Government of South Australia
SA Health

Central Adelaide Local Health Network
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Research Ethics Committee
Level 3, Hanson Institute
Tel: (08) 8222 4139
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Email: rah.ethics@health.sa.gov.au

COPY

19 April 2005

Mr Stuart Howell
GASTROENTEROLOGY DEPARTMENT
ROYAL ADELAIDE HOSPITAL

Dear Mr Howell,

Re: "Multivariate analysis of predictors for severity of mucosal lesions in patients with GORD symptoms (MAPSOMAL): a clinical, epidemiological and endoscopic survey". Patient Information Sheet and Consent Form, Version 1.1 (23 February 2005). RAH PROTOCOL NO: 050402

I am writing to advise that ethical approval has been given to the above project. Please note that the approval is ethical only, and does not imply an approval for funding of the project.

Research Ethics Committee deliberations are guided by the Declaration of Helsinki and NH&MRC National Statement on Ethical Conduct in Research Involving Humans. Copies of these can be forwarded at your request.

Adequate record-keeping is important and you should retain at least the completed consent forms which relate to this project and a list of all those participating in the project, to enable contact with them if necessary, in the future. The Committee will seek a progress report on this project at regular intervals and would like a brief report upon its conclusion.

If the results of your project are to be published, an appropriate acknowledgment of the Hospital should be contained in the article.

Yours sincerely,

for **DR M JAMES**
CHAIRMAN
RESEARCH ETHICS COMMITTEE

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2 March 2006

Mr Stuart Howell
GASTROENTEROLOGY DEPARTMENT
ROYAL ADELAIDE HOSPITAL

Dear Mr Howell,

Re: "Multivariate analysis of predictors for severity of mucosal lesions in patients with GORD symptoms (MAPSOMAL): a clinical, epidemiological and endoscopic survey". Patient Information Sheet and Consent Form, Version 1.1 (23 February 2005).
Protocol Amendment: Addition of 3 Investigators (28 February 2006). Patient Information Sheet & Consent Form,k Version 1.1 (28 February 2006). Patient Assessment Questionnaire.
RAH PROTOCOL NO: 050402a.

I am writing to advise that Research Ethics Committee approval has been given to the above project.

Research Ethics Committee deliberations are guided by the NHMRC National Statement on Ethical Conduct in Research Involving Humans.

The general conditions of approval follow:

- Adequate record-keeping is important. If the project involves signed consent, you should retain the completed consent forms which relate to this project and a list of all those participating in the project, to enable contact with them in the future if necessary. The duration of record retention for all research data is 15 years.
- You must notify the Research Ethics Committee of any events which might warrant review of the approval or which warrant new information being presented to research participants, including:
  (a) serious or unexpected adverse events which warrant protocol change or notification to research participants,
  (b) changes to the protocol,
  (c) premature termination of the study.
- The Committee must be notified within 72 hours of any serious adverse event occurring at this site.
- Approval is ongoing, subject to satisfactory annual review. An annual review form will be forwarded to you at the appropriate time.

Yours sincerely,

for **DR M JAMES**
CHAIRMAN
RESEARCH ETHICS COMMITTEE

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4 July 2006

Prof G Holtmann
GASTROENTEROLOGY DEPARTMENT
ROYAL ADELAIDE HOSPITAL

Dear Prof Howell,

Re: "Multivariate analysis of predictors for severity of mucosal lesions in patients with GORD symptoms (MAPSOMAL): a clinical, epidemiological and endoscopic survey". Patient Information Sheet and Consent Form, Version 1.1 (23 February 2005).
Protocol Amendment: Addition of 3 Investigators (28 February 2006). Patient Information Sheet & Consent Form, Version 1.1 (28 February 2006). Patient Assessment Questionnaire.
Patient Information Sheet & Consent Form, Version 1.2 (3 July 2006).
RAH PROTOCOL NO: 050402b.

I am writing to advise that Research Ethics Committee approval has been given to the above project.
The Amended Information Sheet & Consent Form, Version 1.2 also acknowledges the addition of Mr Michael Lange as a sub-investigator to the study.

Research Ethics Committee deliberations are guided by the NHMRC National Statement on Ethical Conduct in Research Involving Humans.

The general conditions of approval follow:

- Adequate record-keeping is important. If the project involves signed consent, you should retain the completed consent forms which relate to this project and a list of all those participating in the project, to enable contact with them in the future if necessary. The duration of record retention for all research data is 15 years.
- You must notify the Research Ethics Committee of any events which might warrant review of the approval or which warrant new information being presented to research participants, including:
  (a) serious or unexpected adverse events which warrant protocol change or notification to research participants,
  (b) changes to the protocol,
  (c) premature termination of the study.
- The Committee must be notified within 72 hours of any serious adverse event occurring at this site.
- Approval is ongoing, subject to satisfactory annual review. An annual review form will be forwarded to you at the appropriate time.

Yours sincerely,

for **DR M JAMES**
CHAIRMAN
RESEARCH ETHICS COMMITTEE

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23 July 2007

Prof G Holtmann
GASTROENTEROLOGY DEPARTMENT
ROYAL ADELAIDE HOSPITAL

Dear Prof Holtmann,

Re: "Multivariate analysis of predictors for severity of mucosal lesions in patients with GORD symptoms (MAPSOMAL): a clinical, epidemiological and endoscopic survey".
Patient Information Sheet and Consent Form, Version 1.1 (23 February 2005).
Protocol Amendment: Addition of 3 Investigators (28 February 2006). Patient Information Sheet & Consent Form, Version 1.1 (28 February 2006). Patient Assessment Questionnaire. Patient Information Sheet & Consent Form, Version 1.2 (3 July 2006).
Patient Information Sheet & Consent Form, Version 2.0 (19 July 2007).
RAH PROTOCOL NO: 050402c.

I am writing to advise that Research Ethics Committee approval has been given to the above project and listed amendments. Please quote the RAH protocol number on all correspondence..

Research Ethics Committee deliberations are guided by the NHMRC National Statement on Ethical Conduct in Research Involving Humans.

The general conditions of approval follow:

- Adequate record-keeping is important. If the project involves signed consent, you should retain the completed consent forms which relate to this project and a list of all those participating in the project, to enable contact with them in the future if necessary. The duration of record retention for all research data is 15 years.
- You must notify the Research Ethics Committee of any events which might warrant review of the approval or which warrant new information being presented to research participants, including:
  (a) serious or unexpected adverse events which warrant protocol change or notification to research participants,
  (b) changes to the protocol,
  (c) premature termination of the study,
  (d) completion of the study with a study completion report within 3 months of the project completion.
- The Committee must be notified within 72 hours of any serious adverse event occurring at this site.
- Approval is ongoing, subject to satisfactory annual review. Investigators are responsible for providing an annual review to the RAH REC Executive Officer each year using the Annual Review Form available at: http://www.rah.sa.gov.au/rec/index.php

Yours sincerely,

for **Dr M James**
CHAIRMAN
RESEARCH ETHICS COMMITTEE

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7 July 2008

Dr Jane Andrews
GASTROENTEROLOGY DEPARTMENT
ROYAL ADELAIDE HOSPITAL

Dear Dr Andrews,

Re: "Multivariate analysis of predictors for severity of mucosal lesions in patients with GORD symptoms (MAPSOMAL): a clinical, epidemiological and endoscopic survey".
Patient Information Sheet and Consent Form, Version 1.1 (23 February 2005).
Protocol Amendment: Addition of 3 Investigators (28 February 2006). Patient Information Sheet & Consent Form, Version 1.1 (28 February 2006). Patient Assessment Questionnaire.
Patient Information Sheet & Consent Form, Version 1.2 (3 July 2006).
Patient Information Sheet & Consent Form, Version 2.0 (19 July 2007).

RAH PROTOCOL NO: 050402d.

I am pleased to advise that Research Ethics Committee APPROVAL is given to the following Amendments in relation to the above project.

- ***Protocol Amendment 1 - Protocol Version 2.0 (30 June 2008).***
- ***Patient Information Sheet & Consent Form, Version 2.1 (26 June 2008).***

Please quote the RAH Protocol Number on all correspondence. Research Ethics Committee deliberations are guided by the NHMRC National Statement on Ethical Conduct in Human Research 2007.

The general conditions of approval follow:

- Adequate record-keeping is important. If the project involves signed consent, you should retain the completed consent forms which relate to this project and a list of all those participating in the project, to enable contact with them in the future if necessary. The duration of record retention for all research data is 15 years.
- You must notify the Research Ethics Committee of any events which might warrant review of the approval or which warrant new information being presented to research participants, including:
  (a) serious or unexpected adverse events which warrant protocol change or notification to research participants,
  (b) changes to the protocol,
  (c) premature termination of the study,
  (d) a study completion report within 3 months of the project completion.
- The Committee must be notified within 72 hours of any serious adverse event occurring at this site.
- Approval is ongoing, subject to satisfactory annual review. Investigators are responsible for providing an annual review to the RAH REC Executive Officer each year using the Annual Review Form available at: http://www.rah.sa.gov.au/rec/index.php

Yours sincerely,

for **Dr M James**
CHAIRMAN
RESEARCH ETHICS COMMITTEE