UTS IMPACCT Trials Coordination Centre

Guidance 2

Documentation of Consent (example)
Consent
▪ To be completed in the clinical record at any time during the process of consent and when informed consent is provided. This applies to consent for participation in the main study as well as any optional sub-study (e.g. caregiver) or additional genomic testing, details of which should also be recorded.
Date, Palliative care research *[Study name] was presented to [patient] and [other family members present] after being referred by [Dr ….]. The study participant information sheet and consent form [current local approved version number and date] was used as a basis for discussing the study. The discussion included: purpose, duration, intervention, assessments, risks and side effects, confidentiality, and voluntary nature of the study. The [participant or family] asked about …….. and the following questions were answered to their satisfaction with further information [provide detail of the question and responses]. Following this discussion, the consent forms have been signed by [provide details of all signatories- participant, person obtaining consent and impartial witness as applicable] and a copy was provided to the patient. The study eligibility will now be completed.*
Progress notations
▪ To be completed in the clinical record at any time of contact with the participant, either as face-to-face visit or telephone contact.
Date, Palliative care research *[Patient] is participating in the [study name] and is currently on day x of x. The intervention has been administered without problem. [Patient] has been assessed for response and is currently scoring [outcome measure]. There have been no new adverse events/ new adverse events include….. Vital signs (if not recorded in nursing charts) are T… P… R… BP …/… [patient] will be reviewed again [next visit scheduled], instructions [until next visit] are…..*
Exit notation
▪ To be completed in the clinical record when the participant completes the study intervention for any reason, including cessation (if prior to primary endpoint) and exit (at primary endpoint).
Date, Palliative care research *[Patient] is completing the [study name] today. The intervention will cease at [time]. [Patient] has been assessed for response and is currently scoring [outcome measure]. There have been no new adverse events/ new adverse events include….. Vital signs (if not recorded in nursing charts) are T… P… R… BP …/… [Patient] will now be commenced on [clinical intervention] and will be reviewed weekly for the next 4 weeks for safety and economic data.*