

12 June 2014

Dr Matthew Winter  
Department of Urology  
Gosford District Hospital  
Holden Street  
Gosford NSW 2250

Dear Dr Winter,

**NSLHD reference: RESP/14/45**

**Study Title: The Use of Portable Video Media Versus Standard Verbal Communication In The Urological Consent Process: A Randomised Trial**

**HREC reference: LNR/14/HAWKE/64**

Thank you for submitting the above project for review. Based on the information you have provided and in accordance with the NHMRC National Statement 2007 and NSW Health Policy Directive PD2010\_055 Ethical and Scientific Review of Human Research in NSW Public Health Organisations, this project has been assessed as low/negligible risk and is therefore exempt from full HREC review.

This HREC has been accredited by NSW Ministry of Health as a Lead HREC under the model for single ethical and scientific review and Certified by the NHMRC under the National model for Harmonisation of Multicentre Ethical Review (HoMER). This lead HREC is constituted and operates in accordance with the National Health and Medical Research Council's *National Statement on Ethical Conduct in Human Research* and the *CPMP/ICH Note for Guidance on Good Clinical Practice*. No HREC members with a conflict of interest were present for review of this project.

I am pleased to advise that the HREC, at a meeting of its Executive Committee held on **11 June 2014** has granted ethical and scientific approval of the above **single centre** project.

**You are reminded that this letter constitutes *ETHICAL* and *SCIENTIFIC* approval only. You must not commence this research project at a site until a completed Site Specific Assessment Form and associated documentation have been submitted to the site Research Governance Officer and Authorised. A copy of this letter must be forwarded to all site investigators for submission to the relevant Research Governance Officer.**

The project is approved to be conducted at

- **Gosford District Hospital**

If a new site(s) is to be added please inform the HREC in writing and submit a Site Specific Assessment Form (SSA) to the Research Governance Officer at the new site.

The following documents have been approved:

Document	Version	Date
Protocol	2	9 May 2014
Participant Information Sheet and Consent Form	2	17 April 2014
Patient Questionnaire (CSQ-8)	--	--

The HREC also noted your Cystoscopy video (unedited version). Please forward a copy of the final version of this video to the Research Office once complete.

The Low and Negligible Risk Research Form (LNR) reviewed by the HREC was **LNR AU/6/20F6117**.

Please note the following conditions of approval:

- HREC approval is valid for **5 years** from the date of the HREC Executive Committee meeting and expires on **11 June 2019**. The Co-ordinating Investigator is required to notify the HREC 6 months prior to this date if the project is expected to extend beyond the original approval date at which time the HREC will advise of the requirements for ongoing approval of the study.
- The Coordinating Investigator will provide an annual progress report beginning in **June 2015**, to the HREC as well as a final study report at the completion of the project in the specified format.
- The Coordinating Investigator will immediately report anything which might warrant review of ethical approval of the project in the specified format, including unforeseen events that might affect continued ethical acceptability of the project and any complaints made by participants regarding the conduct of the project.
- Proposed changes to the research protocol, conduct of the research, or length of approval will be provided to the HREC Executive for review, in the specified format.
- The HREC Executive will be notified, giving reasons, if the project is discontinued before the expected date of completion.
- Investigators holding an academic appointment (including conjoint appointments) and students undertaking a project as part of a university course are advised to contact the relevant university HREC regarding any additional requirements for the project.

Should you have any queries about your project please contact the Research Office, ph: 9926 4590, email [NSLHD-Research@health.nsw.gov.au](mailto:NSLHD-Research@health.nsw.gov.au) .

Please quote **NSLHD reference RESP/14/45** in all correspondence.

The HREC wishes you every success in your research.

Yours sincerely



**Ellie Pratt**  
*Research Ethics Manager*  
Research Office  
NORTHERN SYDNEY LOCAL HEALTH DISTRICT

cc .Ellen Hardy

TRIM RESD/14/4076