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 ask questions before consent is accepted.

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

- Proceed with tumour sample submission & allocated treatment

1

Initial remote verbal consent is allowed for convenience

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

2

Site processes remote verbal consent & contacts WCTU

- Investigator must formally document remote verbal consent
- Site completes randomisation form & contacts WCTU
- WCTU will record remote verbal consent only has been given
- Site proceeds with tumour sample submission

3

Site notifies WCTU once written consent form is completed

- Investigator who received verbal consent should countersign form (exception is allowed if unavailable)
- WCTU will release 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

- 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

- 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 notify WCTU that full verbal consent has been received by completing CRF#2a
- Patient should be sent a copy of both the 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 consent documents to WCTU!