

MANDATORY

GUI 17.012A: Remote Consent

There may be instances where remote consent is suitable for example:

- Minor amendment to the study.
- Amendment does not impact participants.
- Reduce footfall and infection risk

Remote consent can save time, resources and minimise travel for participants and study team.

Procedure

1. Once remote consent has been agreed with the study sponsor, document the remote consent process in a separate file note. Two copies of the Consent Form must be sent to the potential participant, by method agreed by the sponsor (e.g. post, email).
2. Once received the participant must contact the study team to confirm receipt and arrange a telephone call to discuss the study.
3. During the telephone call a member of the study team discusses the entire document, confirming version number and date of PIS and informed consent form, answering questions and taking notes about the participant's questions. Time and date of the conversation should be recorded in the participant's electronic health record.
4. Once all questions are answered and the participant is willing to take part both copies of the consent form should be signed by the participant and returned to the facility in the provided self-addressed envelope.
5. The consent form can be scanned and returned via email, if applicable, by the participant to allow time limited research processes to occur. On receipt of the scanned consent form the study team must quality check the document for legibility. The scanned version must be printed, signed and dated (date received scanned copy) by the person receiving remote consent. The original consent should be returned by the participant to the facility by post in the self-addressed envelope.
6. Once original consent form is received by the study team, the person receiving remote consent should sign the consent form and date with the date received (not the date of telephone call).
7. If the consent form is not received within a reasonable time the study team must contact participant to confirm they wish to take part and send further copies of the consent form (if required). The timeline and number of attempts to contact the participant will be agreed by the study team.
8. A copy of the fully signed consent form must be returned to the participant for their records, a copy filed in the participant's health record and the Investigator Site File

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