

## Glasgow Clinical Trials Unit Guideline

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| Guideline number | <b>17.012A</b>        | Version | <b>2.0</b> |
| Title            | <b>Remote Consent</b> |         |            |

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

- Minor modification to the study.
- Modification 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. The Consent Form must be sent to the potential participant by method agreed by the sponsor (e.g. email/ post).
2. Once received the participant must confirm receipt and a call must be arranged to discuss the study.
3. During the 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, 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. If not legible, or incorrect, the study team must request the participant to alter and/or resend the consent form. 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, or returned at the next face to face study visit, if appropriate.
6. Once original consent form is received by the study team, the person receiving remote consent should check for accuracy and sign the consent form and date with the date received (not the date of telephone call). If completed incorrectly, the study team must contact the participant and request a correctly completed copy is returned to the study team.
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.

**Guideline signatories**

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**Document history**

| Version | Date       | Description  | Retrospective Implementation |
|---------|------------|--|------------------------------|
| 1.0     | 05/05/2021 | First release  | No                           |
| 2.0     | 05/01/2026 | Transfer to updated GUI template<br>Change of Author/approver<br>Clarification of correction process | No                           |

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