Application Form for Ethical and Scientific Review of Low and Negligible Risk Research (N.S 2.1.6-2.1.7, 5.1.8-5.1.23) – New South Wales

Purpose of this form

The purpose of this form is to enable applicants to provide sufficient detail about the research project to allow the Human Research Ethics Committee (HREC) to make an informed decision about the ethical and scientific acceptability of the proposal.

HREC approval and authorisation by the Public Health Organisation are required for all human research projects prior to commencement.

Use of this form

This form must be completed by the Co-ordinating Investigator responsible for the conduct of the research project within the NSW public health system.

If you believe that the research project involves only low or negligible risk to participants and may be eligible for expedited ethical and scientific review, it is recommended ***you read the guidance and discuss the project with an HREC Executive Officer before completing this form.***

If the HREC Executive Officer advises that the project is not eligible for expedited review, you must complete an application for full HREC review using the National Ethics Application Form (NEAF) accessible at https://ethicsform.org/au/SignIn.aspx.

The HREC may request a full review using NEAF following assessment of your application for expedited review if it considers the risk to participants to be greater than low risk.

Examples of research with low and negligible risk include, but are not limited to, the following:

- *Research involving only questionnaires and general surveys on non-controversial, non-personal issues that also include only basic demographic data and where, in all instances, respondents are not identified;*
- *Research involving only the use and/or disclosure of information from existing data collections, where the identity of the person cannot reasonably be ascertained from the information to be disclosed to researchers;*
- *Research involving human tissue where participant consent is not required because broad consent has been provided for use of the tissue in research and specific individuals cannot be identified from specimens used e.g. where specimens have never been labelled with individual identifiers or individual identifiers have been permanently removed; and*
- *Research requiring access to individual medical records or to information stored electronically, through the site's medical records department or other department/specialty, but where participant consent is not required or where a waiver of consent requirement is being requested because, in all instances, individuals cannot be identified from data extracted or provided.*

How have you confirmed your project is eligible for expedited ethical and scientific review (low and negligible risk project)?

☐ I have read the guidance; and/or

☑ I have discussed the project with an HREC Executive Officer

1. Project reference N.S 1.1

1.1. Project type

◉ Single-centre ○ Multi-centre

○ Low risk ◉ Negligible risk

1.2. Project title

State the full title of the project.
Upper Gastrointestinal & Endosurgery Database

1.2a Project Short title

State the short title of the project.
UGI Database

2. Research personnel N.S 5.2.5-5.2.15

2.1. Co-ordinating Investigator

Title:	A/Prof
First Name:	Greg
Surname:	Falk
Position:	Head of Department
Department:	Upper Gastrointestinal & Endosurgery
Organisation:	Concord Repatriation General Hospital
Mailing Address:	Hospital Road -Ground West (Dept. Surgery)
Suburb/Town:	Concord
State:	NSW
Postcode:	2139
Phone (business):	02 9767 6385
Phone (mobile):	
Fax:	02 9767 7436
E-mail:	sydney.heartburn@gmail.com
Qualifications, Experience and skills	MBBS, FRACS, FACS. Head of Department, Specialist Surgeon. Upper Gastrointestinal Surgery, Laparoscopy, Therapeutic Endoscopy
Role:	Principal Investigator
Is this person the nominated contact person for this project?	(●) Yes ( ) No
Is the Co-ordinating Investigator a student?	( ) Yes (●) No

2.2. Principal Investigator/s

Principal investigator 1

Site:	Concord Repatriation General Hospital
Title:	A/Prof
First Name:	Greg
Surname:	Falk
Position:	Head of Department
Department:	Upper Gastrointestinal & Endosurgery
Organisation:	Concord Repatriation General Hospital
Mailing Address:	Hospital Road -Ground West (Dept. Surgery)
Suburb/Town:	Concord
State:	NSW
Postcode:	2138
Phone (business):	02 9767 6385
Phone (mobile):	

Fax:	02 9767 7436
E-mail:	sydney.heartburn@gmail.com
Qualifications, Experience and skills	MBBS, FRACS, FACS. Head of Department, Specialist Surgeon Upper Gastrointestinal Surgery, Laparoscopy and Therapeutic Endoscopy
Role:	Principal Investigator

Is the Principal Investigator a student? ○ Yes ◉ No

Principal investigator 2

Site:	Concord Repatriation General Hospital
Title:	Dr
First Name:	Guillermo
Surname:	Becerril
Position:	Clinical Superintendent of Surgery
Department:	Surgery
Organisation:	Concord Repatriation General Hospital
Mailing Address:	Hospital Road -Ground West (Dept. Surgery)
Suburb/Town:	Concord
State:	NSW
Postcode:	2139
Phone (business):	02 9767 6350
Phone (mobile):	
Fax:	02 9767 7436
E-mail:	Guillermo.Becerril@sswahs.nsw.gov.au
Qualifications, Experience and skills	MBBS. Clinical Superintendent of Surgery. Specialist Surgeon General Surgery, Upper Gastrointestinal Surgery, Laparoscopy, Therpaeutic Endoscopy.
Role:	Investigator

Is the Principal Investigator a student? ○ Yes ◉ No

2.3. Investigator/s

2.4. Other personnel

How many other personnel are involved in this project? Please provide details (for example study nurses, research assistants)
Concord Upper Gastrointestinal Unit
Head of Department
4 Visiting Medical Officers
1 Staff specialist
2 Postgraduate Fellows
1 Registrar (Accredited trainee)
1 CNC
1 NUM
2 Administrative assistants
1-2 Medical students

2.5. Nominated Contact for project

Title:	A/Prof
First Name:	Greg

Surname:	Falk
Position:	Head of Department
Department:	Upper Gastrointestinal & Endosurgery
Organisation:	Concord Repatriation General Hospital
Mailing Address:	Hospital Road -Ground West (Dept. Surgery)
Suburb/Town:	Concord
State:	NSW
Postcode:	2139
Phone (business):	02 9767 6385
Phone (mobile):	
Fax:	02 9767 7436
E-mail:	sydney.heartburn@gmail.com

3. Name/ID of HREC reviewing the project

Select the name/ID of the HREC that this application will be submitted to.
Sydney Local Health District - CRGH (EC00118)

3.1. Site/s involved in this project for which ethical and scientific approval is being sought from this HREC

List all number and names of all sites (including those external to NSW Health) involved in the project and indicate the site/s requiring ethical and scientific approval from this HREC.

a) In how many sites will the project be undertaken? 1

b) Please provide the site details:

Site name:	Does the site require ethical and scientific approval from this HREC?:
Concord Repatriation General Hospital	◉ Yes ○ No

3.2. Previous ethical review N.S 5.3

Is this project being submitted to (or has it previously been submitted to) other ethical review bodies?
◉ Yes ○ No

If yes, provide details.
CH62/6/2011-092

3.3. Peer review N.S 1.2, Code of Conduct, Section 6

Has the project been peer-reviewed?
○ Yes ◉ No

3.4. Funding N.S 1.1(f)

What is the source of funds available to conduct this project?

Provide details in the table below.

Type of funding	Name of funding organisation/source of funding	Amount $
External funding e.g. NHMRC, Foundations etc.	N/A	None
Internal/Departmental funding	N/A	None

3.5. Conflicts of interest N.S 5.4

Are any 'conflict of interest' issues likely to arise in relation to this research?
○ Yes ◉ No

3.6. Publications and Dissemination of results N.S 1.3 and Code of Conduct, Section 4

How is it intended to disseminate the results of the research? For example a report, publication or thesis.
Quality assurance reports, case-series, clinical outcomes publications.
Provide basis for future research projects

4. Anticipated start and finish dates

4.1. Anticipated start date

State the date on which any study procedure or any part of the protocol is expected to be implemented.
01/11/2012

4.2. Anticipated finish date

State the date on which data analysis is expected to be completed at all sites involved in the project.
31/10/2015

5. Project details N.S 1.1

5.1. Project summary

Provide an overview of the project in plain language describing the aims, the research design, the methods used to achieve those aims and possible outcomes.
De-identified, password-protected Data collection of all cases admitted to the Upper Gastrointestinal Department to keep a database.

5.2. Research aims and significance

Briefly state the aims, research objectives, key research questions and/or the hypothesis to be tested, where appropriate.
Ongoing maintenance of database of admissions, diagnosis, procedures, complications, outcomes recorded for quality-assurance and clinical research reports (case-series, surgical outcomes, survival, morbidity and mortality, case-reports)

5.3. Research methodology NS 1.1(a-d)

Provide details of the proposed method to achieve the aims, including project design, data collection techniques, data to be collected, number of participants, tasks participants will be asked to complete, recruitment of participants and analysis of results. Provide a justification of the proposed sample size, including details of statistical power of the sample, where appropriate.

Prospective collection of new cases admitted to the Department and Retrospective data retrieval from medical records.
Password-protected Software (Excel and Access) kept in single desktop in a secured location.
Prospective data entered weekly
Retrospective data from 1996 obtained thru medical records by Diagnosis or Procedure codes only.

5.4. Likely benefits of the project for the participants, institution and/or community N.S 2.1

Keep an accurate database of all cases treated by the Upper Gastrointestinal Department which will allow easier Quality Assurance records and allow to improve management, procedure safety and patient outcomes.

5.5. Actual or potential risk associated with the project N.S 2.1

None. More risk not to have an ongoing database.

6. Consent N.S 2.2,2.3

6.1. Will informed consent be obtained from participants?

◯ Yes ◉ No

If 'No', outline why participant consent will not be obtained.
Database will not modify their treatment

7. Data and privacy N.S 3.2

7.1. Is there a requirement for the project to collect, use, or disclose individually identifiable or re-identifiable data of a personal nature (including personal health information) about participants from:

Commonwealth departments or agencies?	◯ Yes	◉ No
State/Territory departments or agencies?	◯ Yes	◉ No
Private sector?	◯ Yes	◉ No

7.2. Is there a requirement for the project to collect, use, or disclose individually identifiable or re-identifiable data of a personal nature (including personal health information) about participants without their consent?

◯ Yes ◉ No

7.3. Storage and security of data

Provide this information for each site which requires ethical and scientific approval from this HREC, listed in response to Question 3.1b of this form.

Site name:	Concord Repatriation General Hospital Department of Surgery
Location of stored data:	Ground West Concord Repatriation General Hospital
Format of stored data:	Computer file (Microsoft Office excel, access)
Arrangements for security of stored data:	Password protected local area network computer and password protected file
Duration data will be stored:	Indefinite
Method of destruction of data:	Identifiable data will be deleted prior to collection in database

Declaration by the Co-ordinating Investigator, Principal Investigators, and Investigators (including Supervisors and students where applicable)

Project title:	Upper Gastrointestinal & Endosurgery Database

I/we certify that:

1. All information in this form is truthful and as complete as possible.
2. I/we have had access to and read the NHMRC *National Statement on Ethical Conduct in Human Research 2007* (National Statement) and the *Australian Code for the Responsible Conduct of Research 2007* (The Code)
3. The research will be conducted in accordance with the ethical and research arrangements of the organisations involved.
4. I/we have consulted any relevant legislation and regulations, and the project will be conducted in accordance with these.
5. I/we will immediately report to the HREC anything which might warrant review of the ethical and scientific approval of the proposal, including:
   a. Serious or unexpected adverse effects on participants;
   b. Proposed changes in the protocol;
   c. Unforseen events that might affect continued ethical and scientific acceptability of the project.
6. I/we will inform the HREC and the Public Health Organisation, giving reasons, if the research project is discontinued before the expected date of completion.
7. I/we will not continue the research if ethical approval or site authorisation is withdrawn and will comply with any special conditions required by the HREC and the site.
8. I/we understand and agree that study files and documents and research records and data may be subject to inspection by the HREC, Research Governance Officer, the sponsor or an independent body for audit, inspection and monitoring purposes.
9. I/we will adhere to the conditions of approval stipulated by the HREC and will co-operate with HREC monitoring requirements. At a minimum annual progress reports and a final report will be provided to the HREC and the site.
10. I/we will only commence this research project after obtaining approval from the HREC and authorisation from the Public Health Organisation.

Name	**Designation**	**Signature**	**Date**
A/Prof Greg Falk	Co-ordinating Investigator		
A/Prof Greg Falk	Principal Investigator		11/12/12
Dr Guillermo Becerril	Investigator		
Dr Norman Janu	Supervisor		

Declaration by the Head of Department/School/Research organisation

Project title:	Upper Gastrointestinal & Endosurgery Database

Where an investigator for the study is also the head of department, certification must be sought from the person to whom the head of department is responsible. Investigators must not approve their own research on behalf of the department.

1. I certify that I have read the project application named above.
2. I certify that I have discussed this project and the resource implications for this department with the Co-ordinating/Principal Investigator.
3. I certify that the Co-ordinating/Principal Investigator and other investigators involved in the project have the necessary skills, training and experience to undertake their role, and where necessary, appropriate training and supervision has been arranged.

My signature indicates that I support this project being carried out using the required resources, based on the information provided by the Co-ordinating/Principal Investigator

Name of department: Division of Surgery

Name of head of department: Norman Janu

Signature: ..... **Date:** 13/12/12

Comments: