Guidance on taking Remote Informed Consent

All documents to be sent with approved cover letters; email is preferable to post so there is an audit trail.

Pre-Consent Discussion

- Contact the potential participant and discuss the WILL trial.
- If she would like more information, provide her with the **Introductory Pamphlet**, **Participant Information Sheet (PIS)** and **Informed Consent Form (ICF)** via email or post, and arrange a time for a follow-up call.
- During the follow-up call, answer any questions and confirm the woman's willingness to participate.
- If she is interested in participating, briefly discuss the 2 methods of remote consent and receive consent using the preferred method (see below).
- Document any discussions had in the medical notes.

Choose Method 1 or 2 for ICF completion

Method 1: Participant signs

The person taking consent should…

1) Discuss each statement on the ICF, ask the woman to initial the box next to each statement, and then add her full name, signature and date below the statements*;

2) Ask the woman to take a photo or scan of the completed ICF, and then email it straight away to the person taking consent, preferably whilst still on the phone/video link;

3) Print off and check the ICF, and add…

a) Participant's trial number, last 4 digits of NHS number, and month and year of birth (if not already added)

b) Their details as the person taking consent (full name, date and signature).

** If the woman is unable to sign with a pen, she may type her initials in each box and her name on the signature line. Sites should ensure that they file a copy of the email sent by the woman along with the completed ICF in the ISF.*

Method 2: Site staff sign on behalf of participant

With a witness present†, the person taking consent should…

1) Discuss each statement on the ICF and receive verbal consent from the woman for each statement. Write **their own** initials in the box next to each statement;

2) Print the woman's full name below the statements (but leave the woman's signature and date fields blank);

3) Add their details as the person taking consent (i.e., full name, date and signature).

The witness should ...

4) Add their details to the *Witness Details* section (i.e., full name, date and signature).

† The witness does not need to be GCP-trained or on the delegation log, but it is preferable if they are a member of staff at the Trust, because they are then bound by Trust confidentiality rules.

ICF processing by site staff

The person taking consent should…

1) Document the consent process in the medical notes.
2) Email (or post) a copy of the completed ICF to the participant.
3) File copies of the completed ICF (and if relevant, the email sent by the woman if Method 1 was used) in the Investigator Site File (ISF) and in the medical notes.
4) Send a copy of the completed ICF to the WILL trial office, by post or email gst-tr.willtrial@nhs.net

Key: PIS Patient Information Sheet; ICF Informed Consent Form; ISF Investigator Site File.