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26 November 2007

Dr Stephen Vaughan
Director, Grampians Integrated Cancer Services
1015 Mair Street
Ballarat 3350

Dear Stephen

Bio21:MMIM (Molecular Medicine Informatics Model) Project –Australian Cancer Grid

The above proposal was reviewed by the Ethics Committee at its meeting held on 9 November 2007.

The project was granted ethical approval to proceed, however, I do require confirmation as to role of all local clinicians attached to the project. I understand that you have indicated that you, Kate Hamilton and Geoff Chong will be involved; can you formally advise whether this is still the case, and who will be acting as 'Principal Investigator' for this site. Each member of the team will also need to complete and sign the "Declaration by Researchers", and the nominated Principal Investigator will also need to fill in the "Certification by Principal Researcher"; I have enclosed copies of each.

Please also note the following general conditions of approval:

1. Protocol Amendments

Any changes to the protocol must be submitted to the Ethics Committee for approval and should be accompanied by a summary outlining the reasons for the change together with an indication of ethical implications (if any).

2. Project Reports

The Committee requires that you provide notification of the project commencement date at this site, annual progress reports, notification when it concludes, and a copy of the final report.

The Ballarat Health Services and St John of God Health Care Human Research Ethics Committee is a properly constituted Human Research Ethics Committee in accordance with the "*National Statement on Ethical Conduct in Research Involving Humans*" (NHMRC/ARC/AVCC, 2007).

Yours sincerely

Dr John L Gallichio

Executive Director – Medical Services

**Secretary, Ballarat Health Services and St John of God Health Care
Human Research Ethics Committee**

Cc: Dr Kate Hamilton, Dr Geoff Chong, IMS, BHS

1.39 Certification by Principal Researcher and Head of Department

Project Title:

Certification By Principal Researcher

I accept responsibility for the conduct of this research project according to the principles of the *National Statement on Ethical Conduct in Research Involving Humans* published by the National Health & Medical Research Council (June 1999).

I certify that all researchers and other personnel involved in this project are appropriately qualified and experienced or will undergo appropriate training to fulfil their role in this project.

As principal researcher, I will take responsibility for the confidential maintenance of records for 7 years after completion of the project (15 years in the case of drug trials).

Name of principal researcher:

Signature

Date

Acceptance by Head of Department/Divisional Director/Authorised Institutional Official*

I certify that I have read the research project application named above.

My signature indicates that I support this research project.

Name of Head of Department (or appropriate person):

Name of Department (or relevant section):

Signature

Date

*Where an investigator is also Head of Department, certification must be sought from the person to whom the Head of Department is responsible. Investigators, who are also Department Heads or Divisional Directors, must not approve their own research on behalf of the Institution.