

November 2008

**Document C: RESEARCH & SCIENTIFIC ADVISORY COMMITTEE
PROCEDURES FOR SUBSTUDIES USING THE MEDICAL SCHOOLS OUTCOMES
DATABASE**

A sub study involves the collection of new data from those already participating in the MSOD study. The data collected are usually linked to existing MSOD data to take advantage of the longitudinal aspects of the MSOD Project. Sub studies place demands on participants and their scientific value must be weighed against the avoidance of over-burdening participants. In considering a proposal for a sub study, the Research & Scientific Advisory Committee will take into account its feasibility, scientific value, consistency with the overall aims of the project, and the logistics of running the sub study. The MSOD cohorts are not to be used simply as convenience samples.

Sub studies must be fully funded, including MSOD staff time¹ for consultation, drawing the study sample, assisting with design of survey materials and so on. Further details are available on request.

Any member of the Research & Scientific Advisory Committee who has a direct interest in a proposed sub study should not be involved in the decision to approve the sub study.

To propose and conduct sub studies in conjunction with MSOD data

To propose a sub study you will need to liaise with a nominated MSOD liaison person². You will also need to submit a copy of the Sub study Expression of Interest form (Document G).

All those who plan to conduct a sub study in association with the MSOD data should undertake the following:

1. Familiarise yourself with analyses and sub studies that have been conducted. Completed studies are available from the MSOD website; a list of studies in progress is available from the MSOD staff.
2. Read the relevant Privacy Protocol and Guidelines for use of the MSOD data (Document E).
3. Discuss your proposal informally, to identify any conflicts with existing projects.
4. Complete the Sub study EOI form (Document G) and send it to the MSOD office. Please include preliminary copies of any surveys/interviews you are planning to use.

¹ This will approximate staff salary rate plus on-costs.

² Chair of MSOD Project & Research Committee or nominee

5. The Research & Scientific Advisory Committee will assess the application taking into account the feasibility, scientific value, consistency with the overall aims of the project, and the logistics of running the sub study. A similar level of detail about the project plan as submitted to the NHMRC should be provided. The Research & Scientific Advisory Committee will endorse the application or alternatively may decide to seek clarification, request modifications or reject the application. This stage can be conducted while awaiting results of funding applications.
6. If endorsed, the applicant will be asked to re-read relevant Guidelines and Privacy Protocol, and sign the MOU (Document D) and Confidentiality Statement (Document E).
7. Subject to successful funding, the applicant will be asked to finalise survey/interview materials, letters to participants etc, and ethics applications for all relevant institutions.
8. Sample letters of invitation, consent forms and change of details forms are available from the MSOD office. It is recommended that you use these as templates, as this will also assist with clearance from the ethics committee/s.
9. All sub studies which use data collected during the participants' time in medical school must be cleared with the Human Research Ethics Committees at the Universities from which students are sourced, in addition to the Human Research Ethics Committee/s at the institutions to which collaborator/s belong.
10. The applicant will then finalise the survey materials and inclusion/exclusion criteria and provide Ethics clearance forms.
11. Once survey materials are finalized and HREC clearance forms are provided, the MSOD Data Manager will be informed in writing and requested to make the data available, as all due processes have been fulfilled.
12. The Research & Scientific Advisory Committee should be kept informed of any substantive changes to the content or methods of the sub study. Copies of all relevant paperwork should be provided to the MSOD office. These should include an information sheet for MSOD staff, who may, in some instances, receive participant queries.
13. Provide a copy of the final publication/abstract/book chapter to the MSOD for the MSOD website.
14. The Research & Scientific Advisory Committee will review sub study progress through annual reports to decide whether a project
 - is finished;
 - is progressing satisfactorily;
 - has made insufficient progress and is considered abandoned.

The Research & Scientific Advisory Committee will provide regular reports on the status of all approved sub studies.