

## **INFORMATION SHEET FOR INTERVIEW WITH PARTICIPANTS FAMILIAR 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.

### **Introduction**

Hello, my name is Ketaki Hate. I work with the Society for Nutrition, Education and Health Action (SNEHA) in Mumbai. As you are familiar with research and issues regarding data sharing in research, I would like to invite you to participate in the study. It is important that you understand the information provided here, including what your participation will involve. Please give your consent to participate only if you have understood the study and are aware of your rights as a participant.

### **Who is carrying out this study?**

This study is being carried out by SNEHA in collaboration with The KEMRI-Wellcome Trust Research Programme, Kenya, School of Applied Human Sciences, University of KwaZulu-Natal, South Africa, Mahidol University, Bangkok and Wellcome Trust Major Overseas Programme Oxford University Clinical Research Unit, Viet Nam. The study is funded by the Wellcome Trust and supported by The Ethox Centre, Nuffield Department of Public Health, University of Oxford.

### **What is this study about?**

Policies mandating sharing data from research are becoming widespread and commanding increasing support. Rationales for promoting such sharing are that it will promote faster analysis of datasets by a community of researchers and more efficient use of datasets with cost savings and improve the quality of analysis. Moves towards open access have generated a significant literature concerning the compatibility of open access policies with other important ethical principles and values.

Despite the extensive and growing literature on the ethics of data sharing, which highlights the importance of taking seriously both ethical arguments for sharing data and the importance of developing appropriate governance and protections, there are very few empirically grounded accounts of practical and ethical issues arising in the development of data release policies for biomedical research in low-income countries. Given the increasing amount and diversity of global health research being planned and conducted in low and middle income settings there is a need for research to inform the development of effective, ethical and sustainable approaches to data sharing in low-income settings.

This project aims to identify the key features of good ethical data sharing practice in low and middle income settings. Specific objectives include:

- Examining stakeholders' understandings, concerns and hopes about what will happen to data and their views about and reasons for what might constitute good data sharing practice

- Identifying models of data sharing and governance currently in use and any issues they raise
- Examining contextual considerations affecting data sharing processes
- Identifying perceived principles of good practice in data sharing
- Identifying suitable methods of developing appropriate data sharing processes

### **Why do you want to talk to me and what does it involve?**

In this qualitative study we are seeking the views of a range of stakeholders, including members of communities from which research participants are drawn, community leaders, research staff (including senior researchers, field staff and lab staff), research directors, data managers and Ministry of Health officials. This international study is being conducted in five sites in Mumbai, Kenya, South Africa, Thailand and Viet Nam, as mentioned above.

We would like to talk to you because you are a stakeholder in data sharing. We would like you to take part in 1 or 2 interviews of up to an hour each. We will ask questions about your understanding, experiences and concerns about data sharing and what might constitute good data sharing practice. We would like to record and transcribe the discussion for analysis.

### **Are there any disadvantages or benefits to me of taking part?**

We do not think that there will be any advantages or disadvantages to you if you take part.

### **Who will have access to the information I give?**

- We will not share individual information about you beyond the local research team and your data will be stored securely.
- You are welcome to review the transcript of the interview before it is incorporated into the dataset for analysis.
- Once any information that could identify you has been removed from your data we would like permission to share some individual level data with our research partners at the other sites to facilitate multi-site analysis of certain topics.
- Additionally, we have committed in principle to the release of individual-level data generated by the project. The development of appropriate policies and procedures for sharing data for this study will be an important component of this research and will take place during the data collection and analysis phase. It is anticipated that such release will be via a managed process, and restricted to legitimate researchers with relevant research questions and subject to the terms of a data access agreement. During the interview, your views about the sharing of the data generated by this study, including the data you are contributing, will be sought and will inform the development of the data sharing policy and conditions of access. The data sharing policy and conditions of access will be provided to the relevant research ethics committee once they have been developed and prior to any sharing of data.

### **What will happen if I refuse to participate?**

All participation in research is voluntary. You are free to decide if you want to take part or not. If you do agree you can change your mind at any time without any consequences. You may also withdraw the data you have provided up until the review of the transcript.

**What if I have any questions?**

Please ask me any questions you have about this research. If you have any further questions about the study, you can contact the research team using the details below:

Anuja Jayaraman, Research Director, SNEHA on +91 9167749630 at any time during the study.

This study has been approved by the Mumbai Multi-Institutional Ethics Committee and the Ethics Committee at the Ethox Centre, Nuffield Department of Public Health, University of Oxford.