**Clinical Trials**

When submitting an ethics application for a clinical trial (not clinical research), researchers are expected to address the relevant sections in the National Statement on clinical trials in order for the Human Research Ethics Committee to review this as part of the application package. Researchers are strongly advised to review the information available on the Therapeutic Goods Administration website.

Please address or note **relevant** clinical trial guidance from the National Statement on ethical conduct in Human Research 2018 below:

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| --- | --- | --- |
| National Statement Section | National Statement commentary | Researcher response (if relevant) |
| [National Statement 3.1.7](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#toc__417)  | For any research project that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes, researchers must register the project as a clinical trial on a publicly accessible register complying with international standards (see information on the International Clinical Trials Registry Platform (ICTRP) on the World Health Organisation website) before the recruitment of the first participant  |  |
| [National Statement 3.1.8](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#toc__417) | Where the total project cannot be described in advance because the design and detail of successive stages will be informed by preceding stages, researchers should provide a description of the stages that are foreseen and how they intend to seek ethics approval for each stage.  |  |
| [National Statement 3.1.9](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#toc__417) | Researchers should confirm and reviewers should be satisfied that: 1. a plan is in place to ensure that resources are sufficient to conduct and complete the research as designed; and
2. the facilities, expertise and experience available seem to be appropriately allocated and sufficient for the research to be completed safely
 |  |
| [National Statement 5.1.38](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#toc__1539) | Institutions must be satisfied that sponsors of clinical trials have indemnity, insurance and compensation arrangements in accordance with applicable regulatory requirements. |  |
| [National Statement 5.2.6](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#toc__1687)  | For relevant health research, researchers should show that the research meets the requirements of the CPMP/ICH Note for Guidance on Good Clinical Practice (CPMP/ICH-135/95), ISO 14155 Clinical Investigation of Medical Devices, the World Health Organization International Clinical Trials Registry Platform and the TGA.  |  |
| [National Statement 5.2.18](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#toc__1687) | In any clinical research, a review body should be satisfied that research participants are adequately informed of the funding arrangements of the research. |  |
| [National Statement 5.5.3](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#toc__1826)  | For each clinical trial, institutions and review bodies should ensure that there are appropriate mechanisms for safety monitoring and reporting, including standard safety reporting and the use of a Data and Safety Monitoring Board (DSMB) or (an) identified person/s or committee with suitable expertise to assist and advise the institution and/or review body in carrying out their safety monitoring responsibilities. Researchers should refer to other published NHMRC guidance addressing these matters.  |  |
| [National Statement 5.5.4](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#toc__1826) | Researchers are responsible for notifying the review body that mechanisms for monitoring are in place, and for satisfying the review body that the mechanisms are appropriate to the research.  |  |
| [National Statement 5.5.5](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#toc__1826) | At regular periods – reflecting the degree of risk, and at least annually and at the completion of the project – researchers should provide reports to the relevant review body/ies and institution/s, including information on: (a) progress to date, or outcome in the case of completed research; (b) maintenance and security of records; (c) compliance with the approved proposal; and (d) compliance with any conditions of approval.  |  |
| [National Statement 5.5.6](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#toc__1826) | The granting and extension of ethical approval for a research project must be on the condition that the researchers: 1. conduct the research in compliance with the approved protocol or project description;
2. provide reports of the progress of the trial and any safety reports or monitoring requirements as indicated in NHMRC guidance and in accordance with the manner and form specified by the review body;
3. submit for approval any amendments to the project, including but not limited to amendments that:
4. are proposed or undertaken in order to eliminate immediate risks to participants;
5. may increase the risks to participants; or
6. significantly affect the conduct of the research;
7. inform the review body as soon as possible of any new safety information from other published or unpublished research that may have an impact on the continued ethical acceptability of the research or that may indicate the need for modification of the project;

for clinical trials with implantable medical devices, confirm the existence of, or establish, a system for enabling the tracking of the participant, with consent, for the lifetime of the device.  |  |
| [National Statement 5.5.9](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#toc__1826) | It may be unethical for a researcher to continue a clinical trial if: (a)  there are or have been substantial deviations from the trial protocol; (b)  adverse-effects of unexpected type, severity, or frequency are encountered; or (c)  as the trial progresses, the continuation of the trial would disadvantage some of the participants as determined by the researchers or others monitoring the trial.  |  |

Please save this document and upload it as an attachment to your REMS ethics application.