

Please note: This is the favourable opinion of the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

Tayside medical Science Centre
Residency Block Level 3
George Pirie Way
Ninewells Hospital and Medical School
Dundee DD1 9SY

Professor Nicola P T Innes
Professor of Paediatric Dentistry
School of Dentistry, University of Dundee
Dundee Dental Hospital & School
Park Place
Dundee
DD1 4HN

Date: 14 August 2017
Your Ref:
Our Ref: LR/17/ES/0096
Enquiries to: Mrs Lorraine Reilly
Direct Line: 01382 383878
Email: eosres.tayside@nhs.net

Dear Professor Innes

Study Title: **BRIGHT Trial: Brushing RemInder 4 Good oral Health: the clinical and cost- effectiveness of a Short Messaging Service behaviour change programme to improve the oral health of young people living in deprived areas**

REC reference: **17/ES/0096**

IRAS project ID: **223377**

Thank you for your letter of 09 August 2017, 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, together with other named members as appropriate.

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 hra.studyregistration@nhs.net outlining the reasons for your request.

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

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

Management permission should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise). Guidance on applying for NHS permission for research is available in the Integrated Research Application System, www.hra.nhs.uk or at <http://www.rdforum.nhs.uk>.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations

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 request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from the HRA. Guidance on where to register is provided on the HRA website.

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

I am pleased to confirm that the favourable opinion applies to the following research sites, subject to site management permission being obtained prior to the start of the study at the site (see under 'Conditions of the favourable opinion below').

Research site	Principal Investigator / Local Collaborator
School of Clinical Dentistry, University of Sheffield	Dr Zoe Marshman
School of Dentistry, University of Leeds	Dr Peter Day

Approved documents

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

Document	Version	Date
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [2016DE01 Spon Let & Ins]		12 May 2017
IRAS Checklist XML [Checklist_09082017]		09 August 2017
Letter from funder [15.166.08 agree to fund letter]		13 October 2016
Non-validated questionnaire [BRIGHT Questionnaire Part 1 Baseline (tracked changes)]	2	07 August 2017
Non-validated questionnaire [BRIGHT Questionnaire Part 2 Baseline (tracked changes)]	2	07 August 2017
Non-validated questionnaire [BRIGHT Young Person Dental Assessment Baseline (tracked changes)]	2	07 August 2017
Non-validated questionnaire [BRIGHT Parent Resource Use Questionnaire Baseline (tracked changes)]	2	07 August 2017
Other [Response to REC PO]		
Other [Updated Insurance Cert]		
Participant consent form [BRIGHT Young Person Consent Form (tracked changes)]	2	09 August 2017
Participant consent form [BRIGHT Parent Carer Questionnaire Consent Form (tracked changes)]	2	09 August 2017
Participant consent form [BRIGHT Parent Carer Opt Out Form (tracked changes)]	2	09 August 2017
Participant consent form [BRIGHT T&C Event Parent Carer Consent Form (tracked changes)]	2	09 August 2017
Participant information sheet (PIS) [BRIGHT Parent Carer Information Sheet (tracked changes)]	2	09 August 2017
Participant information sheet (PIS) [BRIGHT Parent Carer Information about Questionnaires (tracked changes)]	2	09 August 2017
Participant information sheet (PIS) [BRIGHT Young Person Information Sheet (tracked changes)]	2	09 August 2017
Participant information sheet (PIS) [BRIGHT T&C Event Parent Carer Information Letter (tracked changes)]	2	09 August 2017
REC Application Form [REC_Form_06072017]		06 July 2017
Research protocol or project proposal [BRIGHT Trial Protocol (tracked changes)]	2	02 August 2017
Summary CV for Chief Investigator (CI) [Innes CV]		
Summary, synopsis or diagram (flowchart) of protocol in non technical language [BRIGHT Trial Design]	1	28 June 2017

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/>

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Please quote this number on all correspondence

With the Committee’s best wishes for the success of this project.

Yours sincerely



pp
Dr Robert Rea
Chair

Email: eosres.tayside@nhs.net

Enclosures: “After ethical review – guidance for researchers”

Copy to: Mrs Hannah Ainsworth
TASC
NHS Tayside R&D office