

## Melissa Carlson

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**From:** no\_reply@regis.health.nsw.gov.au  
**To:** elizabeth.fradgley@newcastle.edu.au  
**Cc:** melissa.carlson@newcastle.edu.au  
**Subject:** 2019/ETH11694: Application HREA - Approved

Date of Decision Notification: **13 Sep 2019**

Dear Dr Fradgley

Thank you for submitting the following Human Research Ethics Application (HREA) for HREC review;

**2019/ETH11694: COPING: COgnitive impairment in People with glioma and distress in the INformal care-Givers**

This project was considered by the **Hunter New England Human Research Ethics Committee** at its meeting held on **11/09/2019** and was determined to meet the requirements of the National Statement on Ethical Conduct in Human Research (2007).

This project has been Approved to be conducted at the following sites:

- **Calvary Mater Newcastle Hospital - Ms Sandy Nixon, Principal Investigator**
- **John Hunter Hospital - Ms Sandy Nixon, Principal Investigator**
- **Royal North Shore Hospital - Ms Marina Kastelan, Principal Investigator**

The following documentation was reviewed and is included in this approval:

- **HREA** (Version 4 dated 6 September 2019)
- **Response to HNEHREC Requirements** (undated)
- **Protocol** (Version 2 dated 12 March 2019)
- **Master Participant Information Statement - Patients** (Version 2 dated 28 August 2019)
- **Participant Consent Form - Patients** (Version 1 dated 12 March 2019)
- **Master Participant Information Statement - Informal Caregivers** (Version 2 dated 28 August 2019)
- **Participant Consent Form - Informal Caregivers** (Version 1 dated 12 March 2019)
- **Master Participant Information Statement - Clinicians** (Version 2 dated 28 August 2019)
- **Verbal Consent Script** (Version 1 dated 12 March 2019)
- **Consent Withdrawal Form** (Version 1 dated 12 March 2019)
- **Expression of Interest - Clinicians Only** (Version 1 dated 12 March 2019)
- **Patient Instrument Baseline** (Version 1 dated 12 March 2019)
- **Caregiver Instrument Baseline** (Version 2 dated 4 September 2019)
- **Interview Guide** (Version 1 dated 12 March 2019)
- **Coping Brochure** (Version 2 dated 28 August 2019)
- **Coping Poster** (Version undated)

[Application Documents](#) - (Please note : Due to security reasons, this link will only be active for 14 days.) It is noted that the Hunter New England Human Research Ethics Committee is constituted in accordance with the National Statement on Human Conduct in Research, 2007 (NHMRC). The approval is for a period of **5 years from the date of this e-mail (13 Sep 2019)**, on condition of the submission of Annual Reports.

We wish you all the best with the project and remind you that any changes to the application and safety reports will need to be submitted and reviewed by the approving HREC prior to implementation.

**This email constitutes ethical and scientific approval only.**

This project cannot proceed at any site until separate research governance authorisation has been obtained from the Institution under whose auspices the research will be conducted at that site.

**This HREC is constituted and operates in accordance with the National Statement on Ethical Conduct in Human Research (2007). The processes used by this HREC to review multi-centre research proposals have been certified by the National Health and Medical Research Council.**

Please contact us if you would like to discuss any aspects of this process further, as per the contact details below. We look forward to managing this application with you throughout the project lifecycle.

Kind regards

***Debbie Madden***

*Ethics Administration Officer*

*Research Ethics & Governance Office*

*Hunter New England Local Health District*

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