

Guidance for reviewing Low or Negligible Risk studies under the NMA:

Background:

NMA SOPs have previously required Low and Negligible Risk (LNR) research to be reviewed by a full HREC using a national ethics form (e.g. HREA).

Following consideration by the NMA Inter-Jurisdictional Working Group, it has been agreed to modify the NMA SOPs (and Fact Sheet) to support the acceptance of LNR research that has been reviewed using non-HREC levels of review, in accordance with the provisions in the *National Statement*.

The following statement has been developed following consultation with all States and Territories regarding their preferred process and stance.

Position Statement for all States and Territories except South Australia:

As with all NMA applications, projects meeting the Low or Negligible Risk (LNR) criteria for a non-HREC level of review according to the *National Statement on Ethical Conduct in Human Research 2007 (updated 2018) (National Statement)* will be reviewed under the NMA scheme only if they are submitted on the Human Research Ethics Application form (HREA).

An LNR project will be accepted under the NMA scheme if the project has been ethically reviewed using a non-HREC level of review described in the *National Statement*.

South Australia only:

Non-HREC levels of review will not be accepted for projects being submitted to South Australian public health organisations under NMA. Acceptable forms of review may include (i) review by a full NMA-participating HREC from another jurisdiction or (ii) re-review by a NMA-participating HREC from South Australia.

Guidance on NMA LNR review Process (excluding South Australia):

- Institutions with NMA-participating HRECs will have non-HREC levels of review that are consistent with the *National Statement* (5.1.20) for reviewing and approving LNR projects.
- As per the *National Statement*, those reviewing research at a non-HREC level must refer to an HREC any research they identify as involving more than low risk [5.1.21].
- In order to facilitate consistency in LNR review, referral may be made to the set of NMA-endorsed guidelines on LNR review, that are consistent with the *National Statement* (attached).