**Template for medical notes - AWI consent**

*All steps taken in the consent process for adults with incapacity (AWI) must be documented to evidence protocol and regulatory compliance. Each trial which includes AWI consent must provide a template to assist site teams with documentation of consent in the medical notes. Please see below some example text which can be made trial specific and used to produce a template to document consent.*

**Use the following text to document obtaining Personal Legal Representative Consent**

Confirmed eligible for the [TRIAL NAME] trial at [time and date of eligibility confirmation HH:MM DD/MMM/YYYY] by [INVESTIGATOR NAME]. An appropriate personal legal representative was present on [date of approach DD/MMM/YYYY] and approached to discuss participation in the [TRIAL NAME] trial. PIS version [X DD/MMM/YYYY] was given to the personal legal representative and the trial discussed with them in detail, they were given adequate time to consider the information and ask any questions. Personal legal rep consent was received by [NAME OF INDIVIDUAL RECEIVING CONSENT] at [time of consent HH:MM, include date if different from date of approach]. A copy of the completed consent form was given to the personal legal representative.

The participant was randomised to [DETAIL STUDY ARM ALLOCATED]. For further information contact [PI contact details].

**Use the following text to document obtaining Professional Legal Representative Consent**

Confirmed eligible for the [TRIAL NAME] trial at [time and date of eligibility confirmation HH:MM DD/MMM/YYYY] by [INVESTIGATOR NAME]. An appropriate personal legal representative was not present to provide consent on behalf of the participant within the protocol required timeframe. An independent medic who meets the criteria for Professional Legal representative as per protocol was therefore approached to discuss participation in the [TRIAL NAME] trial. PIS version [X DD/MMM/YYYY] was given to the professional legal representative and the trial discussed with them in detail, they were given adequate time to consider the information and ask any questions. Professional legal representative consent was received by [NAME OF INDIVIDUAL RECEIVING CONSENT] at [time and date of consent HH:MM DD/MMM/YYYY]. A copy of the completed consent form was filed in the medical notes and is therefore available to the Professional legal representative if required.

Personal legal representative consent will be requested at the earliest opportunity.

The participant was randomised to [DETAIL STUDY ARM ALLOCATED]. For further information contact [PI contact details].

**Use the following text to document the decision to defer consent**

Confirmed eligible for the [TRIAL NAME] trial at [time and date of eligibility confirmation HH:MM DD/MMM/YYYY] by [INVESTIGATOR NAME]. There was no personal legal representative present within the protocol defined timeframe to obtain consent and no professional legal representative was available immediately at the end of this time frame. The decision was therefore made by [Investigator name] at [time and date of decision to defer consent HH:MM DD/MMM/YYYY] to defer consent and enter the participant into the trial as allowed by the protocol.

Professional and/or personal legal representative consent will be requested at the earliest opportunity.

The participant was randomised to [DETAIL STUDY ARM ALLOCATED]. For further information contact [PI contact details].

**Use the following text to document obtaining Regained Capacity Consent**

The participant has now regained capacity and was approached to explain and discuss their participation in the [TRIAL NAME] trial on [date of approach DD/MMM/YYYY]. PIS version [X DD/MMM/YYYY] was given to the participant and the trial discussed with them in detail, they were given adequate time to consider the information and ask any questions.

IF THE PARTICIPANT GIVES CONSENT - Regained capacity consent was received by [NAME OF INDIVIDUAL RECEIVING CONSENT] at [time of consent HH:MM, include date if different from date of approach]. A copy of the completed consent form was given to the participant.

IF PARTICIPANT DECLINES CONSENT - The participant declined to continue in the trial and regained capacity consent was not given. Withdrawal options were discussed with the participant and the participant chose to [detail withdrawal option selected].

**\*\*Please ensure all attempts to follow up professional legal representative, personal legal representative and/or regained capacity consent are documented in the medical notes. If there are instances where a personal legal representative is available however follow up of personal legal representative consent is deemed inappropriate due to the condition of the participant ensure this is also clearly documented in the medical notes\*\***