

[MAY 2019 CLARIFICATION NOTE: The suggested guidance and informed consent (IC) template inserts below are meant as an addition to broader IC texts. The inserts only concern the data-sharing aspect of a research study. The language does not mean to imply that participation in the research project is conditional on participants agreeing to have the information they convey shared.]

Support For Discussing Data Sharing and Offering Consent Script Language in Guidance Provided to Social Scientists Conducting Human Subjects Research

Acknowledging that social science researchers are increasingly required to share data, and that technological developments have increased the opportunities to do so safely, we agree that Institutional Review Boards (IRBs) should discuss data sharing in their guidance to researchers, and offer examples of informed consent language.

Recognizing that each IRB will draft its own guidance and language, the texts below are intended as illustrations.

March 22, 2018

(Drawing on conversations from the “Protecting People, Sharing Data” workshop held in New York City on September 15, 2017)

SAMPLE TEXT TO BE ADDED TO EXISTING GUIDANCE FOR RESEARCHERS

Given the increasing prevalence of data sharing mandates in the social sciences, you are likely to encounter research funders/sponsors and academic journals that require scholars to make data from their studies available to the research community. So that you can meaningfully, ethically, and legally meet these expectations, we strongly recommend that you plan for data sharing while you are designing your project. In particular, we suggest that you include an explicit discussion of data sharing in the script that you will use to solicit informed consent from your study participants. If you do not do so, you might not be able to share the data generated through the interaction without re-contacting all of your participants to obtain retroactive consent for data sharing, which may be difficult, if not impossible.

In developing the language you will use, it can be helpful to discuss options with the venue through which you plan to make your data available. Repository personnel can help you consider options that you can then discuss with your study participants. These options will be impacted by the context of your research and the type of information your participants provide. Such options include:

- redaction/omission of certain portions of information that was provided;

- sharing of a subset of data files only;
- placing access controls or conditions on data that are not fully de-identified;
- conditions you might set for the secondary use of the data once they are shared; and
- different choices for different forms of data (e.g., audio recorded materials vs. typed interview transcripts), etc.

Offering these details will allow your participants to make a better informed choice about the sharing of the information they provide to you.

SAMPLE LANGUAGE REGARDING INFORMED CONSENT TO THE SHARING OF THE INFORMATION CONVEYED IN THE EXCHANGE

We offer three types of model language for inclusion in traditional informed consent scripts. The first is for use when data will be de-identified (A). The second is for use when full de-identification might not be possible (B), and the third is for use when de-identification is not necessary (C).

A. De-identified data generated from the information you provide in our interaction may be shared with the research community (most likely in digital form via the internet) to advance scholarly knowledge. I plan to deposit the data at REPOSITORY X, or at a similar social science domain repository. I will use my best efforts to remove or code (e.g., reference as “Participant #1) personal information that could identify you before the data are shared in an effort to ensure that, by current scientific standards and known methods, no one will be able to identify you from the shared data. Despite these measures, I cannot guarantee complete anonymity.

B. Data generated from the information you provide in our interaction may be shared with the research community (most likely in digital form via the internet) to advance scholarly knowledge. Due to the nature of the information, full de-identification of those data might not be possible. As a result, other measures will be taken before sharing. I plan to deposit the data at REPOSITORY X, or at a similar social science domain repository. Your data will BE MADE AVAILABLE UNDER THE FOLLOWING ACCESS CONDITIONS. Despite my taking these measures it is not possible to predict how those who access the data will use them.

C. Data generated from the information you provide in our interaction may be shared with the research community (most likely in digital form via the internet) to advance scholarly knowledge. We have discussed the benefits and risks of sharing the data and you agree that the data may be shared without de-identification or other protective measures.

ENDORSED BY:

The IRB professionals listed here are signing in their personal capacity as expert members of their community and not on behalf of their respective institutions.

IRB professionals who wish to add their signatures should please contact Dessi Kirilova at dessi.kirilova@syr.edu.

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