

Statistical Review Process

Introduction

Starting July 2018, all human research protocols will require statistical review before submission to the Melbourne Health Office for Research, and evidence of this review must be submitted with the application. The Melbourne Health Human Research Ethics Committee (HREC) will not accept for review projects that do not fulfil statistical review requirements.

The purpose of the statistical review is to determine if the proposed research is well designed. Each research project must be carefully designed to answer the research question.

When should Statistical Review take place?

Statistical review of a project must always occur before the application is submitted for HREC review. The investigators must allow sufficient time to find a reviewer, allow the reviewer to conduct the statistical review and to address the reviewer's comments adequately, prior to submission to the HREC.

A proforma for statistical review is provided on the [Melbourne Health Office for Research website](#).

When is a Statistical Review not required?

Projects which have already had a rigorous independent review conducted on the **final** version of the research protocol do not need to undergo additional statistical review prior to submission. Circumstances where this has occurred may include:

- Commercially sponsored projects to be carried out on behalf of the sponsor where the Protocol has been subjected to rigorous independent review processes organised by the sponsoring organisation
(Note: commercially funded/supported projects involving significant academic/intellectual inputs from the local researchers are, in effect, research partnerships. Evidence of independent statistical review is required for such projects)
- Multicentre trials run by cooperative groups/clinical trials networks with processes for rigorous independent statistical review of research protocols. For example, studies run by the Australasian Leukaemia & Lymphoma Group, Australasian Kidney Trials Network, etc.
- Applications for Melbourne Health Governance Authorisation only i.e. HREC approval provided by another accredited HREC under the National Mutual Acceptance (NMA) Scheme.

If your project falls into one of the above categories:

- 1. Include a statement in your Statistical Review Proforma explaining why statistical review was not sought; and**
- 2. Attach documentation to support the explanation, where appropriate.**

The process for Statistical Review:

- 1.** Investigators source an appropriate statistical reviewer and send to them the (to date) final research protocol and Statistical Review Proforma
- 2.** The statistical reviewer returns the completed Statistical Review Proforma to the investigators
- 3.** The principal investigator submits the completed Statistical Review Proforma, and the project documents for HREC review.

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