

**NRES Committees - North of Scotland**

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18 September 2015

Professor Markus Reuber  
Academic Neurology Unit  
Royal Hallamshire Hospital  
Glossop Road  
SHEFFIELD  
S10 2JF

Dear Professor Reuber

**Study title:** Developing a writing intervention for patients with epilepsy and non-epileptic attack disorder  
**REC reference:** 15/NS/0078  
**IRAS project ID:** 172482

Thank you for your letter of 11 September 2015, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to make a request to postpone publication, please contact the REC Manager, Mrs Carol Irvine, nosres@nhs.net.

**Confirmation of ethical opinion**

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

**Conditions of the favourable opinion**

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

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Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at <http://www.rdforum.nhs.uk>.

### Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database within 6 weeks of recruitment of the first participant (for medical device studies, within the timeline determined by the current registration and publication trees).

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non clinical trials this is not currently mandatory.

If a sponsor wishes to contest the need for registration they should contact Catherine Blewett ([catherineblewett@nhs.net](mailto:catherineblewett@nhs.net)), the HRA does not, however, expect exceptions to be made. Guidance on where to register is provided within IRAS.

**It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).**

### **Ethical review of research sites**

#### NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

#### Non-NHS sites

The Committee has not yet completed any site-specific assessment (SSA) for the non-NHS research site(s) taking part in this study. The favourable opinion does not therefore apply to any non-NHS site at present. We will write to you again as soon as an SSA application(s) has been reviewed. In the meantime no study procedures should be initiated at non-NHS sites.

### **Approved documents**

The final list of documents reviewed and approved by the Committee is as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Covering letter on headed paper: REC response letter		11 September 2015
GP/consultant information sheets or letters	1	11 September 2015
Instructions for use of medical device: Writing instructions for Participants	2	11 September 2015

<i>Document</i>	<i>Version</i>	<i>Date</i>
IRAS Checklist XML: Checklist 16092015		16 September 2015
Letters of invitation to participant: Social Media	1	14 July 2015
Non-validated questionnaire: Writing Task Questionnaire	1	14 July 2015
Letter of Invitation to Participant - Sheffield Teaching Hospital	1	14 July 2015
Independent Scientific Review	1	14 July 2015
Focused Expressive Writing Booklet	1	14 July 2015
Control Writing Booklet	1	14 July 2015
Writing Session Timetable	1	11 September 2015
Participant Consent Form: Patient	2	11 September 2015
Participant Information Sheet (PIS): Social Media	1	14 July 2015
Participant Information Sheet (PIS): Sheffield Teaching Hospital	1	14 July 2015
REC Application Form: REC Form 22072015		22 July 2015
Referee's report or other scientific critique report: Independent Scientific Review - Higher Degree Review Scheme	1	14 July 2015
Research protocol or project proposal	1	29 July 2015
Summary CV for Chief Investigator (CI): Markus Reuber		27 July 2015
Summary CV for Supervisor (student research): Gregg Rawlings		27 July 2015
Validated questionnaire: Outcome Measures	1	15 July 2015

### **Statement of compliance**

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

### **After ethical review**

#### Reporting requirements

The attached document "*After ethical review – guidance for researchers*" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

### **User Feedback**

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: <http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/>

## HRA Training

We are pleased to welcome researchers and R&D staff at our training days – see details at <http://www.hra.nhs.uk/hra-training/>

<b>15/NS/0078</b>	<b>Please quote this number on all correspondence</b>
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With the Committee's best wishes for the success of this project.

Yours sincerely



pp'd on behalf of  
**Mr Gary Cooper**  
Chair

Enclosures: "After ethical review – guidance for researchers" SL-AR2

Copy to: Mrs Samantha Lewis, Sheffield Teaching Hospitals NHS Foundation  
Trust, Research Department