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## INFORMATION SHEET

### An Analysis of Research Ethics and the Ethical Review Process as Culture and Cultural Process

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The purpose of this project is to conduct an anthropological analysis of research ethics and the ethical review process as culture and cultural process. The intent is to better understand why some kinds of research present difficulties for ethical review committees and other research gatekeepers and the researchers who submit applications for ethical review. The work includes an analysis of Australian and international ethics review-related documents and processes, case studies, the literature on issues in research ethics, and the observation of ethics committees in the process of deliberation on ethics applications. It focuses primarily on projects, documents, and the literature associated with the paradigms and methods used or borrowed from the social sciences and topics and populations that seem to be the most vulnerable and problematic in the ethical review of applications. The understanding derived from this project might help us better address the issues involved from an empirical rather than emotive stance and allow the development of policies and applications that are less problematic for all concerned. It will help facilitate the efficient and effective development and review of research proposals that are of the highest ethical standard.

The focus of the project is on research ethics, the ethical review process, and the associated explicit and implicit issues that arise in the process of ethical review. Participation in this project is voluntary and can include one or more of the following activities:

- contributing a case study and, if relevant, any associated documentation (e.g., application forms, letters to or from ethics committees with any specific identification information deleted)
- engaging in discussions on ethics, the ethical review process, and any particulars related to any cases you offer, in the manner most suitable for you (email, telephone conversation or in person at a convenient time and place)
- allowing the observation of the ethical review process and any resulting documentation (e.g., minutes of meetings) using fieldnotes.

Should you agree to participate you may do so anonymously. No identifying information will be collected or used without your explicit permission. You may withdraw from this study at any time without prejudice.

Observations of the ethical review process by ethics committees will focus on the deliberations and the topics discussed, not specific applications. No identifying information on any applicants or information that will allow the identification of specific applications or projects will be recorded or used in any way.

If you would like to be involved or have any questions or comments, please contact Dr Maureen H. Fitzgerald, School of Occupation and Leisure Sciences, Faculty of Health Sciences, The University of Sydney, PO Box 170, Lidcombe NSW 1825, Australia. Telephone +61 2 9351 9216, Fax +61 2 9351 9197, Email [m.fitzgerald@fhs.usyd.edu.au](mailto:m.fitzgerald@fhs.usyd.edu.au), or Paul Phillips on Telephone +61 2 9351 9509, email [p.phillips@fhs.usyd.edu.au](mailto:p.phillips@fhs.usyd.edu.au).

**Any person with concerns or complaints about the conduct of a research study can contact the Manager of Ethics and Biosafety Administration, University of Sydney, on (02) 9351 4811.**