



ETHICS COMMITTEE CERTIFICATE OF APPROVAL

This is to certify that

Project No: 98/06

Project Title: Bio21 MMIM Project - Phase Two

Principal Researcher: A/Professor John Wilson

Protocol No: 98/06

*was considered by the Ethics Committee on 25 May-2006 and is **APPROVED**.*

Approval date: 29-May-2006 **Expiry date:** 29-May-2008

It is the Principal Researcher's responsibility to ensure that all researchers associated with this project are aware of the conditions of approval and which documents have been approved.

The Principal Researcher is required to notify the Secretary of the Ethics Committee, via amendment or progress report, of

- Any significant change to the project and the reason for that change, including an indication of ethical implications (if any);
- Serious adverse effects on participants and the action taken to address those effects;
- Any other unforeseen events or unexpected developments that merit notification;
- The inability of the Principal Researcher to continue in that role, or any other change in research personnel involved in the project;
- Any expiry of the insurance coverage provided with respect to sponsored clinical trials and proof of re-insurance;
- A delay of more than 12 months in the commencement of the project; and,
- Termination or closure of the project.

Additionally, the Principal Researcher is required to submit

- A Progress Report every 12 months for the duration of the project (*forms to be provided*);
- A Request for Extension of the project prior to the expiry date, if applicable; and,
- A detailed Final Report at the conclusion of the project.

The Ethics Committee may conduct an audit at any time.

All research subject to the Alfred Hospital Ethics Committee review must be conducted in accordance with the National Statement on Ethical Conduct in Research Involving Humans (1999).

The Alfred Hospital Ethics Committee is a properly constituted Human Research Ethics Committee in accordance with the National Statement on Ethical Conduct in Research Involving Humans (1999).

SPECIAL CONDITIONS

None

SIGNED: 

Chair, Ethics Committee (or delegate) 1/6/06

Please quote Project No and Title in all correspondence

**R. FREW
SECRETARY
ETHICS COMMITTEE**