

Remote consent for OPTIMA

Discussions about the trial and participation may be in person, by telephone or video consultation, or in any combination.

Patients must be provided with the PIS & given an opportunity to consider the trial and to ask questions before consent is accepted.

WRITTEN CONSENT

For patients not attending clinic who can return a signed consent form to you without delaying randomisation...

(i.e they can sign and email the form to you without delay or will be coming to clinic soon)

1

Patient completes consent form remotely & returns to site

Consent form may be returned by:

- By post
- In person
- Scan/ photograph of full consent form sent electronically e.g. to approved email address

2

Consent form is countersigned by the investigator

- Investigator who discussed trial should countersign form
 - Investigator must be satisfied that consent is genuine
- NB No requirement for same investigator & patient signature dates*

3

Site completes randomisation form & contacts WCTU

- Site proceeds with tumour sample submission and treatment

REMOTE VERBAL CONSENT

Option for patients not attending clinic who cannot return a signed consent form to you without delaying randomisation...

- Used to avoid delays – e.g. postal return of signed consent form
- Limited scope: allows only randomisation & sample processing

1

Patient gives verbal consent during remote consultation

2

Site processes remote verbal consent & contacts WCTU

- Investigator formally documents remote verbal consent
- Site completes randomisation form & contacts WCTU
- Site proceeds with tumour sample submission

3

Site notifies WCTU once written consent form is completed

- Investigator who received verbal consent should countersign form
- NB Exception allowed if investigator unavailable*
- WCTU releases treatment allocation only when notified that full written consent has been completed

Randomisation and Sample processing can occur following either full *Written Consent*, or *Initial Remote Verbal Consent*.
Treatment Allocation requires completion of *Written Consent*.

Documenting and processing remote consent

WRITTEN CONSENT

Paperwork timeline:

Written consent (original or copy of *Consent Form*) received

1. Complete **CRF 2: Randomisation Form**
2. Call Randomisation Line
3. Send CRF 2 to WCTU

- Standard consent form contains additional investigator sections to record:
 - i. Whether consent form completed remotely
 - ii. Whether previous remote verbal consent received
- Where patient has returned photograph of consent form investigator should complete the signature section of a blank consent form and print & attach to the photograph to the countersigned blank form
- Patient should be sent a copy of the countersigned form by post or email according to local policy

REMOTE VERBAL CONSENT

Paperwork timeline:

Remote verbal consent received

1. Document this on the *OPTIMA Documentation Remote Consent* form
2. Complete **CRF 2: Randomisation Form**
3. Call Randomisation Line
4. Send CRF 2 to WCTU

Written consent (original or copy of *Consent Form*) received

1. Complete **CRF 2a: Confirmation of written consent**
2. Complete question on sample donation on the Tissue Transit Form
3. Send CRF 2a and updated TTF to WCTU

- Investigator receiving remote verbal consent must record this on the “Documentation of Remote Verbal Consent for OPTIMA study” form
- The OPTIMA randomisation form (CRF 2) contains a check box which must be completed to indicate that the patient has only given verbal consent
- Once written consent has been received
 - i. Investigator should countersign the form. This should be the investigator who received remote verbal consent wherever possible but if unavailable then another qualified investigator may countersign
 - ii. Site should complete CRF 2a to notify WCTU that full consent has been received
 - iii. Site should complete the question on tumour sample donation on the TTF
- Patient should be sent a copy of both the documentation of remote verbal consent form and the countersigned standard consent form by post or email according to local policy
- Patients who give remote verbal consent but not subsequent written consent will be treated as a complete withdrawal.

Please do not send the *OPTIMA Documentation Remote Consent* form or the *OPTIMA Consent Forms* to WCTU!