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| --- | --- | --- | --- |
| **Initial Consent** | | | |
| **Trial:** |  | **PICF name:** |  |
| **Ethics Reference:** |  | **Local Governance Version:** |  |
| **Name:**  **DOB:**  **URN:**  *Or place Pt Label here* | | **Local Governance Date:** |  |
| **Master Version:** |  |
| **Master Date:** |  |

During a consultation on \_\_ \_\_ / \_\_ \_\_ \_\_ / \_\_ \_\_ \_\_ \_\_ with me, Dr \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, informed consent was given for the above mentioned participant to take part in the above mentioned study.

I confirm that the informed consent process complies with applicable regulatory requirement(s), adheres to GCP and the ethical principles that have their origin in the Declaration of Helsinki, as well as the Australian National Statement on Ethical Conduct in Human Research, 2007, (updated 2018).

The participant or legally acceptable representative (LAR) was provided with a copy of the current approved PICF.

The participant or LAR has been presented with the information about the study and the requirements of their participation in a suitable way.

The participant or LAR was provided the opportunity to ask questions and to discuss the information and their decision with others, if they wish.

The participant or LAR is aware that their decision to participate in research is voluntary and that they may refuse to participate or withdraw from the trial, at any time, without penalty or loss of benefits to which the participant is otherwise entitled.

The participant or LAR has been presented with the alternative procedure(s) or course(s) of treatment that may be available to the participant, and their important potential benefits and risks.

The participant is considered to fulfil inclusion criteria, and meet none of the exclusion criteria for the trial.

No study specific procedures have been conducted prior to informed consent, screening will now commence to confirm eligibility.

The PICF was signed and personally dated by the participant or LAR, and a copy of the signed PICF has been provided to them.

**Investigator Name (please print):**

**Investigator Signature: Date: \_\_ \_\_ / \_\_ \_\_ \_\_ / \_\_ \_\_ \_\_ \_\_**