

Quick Guide to receiving Consent

1. Directly with participant

This is the preferred method of receiving consent. It allows the participant to have a full discussion with the research team and ask any questions they have. Please watch the training video on consent which explains the key points to cover.

A common question is what to do with the paper consent form once signed by the participant. Although we have received advice from NHS England that such forms (if taken into the room fresh and the patient signs after cleaning their hands) can be taken out of the room, we understand that is not always allowed by local infection control policies. The options are:

- a) Take an image of the signed consent form and transfer this to the electronic health record (ideally) or print it out and file as described as below. Please ensure you follow local information governance advice.
- b) If that is not possible, use the second method of obtaining consent



2. Witnessed consent

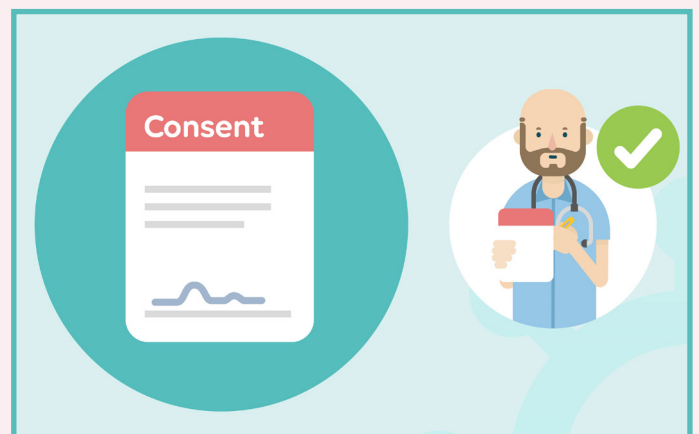
If the participant cannot read the information and/or sign the consent form (including for the reasons above), but does have capacity, then the researcher should still have the same consent discussion as before. However, this should be witnessed by a third party (another person in the research or clinical team, or a friend or relative). Such witnessing may be done by listening at the door or over the room's intercom phone and the consent form can then be completed by the person who took consent and this witness.



3. Legal representative

If the participant does not have capacity, then consent can be obtained from a legal representative. If a suitable relative or close friend is not available, this can be a doctor who is independent of the trial (i.e. not the principal investigator). If the representative has any questions about this role, please provide them with the Legal Representative Participant Information Sheet from the website.

When the patient regains capacity, then consent should be obtained from them by one of the first two methods. If they do not regain capacity, then no further consent process is required.



What should we do with the completed form?

Copies are required for:

- a) The participant
- b) The medical records (if possible, please make this an electronic copy)
- c) The site file (typically held by the principal investigator; this is where the original should go)

