**Participant safety checklist for management of interventional research activity**

The purpose of this checklist is to ensure that procedures and participant care planning associated with interventional research activity are appropriate and will:

* minimise risk/harm to participants
* minimise institutional risk
* enhance trial integrity

This checklist is not comprehensive. It is the Principal Investigator’s (PI) responsibility to ensure all possible risks associated with the study have been considered, minimised and are appropriately monitored (National Statement Section [2 .1](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#toc__161), GCP 4.3, 4.6, 4.11, 6.8).

The information in this checklist is required in addition to a thorough description of safety definitions, reporting and monitoring processes within the study protocol.

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| **Project Title** |  |
| **RGS reference number** |  |

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| Describe the study participants (include age, gender, health status, condition under study) |  |
| Provide a description of the study design |  |
| Outline the study inclusion and exclusion criteria (confirm if a checklist is in place to determine eligibility and attach) |  |
| Do the inclusion and exclusion criteria include objective measures, which would indicate if a participant is well enough to receive study treatment? |  |
| Describe the procedure to confirm that the participant is allocated to the appropriate study arm or risk category (if applicable) |  |
| Nominate the location in the hospital/institution where interventional research activity will occur  **\*Head of Department signature required on SSA to confirm discussion of safety requirements and support for the research activity** |  |
| Describe how the PI will ensure research team members have appropriate training to meet any organisational and or department specific requirements for the location where interventional research activity will occur |  |
| Name the nominated clinician responsible for the participant during and after the interventional activity. |  |
| Document procedure to monitor the outcome of the study intervention.  Include:   * Duration and frequency of monitoring prior to discharge * Specific monitoring requirements (e.g. vital signs and or other objective measures that are study specific) * Process to determine whether or not a participant should continue on the study * Name and contact details of senior registrar or consultant who is able to authorise discharge following interventional activity * List the supportive medications to be given to a participant on discharge, if applicable |  |
| Outline the information and resources that will be supplied to study participants on discharge. Include the participant process to follow in the event of a side effect or adverse event post discharge and the action plan for the participant to seek appropriate medical assistance. |  |
| What is the likelihood (if known) of an adverse event? (refer to the IB/Protocol) |  |
| Document the procedure to follow if an adverse event occurs while a participant is on site (e.g. describe the procedure in the event of a hypersensitivity reaction outline the emergency procedures and risk minimisation procedures that are in place) |  |
| Describe clinician/s availability and accessibility in case of an adverse event (include; name/s, position/s, roster pattern if relevant, contact details). |  |
| Describe how clinicians identified above will be notified of study activity. Include timeframes and process for notification. |  |
| Confirm after hours contact procedures for participants regarding safety (side effects and adverse events) have been tested. |  |
| Is there an independent Data and Safety Monitoring Committee and study stopping rule in place? |  |
| Record date this checklist was submitted for review by the Clinical Trial Sub-Committee |  |

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| PI Name |  |
| PI Signature |  |
| Date |  |