Supplementary Appendix

This appendix has been provided by the authors to give readers additional information about their work.

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Appendix
to
"Clinical Trial Participants' Views of the Risks and Benefits of Clinical Trial Data Sharing"

1. Additional information on selection of trials and survey completion rates 2
Table S1. Survey Completion Rates, by Trial and Survey Modality 4

2. Conceptual framework 5
Figure S1. Logic model 5

3. Additional information on regression modeling 6
Selection of outcome variables 6
Collinearity checks 6
Model specification strategy 6
Treatment of missing data 7
Table S2: Observations Missing Data on Variables Included in One or More Regression Models† 7

4. Regression results 8
Table S3: Logistic Regression Results: Predictors of Perceiving That the Negative Consequences of Data Sharing Outweigh the Potential Benefits 9
Table S4: Logistic Regression Results: Predictors of Being Somewhat or Very Unlikely to Allow Own Clinical Trial Data to Be Shared With Scientists in Not-for-Profit Settings 9
Table S5: Logistic Regression Results: Predictors of Being Somewhat or Very Unlikely to Allow Own Clinical Trial Data to Be Shared With Scientists in Drug Companies 9

5. Additional information on survey development 9

6. Additional demographic data on sample 10
Table S6. Sample Characteristics (*n*=771) † 10

7. Further descriptive results 11
Table S7. Most Concerning Potential Negative Consequence of Data Sharing† 12
Table S8. Most Important Potential Benefit of Data Sharing† 13
Table S9. Detailed Results: Anticipated Beneficiaries of Data Sharing† 14
Table S10. Detailed Results: Overall Perceptions of Data Sharing† 14
Table S11. Trust in Organizations and Individuals Involved in Using Health Information† 15

8. Full text of survey questionnaire 15

1. Additional information on selection of trials and survey completion rates

We aspired to create a sample that would be broadly representative of participants in clinical trials conducted at academic medical centers. Early on, we decided to utilize clinical trial teams to hand out surveys, rather than contacting clinical trial participants ourselves, to ensure that HIPAA-protected health information did not leave the medical centers. That decision made us reliant on the goodwill of clinical trial PIs to distribute our surveys. Consequently, our recruitment strategy focused on personal contacts. We contacted clinical trialists of our acquaintance to ask them to facilitate access to their trial participants and/or refer us to colleagues who might be able to do so. We also searched clinicaltrials.gov to identify trials at Stanford and Harvard, where Dr. Mello has faculty appointments.

When talking with PIs, we requested participants from as diverse a sample of trials as possible. We especially stressed our interest in recruiting relatively sick patients (to counterbalance our strong early enrollment of persons in nutrition- and weight-related trials) and racial and ethnic minority participants.

Our study design called for distributing approximately 1200 surveys with the aim of achieving a 60% response rate, or 720 completes. We based this number on calculations that a sample of that size would be adequate to provide a confidence interval width of no smaller than ±4% for the entire sample, ±7% for subgroups of 200 and ± 10% for subgroups of 100. Comparing groups of size 175, for instance, would provide 80% power to detect a 15% difference between subgroups. We stopped recruiting trials when we reached 1200 invited participants.

Every member of our sample completed the survey with pen and paper. We offered clinical trial PIs a choice of three modalities in order to be as accommodating as possible to their customary way of communicating with their participants. However, none chose email, and the "in clinic" option was not an "in person" survey in the sense of being administered orally or otherwise aided by a member of the research staff. Instead, a research assistant or receptionist handed out the paper survey to patients who checked in for a clinic visit and asked them to drop it off with the receptionist before they left. Clinic staff did not participate in administering informed consent, asking survey questions, or answering questions about the study or individual survey items, and they did not talk with participants about their answers. Therefore, the two modalities used (mail and "in clinic") were quite similar.

The percentage of nonresponders by trial and survey modality is presented in Table S1. Nonresponse was lower in the clinic setting. However, we are fairly confident that pressure to participate in the survey was not a problem, because of the nature of the setting where most in-clinic participants were recruited. Seventy-four percent (312/421) of the participants who completed the survey in a clinic waiting room did so at Inpatient Clinical Research Center for the Indiana CTSI. This is a core resource that supports all the adult inpatient clinical trials conducted through the CTSI. It is not run by the staff of the individual clinical trials. Our survey participants were drawn from 106 different trials that utilize the Clinical Research Center for study visits. The patients may have been familiar with the Clinical Research Center receptionists, but this was not an intimate setting where they likely formed a strong bond with

those staff members. Further, the research assistants that handed out surveys in the waiting room were not attached to any particular trial.

The remaining 26% of participants who completed surveys in a clinic setting were drawn from 3 other trials that contributed 81, 9, and 19 participants, respectively. We lack information about the nature of the relationship between the participants and the specific clinic personnel who handed out those surveys. But we suspect that trial participants' very positive experiences in the trials, combined with the $40 payment for filling out the survey, are more likely explanations for their willingness to complete the survey than coercion. In the trial contributing 81 surveys, for example, 73% of respondents characterized their trial experience as "very positive" and another 18% as "somewhat positive".

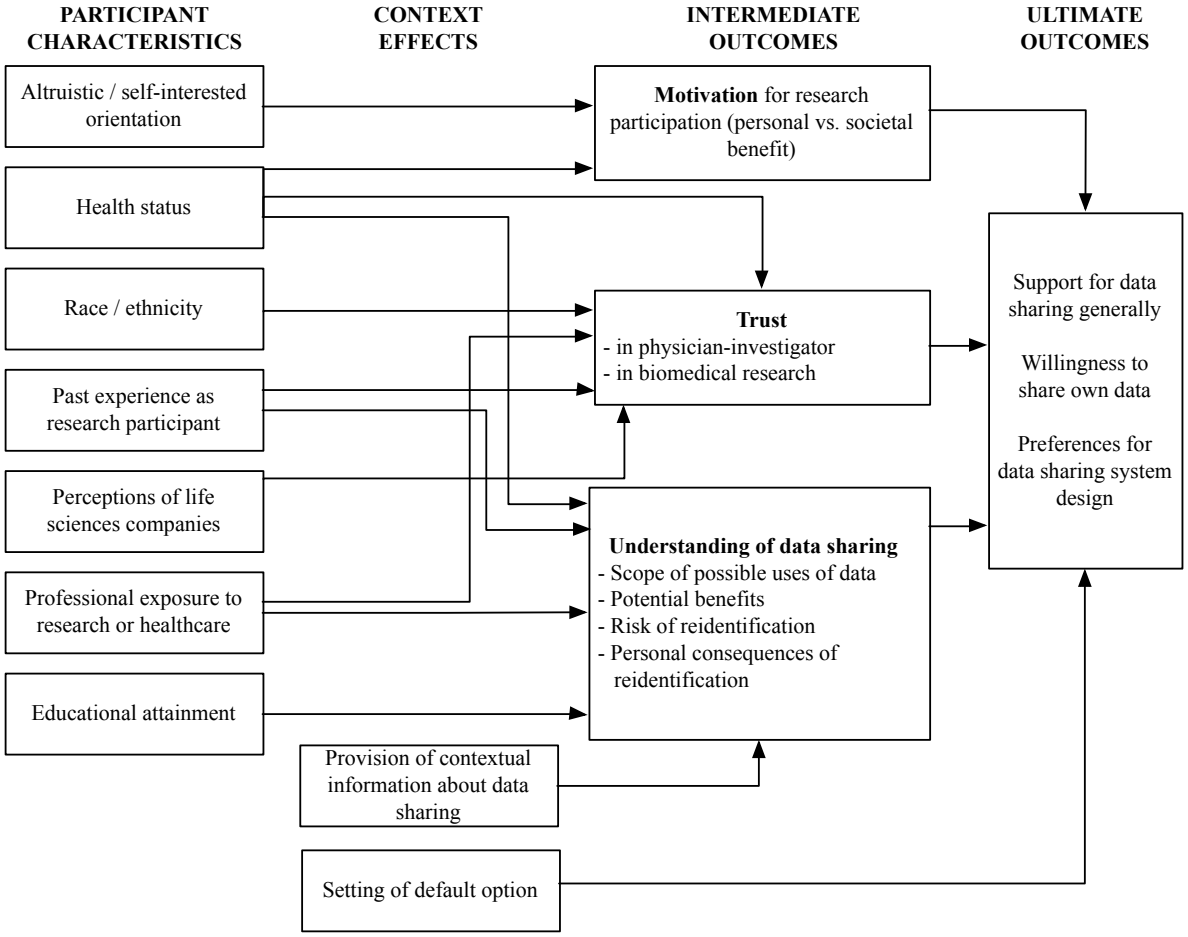
Table S1. Survey Completion Rates, by Trial and Survey Modality

		Both Modalities			Mail			In Clinic		
Medical Center	**Trial Topic**	**Invited**	**Completed**	**Completion rate**	**Invited**	**Completed**	**Completion rate**	**Invited**	**Completed**	**Completion rate**
A	Nutrition/weight /vitamins	177	94	53.1%	177	94	53.1%	NA	NA	NA
A	Diabetes	121	105	86.8%	40	24	60.0%	81	81	100.0%
A	Tobacco Use	91	52	57.1%	91	52	57.1%	NA	NA	NA
B	Kidney disease	14	10	71.4%	14	10	71.4%	NA	NA	NA
B	Cardiovascular	79	61	77.2%	79	61	77.2%	NA	NA	NA
B	Lung problems	25	11	44.0%	25	11	44.0%	NA	NA	NA
B	Nutrition/weight /vitamins	121	98	81.0%	121	98	81.0%	NA	NA	NA
B	Kidney disease	12	9	75.0%	NA	NA	NA	12	9	75.0%
C	Miscellaneous (106 trials)	317	312	98.4%	NA	NA	NA	317	312	98.4%
C	Cancer	21	19	90.5%	NA	NA	NA	21	19	90.5%
	Overall:	**978**	**771**	**78.8%**	**547**	**350**	**64.0%**	**431**	**421**	**97.7%**

2. Conceptual framework

The logic model that informed the selection of initial domains for survey questions is presented in Figure S1.

Figure S1. Logic model



3. Additional information on regression modeling

Selection of outcome variables

For measures of support for data sharing and willingness to share one's own data, strong majorities of respondents expressed positive views. Therefore, we believed it would be most interesting to examine whether the minority of respondents who expressed negative views had distinctive characteristics. We therefore dichotomized 3 key measures (perceptions of how the benefits of data sharing weighed against the potential negative consequences, likelihood of sharing one's own clinical trial data with university scientists, and likelihood of sharing one's own clinical trial data with drug company scientists) so that a value of 1 indicated a negative view (negatives outweigh benefits; and somewhat or very unlikely to share data).

Collinearity checks

Pairwise correlation coefficients were examined for all variables that were potential candidates, on theoretical grounds, for inclusion in the regression models. The only coefficients above 0.50 were among the 4 variables representing perceived risk in different domains. (To create those variables, we classified each risk about which the survey inquired into one of 4 domains: information theft, reidentification, misappropriation of data, and threats to science. If a respondent said he/she was somewhat or very concerned about 1 or more risks in that domain, the domain variable was coded with a value of 1. If not, it was coded as 0.) Our model specification strategy resulted in no more than 2 of the 4 domains being included in any of the final models.

Model specification strategy

For each outcome variable, an initial "full specification" model was tested, incorporating all explanatory variables that theory suggested might be associated with the outcome. This list of explanatory variables consisted of the following:

- Low trust in drug companies
- Low trust in universities
- Low trust in people
- Had personal information breached in the past
- Fair or poor self-reported health status
- Altruistic motivation for trial participation
- Participated in trial as a patient with the health condition being studied (rather than a person at risk for developing the condition, or a healthy volunteer)
- Native American
- Black
- Other nonwhite race
- Young (<45)
- Elderly (65+)
- Male
- Income at or above the national median ($55,000)
- Someone besides respondent was the trial participant (e.g., a child)
- College and/or graduate degree

- Very or somewhat concerned about one or more risks in the re-identification domain
- Very or somewhat concerned about one or more risks in the information theft domain
- Very or somewhat concerned about or more risks in the misappropriation domain
- Very or somewhat concerned about one or more risks in the "threats to science" domain

We then ran a second specification that excluded the last 4 variables on this list, pertaining to domains of perceived risks of data sharing. The rationale for this exclusion was that these variables might be absorbing effects due to demographic characteristics.

If a variable achieved a p-value of 0.2 or less in *either* specification, we included it in the final model for that outcome variable. We repeated this process for each outcome variable.

Treatment of missing data

Missing data counts for each variable included in the regression modeling are presented below in Table S2. No more than 5.5% of individual item responses were missing.

Table S2: Observations Missing Data on Variables Included in One or More Regression Models[†]

	Number Missing	% Missing
Outcome variables:		
Perceive that negative consequences of data sharing outweigh potential benefits	23	3.0
Somewhat or very unlikely to allow own clinical trial data to be shared with scientists in not-for-profit settings	9	1.2
Somewhat or very unlikely to allow own clinical trial data to be shared with scientists in drug companies	14	1.8
Explanatory variables:		
Low trust in drug companies	16	2.1
Low trust in universities	15	2.0
Low trust in people	11	1.4
Had personal information breached in the past	19	2.5
Fair or poor self-reported health status	14	1.8
Altruistic motivation for trial participation	10	1.3
Participated in trial as a patient with the health condition being studied (rather than a person at risk for developing the condition, or a healthy volunteer)	42	5.5
Native American	35	4.5
Black	35	4.5
Other nonwhite race	35	4.5
Young (<45)	9	1.2
Elderly (65+)	9	1.2
Male	9	1.2
Income at or above the national median ($55,000)	29	3.8
Someone besides respondent was the trial participant (e.g., a	11	1.4

child)		
College and/or graduate degree	19	2.5
Very or somewhat concerned about one or more risks in the re-identification domain	14	1.8
Very or somewhat concerned about one or more risks in the information theft domain	10	1.3
Very or somewhat concerned about or more risks in the misappropriation domain	21	2.7
Very or somewhat concerned about one or more risks in the "threats to science" domain	27	3.5

† Out of 771 total responses. Tables S2-S4 describe the variables that were included in each final model specification.

In the regressions, the maximum number of incomplete cases (i.e., observations missing data on one or more variables included in the final model) was 11.5%:

- Predictors of Perceiving That the Negative Consequences of Data Sharing Outweigh the Potential Benefits: 89 observations (11.5%)
- Predictors of Being Somewhat or Very Unlikely to Allow Own Clinical Trial Data to Be Shared With Scientists in Not-for-Profit Settings: 82 observations (10.6%)
- Predictors of Being Somewhat or Very Unlikely to Allow Own Clinical Trial Data to Be Shared With Scientists in Drug Companies: 79 observations (10.2%)

Our main analysis (Tables S3-S5 below) used multiple imputation to account for missing data. We performed the imputation using Stata's "mi" platform.

Results for a complete case analysis were similar. The only changes observed in significance levels were as follows:

- In the model predicting perception that the negatives of data sharing outweigh the positives, having low trust in people was not statistically significant at the $p<0.05$ level in the complete case analysis. (It was significant in the other 2 models.)
- In the model predicting unwillingness to share with scientists in not-for-profit settings, concern about risk of information theft was less highly significant in the complete case analysis, shifting from the $p\leq 0.01$ level to the $0.01<p\leq 0.05$ level.

4. Regression results

Regression results are presented below for models that predicted the following outcomes:

- Table S3: Perceiving that the negative consequences of data sharing outweigh the potential benefits (response categories, from 7-point scale: "negatives strongly outweigh the benefits," "negatives moderately outweigh the benefits," or "negatives outweigh the benefits a little")
- Table S4: Being somewhat or very unlikely to allow their own clinical trial data to be shared with scientists in not-for-profit settings
- Table S5: Being somewhat or very unlikely to allow their own clinical trial data to be shared with scientists in drug companies

Table S3: Logistic Regression Results: Predictors of Perceiving That the Negative Consequences of Data Sharing Outweigh the Potential Benefits

	OR	95% CI
Low trust in drug companies	0.65	0.39 – 1.10
Low trust in people	2.34*	1.19 – 4.61
Black	1.68[b]	0.92 – 3.08
Other nonwhite race	1.74	0.88 – 3.44
Concerned about risk of reidentification	2.36**	1.23 – 4.53
Concerned about risk of information theft	2.21*	1.20 – 4.08
Elderly (age 65+)	1.52	0.87 – 2.64
College degree	0.27**	0.15 – 0.49
Constant	0.07	0.04 – 0.12

[b] = $p<0.10$; * = $p<0.05$; **=$p<0.01$. Numbers were rounded to the nearest hundredth.

Table S4: Logistic Regression Results: Predictors of Being Somewhat or Very Unlikely to Allow Own Clinical Trial Data to Be Shared With Scientists in Not-for-Profit Settings

	OR	95% CI
Low trust in people	3.68**	1.63 – 8.30
Altruistic motivation for trial participation	0.76	0.34 – 1.69
Native American	1.79	0.62 – 5.19
Other nonwhite race	0.52	0.15 – 1.87
Concerned about risk of information theft	2.75**	1.32 – 5.71
College degree	0.28*	0.10 – 0.78
Income ≥ national median ($55,000)	0.36[b]	0.12 – 1.03
Constant	0.05	0.03 – 0.11

[b] = $p<0.10$; * = $p<0.05$; **=$p<0.01$. Numbers were rounded to the nearest hundredth.

Table S5: Logistic Regression Results: Predictors of Being Somewhat or Very Unlikely to Allow Own Clinical Trial Data to Be Shared With Scientists in Drug Companies

	OR	95% CI
Low trust in drug companies	2.43**	1.42 – 4.17
Low trust in people	2.49**	1.29 – 4.82
Native American	1.41	0.59 – 3.36
Male	0.68	0.40 – 1.15
Trial participant was someone other than respondent (e.g., child)	0.50	0.18 – 1.42
Constant	0.08	0.04 – 0.11

[b] = $p<0.10$; * = $p<0.05$; **=$p<0.01$. Numbers were rounded to the nearest hundredth.

5. Additional information on survey development

Because of the complexity of the issues, extensive survey development work was undertaken. Based on a review of published literature about data sharing and prior surveys related to data sharing and biobanking, a conceptual framework was developed hypothesizing

relationships between participant characteristics, trust in research, and views of data sharing (see section 2 above). This formed the basis for initial survey question domains.

We convened 2 focus groups to refine question constructs and identify concepts that laypersons may have difficulty understanding. Sixteen participants were recruited from the Stanford Research Registry, a database of Stanford patients and community members. Focus group members were about half nonwhite, half female, and included clinical trial participants and persons in non-professional jobs. The 90-minute discussions were moderated by the PI using a written guide. Interpretation was aided by tapes and debriefings among team members.

A first draft of the questionnaire was then developed with input from 2 experts in survey psychometrics, 3 experts on data sharing, and the community advisory board of a diabetes prevention trial in Native Americans. The survey was piloted on 6 current or recent clinical trial participants who underwent cognitive debriefing interviews immediately after taking the survey.

The final questionnaire provided plain-English definitions of clinical trial, data sharing, and clinical trial data (see section 6 below). It included several reminders that the survey was asking about sharing of individual-level information about trial participants, not research results, and that they should assume data were de-identified.

6. Additional demographic data on sample

Table S6 provides additional details about the sample characteristics.

Table S6. Sample Characteristics (*n*=771) [†]

	n	%		*n*	%
Female	380	49.9	**Participant in current clinical trial:**		
Age:			Self only	689	90.2
<25	63	8.3	Child only	54	7.1
25-44	177	23.2	Other person only	12	1.6
45-64	286	37.5	Self and someone else	5	0.7
≥65	236	31.0	Unsure	4	0.5
Hispanic	101	13.3	**Trial topic:** [¥]		
Race:			Nutrition/weight/vitamins	172	22.3
White	518	67.2	Diabetes	172	22.3
Black/African American	113	14.7	Cardiovascular	71	9.2
American Indian/Alaskan Native	51	6.6	Aging/ neurodegenerative disease/ memory	64	8.3
Asian	25	3.2	Tobacco use	52	6.7
Native Hawaiian/Pacific Islander	4	0.5	Liver disease	49	6.4
Other, including mixed race	57	7.4	Mental illness	41	5.3
Education:			Cancer	39	5.1
Less than high school	40	5.3	Kidney disease	26	3.4
High school diploma	125	16.6	Lung problems	23	2.9
Some college	206	27.4	Alcohol use	17	2.2
College degree	238	31.7	Bone disease	13	1.7
Graduate degree	143	19.0	Other neurological	10	1.3

Family income:			Neonatal	4	0.1
<$15,000	83	11.2	Other	18	2.3
$15,000-$24,999	90	12.1	**Primary reason for trial participation:**		
$25,000-$54,999	206	27.8	Make money	70	9.6
$55,000-$99,999	189	25.5	Help others	245	33.4
$100,000-$149,999	91	12.3	Get a health benefit	370	50.5
≥$150,000	83	11.2	Other	48	6.6
Health status:			**Overall experience as a trial participant:**		
Excellent	168	22.2	Very positive	573	76.2
Good	420	55.5	Somewhat positive	136	18.1
Fair	53	20.6	Neither positive nor negative	34	4.5
Poor	13	1.7	Somewhat negative	9	1.2
			Very negative	0	0
Ever had personal or financial information stolen or breached			**Participated in trial(s) in last 2 years as:**		
Yes	344	45.7	Person with the health condition being studied	301	41.5
No	408	54.3	Healthy volunteer or person at risk for developing the health condition being studied	400	55.1
			Both	25	3.4

† Percentages may not sum to 100 due to rounding or blank responses. Numbers were rounded to the nearest tenth.

7. Further descriptive results

Tables S7 and S8 provide full descriptive data regarding respondents' level of concern about the the proposed risks and benefits of clinical trial data sharing, including the risk and benefit respondents selected as most important.

Table S9 provides full data concerning how respondents expected different parties would benefit from data sharing.

Table S10 provides a full breakdown of responses for the end-of-survey item asking respondents to weigh the benefits against the potential negative consequences of data sharing overall.

Table S11 provides information on respondents' level of trust in physicians and organizations involved in use of health information.

Table S7. Most Concerning Potential Negative Consequence of Data Sharing[†]

Potential Consequence	Selected As the Most Concerning Potential Consequence (%)[†]
My information might be stolen.	14.6
Companies might use the information for marketing purposes instead of scientific purposes.	10.9
It could be harder to get people to agree to be in clinical trials if they know their data will be shared.	10.3
People might use the data to do poor-quality science.	9.2
Scientists and companies might have less incentive to invest time and money in doing clinical trials.	8.7
Someone who is good with computers could identify me	6.6
I could be discriminated against if the information was linked back to me.	5.1
My information might be used in scientific projects that I wouldn't approve of.	4.9
Scientists or companies could unfairly "free ride" on the work of others.	3.0
Some person or company could make a lot of money developing products using my information.	2.9
It could be embarrassing if the information was linked back to me.	2.5

[†] Percentages do not sum to 100 because about 21% of respondents left this item blank. Numbers were rounded to the nearest tenth.

Table S8. Most Important Potential Benefit of Data Sharing[†]

Potential Consequence	Selected As the Most Important Potential Benefit (%)
Make sure people's participation in clinical trials leads to the most scientific benefit possible	18.1
Help get answers to scientific questions faster using information that others have already gathered	17.3
Help patients and groups of patients learn more about health problems that affect them	15.8
Support learning about diseases that only a small number of people have (by combining data from many clinical trials)	11.4
Help scientists check the accuracy of research results announced by other scientists (by re-doing the analyses)	6.6
Discourage scientists and companies from hiding or distorting their clinical trial results (by making it possible for others to check their analyses)	4.9
Lower the cost of developing new medical products	4.7
Help lawyers prove their case in lawsuits claiming that medical products are unsafe	2.0
Help ensure that research dollars are spent as wisely as possible	1.4

[†] Percentages do not sum to 100 because about 18% of respondents left this item blank. Numbers were rounded to the nearest tenth.

Table S9. Detailed Results: Anticipated Beneficiaries of Data Sharing[†]

How much do you think the following groups could benefit from sharing anonymous, individual clinical trial data?	A Great Deal (%)	A Lot (%)	A Moderate Amount (%)	A Little (%)	Not at All (%)
Scientists in universities and other not-for-profit organizations	57.4	28.1	11.4	2.1	1.1
Patients	43.6	28.3	17.0	9.1	2.0
Companies developing medical products, such as prescription drugs	44.6	34.1	16.4	3.7	1.2
Doctors taking care of patients	53.7	27.7	11.9	5.1	1.6

[†] Percentages may not sum to 100 due to rounding or blank responses. Numbers were rounded to the nearest tenth.

Table S10. Detailed Results: Overall Perceptions of Data Sharing[†]

Overall, how do you think the potential benefits of sharing anonymous, individual clinical trial data weigh against the potential negative consequences?	%
Negatives strongly outweigh the benefits	2.9
Negatives moderately outweigh the benefits	2.4
Negatives outweigh the benefits a little	3.1
Benefits and negatives are equal	9.6
Benefits outweigh the negatives a little	9.8
Benefits moderately outweigh the negatives	26.6
Benefits strongly outweigh the negatives	45.6

[†] Percentages may not sum to 100 due to rounding or blank responses. Numbers were rounded to the nearest tenth.

Table S11. Trust in Organizations and Individuals Involved in Using Health Information[†]

How much do you trust…	A Great Deal (%)	A Lot (%)	A Moderate Amount (%)	A Little (%)	Not at All (%)
Universities	23.9	40.2	29.4	4.9	1.6
Drug companies	3.7	14.7	37.5	31.5	12.6
Government agencies that fund medical research	9.7	25.9	40.9	18.9	4.7
Health insurance companies	3.6	12.0	34.0	33.3	17.1
Doctors	28.8	48.2	18.4	4.0	0.7

[†] Percentages may not sum to 100 due to rounding or blank responses. Numbers were rounded to the nearest tenth.

8. Full text of survey questionnaire

The survey questions, reprinted below, are available for public use.

Survey on

Sharing Data From Clinical Trials

Conducted by:

Stanford University School of Medicine
Department of Health Research and Policy

Funding provided by:

The Greenwall Foundation

Study ID: _____

Version: 8/8/16

Information For Participants

Why are we doing this survey?

You are invited to participate in a research study about how clinical trial participants feel about clinical trial data sharing. ***Data sharing*** is when the researchers who collected information about individual clinical trial participants allow others to see and use it, after deleting information that could identify people.

We would like to ask your opinions about clinical trial data sharing in a survey. The Greenwall Foundation, a not-for-profit foundation that funds research on ethical issues, is funding this study. We hope the study findings will help ensure that if clinical trial data are shared, it's done in a way that respects research participants' preferences.

We are interested in your opinions because you have experience as a clinical trial participant or are the parent of a participant. But **your participation in this survey, and the responses you give to survey questions, won't affect what happens to your own clinical trial data.**

What does taking the survey involve?

If you decide to participate, you will take a 15-minute survey that asks for your opinions about the benefits and risks of clinical trial data sharing, your preferences regarding informed consent and privacy protection, your level of trust in researchers, and related issues. A few questions will ask you for personal information, such as your educational background, general health status, and what kinds of research you have participated in. You are free to skip any questions you do not want to answer, or to stop the survey at any time.

Payments:

You will receive a $40 gift card as payment for completing the survey. This payment may only be made to U.S. citizens, legal resident aliens, and those who have a work eligible visa.

Risks and benefits:

Study participation has no direct benefits to you. The only risk posed by participating in the survey is a possible breach of confidentiality. We will make every effort to protect your response by storing it securely and identifying you only with a study ID number. The survey team will never have access to your identifying information. You received this survey through your clinical trial team, who released no information about you.

Your rights:

If you have decided to participate in this project, please understand:

- Your participation is voluntary and you can withdraw your consent or stop participating at any time without penalty or loss of benefits.
- Your ability to continue in the clinical trial, if you are currently participating in one, will not be affected by your decision about this survey study.
- The results of this study may be presented at scientific meetings or published in scientific journals and the survey data may be shared with other researchers. However, your identity will not be disclosed**.**

If you have questions:

If you have any questions, concerns or complaints about this research study, you should ask the Protocol Director, Dr. Michelle Mello, Stanford University School of Medicine, Department of Health Research and Policy, Redwood Building Room T108, 150 Governor's Lane, Stanford, CA 94305; (650) 725-3894; mmello@law.stanford.edu.

If you are not satisfied with how this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a participant, please contact the Stanford Institutional Review Board (IRB) toll free at 1-866-680-2906 to speak to someone independent of the research team. You can also write to the Stanford IRB, Stanford University, 3000 El Camino Real, Five Palo Alto Square, 4th Floor, Palo Alto, CA 94306.

Statement of consent:

By completing and returning the survey, you are giving your informed consent to participate in the study.

Survey on Sharing Data From Clinical Trials

This survey asks your opinions on **clinical trial data sharing**. What do we mean by this?

A **clinical trial** is a medical study in which human participants receive specific interventions according to a research plan. These interventions could be medical products such as drugs; medical procedures; or changes to participants' behavior, such as diet. Clinical trials may be designed to study a new intervention or to learn more about the safety and effectiveness of interventions that are already in use.

Data sharing means removing personal identifiers (like names and birthdates) from the information that is collected about individual clinical trial participants and then allowing other people who aren't part of the clinical trial research team to see and use the data. Data could be shared with other researchers, companies developing medical products, patients, and others.

Remember, data sharing means sharing information about each individual research participant—for example, your age, health conditions, and response to the treatment being tested—not just the results of the study.

A participant's **clinical trial data** include personal characteristics and health information, including information about how he or she responded to the intervention being tested. Genetic information may or may not be included.

1. Who participated in the clinical trial through which you got this survey?

- ❑ Me
- ❑ My child
- ❑ Other
- ❑ Not sure how I got this survey

2. Thinking about the most recent clinical trial you/your child participated in, what was the most important reason you decided to be in the study? *(choose one)*

- ❑ I thought there was a chance I / my child might get a health benefit.
- ❑ I wanted to help others.
- ❑ I valued the chance to make some money.
- ❑ Some other reason.

If <u>your child or another person</u> was the clinical trial participant, please answer the questions on this page about <u>them</u>. If <u>you</u> were the participant, please answer about <u>yourself</u>.

3. How would you describe your / your child's current health status?

- ❑ Excellent
- ❑ Good
- ❑ Fair
- ❑ Poor

4. In the last 2 years, did you / your child participate in a clinical trial as …
(<u>check all that apply</u>)

- ❑ … a person who has the health condition being studied?
- ❑ … a healthy volunteer, or a person who is at risk for developing the health condition being studied?

5. Which health issues did the clinical trial(s) in which you / your child participated in the last 2 years relate to? *(<u>check all that apply</u>)*

- ❑ Breast cancer
- ❑ Other cancer
- ❑ Diabetes
- ❑ Gastro-intestinal problem other than cancer
- ❑ Kidney problem other than cancer
- ❑ Heart problem other than cancer
- ❑ Nutrition or weight loss
- ❑ Tobacco use
- ❑ Alcohol use
- ❑ Other. Explain: _____
- ❑ Not sure
- ❑ Prefer not to answer

6. Overall, how would you describe your / your child's experience(s) as a clinical trial participant?

- ❑ Very positive
- ❑ Somewhat positive
- ❑ Neither positive nor negative
- ❑ Somewhat negative
- ❑ Very negative

Your Opinions of Data Sharing

When you answer these questions:

- Remember, we're not asking you to let the team conducting the clinical trial you're in (or were in) share your data. This is just an opinion survey. *It won't affect what happens to your actual data.*
- Remember that by "clinical trial data" we mean individual-level information about participants, like each participant's age and response to the treatment, not just the overall research results.
- Assume that before clinical trial data are shared, they are made anonymous, meaning that information that could identify participants such as names and birthdates is gone.
- If your child was the clinical trial participant, please answer these questions thinking about your child's clinical trial data. If you were the participant, please think about your own data.

7. How concerned are you about the following potential consequences of sharing anonymous, individual clinical trial data?

	Very Concerned	Somewhat Concerned	Not Very Concerned	Not at All Concerned
a. Someone who is good with computers could identify me.	❑	❑	❑	❑
b. I could be discriminated against if the information was linked back to me.	❑	❑	❑	❑
c. It could be embarrassing if the information was linked back to me.	❑	❑	❑	❑
d. People might use the data to do poor-quality science.	❑	❑	❑	❑
e. My information might be used in scientific projects that I wouldn't approve of.	❑	❑	❑	❑
f. Some person or company could make a lot of money developing products using my information.	❑	❑	❑	❑
g. It could be harder to get people to agree to be in clinical trials if they know their data will be shared.	❑	❑	❑	❑
h. My information might be stolen.	❑	❑	❑	❑
i. Companies might use the information for marketing purposes instead of scientific purposes.	❑	❑	❑	❑
j. Scientists or companies could unfairly "free ride" on the work of others.	❑	❑	❑	❑
k. Scientists and companies might have less incentive to invest time and money in doing clinical trials.	❑	❑	❑	❑

8. From that list of potential consequences of clinical trial data sharing, which is the ONE most concerning consequence? Please circle it in Question 7 above.

9. How much do you think sharing anonymous, individual clinical trial data can …

	A great deal	A lot	A moderate amount	A little	Not at all
a. … help get answers to scientific questions faster using information that others have already gathered?	❑	❑	❑	❑	❑
b. … help ensure that research dollars are spent as wisely as possible?	❑	❑	❑	❑	❑
c. … lower the cost of developing new medical products?	❑	❑	❑	❑	❑
d. … help patients and groups of patients learn more about health problems that affect them?	❑	❑	❑	❑	❑
e. … help scientists check the accuracy of research results announced by other scientists or companies (by re-doing the analyses)?	❑	❑	❑	❑	❑
f. … support learning about diseases that only a small number of people have (by combining data from many clinical trials)?	❑	❑	❑	❑	❑
g. … discourage scientists and companies from hiding or distorting their clinical trial results (by making it possible for others to check their analyses)?	❑	❑	❑	❑	❑
h. … help lawyers prove their case in lawsuits claiming that medical products are unsafe?	❑	❑	❑	❑	❑
i. … make sure people's participation in clinical trials leads to the most scientific benefit possible?	❑	❑	❑	❑	❑

10. From that list potential benefits of clinical trial data sharing, which is the ONE most important benefit? Please circle it in Question 9 above.

11. How much do you think the following groups could benefit from sharing anonymous, individual clinical trial data?

	A great deal	A lot	A moderate amount	A little	Not at all
a. Scientists in universities and other not-for-profit organizations	❑	❑	❑	❑	❑
b. Patients	❑	❑	❑	❑	❑
c. Companies developing medical products, such as prescription drugs	❑	❑	❑	❑	❑

d. Doctors taking care of patients	❑	❑	❑	❑	❑

12. How likely would you be to allow your anonymous, individual clinical trial data to be shared with …

	Very likely	Somewhat likely	Neither likely nor unlikely	Somewhat unlikely	Very unlikely
a. … scientists in universities and other not-for-profit organizations?	❑	❑	❑	❑	❑
b. … scientists in companies developing medical products, such as prescription drugs?	❑	❑	❑	❑	❑

13. How likely would you be to allow your anonymous, individual clinical trial data to be used in the following ways?

	Very likely	Somewhat likely	Neither likely nor unlikely	Somewhat unlikely	Very unlikely
a. To help scientists check the accuracy of research results announced by other scientists or companies (by re-doing the analyses)?	❑	❑	❑	❑	❑
b. To help patients and groups of patients learn more about health problems that affect them.	❑	❑	❑	❑	❑
c. To do research on health problems that affect my family or me.	❑	❑	❑	❑	❑
d. To help get answers to scientific questions faster using information that others have already gathered.	❑	❑	❑	❑	❑
e. To do research that will help others.	❑	❑	❑	❑	❑
f. To help lawyers prove their case in lawsuits claiming that medical products are unsafe.	❑	❑	❑	❑	❑
g. To learn more about diseases that only a small number of people have (by combining data from many clinical trials).	❑	❑	❑	❑	❑

14. Generally speaking, how often can you trust other people?

- ❑ Always
- ❑ Most of the time
- ❑ About half the time
- ❑ Once in awhile
- ❑ Never

15. How much do you trust …

	A great deal	A lot	A moderate amount	A little	Not at all
a. … universities?	❑	❑	❑	❑	❑
b. … drug companies?	❑	❑	❑	❑	❑
c. … government agencies that fund medical research?	❑	❑	❑	❑	❑
d. … health insurance companies?	❑	❑	❑	❑	❑
e. … doctors?	❑	❑	❑	❑	❑

Your Advice on Seeking Permission for Data Sharing

When you answer these questions:

- Keep in mind that your response won't affect what happens to your actual clinical trial data
- Remember that by "clinical trial data" we mean individual-level information about participants, like each participant's age and response to the treatment, not just the overall research results.
- Assume that before clinical trial data are shared, they are made anonymous, meaning that information that could identify participants such as names and birthdates is gone.

16. Which of the following best describes how you would feel about being asked for permission to share your anonymous, individual clinical trial data with people outside of the trial? *(check one)*

- ❑ The informed consent form should ask me for specific permission to share my data, separate from my overall consent to be in the clinical trial (and tell me how the researchers will protect my identity).
- ❑ The informed consent form should explain that my data are going to be shared (and tell me how the researchers will protect my identity).
- ❑ As long as the researchers have good data security protections, data sharing doesn't need to be discussed in the informed consent form.

17. Which of the following better describes how you would like the clinical trial researchers to ask you for permission to share your anonymous, individual clinical trial data? *(check one)*

- ❑ Ask me every time someone wants to use my data; tell me who wants it and why.
- ❑ Ask me once for broad permission to share my data.

18. Suppose it's true that *when more people decide not to share their individual clinical trial data, the scientific value of the remaining participants' data is lower*. Please think about whether that would change your last 2 answers above, and answer those 2 questions again below:

a. Which of the following best describes how you would feel about being asked for permission to share your anonymous, individual clinical trial data with people outside of the trial? *(check one)*

- ❑ The informed consent form should ask me for specific permission to share my data, separate from my overall consent to be in the clinical trial (and tell me how the researchers will protect my identity).
- ❑ The informed consent form should explain that my data are going to be shared (and tell me how the researchers will protect my identity).
- ❑ As long as the researchers have good data security protections, data sharing doesn't need to be discussed in the informed consent form.

b. Which of the following better describes how you would like researchers to ask you for permission to share your anonymous, individual clinical trial data? *(check one)*

- ❑ Ask me every time someone wants to use my data; tell me who wants it and why.
- ❑ Ask me once for broad permission to share my data.

19. Suppose a clinical trial has already finished and the participants weren't informed that their data might be shared. The research team just promised to protect against security breaches. There's no way to get in touch with participants now. Which of the following better describes your view? *(check one)*

- ❑ The data shouldn't be shared, even if means a loss to science.
- ❑ It's okay to share the data as long as there is no identifying information attached.

20. What is the most important reason, if any, to ask participants before sharing their anonymous, individual clinical trial data? *(check one)*

- ❑ There is always some risk to participants, even with good security protections in place.
- ❑ It's part of showing respect for participants.
- ❑ Neither; it's not necessary to consult participants.

Data Sharing Systems

Please read the following descriptions of 3 possible systems for sharing clinical trial data. You will then be asked which system you would prefer, if you had to choose. Again, assume that the data are anonymous.

In the **Sponsor System**, the company or other sponsor that paid for the clinical trial holds the data and considers requests to share it. The sponsor says it will share the data whenever someone proposes a use that may advance scientific knowledge and agrees to follow data security procedures.

In the **Independent System**, an independent organization (such as a university or other not-for-profit organization) receives the data, sets up a website where people can request it, and considers requests. The organization says it will share the data whenever someone proposes a use that may advance scientific knowledge and agrees to follow data security procedures.

In the **Open Access System**, the data are posted on a website and anyone can download the data after providing their name and organization.

21. All things considered, which system for clinical trial data sharing would you prefer?

- ❑ Sponsor System
- ❑ Independent System
- ❑ Open Access System

22. In choosing that system, which of the following was most important to you? *(check one)*

- ❑ Making sure that fair decisions are made about who gets to have the data.
- ❑ Making sure that the data are used for legitimate purposes.
- ❑ Having a trustworthy system.
- ❑ Making sure the system provides good data security.
- ❑ Making sure that the rules of the system are followed.
- ❑ Other. Explain:_____

_____

23. Overall, how do you think the potential benefits of sharing anonymous, individual clinical trial data weigh against the potential negative consequences? *(check one)*

Negatives strongly outweigh the benefits	Negatives moderately outweigh the benefits	Negatives outweigh the benefits a little	Benefits and negatives are equal	Benefits outweigh the negatives a little	Benefits moderately outweigh the negatives	Benefits strongly outweigh the negatives
❑	❑	❑	❑	❑	❑	❑

If there is anything you would like to explain about the answer you gave about your overall view, please do so:

About You

Please provide some information about yourself to help us understand how different groups of people feel about data sharing.

24. What is your gender?

- ❑ Male
- ❑ Female
- ❑ Transgender

25. What is your age group?

- ❑ Under 25
- ❑ 25-44
- ❑ 45-64
- ❑ 65 or over

26. Are you Hispanic or Latino?

- ❑ Yes
- ❑ No

27. What is your race?

- ❑ American Indian or Alaskan Native
- ❑ Asian
- ❑ Black or African American
- ❑ Native Hawaiian or Other Pacific Islander
- ❑ White

- ❑ Other. Explain: _____

28. What is the highest level of education you completed?

- ❑ Less than high school
- ❑ High school diploma
- ❑ Some college
- ❑ College degree
- ❑ Graduate degree

29. In which of these groups was your total family income, from all sources, in 2015, before taxes?

- ❑ Less than $15,000
- ❑ $15,000 - $24,999
- ❑ $25,000 - $54,999
- ❑ $55,000 - $99,999
- ❑ $100,000 - $149,999
- ❑ $150,000 or more

30. Have you or someone in your family ever had your personal or financial information stolen, or been told that the security of that information was breached?

- ❑ Yes
- ❑ No, not that I know of

THANK YOU for completing this survey!

If you received the survey in the mail, please mail it back in the self-addressed, postage-prepaid envelope provided.

If you received the survey in a medical office, please return it to the desk before you leave and collect your gift card.