

Human Research Ethics Committee

Upper Floor Moorlands House, The Wesley Hospital
451 Coronation Drive, Auchenflower Q 4066

PO Box 499 Toowong Q 4066
Phone: 3232 7500 Facsimile: 3232 7234
Email: ethics@uhealth.com.au

Document Submission and Approval Form

Our reference 2013.30.102 Your reference

25th October 2013

Correspondence: from Dr Kevin Lah dated 3rd Septebmer 2013

Study Title: *Outcomes of using barbed polyglyconate suture (V-Loc 180) for vesico-urethral anastomosis in robot-assisted radical prostatectomy*

Investigators: Dr Troy Gianduzzo, Dr Kevin Lah

Details of documents reviewed:

- Application to conduct above named research project

The document/s listed above were received, reviewed and approved.

A handwritten signature in black ink, appearing to read "Douglas Killer", with a long horizontal line extending to the right.

Douglas Killer MBBS FRACP
Executive Officer



Human Research Ethics Committee

Initial Application for Ethical Review of Low Risk Research Involving Humans

About this Form:

This application form should be used by researchers seeking ethical approval for human research projects that meet the criteria of “low risk” research. Please complete the “Checklist for Low Risk Research Projects” to assess whether the project satisfies the criteria for low risk research ethical review and submit with the completed “Initial Application for Ethics Review of Low Risk Research Involving Humans” form to the UnitingCare Health HREC for review and approval.

Information regarding Low Risk Research Ethical Review

The National Health and Medical Research Council (NHMRC) “National Statement on Ethical Conduct in Human Research 2007”, herein called “The National Statement” recognises that human research involves a wide range of activities that have variable risks and potential benefits. The “National Statement” establishes different levels of ethical review, based on the degree of risk involved.

There are three levels of risk:

- Harm
- Discomfort
- Inconvenience

Researchers and Human Research Ethics Committees are required to determine the existence, likelihood and severity of these risks based on the research methodology and design, participant population and research activity.

Low Risk Research

The National Statement Section 2.1.6 describes research as “Low Risk” where the only foreseeable risk is one of discomfort. Discomforts may include minor side-effects of medication, discomforts related to measuring blood pressure or anxiety induced by an interview. Where the risk, even if unlikely, is more serious than discomfort, the research is not low risk. However, for research involving certain groups, methodologies or procedures, only full Human Research Ethics Committee review is allowable, irrespective of the level of the risk (see checklist).

Research Greater than Low Risk

Research involving more than low risk must complete either the “UnitingCare Health HREC Initial Application for Ethics Approval for Research Involving Humans” or “National Ethics Application Form” (NEAF) and submit for review and approval by the UnitingCare Health HREC.

Human Research Ethics Committee

Initial Application for Ethical Review of Low Risk Research Involving Humans

Checklist for Low Risk Research Projects

NHMRC "National Statement on Ethical Conduct in Human Research"
Sections 2.1.7, 5.1.18 -5.1.23

If the project includes any of the nine following types of research and/or participants, it will require full review by the HREC and **will not be eligible for low risk ethical review.**

- 1 Interventions and therapies, including clinical and non-clinical trials and innovations of new treatment modalities;
- 2 Human genetics;
- 3 Human stem cells;
- 4 Women who are pregnant and the human foetus;
- 5 People who are highly dependent on medical care who may be unable to give consent;
- 6 People with cognitive impairment;
- 7 People with an intellectual disability or a mental illness;
- 8 Research specifically targeting Aboriginal or Torres Strait Islanders;
- 9 People who may be involved in illegal activities.

If a project does **NOT** include any of the above, complete the detailed checklist below to ascertain whether the proposed research is eligible for consideration for low risk ethical review by the UnitingCare Health HREC.

1 Are any of the following topics covered in part or in whole?

- | | | |
|--|------------------------------|--|
| ▪ Research about parenting issues | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |
| ▪ Research investigating sensitive personal issues | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |
| ▪ Research investigating sensitive cultural issues | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |
| ▪ Explorations of grief, death or serious/traumatic loss | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |
| ▪ Mental Disorders e.g. depression, mood states, anxiety | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |
| ▪ Gambling | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |
| ▪ Eating disorders | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |
| ▪ Illicit drug use | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |
| ▪ Substance abuse (prescribed or over the counter) | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |
| ▪ Self report of criminal behaviour | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |
| ▪ Any psychological disorder | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |
| ▪ Suicide risks | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |
| ▪ Gender identity | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |
| ▪ Sexuality | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |
| ▪ Race or ethnic identity | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |
| ▪ Any disease or health problem | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |
| ▪ Fertility | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |
| ▪ Termination of pregnancy | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |