

Verbal informed consent protocol

This protocol is designed to give guidance to researchers about gaining informed consent from participants through verbal means rather than written informed consent procedures. This protocol should be read alongside the protocol on informed consent¹. The principles of informed consent are exactly the same for both written and verbal informed consent.

Why you might consider using verbal informed consent?

- Where written informed consent is not possible, for instance in telephone interviews.
- Where informal data collection methods are to be used, as happens in neighbourhood and community studies, for instance.
- Where participants in the research are illiterate or semi-literate.
- Where asking participants to review and sign forms that have an air of officialdom about them might be considered risky by the participant.
- Where cultural issues are raised by signing any kind of document as is the case in some Middle Eastern Societies.

Justifying the use of verbal informed consent

Researchers should be able to demonstrate why there is no practical way in which written informed consent cannot be obtained (see Informed Consent). For example:

1. Telephone interviews: although it should normally be possible to send an information sheet to the participant by post before the proposed telephone interview it may not be practical to get written verification from the participant.
2. Where the study design is such that it is likely that data will be collected in settings where it would be inappropriate or technically difficult to obtain written informed consent. These interactions may include informal data collection activities, such as meeting key informants in the street, at meetings, or in their place of work.
3. Where there is a likelihood that participants may be illiterate or semi-literate consideration should be given to how processes of consent will be managed in the research. Most often researchers only find out that a participant is unable to read the information sheet when they discuss its content with the participant.
4. In a limited number of research settings the use of official forms such as information sheets and consent forms might be perceived by participants to be threatening. In such circumstances the researchers will need to describe the salient characteristics of the groups or individuals they wish to sample, and explain the reasons why they have chosen to use verbal informed consent processes alongside written consent procedures.

The process of verbal informed consent

5. Researchers should consider how they will ensure that the information about the research is communicated with participants and ensure the research design shows how informed consent has been recorded as it is important to keep records of the participants' consent.
6. An information sheet and consent form should be prepared and submitted to the REC (see Model Information Sheet and Model Participant Consent Form) and should include a script of the verbal consent language and content. This should be free of technical language. The REC will wish to review in advance the language that will be used to obtain verbal informed consent.

¹ http://ris.leeds.ac.uk/ris/downloads/file/518/informed_consent_protocol

7. Researchers should show how they propose to initiate and maintain a verbal informed consent process in the research. They should demonstrate that they are aware that informed consent is not a one-off event in ethical research practice, but will be revisited throughout the research process. Information may be provided to participants at the outset, this may be repeated and reinforced during the research, and returned to at important stages in the research, such as at the end of interviews or focus groups.
8. The ESRC Framework for Research Ethics identifies the use of a witness as the most appropriate way in which to verify verbal informed consent. This approach, however, may not be practical in many research settings, nor is it likely that a witness will be available throughout on-going consent processes. A further way in which verbal informed consent can be verified is through recording the process and ensuring that this is part of any transcript of the research.