

Statement from Australia's National Health and Medical Research Council (NHMRC) in response to questions from ABC RN's Science Friction:

As of 31 August 2017

- **Does the NHMRC now have a policy in place re: funding being contingent on both female and male animal models being included. If yes, when was it introduced? If no, what are the plans?**

Yes. This requirement was introduced in the 2017 Project Grants round for funding commencing in 2018.

- **What are the requirements for using both sexes in human clinical trials in Australia?**

In Australia, all human research—including clinical trials must conform with the *National Statement on Ethical Conduct in Human Research* (2007) ('National Statement').

The National Statement provides that the design, review and conduct of research must reflect the following values: scientific merit and integrity, beneficence, respect, and justice.

Because of the variability of research, the National Statement does not require the equal participation of males and females in clinical trials for all studies. However, a clinical trial designed with scientific merit and integrity would ensure that 'the size **and profile** of the sample to be recruited is adequate to answer the research question' (National Statement, 3.3.3(c)) [emphasis added]. An appropriate balance of male and female participants may be necessary to ensure the profile of participants is representative of the community in which the, for example, new drug or device will be used.

Likewise, a clinical trial designed and conducted with justice will ensure that the 'benefits' and 'burdens' of the research are fairly distributed and 'taking into account the scope and objectives of the proposed research, the **selection, exclusion** and inclusion of categories of research participants is fair, and is accurately described in the results of the research.' (National Statement, 1.4(a),(c),(d)) [emphasis added]. If one sex is to be excluded from a clinical trial, a researcher would need to justify this to the reviewing Human Research Ethics Committee.

In addition to the National Statement – which applies to all human research conducted in Australia – NHMRC advises researchers seeking NHMRC funding that their clinical trial research plan should include 'details to achieve balance of male and female clinical participants, and male and female cell and animal models, including justification where it is unwarranted.'

END OF STATEMENT.