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NSW GOVERNMENT Health
Northern Sydney
Local Health District

15 July 2014

A/Prof Loyola McLean
Westmead Psychotherapy Program
Mental Health Sciences Building
Locked Bag 7118
Parramatta BC NSW 2124

Dear A/Prof McLean,

Study Title: 1. A Quality Improvement Project on Psychosocial screening and Outcome Tracking Following Severe Burns Injury and the Creation of a Psychosocial Database
2. A randomized-control trial (RCT) of Eye Movement Desensitisation and Reprocessing (EMDR) for post-traumatic stress (PTS) symptoms following Severe Burns Injury.
NSLHD reference: RESP/14/57
HREC reference: HREC/14/HAWKE/79

Thank you for submitting a response, dated **7 July 2014**, to the Northern Sydney Local Health District HREC's request for additional information/modification for the above project, which was first considered by the HREC at its meeting held on 14 April 2014. 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 Committee at an Executive meeting held out of session on the **14 July 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/Access Request 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:

- **Royal North Shore 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 documentation has been reviewed and approved by the HREC:

Document	Version	Date
Study Protocol	5	30 June 2014
Participant Information Sheet and Consent Form – Screening study	6	11 July 2014
Participant Information Sheet and Consent Form – Main study	6	11 July 2014
Participant Demographic Data Collection Form	1	28 March 2014
Mental Health Disorders Screening Form for the screening phase/study (S1)	1	28 March 2014
Mental Health Disorders Screening Form for the treatment phase/study (S2)	1	28 March 2014
ABCD-SRR	1	14 March 2014

Relationship Questionnaire (RQ)	1	10 November 2012
Burns modified adult attachment interview (BM-AAI)	1	28 March 2014
Burns Specific Health Scale	1	14 March 2014
Types of Interventions	1	14 March 2014
Interview guide for burns early recovery experience	1	27 March 2014

The following documentation was noted:
COPE questionnaire, DS-16, DASS questionnaire, IES-R Test, Alcohol Screen (AUDIT), PTSD Checklist – (PCL-C), PTSD Checklist – (PCL-M), DES-II, Clinician-Administered PTSD Scale for DSM-IV, A-TIP.

The National Ethics Application Form (NEAF) document reviewed by the HREC was **NEAF AU/1/AA97113**.

Please note the following conditions of approval:

- HREC approval is valid for **5 years** from the date of approval and expires on **14 July 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 Co-ordinating Investigator will provide an annual progress report beginning in **July 2015**, to the HREC as well as a final study report at the completion of the project in the specified format.
- The Co-ordinating 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 study participants regarding the conduct of the study.
- Proposed changes to the research protocol, conduct of the research, or length of HREC approval will be provided to the HREC for review, in the specified format.
- The HREC 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.

Please note it is the responsibility of the sponsor or the co-ordinating investigator of the project to register this study on a publicly available online registry (eg Australian Clinical Trial Registry www.actr.org.au) if applicable.

Should you have any queries about your project please contact the Research Office, Tel: 9926 4590, email NSLHD-Research@health.nsw.gov.au.

Please quote **NSLHD reference RESP/14/57** in all correspondence.

The HREC wishes you every success in your research.

Yours sincerely

Ellie Pratt
Research Ethics Manager
NORTHERN SYDNEY LOCAL HEALTH DISTRICT

cc. Julia Kwiet
TRIM RESD/14/5173