentified personal information for research, and were supportive of this practice. Transparency was important. Participants wanted to know when their data were accessed, for what purpose, and by whom. Some wanted to have some control over the use of their data valuing the chance to opt-out. Finally, participants supported establishment of an advisory council or group with responsibility for deciding what data were used, who was accessing those data, and whether data could be shared.

**Discussion and Conclusions:** The trust people have in their local institutions should be considered fragile, and institutions should not take that trust for granted. How institutions choose to govern patients' data and what voices are included in decisions about use and access are critical to maintaining the trust of the public.

**Key words:** data access and use, data governance, qualitative study, personal health data

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### Lay Summary

Scientists are increasingly collecting and using large volumes of data for their research. In many instances, these data do not have personal identifiers (ie, are deidentified), and current federal regulations allow scientists to use these data without asking patients' permission. The goal of this study was to explore public perspectives about the policies and process institutions have in place for scientists to access, use, and share deidentified patient data. We conducted 6 focus groups with a total of 37 participants, ages 18–76. Most participants were not surprised that scientists accessed and used deidentified personal information for research, and were supportive of this practice. That said, transparency was important to them. Participants wanted to know when their data were accessed, for what purpose, and by whom, and they supported establishment of an advisory council or group with responsibility for deciding what data were used, who was accessing those data, and whether data could be shared. The trust people have in their medical institutions should be considered fragile, and institutions should not take that trust for granted. How institutions choose to govern patients' data and what voices are included in decisions about use and access are critical to maintaining public trust.

## INTRODUCTION

Biomedical and public health sciences researchers are increasingly collecting and combining large amounts of data about individuals to address important health-related challenges and answer broad fundamental questions about healthy state versus diseased state. Sometimes referred to as “big data,” these are typically deidentified data and mined from both healthcare- and nonhealthcare-related sources.<sup>1</sup> Those sources include electronic medical records, biobanks, and insurance claims as well as nonhealthcare-related sources such as life-style questionnaires and social media sites.

Researchers have benefited from having access to big data in multiple ways. By combining research participants’ data into large repositories, investigators can examine differences, for example, between healthy populations and populations with a specific disease phenotype. Because they can access sample sizes larger than what they could collect on their own, researchers also can investigate variations among populations of different ethnicities, socioeconomic backgrounds, and geocodes. This volume of data also can enable deeper understanding of how different molecules within a biological system interact and influence healthy and diseased states.<sup>2</sup> In fact, the National Institutes of Health All of Us program is based on using large volumes of data to benefit public health.<sup>3</sup>

While current U.S. federal regulations permit researchers to use collected and combined deidentified health-related data without seeking explicit consent from patients,<sup>4–6</sup> they often are unaware that patient health information, which was collected for clinical use, might be repurposed for research.<sup>7,8</sup> Nonetheless, studies have found broad support for this practice, as evidenced by a systematic review of 25 qualitative studies.<sup>9</sup> Studies have shown that some research participants support data sharing as a means of contributing to advancements in healthcare—the “greater good”—while others see the potential to learn health information about themselves or to help others with the same health condition or disease.<sup>10–13</sup>

Still, research has shown that in many cases, participants’ support is conditional. Researchers have found, for instance, that participants want “granular control”—that is, they will share some information but not necessarily information they consider “sensitive.”<sup>14</sup> Furthermore, they want to choose or control with whom information is shared.<sup>14,15</sup> Other studies have found that participants’ willingness for their data to be shared is linked to being consulted or consented,<sup>16,17</sup> to the healthcare systems in which they are patients, or with nonprofits.<sup>12,17–19</sup> However, participants are less inclined to want their health data shared if the entities involved are private companies such as insurers or government agencies.<sup>11,15,17–20</sup> Perhaps not surprisingly, study participants have fewer reservations when their data are anonymized although some people hesitate even then.<sup>17,21,22</sup> It should be noted that many of these studies specifically ask participants about biobank samples and data in the electronic medical record.

A frequent concern cited by study participants involves the security of their health-related data shared<sup>23,24</sup> or security breaches that would allow for inadvertent sharing of their data.<sup>7,15</sup> That concern is heightened when the sharing of data is across healthcare organizations or with entities not directly delivering patient care.<sup>16,17</sup> Patients want to know more about the kinds of protections in place to protect their information.<sup>16</sup> Researchers also report that some patients are more concerned about security of financial information or personal identity than they are about their health data.<sup>12</sup> In some studies, participants raise concerns that broad data sharing could lead to stigmatization of communities or negative treatment and discrimination of certain ethnicities.<sup>7,11,20</sup>

While multiple studies have explored patients’ views on the sharing of their health-related data, few have investigated patient views on the policies institutions have in place or should have in place for the sharing of those data. Such policies would include who has oversight responsibility for the sharing of deidentified patient data; who is deciding about what entities can access data; and what mechanisms are in place to ensure that shared data are used appropriately. These are questions about data governance. A European study involving patients in 10 countries is one of the few to specifically ask participants for their views on governance structures for managing the large amount of health and genetic data being collected.<sup>25</sup> Those researchers found that participants wanted experts within the organization that was home to the data to review requests for data access. Those same experts should monitor how those data were used. Participants define those experts as healthcare professionals, researchers, patient representatives, and lay persons among others.<sup>25</sup>

Given the few studies that have explored who is making decisions about data access and use, we conducted an exploratory study using focus groups to fill this gap and investigated people’s views how the access and use of their deidentified health-related information should be managed. Here we discuss the most salient findings: (1) participants have concerns about whether the data would be shared and with whom; (2) participants view some institutions as trustworthy and others as not; and (3) participants value transparency about who should make decisions about the access and use of personal data by researchers.

## MATERIALS AND METHODS

We held 5 focus groups with participants who live within a 20-mile radius of an academic medical center in rural Pennsylvania. Participants were recruited through flyers, articles in local newspapers, and StudyFinder. (StudyFinder is a Pennsylvania State University website for the public to search for actively recruiting university clinical research studies by keyword or browse by health condition. The University of Minnesota Clinical and Translational Science Institute developed the StudyFinder platform (UL1TR000114) and shared it throughout the National Center for Advancing Translational Sciences’ Clinical and Translational Science Award Program. Pennsylvania State University Clinical and Translational Science Institute (UL1TR002014) customized the StudyFinder platform and supports it for Pennsylvania State University.) Inclusion criteria were English speaking, willingness to share in a group, and 18 years of age and older. To explore whether generational differences might influence perspectives, we also recruited undergraduate students ( $n = 10$ ) at a nearby institution of higher education.

Participants completed a demographic questionnaire that included questions on age, gender, marital status, occupation, educational achievement, and ethnicity. They were also asked if they or members of their families had previously taken part in a research study. A discussion guide with open-ended questions was developed to explore participants’ understanding of what personal data are being accessed and used by researchers. One research team member (JBM) facilitated each group. Each focus group lasted between 60 and 75 min. Discussions were audio recorded and transcribed by a member of the research team (MAH).

At the start of each discussion, we provided general information on what is meant by personal health-related data, sources of those data, and the concepts of “deidentification” and “anonymity.” We encouraged participants to ask questions and offer opinions in order

to arrive at a shared understanding of those concepts. With this framing, we then moved to participants' perspectives on whether they supported the use of their deidentified health-related data for research, whether participants wanted to be informed about research studies that access and use their data, and whether personal data collected at one institution should be shared across academic institutions and with other entities such as pharmaceutical questions. We also asked who should be making decisions about how patients' personal health-related data are accessed and used. These questions were asked of each focus group. The discussion guide is available upon request.

The initial 5 focus groups were held in Fall 2018 at which point, saturation of data was reached. However, because only 2 of 27 participants were younger than 40 years of age, we deliberately sought to hold a focus group of younger participants in order to explore generational differences. This focus group was held in Spring 2019 on the campus of a nearby institution for student convenience. This focus group was 45 min because of students' class schedules.

Both authors (JBM, MAH) read each transcript individually, identifying themes that emerged from the data. After sharing and discussing these, we developed a preliminary codebook based on the most prominent themes that we agreed upon. We then re-read the transcripts, revising and refining the codebook in an iterative process. Disagreements about codes were resolved through discussion.<sup>26</sup> NVivo 12 (QSR International) was used for coding.

This study was approved by the Pennsylvania State University Institutional Review Board, and all participants provided verbal informed consent.

## RESULTS

### Participant characteristics

The initial focus groups included 27 participants (20 women and 7 men; average age was 58 years). Twenty-five participants self-identified as white, one self-identified as American Indian, one as multiracial. Educational levels ranged from completion of a GED ( $n = 1$ ), graduation from high school and junior college ( $n = 9$ ), completion of a 4-year degree ( $n = 10$ ) to completion of graduate and professional degrees ( $n = 7$ ). One participant worked in health care as a registered nurse while 13 self-identified as retired. Participants also were asked if they had concerns about who has access to their personal information. While most didn't ( $n = 17$ ), a notable number did ( $n = 10$ ). The ages of those who participated in the undergraduate student focus group were between 18 and 22 years with 1 returning adult who was 34 years old.

Below we describe 3 findings that emerged from the initial 5 focus groups. This is followed by data from the student focus group.

### Concerns about whether personal health data will be shared and with whom

While participants were broadly supportive of research and willing to have their data used by researchers with their academic medical institution, more than half of participants were less willing for their data to be shared with other institutions. These participants' reasons mostly reflected uncertainty about downstream use of their data. For instance, one participant worried that purpose of the research might change: "Cause you don't know what the next institution's gonna do or who they're gonna give it [the data] to." (Male 3, Focus Group 4). Another who had misgivings about sharing her personal

information with researchers at her healthcare institution assumed that downstream sharing of information could lead to identification of patients: "I would be worried at some point that people would be identified. If it's going so many places, so many people are involved, so many people seeing that data, that would be a little worrisome to me" (Female 3, Focus Group 1).

Concerns also were raised about what happens with data given possible mergers and acquisitions. "You don't know in the future what [this institution] will evolve into. To some extent you're just letting it go" (Female 6, Focus Group 2).

Few participants wanted their data shared with pharmaceutical companies or companies that stood to benefit financially from it. While pharmaceutical companies were mentioned by 8 participants, 3 participants also took issue with biotech companies such as 23&Me that share personal information. "If my data is [sic] being used with private companies that are all about profits, that's when I think I would have more of an issue with it" (Male 4, Focus Group 4).

Such concerns led a third of participants to want some control over the use of their data. For instance, they wanted limits on how long their data could be used or how their data were used: "...I want to know how the data was used to help other people or you know, maybe led to another study to get closer to what you're trying to find" (Female 6, Focus Group 2). Others wanted researchers to ask participants for permission to share their data with one participant suggesting that patients be provided with a checklist of possible entities with whom data could be shared.

A few, however, were comfortable with having their data shared as long as they knew about the sharing or were notified. Four participants noted that they assumed the practice of sharing their data was already occurring so were not surprised when informed about it. Three additional participants were willing to have their data shared with other institutions but only if those institutions provided their research protocols or signed agreements to follow "the same standards and responsibilities and ethical considerations. ..." of the data-granting institution (Female 6, Focus Group 2).

### Why some institutions are trustworthy and others are not

A quarter of participants described themselves as being inherently trusting, and trusting "...until you give me a reason not to trust you" (Female 2, Focus Group 4). A third of participants extended this trust to their healthcare organization: "I trust [the academic medical center where this study occurred] because I haven't been burned by it" (Male 2, Focus Group 4). Another cited her positive experience with her doctor as her reason for her trust in the organization while a third participant said she trusted the hospital because "it's been around for a long time" (Female 3, Focus Group 1). Others based their trust in their local healthcare organization simply because they and their family members have received treatment there or known people employed by it.

While participants noted the organization's positive reputation, they also acknowledged they had had some negative experiences. Reflecting on those, one participant recognized she had not only learned more about the institution from those experiences but they had also solidified rather than weakened her trust in the institution: "I know them well enough to trust them" (Female 2, Focus Group 1).

Six participants expressed trust in the biomedical research enterprise. They noted the existence of research protocols, protections such as HIPAA, and physicians' Hippocratic Oath as sources of trust: "I think that's why a lot of people kind of trust the researchers

here ... because you're doing no harm, you're doing good. That benefits you to be doing research in this setting," said a participant (Female 6, Focus Group 2).

That trust didn't always extend to other academic medical centers. Asked about sharing data with other universities, one participant commented, "I'd want to know more. You can't just say, oh, it's Princeton. Who at Princeton, you know?" (Female 6, Focus Group 2). Said another, "Cleveland Institution or whatever you mentioned, I would probably not do anything with them at this point because I know nothing about them" (Female 2, Focus Group 1).

A third of participants had even less trust in institutions such as pharmaceutical companies and biotechnology corporations. Big Pharma, said one participant, "isn't really interested in a healthy population. They're interested in selling as many of their drugs as they can produce" (Male 1, Focus Group 5). Another participant cited pricing issues as a source of his distrust: "I read that some pharmaceutical companies when they find a particular medication that's most popular, they tend to increase the prices on them ... I don't like that" (Female 4, Focus Group 1).

Participants who were distrustful of pharmaceutical companies also tended to be distrustful of biotechnology companies and of government agencies' use of genetic databases produced by biotech companies. In response to a question about providing a genetic sample to the National Institutes of Health, one participant noting that the possibility "freaks me out. You know, it's gonna come back, and it's gonna bite you in the butt" (Female 1, Focus Group 2). Said another, "I do question the government thing [and am] wary of what they're (sic) gonna do with it... Things like government, I feel they're always out to get you" (Female 5, Focus Group 2).

### Who should make decisions about researchers' access and use of patients' personal data

All participants supported establishment of an advisory council or group to make decisions about what data were used, who was accessing those data, and whether data could be shared. This group would function as a "gatekeeper between the data and the use, so that a researcher who wants the data needs to make a very formal proposal to this council before you open up the doors to all the data" (Female 7, Focus Group 2). This group should be formalized through policy so that "you don't just have a group of people who get together Monday morning with a cup of coffee and say, ok, we're gonna let him have the data" (Male 1, Focus Group 3).

No consensus was reached about the size of this group although almost all participants across focus groups advocated for a team of individuals rather than a sole individual. Their argument was that a team would keep the decisions from being hijacked by a single decision-maker with an agenda: "There needs to be a group table because everybody's looking out for their own agenda" (Female 2, Focus Group 5); "That's why I want 5 [at the table]. They're gonna have 5 different agenda, but they have to agree on how it's [the data] is used, so one agenda can't take priority over the others" (Female 2, Focus Group 1).

While no consensus was reached about the number of seats at the table, there was consensus that members of this advisory group were not just "Joe Blow from down the road" (Female 5, Focus Group 1) and didn't "have to be all doctors" (Female 2, Focus Group 1). More specifically, stakeholders should include lawyers, a cybersecurity expert or computer scientist, medical professionals, and researchers, the last of which included both those involved in the study and those with expertise about the specific area of research

such as department heads. "A team of folks that understands what the whole mission of the research is, whatever the research is," noted one participant (Female 2, Focus Group 3). Said another, "someone who can determine the need to know, who knows who needs to know" (Female 4, Focus Group 1). Inclusion of hospital administrators, members of hospital ethics committees, and privacy advocates also was mentioned.

Opinions differed about whether patients and volunteers should also be represented with one participant asking, "who would choose that person from the public and what makes that person from the public qualified?" (Female 2, Focus Group 1). However, about a third of participants endorsed having volunteers or someone representing research volunteers on the advisory group, noting the need for "representatives that are like us, that are participants who can get their voice heard. That would at least give people the sense that it's not just researchers that are making the decisions" (Female 6, Focus Group 2). It was also suggested that the advisory group membership fluctuate depending upon the purpose of the study or the population to be studied: "Maybe the group is multiple. It's not one set group because of the different types of research that you're dealing with" (Female 4, Focus Group 3).

### Exploring university students' attitudes about data sharing, data governance

Participants in this focus group recognized that the sharing of personal data through information technologies is ubiquitous, and they largely accepted that as the price of being connected. However, opinions differed about the acceptability of sharing of personal health data. Two students assumed that from a medical perspective, their health data would have little value: "Nothing special [has] happened to me, so I don't really care [if health data shared]—especially if it's going to benefit in a positive way" (Female 4, Focus Group 6).

Even so, half of the student participants wanted some control over the sharing of and access to their information. They wanted to sign a consent form or be asked for permission before their personal health information was shared. Another wanted to be assured the purpose was good—"I want you to cure something" (Female 4, Focus Group 6). Yet others wanted "the ability to revoke the use of information," depending upon the purpose of the research and the recipient of the information (Female 7, Male 9, Focus Group 6).

Unlike other participants, these students wanted to know the results of any research that used their data. Once the research was finished, students wanted to see either the full report or a short summary explaining how their data were used. As one student suggested, learning this could assure them the data were deidentified: "You want to make sure you're not out there" (Male 10, Focus group 6).

As for who should make decisions about the access and sharing of health-related data, the student participants added a privacy advocate and an enforcer to ensure that policies are followed. They hedged on inclusion of a student on the advisory board: "Someone who can speak on behalf of students, but I don't know that a student would be in the best position to understand the ramifications of things" (Female 7, Group 6).

## DISCUSSION

Overall, our participants were supportive of health-related research and trusting of biomedical and public health sciences researchers. While generally unaware that their personal data could be accessed and used by researchers, they had few reservations about this prac-

tice when pursued at their local institution. However, participants were less supportive of having their data shared with other organizations. Some participants wanted only researchers at their local institution to use their data while others wanted to be consented every time their data might be shared outside the local institution.

For our participants, transparency was key. They wanted to know when their data were accessed, for what purpose, and by whom. Some also wanted to know the purpose of the study so as to determine if they agreed with it or to opt-out. For others, the determining factor was whether their data were going to be shared outside of their local institution. Across the focus groups, however, wanting some control didn't conflict with participants' support of the use of their data for research.

Participants saw advisory boards as foundational to that transparency. Those board would develop and implement policies and procedures that would address participants' questions about when their data were accessed, for what purpose, and by whom as well as whether and with whom their data would be shared. As such, these boards' mission would be fundamentally different than institutional review boards (IRBs) that oversee the safety and well-being of individuals who participate in research. While the IRB has 1 or 2 community members, the rest of the membership are individuals with expertise in research using humans and the regulations for research using humans, that is, the Common Rule. A data governance board would have individuals with expertise in data science, data sharing and privacy, computer science and cybersecurity, and federal and institutional policies about data access, use, and sharing.

Underlying participants' concern whether their data would leave the boundaries of their local institution were issues of trust. As has been concluded by other researchers, people generally are more trusting of known or familiar organizations.<sup>27–32</sup> Hence, our participants trusted their local academic medical institution, but were less trusting of other academic medical institutions—even nationally known ones such as Princeton University. Our participants also didn't trust commercial entities such as insurance companies and pharmaceutical companies. Sharing of their data with pharmaceutical companies in particular was not supported if that sharing were to result in profits for a company or the industry as a whole.

The trust people have in their local institutions should be considered fragile, and institutions should not take that trust for granted. Patients expect that their healthcare institutions will be careful, conscientious, and responsible caretakers of the personal information with which they are entrusted.<sup>33–35</sup> To that end, our participants supported establishment of an advisory council or group with responsibility for deciding what data were used, who was accessing those data, and whether data could be shared. Our participants also expressed interest in knowing who serves on that data governance board and what their backgrounds and expertise are.

How institutions choose to govern patients' data and what voices they include in decisions about use and access are critical to maintaining the trust of the public. As a concept and a practice, governance is said to provide a way for addressing the ethical, regulatory, and policy challenges of research with personal information. More specifically, governance addresses how and why deidentified data are accessed and used by researchers, who makes those decisions, and how these decisions are made—all of which may not be known by patients who are providing the data.

This study has several limitations. The study is qualitative with a small sample size, and as such the findings are not generalizable. The majority of our participants are 35 years or older. Additionally, 17 of the 27 participants were college graduates or had advanced

professional training, raising the questions of whether focus groups of participants with less educational achievement would result in similar findings and whether those with less education felt they could contribute meaningfully. (Focus groups have been used in communities with low literacy successfully. See, for example, Refs.<sup>36,37</sup>) Most of our participants are white as well as patients at the local academic medical center. Their race/ethnicity may have generated a sense of trust in institutional researchers that black or brown participants might not have had, given historical medical inequities. The same is true for whether familiarity with the academic medical center might have resulted in more trust than a non-patient participant population might have had.

Another limitation is the technical background of the participants in the student focus group, all of whom are pursuing degrees in information technologies. Selection of these students was not deliberate but occurred through friend-of-a-friend recruitment by one student who also participated in the group.

Finally, we conducted these focus groups prior to the COVID-19 epidemic. In this new era we are witnessing more surveillance and less trust in certain institutions, though confidence in medical scientists has grown since the coronavirus outbreak.<sup>38–41</sup>

In spite of these limitations, our findings provide initial insights into what patients think about who should be making decisions about data access and use and how those decisions should be made, and as such, provide the basis for larger more generalizable future work.

## CONCLUSION

Participants in our study were clear in wanting to know about their local institution's governance processes and policies. They advocated for a diverse group of stakeholders from researchers to patients to serve on an advisory or governance committee. The also advocated for more information either to be provided or to be available that spelled out the governance processes and policies.

Healthcare institutions typically provide materials outlining that patient information may be used for research, education, and quality improvement purposes. In addition, institutions might consider notifying patients when and how their personal information is being used for research by, for example, sending periodic letters to patients or hanging posters hanging in waiting rooms. Others have suggested similar types of notification.<sup>42</sup> Ultimately, transparency of this sort may have an important influence on patient trust in both their healthcare institutions and the biomedical research enterprise.<sup>23,43–45</sup> That said, little is known about whether patients understand what is meant by “patient information” or how they conceptualize “research, education, and quality improvement purposes.” Moreover, there is a paucity of evidence on whether this kind of transparency actually increases patient trust.

While we initiated each focus group with background on what is personal health information, what are sources of health information, and what does deidentification mean, these topics are multilayered and complicated. Given that, providing materials may not be the best means of addressing the transparency about data governance policies and processes that our participants said they wanted. Our findings, thus, provide a basis for additional investigation into what patients think about who should be making decisions about researchers' access and use of personal data as well as how those decisions should be made.

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## AUTHOR CONTRIBUTIONS

Both authors contributed to the study design, data collection and analysis, and manuscript preparation.

## ETHICS APPROVAL AND CONSENT TO PARTICIPATE

This study was approved by the Pennsylvania State University Institutional Review Board (IRB). Approval was granted for obtaining oral consent. Everyone in the study consented to participate, including audio recording of the conversation, transcribing of the recording, and analyzing and publication of the data produced.

## CONSENT FOR PUBLICATION

Both authors have consented to the publication of this manuscript.

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## CONFLICT OF INTEREST STATEMENT

None declared.

## DATA AVAILABILITY

The data sets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

## REFERENCES

1. Luo J, Wu M, Gopukumar D, Zhao Y. Big data application in biomedical research and health care: a literature review. *Biomed Inform Insights* 2016; 8: 1–10.
2. Scruggs SB, Watson K, Su AL, et al. Harnessing the heart of big data. *Circ Res* 2015; 116 (7): 1115–9.
3. National Institutes of Health. *All of Us Research Program*. <https://allofus.nih.gov/about/all-us-research-program-overview> Accessed September 28, 2020.
4. US Department of Health and Human Services. *Summary of the HIPAA Privacy Rule*. Washington, DC; 2013. <https://www.hhs.gov/hipaa/for-professionals/privacy/laws-regulations/index.html> Accessed September 28, 2020.
5. Office for Human Research Protections, US Department of Health and Human Services. *Federal Policy for the Protection of Human Subjects: Common Rule*. 2016. <https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html> Accessed September 28, 2020.
6. US Department of Health and Human Services. *Methods for Deidentification of PHI*. 2015. <https://www.hhs.gov/hipaa/for-professionals/privacy/special-topics/de-identification/index.html> Accessed September 28, 2020.
7. Goytia CN, Kastenbaum I, Shelley D, Horowitz CR, Kaushal R. A tale of 2 constituencies: exploring patient and clinician perspectives in the age of big data. *Med Care* 2018; 56 (10 Suppl 1): S64–9.
8. Spencer K, Sanders C, Whitley EA, Lund D, Kaye J, Dixon WG. Patient perspectives on sharing anonymized personal health data using a digital system for dynamic consent and research feedback: a qualitative study. *J Med Internet Res* 2016; 18 (4): e66.
9. Aitken M, de St Jorre J, Pagliari C, Jepson R, Cunningham-Burley S. Public responses to the sharing and linkage of health data for research purposes: a systematic review and thematic synthesis of qualitative studies. *BMC Med Ethics* 2016; 17 (1): 73.
10. Kalkman S, van Delden J, Banerjee A, Tyl B, Mostert M, van Thiel G. Patients' and public views and attitudes towards the sharing of health data for research: a narrative review of the empirical evidence [published online ahead of print November 12, 2019]. *J Med Ethics* 2019. doi: 10.1136/medethics-2019-105651.
11. Lemke AA, Wolf WA, Hebert-Beirne J, Smith ME. Public and biobank participant attitudes toward genetic research participation and data sharing. *Public Health Genomics* 2010; 13 (6): 368–77.
12. Goodman D, Johnson CO, Bowen D, Smith M, Wenzel L, Edwards K. De-identified genomic data sharing: the research participant perspective. *J Commun Genet* 2017; 8 (3): 173–81.
13. Willison DJ, Steeves V, Charles C, et al. Consent for use of personal information for health research: do people with potentially stigmatizing health conditions and the general public differ in their opinions? *BMC Med Ethics* 2009; 10: 10.
14. Caine K, Hanania R. Patients want granular privacy control over health information in electronic medical records. *J Am Med Inform Assoc* 2013; 20 (1): 7–15.
15. Bell EA, Ohno-Machado L, Grando MA. Sharing my health data: a survey of data sharing preferences of healthy individuals. *AMIA Annu Symp Proc* 2014; 2014: 1699–708.
16. Mamo LA, Browe DK, Logan HC, Kim KK. Patient informed governance of distributed research networks: results and discussion from six patient focus groups. *AMIA Annu Symp Proc* 2013; 2013: 920–9.
17. Whiddett R, Hunter I, Engelbrecht J, Handy J. Patients' attitudes towards sharing their health information. *Int J Med Inform* 2006; 75 (7): 530–41.
18. Kim J, Kim H, Bell E, et al. Patient perspectives about decisions to share medical data and biospecimens for research. *JAMA Netw Open* 2019; 2 (8): e199550.
19. Joly Y, Dalpé G, So D, Birko S. Fair shares and sharing fairly: a survey of public views on open science, informed consent and participatory research in biobanking. *PLoS One* 2015; 10 (7): e0129893.
20. Haga SB, O'Daniel J. Public perspectives regarding data-sharing practices in genomic research. *Public Health Genomics* 2011; 14 (6): 319–24.
21. Davidson S, McLean C, Treanor S, et al. Public acceptability of data sharing between the public, private and third sectors for research purposes (social research series). Scottish Government; 2013.
22. Grant A, Ure J, Nicolson DJ, et al. Acceptability and perceived barriers and facilitators to creating a national research register to enable 'direct to patient' enrolment into research: the Scottish Health Research Register (SHARE). *BMC Health Serv Res* 2013; 13: 422.
23. Saxena N, Canadian Policy Research Networks, Public Involvement Network. *Understanding Canadians' Attitudes and Expectations: Citizens' Dialogue on Privacy and the Use of Personal Information for Health Research in Canada*. Ottawa, Ontario, Canada: Canadian Policy Research Networks, Inc; 2006.
24. Spruill IJ, Gibbs YC, Laken M, Williams T. Perceptions toward establishing a biobank and clinical data warehouse: voices from the community. *Clin Nurs Stud* 2014; 2 (3): 97–106.
25. Shah N, Coathup V, Teare H, et al. Sharing data for future research: engaging participants' views about data governance beyond the original project: a DIRECT Study. *Genet Med* 2019; 21 (5): 1131–8.
26. Krueger RA, Casey MA. *Focus Groups: A Practical Guide for Applied Research*. 4th ed. Washington, DC: SAGE; 2008.

27. Damschroder LJ, Pritts JL, Neblo MA, Kalarickal RJ, Creswell JW, Hayward RA. Patients, privacy and trust: patients' willingness to allow researchers to access their medical records. *Soc Sci Med* 2007; 64 (1): 223–35.
28. Robling MR, Hood K, Houston H, Pill R, Fay J, Evans HM. Public attitudes towards the use of primary care patient record data in medical research without consent: a qualitative study. *J Med Ethics* 2004; 30 (1): 104–9.
29. Stone MA, Redsell SA, Ling JT, Hay AD. Sharing patient data: competing demands of privacy, trust and research in primary care. *Br J Gen Pract* 2005; 55 (519): 783–9.
30. Trinidad SB, Fullerton SM, Bares JM, Jarvik GP, Larson EB, Burke W. Genomic research and wide data sharing: views of prospective participants. *Genet Med* 2010; 12 (8): 486–95.
31. ) Weitzman ER, Kaci L, Mandl KD. Sharing medical data for health research: the early personal health record experience. *J Med Internet Res* 2010; 12 (2): e14.
32. Willison DJ, Keshavjee K, Nair K, Goldsmith C, Holbrook AM; Computerization of Medical Practices for the Enhancement of Therapeutic Effectiveness Investigators. Patients' consent preferences for research uses of information in electronic medical records: interview and survey data. *BMJ* 2003; 326 (7385): 373.
33. Fullerton SM, Anderson NR, Guzauskas G, Freeman D, Fryer-Edwards K. Meeting the governance challenges of next-generation biorepository research. *Sci Transl Med* 2010; 2 (15): 15cm3.
34. Henderson GE, Edwards TP, Cadigan J, et al. Stewardship practices of U.S. biobanks. *Sci Transl Med* 2013; 5 (215): 215cm7.
35. O'Brien SJ. Stewardship of human biospecimens, DNA, genotype, and clinical data in the GWAS era. *Annu Rev Genomics Hum Genet* 2009; 10: 193–209.
36. Jakobsen H. Focus groups and methodological rigour outside the minority world: making the method work to its strengths in Tanzania. *Qual Res* 2012; 12 (2): 111–30.
37. Brugge D, Edgar T, George K, et al. Beyond literacy and numeracy in patient provider communication: focus groups suggest roles for empowerment, provider attitude and language. *BMC Public Health* 2009; 9: 354.
38. Simmons-Duffin S. Trust in CDC and FDA is at a Low, from *All Things Considered, National Public Radio*. September 25, 2020. <https://www.npr.org/2020/09/25/917014322/trust-in-cdc-and-fda-is-at-a-low> Accessed November 12, 2021.
39. Ortiz A. Confidence in police is at a record low, Gallup survey finds. *New York Times* 12.
40. Harrington M. Survey: people's trust has declined in business, media, government, and NGOs. *Harv Bus Rev* <https://hbr.org/2017/01/survey-peoples-trust-has-declined-in-business-media-government-and-ngos> September 28, 2020.
41. Fink C, Kennedy B, Johnson C. *Trust in Medical Scientists Has Grown in U.S., but Mainly Among Democrats*. Washington, DC: Pew Research Center. <https://www.pewresearch.org/science/2020/05/21/trust-in-medical-scientists-has-grown-in-u-s-but-mainly-among-democrats/> Accessed September 24, 2020.
42. Botkin JR. Transparency and choice in learning healthcare systems. *Learn Health Sys* 2018; 2 (1): e10049.
43. Patient Empowerment Network. *Why Health Systems and Hospitals Should Be Transparent to Earn Trust*. <https://powerfulpatients.org/2018/02/26/why-health-systems-and-hospitals-should-be-transparent-to-earn-trust/> Accessed September 24, 2020.
44. Abrams L. How transparency can empower patients and fix health care. *The Atlantic*. 19 September 2012. <https://www.theatlantic.com/health/archive/2012/09/how-transparency-can-empower-patients-and-fix-health-care/262531/>. Accessed 24 September 2020.
45. McGuire AL, Hamilton JA, Lunstroth R, McCullough LB, Goldman A. DNA data sharing: research participants' perspectives. *Genet Med* 2008; 10 (1): 46–53.