

TOPIC GUIDE FOR PARTICIPANTS WITH LIMITED FAMILIARITY WITH DATA SHARING IN RESEARCH

Study Title: Examining the views of stakeholders in lower and middle income settings on how public health research data should be shared

1. Background

Please tell me a little about your current role

How long you have worked with this organization (and prior roles if relevant)?

What is your field of interest / specialist area / specialist training?

What kinds of research has your organisation been involved in?

What kinds of datasets are generated in your organisation?

With whom has your organisation collaborated for research?

Funding sources

2. Generating data which could be shared

I would now like to look more closely at research where data has been shared beyond the research team or you think a dataset was generated that could have been valuable to share

- What kinds of data do you work with?
- Please tell me about your involvement in research / or cases you've come across where you think data sharing is or might have been relevant?
- Please tell me about your experience in research in which data has been shared beyond the research team?
- People define research data in different ways - what do you consider to be data (or not – such as images)?
- Do you consider some kinds of research data to be more sensitive than others?
- What kinds? Why?

3. Views of data sharing

- What are your views about data sharing?
- What might be advantages of data sharing?

How do these benefit you?

- What might be disadvantages of data sharing?

Have these affected you?

- What do you see are contributing factors to advantages and disadvantages of data sharing?

Maximising utility / cost effectiveness / better research

Potential costs to researchers / participants

- What do you think are the most important kinds of data to share and why?
- Are there any kinds of data that you think shouldn't be shared?
- What rights and obligations do you think that researchers producing datasets for sharing should have?

4. Obligations and responsibilities

- What obligations are there to protect participants?
- Do you think these obligations and participants rights change:

Over time?

Depending on the type of data?

Depending on the type of research?

- How do you think participants' interests can be best taken into account in data sharing processes?
- Who do you think 'owns' this data?

(For staff who recruit participants whose data will be shared)

- Issues relating to the recruitment process and to consent
- Understanding
- Voluntariness
- Processes
- Recommendations
- Who are the stakeholders?
- Community views – including community requests for data
- Methods to engage with other stakeholders
- Experiences of situations where data is not given or falsified (try to restrict conversation to concerns about data sharing, not more generally about research concerns if possible)
- Do they see themselves as part of the data sharing decision-making process (authority/power)?

5. Exploring the concepts of data and sharing

- How do you think data is understood in your research context?

- How do you think sharing is understood in your research context?
- How might these ideas of sharing differ between cultures?
- How can we take account of community values in data sharing processes?
- What are your views about intellectual property rights within the framework of data sharing?
- How does one manage intellectual property rights in a multisite study where there is an imbalance in power within the sites that are collaborating on a particular project?

Most established protocols on data sharing have emerged from developed countries especially the UK and USA with some from Canada and New Zealand, what are your views regarding this? Do you think they are relevant to the Indian context? *[Probe on why they are or are not relevant? If they are not relevant what can be done to make them more relevant?]*

6. Consent

I'd now like to look more closely at how we might best recruit participants into research where data will be shared

- How should we recruit participants into research where data will be shared, what kinds of topics should be covered in the consent process?
- Do you have any suggestions for improving consent processes for such research?
- What do you think about (or what are the advantages and disadvantages of seeking...)

Broad consent, (i.e. when a participant is enrolled in research they're asked if they consent for the data to be shared for future research purposes without further details?)

Explicit consent (i.e. where participants are approached to re-consent to any future research with data that they've contributed)

There is a middle ground where participants are asked to consent to classes of research when they enrol in the study, such as research into specific diseases

- What kinds of constraints do you think participants might want to place on secondary uses of data?

Geography?

Types of research?

Who should be able to access it?

What do you think about putting these kinds of constraints on data uses?

- Are the cases where you think that explicit consent to data sharing may not be necessary?

Anonymised data

Archived data

7. Sharing the data from this interview

Explanation of what will happen to the data from this interview and our commitment to share data in principle

What do you think about sharing the data generated by this interview?

- Why?

ONLY if concerns are expressed – explore how these might be responded to

- Does the interviewee want to place constraints on the use – what are the constraints?

- Does the interviewee want more information, such as the data release policy?

- What might be needed to respond to these kinds of concerns from participants in other health research where data is to be shared?

Thank you for your time and patience.

- Would you be willing to participate in a follow up interview?
- Can you suggest someone whom we can contact to talk about issues related to data sharing in research?