Q1_3   **1. The clinical research community should promote and facilitate clinical trial data sharing.**

□₁ **Strongly agree**   □₂ **Somewhat agree**   □₃ **Somewhat disagree**   □₄ **Strongly disagree**

2. Please briefly explain your answer.

The following questions focus on your perceptions of sharing clinical trial data through data repositories, archives of clinical trial data accessible to external investigators and managed by at least one research funder. For instance, you may be familiar with the data repository managed by the National Heart, Lung, and Blood Institute (NHLBI) of the U.S. National Institutes of Health (NIH).

Q2_2   **3. Were you required by the research funder to share data from your study "[insert publication title]" through a data repository?**

□₁ **Yes**   □₂ **No**

4. If you had been required to share the deidentified data from this study through a data repository, would you have any of the following concerns? (Please check all that apply)

Q2_3_1 □ **Concerns Related to Investigator or Funder Interests**

Q2_3_2 □ **Concerns Related to the Protection of Research Subjects**

Q2_3_3 □ **Concerns Related to Appropriate Data Use**

Q2_3_4 □ **Other Concerns**

Q2_3_5 □ **No Concerns**

4a. Which of the following issues related to *investigator or funder interests* would be concerning to you and how significant would they be?

Q2_4_1 -   Ensuring my ability to publish original research using the data

□₁ Major concerns   □₂ Minor concerns   □₃ No concerns

Q2_4_2 -   Ensuring my colleague's ability to publish original research using the data

□₁ Major concerns   □₂ Minor concerns   □₃ No concerns

Q2_4_3 -   Ensuring that I receive sufficient academic/scientific recognition for sharing my clinical trial data

□₁ Major concerns   □₂ Minor concerns   □₃ No concerns

Q2_4_4 -   Incurring expenses associated with sharing data (i.e., direct costs)

□₁ Major concerns   □₂ Minor concerns   □₃ No concerns

Q2_4_5 -   Spending undue time or effort to prepare data for sharing (i.e., indirect costs)

□₁ Major concerns   □₂ Minor concerns   □₃ No concerns

Q2_4_6 -   Protecting commercially sensitive information

□₁ Major concerns   □₂ Minor concerns   □₃ No concerns

PROMOTE: 1 = Agree
2 = Disagree

Comment [KS1]: Only see if Q2_3_1=1

Q4A_1: 0 = No Concerns
1 = Concerns

Q4A_2: 0 = No Concerns
1 = Concerns

Q4A_3: 0 = No Concerns
1 = Concerns

Q4A_4: 0 = No Concerns
1 = Concerns

Q4A_5: 0 = No Concerns
1 = Concerns

Q4A_6: 0 = No Concerns
1 = Concerns

(Optional) Please briefly describe any other issues related to *investigator or funder interests* that would be concerning to you.

4b. Which of the following issues related to the *protection of research subjects* would be concerning to you and how significant would they be?

Q2_6_1 - Maintaining patient confidentiality

□₁ Major concerns   □₂ Minor concerns   □₃ No concerns

Q4B_1: 0 = No Concerns
1 = Concerns

Q2_6_2 - Obtaining research subject consent

□₁ Major concerns   □₂ Minor concerns   □₃ No concerns

Q4B_2: 0 = No Concerns
1 = Concerns

(Optional) Please briefly describe any other issues related to the *protection of research subjects* that would be concerning to you.

4c. Which of the following issues related to *appropriate data use* would be concerning to you and how significant would they be?

Q2_8_1 - Ensuring clarity of data elements for other investigators

□₁ Major concerns   □₂ Minor concerns   □₃ No concerns

Q4C_1: 0 = No Concerns
1 = Concerns

Q2_8_2 - Ensuring appropriate data use by other investigators

□₁ Major concerns   □₂ Minor concerns   □₃ No concerns

Q4C_2: 0 = No Concerns
1 = Concerns

Q2_8_3 - Preventing misinterpretation or misleading secondary analyses

□₁ Major concerns   □₂ Minor concerns   □₃ No concerns

Q4C_3: 0 = No Concerns
1 = Concerns

(Optional) Please briefly describe any other issues related to *appropriate data use* that would be concerning to you.

4d. Please briefly describe any other concerns you would have if you had been required to share the deidentified data from this study through a data repository.

Q2_11 5. Has the data been deposited in a repository?

□₁ Yes   □₂ No

Q2_28 **8. If required to share data through a data repository, how long after study completion (i.e., final study data set is ready for analysis) should investigators be entitled to the right of first use of the data?**

□₁ **No Right of First Use – the rights to data should be released immediately after study completion**

□₂ **One Year** □₃ **Two Years** □₄ **Three Years** □₅ **Four Years** □₆ **Five Years or More**

□₇ **No Time Limit – the right of first use is entitled until the main findings are accepted for publication**

TIME: 1 = No Right of First Use
2 = 1 - 2 year
3 = 3 - 5 year
4 = No Time Limit

Q2_29 **9. Assume that research funders take on the following responsibilities:**

1) **Provide for the assembly and maintenance of the repository**
2) **Cover all monetary expenses (i.e., direct costs) associated with the repository**
3) **Oversee the application process to ensure intended data use is appropriate**

All authors of a published clinical study should be required to deposit the deidentified data from the study in a data repository.

□₁ **Strongly agree** □₂ **Somewhat agree** □₃ **Somewhat disagree** □₄ **Strongly disagree**

DATA_DEP: 1 = Agree
2 = Disagree

10. (Optional) Do you have any additional comments related to sharing data through data repositories?

The following questions focus on your own experience with sharing clinical trial data in response to personal requests. A personal data sharing request is any situation in which the author of a published clinical study is directly contacted by an individual requesting access to data relating to that publication.

Q3_2 **11. Have you received any personal requests to share patient-level clinical trial research data from your study "[insert study title]"?**

□₁ **Yes** □₂ **No**

Q3_3 12. How many personal data sharing requests have you received for this study?

□₁ One □₂ Two □₃ Three □₄ Four or More

Comment [KS9]: Only see if Q3_2=1

13. For what purpose(s) were the data request(s) made? (Please check all that apply)

Comment [KS10]: Only see if Q3_2=1

Q3_4_1 □ Systematic review/meta-analysis   □ Cost analysis Q3_4_6

Q3_4_2 □ Subgroup analysis of originally published study   □ Novel research question Q3_4_7

Q3_4_4 □ Verification of originally published study   □ Academically oriented editorial Q3_4_3

Q3_4_8 □ Non-academically oriented editorial   □ Other purposes (please specify): Q3_4_9

Q3_4_5 □ Did not specify   Q3_4_9_TEXT

Q3_5 | 14. How many personal data sharing requests have you granted for this study?

┌─────────────────────────┐
│ GRANTED: 0 = None   │
│   1 = At least 1 │
└─────────────────────────┘

□₁ None   □₂ One   □₃ Two   □₄ Three   □₅ Four or More

Q3_22 | 15. How many personal data sharing requests have you declined/refused for this study?

□₁ None   □₂ One   □₃ Two   □₄ Three   □₅ Four or More

┌─────────────────────────┐
│ DENIED: 0 = None   │
│   1 = At least 1 │
└─────────────────────────┘

16. For what general reason(s) did you share the study data? (Please check all that apply)

Q3_6_1 | □ **Administrative Requirements**

Q3_6_2 | □ **Promote Open Science**

Q3_6_3 | □ **Academic Benefits or Recognition**

Q3_6_4 | □ **Other Reasons**

Q3_6_5 | □ **I would never share data if requested** *(only applicable to those who have never been asked to share data or have never shared their data)*

16a. For what specific reason(s) related to *administrative requirements* did you share the study data? (Please check all that apply)

Q3_7_1 | □ Comply with journal policy on data sharing

Q3_7_2 | □ Comply with employer/research funder policy on data sharing

(Optional) Please briefly describe any other reasons related to *administrative requirements*.

16b. For what specific reason(s) related to *promoting open science* did you share the study data? (Please check all that apply)

Q3_9_1 | □ Belief in open scientific inquiry

Q3_9_2 | □ Promote new research using existing data

Q3_9_3 | □ Enhance robustness of previously conducted research

Q3_9_4 | □ Avoid redundant clinical trial data collection

Q3_9_5 | □ Facilitate student/fellow opportunities for data analysis

(Optional) Please briefly describe any other reasons related to *promoting open science*.

16c. For what specific reason(s) related to *academic benefits or recognition* did you share the study data? (Please check all that apply)

Q3_11_1 | □ Potential to receive additional academic recognition for sharing data

Q3_11_2 | □ Potential to increase the impact of own research

Q3_11_3 | □ Professional or personal relationship with requester

(Optional) Please briefly describe any other reasons related to *academic benefits or recognition*.

16d. For what other specific reason(s) did you share the study data?

17. For what general reason(s) did you NOT share the study data? (Please check all that apply)

Q3_23_1 □ **Protect Investigator or Funder Interests**

Q3_23_2 □ **Protect Research Subjects**

Q3_23_3 □ **Ensure Appropriate Data Use**

Q3_23_4 □ **Other Reasons**

Q3_23_5 □ **I would always share data if requested** *(only applicable to those who have never had data requested or have always shared data when requested)*

17a. For what specific reason(s) related to *protecting investigator or funder interests* did you NOT share the study data? (Please check all that apply)

Q3_24_1 □ Ensure my ability to publish original research using the data

□ Ensure my colleague's ability to publish original research using the data Q3_24_5

Q3_24_3 □ Monetary expenses associated with sharing data (i.e., direct costs)

□ Time or effort involved in preparing data for sharing (i.e., indirect costs) Q3_24_7

Q3_24_2 □ Protect commercially sensitive information

□ Lack of academic recognition for sharing clinical trial data Q3_24_6

Q3_24_4 □ Prohibited by formal agreement with trial funder

□ Unsure of employer/research funder policy on data sharing Q3_24_8

(Optional) Please briefly describe any other reasons related to *protecting investigator or funder interests*.

17b. For what specific reason(s) related to *protecting research subjects* did you NOT share the study data? (Please check all that apply)

Q3_26_1 □ Protect patient confidentiality

Q3_26_2 □ Lack of patient informed consent to share

(Optional) Please briefly describe any other reasons related to *protecting research subjects*.

17c. For what specific reason(s) related to *ensuring appropriate data use* did you NOT share the study data? (Please check all that apply)

Q3_28_1 □ Did not trust data requester's intent

Q3_28_2 □ Data not appropriate for requested purpose

Q3_28_3 □ Potential for misinterpretation of data

Q3_28_4 □ Potential for misleading secondary analyses

(Optional) Please briefly describe any other reasons related to *ensuring appropriate data use*.

17d. For what other specific reason(s) did you NOT share the study data?

Q3_39 18. If you had received a personal request, would you be willing to share patient-level clinical data from this study?

□1 Yes □2 No

Q3_56 **21. Have you ever made a personal request to another investigator with whom you were not collaborating to share patient-level clinical trial research data from a previously conducted study?**

□1 **Yes** □2 **No**

Q3_57 22. How many personal data sharing requests have you made to other clinical investigators?

□1 One □2 Two □3 Three □4 Four or More

23. For what purpose(s) did you make the data sharing request(s)? (Please check all that apply)

Q3_58_1 □ Systematic review/meta-analysis   □ Cost analysis Q3_58_2

Q3_58_4 □ Subgroup analysis of originally published study   □ Novel research question Q3_58_3

Q3_58_5 □ Verification of originally published study   □ Academically oriented editorial Q3_58_6

Q3_58_7 □ Non-academically oriented editorial   □ Other purposes (please specify): Q3_58_8 Q3_58_8_TEXT

Q3_59 24. How many of your personal data sharing requests were granted?

□1 None □2 One □3 Two □4 Three □5 Four or More

Q3_60 25. How many of your personal data sharing requests were declined/refused?

□1 None □2 One □3 Two □4 Three □5 Four or More

Q3_61 26. Assume personal data sharing requests operate under the following conditions:

    1) The data requesters would cover all monetary expenses (i.e., direct costs) associated with sharing data in response to personal requests.

    2) Investigators would be under no obligation to release data in response to a personal request if they do not trust the data requester's intent or determine that the data may not be used appropriately.

All authors of a published clinical study should be required to share the deidentified data relating to that publication in response to personal requests.

□₁ **Strongly agree** □₂ **Somewhat agree** □₃ **Somewhat disagree** □₄ **Strongly disagree**

PERS_REQ: 1 = Agree
2 = Disagree

27. (Optional) Do you have any additional comments related to sharing data in response to personal requests?

The final questions focus on you.

Q4_2 28. Please indicate your age range.

    □₁ **34 years or younger** □₂ **35-49 years** □₃ **50-64 years** □₄ **65 years or older**

AGE: 1 = <= 49 years
2 = 50-64 years
3 = >= 65 years

Q4_3 29. Please indicate your gender.

    □₁ **Male** □₂ **Female**

Q4_4 30. How many years have passed since the completion of your highest professional degree?

    □₁ **0-9 years** □₂ **10-24 years** □₃ **25 years or more**

Q4_5 31. Where did you receive scientific training while completing your highest professional degree?

    □₁ **United States or Canada** □₂ **Western Europe** □₃ **Elsewhere**

Q4_6 32. Which of the following best classifies your current primary employer?

    □₁ **Academic institution** □₄ **Private Industry** □₃ **Non-profit organization**
    □₅ **For-profit hospital** □₂ **Government**

EMPLOY: 1 = Academic
2 = Non-Academic

Q4_7 33. Which of the following best describes your academic rank?

    □₁ Lecturer, Fellow, or Student □₂ Affiliated Professor □₃ Assistant Professor
    □₄ Associate Professor □₅ Full Professor

Comment [KS33]: Only see if Q4_6=1

ACAD_RANK : 1 = <= Asst. prof
2 = Assoc. prof
3 = Full prof

Q4_8 34. What percent of your overall job effort did you devote to research time during fiscal year 2010-2011?

    □₁ **Less than 25%** □₂ **25% - 49%** □₃ **50% - 74%** □₄ **75% or greater**

RESEARCH : 1 = <= 49%
2 = 50-74%
3 = >=75%

Q4_9 **35. Over the past three years, approximately how many articles have you published in peer reviewed journals?**

    □₁ **1-5**   □₂ **6-10**   □₃ **11-25**   □₄ **More than 25**

ARTICLES :

ARTICLES : 1 = 1 - 10
              2 = 11 - 25
              3 = > 25

Q4_10 **36. Over the past three years, approximately how many research grants and contracts (either internally or externally funded) from any source have you been awarded on which you are the principal investigator?**

    □₁ **None**   □₂ **1-3**   □₃ **4-6**   □₄ **7-10**   □₅ **More than 10**

GRANTS : 1 = None
            2 = 1 - 3
            3 = >= 4

37. What type of organizations awarded these research grants and contracts? (Please check all that apply)

Comment [KS34]: Only see if Q4_10 in (2,3,4,5)

Internal funding (funding from your employer): Q4_11_1_2

Q4_11_1_1 □ Government   □ Non-profit organizations   □ Private industry Q4_11_1_3

External funding (funding from sources outside of your employer):

Q4_11_2_1 □ Government   □ Non-profit organizations   □ Private industry Q4_11_2_3
Q4_11_2_2

Q4_12 38. Over the past three years, what was the total direct cost associated with these grants and contracts?

Comment [KS35]: Only see if Q4_10 in (2,3,4,5)

  □₁ Less than $50,000   □₂ $50,000 - $499,999   □₃ $500,000 - $999,999
  □₄ $1,000,000 - $4,999,999   □₅ More than $5,000,000

COST : 1 = None
         2 = < $1 million
         3 = >= $1 million

PLEASE NOTE: The COST variable removes the skip pattern, however, Q4_12 still observes the skip pattern.

ADDITIONAL DEMOGRAPHIC VARIABLES:

COMPLETION STATUS :
      0 = No, did not complete survey
      1 = Yes, completed survey

EMPLOYER:
      1 = Medical School or Hospital
      2 = Private Industry
      3 = Government
      4 = Other

LOCATION:
      1 = U.S. or Canada
      2 = Western Europe
      3 = Other

TRIAL SIZE = Continuous count variable

FUNDER:
      1 = Government
      2 = Industry
      3 = Other
      4 = Mixed

JOURNAL:
      1 = NEJM
      2 = Lancet
      3 = JAMA
      4 = Annals of Internal Medicine
      5 = BMJ
      6 = PLoS Medicine