Tele-Trials Remote Consent Process
(COSA Version 2.0 Date 04 Jan 2020)

Please refer to SOP 90 in the Australian ICH GCP SOPs (including tele-trials)
https://www.health.qld.gov.au/hiiro/html/regu/for_researcher/gcp,research-ethics-and-governance-standard-operating-procedures-sop

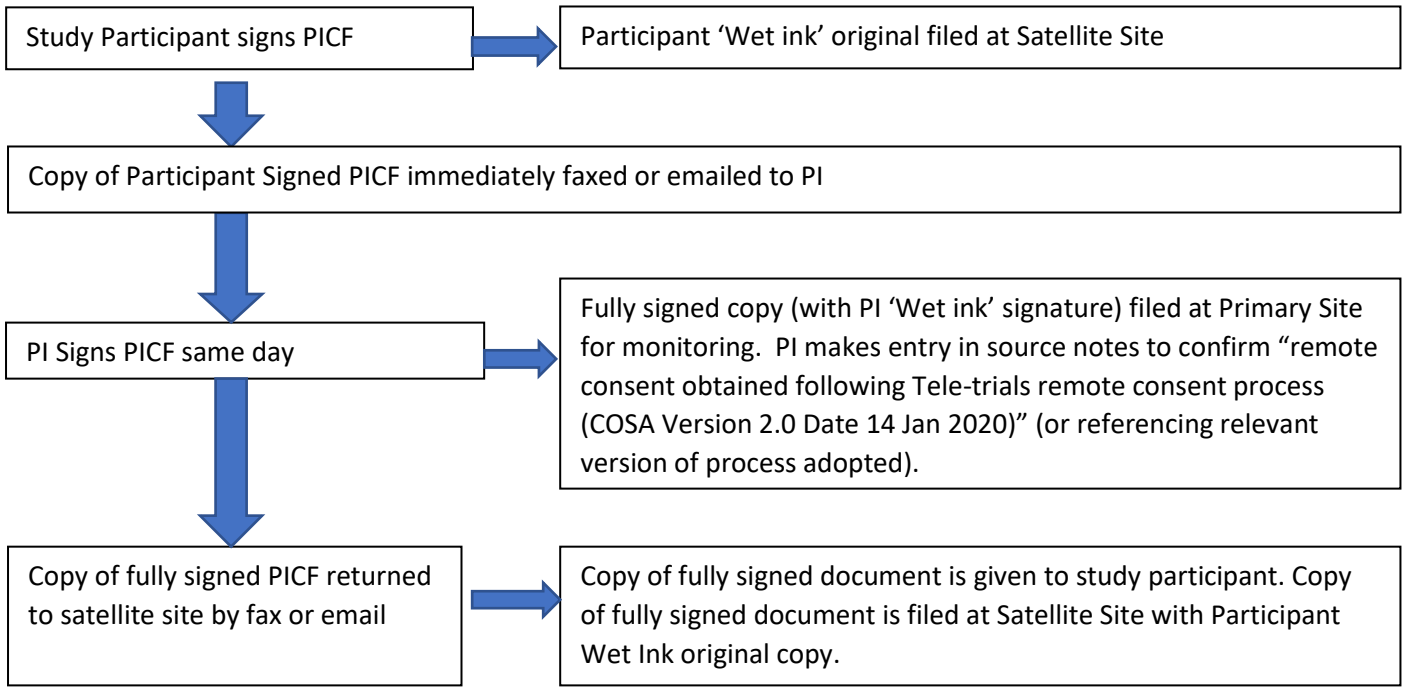
Remote consent is used when the Principal Investigator (PI) or delegated investigator conducting the consent discussion is not in the same room as the study participant and the consent discussion is conducted via telehealth or videoconferencing. This process provides a simple paper based approach to remote consent that will provide clear documentation of the consent process. Other approaches (for example, a suitable e-consent system) are also possible.

The remote consent process is to be clearly documented in the HREC application for the relevant study and referenced in the research unit's SOP on Informed Consent.

The interview should involve two-way communication in real time and allow confirmation of all person's identity (photographic identification of each study personnel's identity and study participant). It is important that confidentiality is maintained, and that the communication method is secure.

The remote consent process described here is for interventional trials where the Sponsor requires a copy of the consent form to be signed by both the PI (or delegated investigator) and the study participant during the telehealth consent consultation. The PI or delegated investigator receives a scan of the consent form signed by the study participant from the satellite site, wet ink signs the consent form and returns a scanned image containing all signatures to the satellite site during the telehealth consent consultation. This process is described in Figure 1.

Figure 1. Remote Consent Process for Interventional Tele-trials



To ensure the sponsor is aware of the remote informed consent process followed at the site, the site team should clearly describe the process to the sponsor to record in the Site selection visit / Initiation Visit Report (referencing this version controlled process document the study unit's SOP on Consent (as applicable).

Please note if telehealth is not possible and consent occurs via telephone/ internet voice call then the process should be updated and confirmed as acceptable by the Ethics Committee.