Health Research Authority

London - Surrey Research Ethics Committee
Nottingham Centre
The Old Chapel
Royal Standard Place
Nottingham
NG1 6FS

06 November 2019

Dr Dawn Carnes
Professorial Research Fellow
University College of Osteopathy
275 Borough High St
London
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Dear Dr Carnes

Study title:	**Crying Unsettled and disTressed Infants: Effectiveness Study of osteopathic care: a randomised controlled trial**
REC reference:	**19/LO/1620**
IRAS project ID:	**268925**

Thank you for your letter of 04 November 2019, 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 and Dr Gibson.

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.

Confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or NHS management permission (in Scotland) 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 HRA and HCRW Approval (England and Wales)/ NHS permission for research is available in the Integrated Research Application System.

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

It is a condition of the REC favourable opinion that **all clinical trials are registered** on a publicly accessible database. For this purpose, 'clinical trials' are defined as the first four project categories in IRAS project filter question 2. Registration is a legal requirement for clinical trials of investigational medicinal products (CTIMPs), except for phase I trials in healthy volunteers (these must still register as a condition of the REC favourable opinion).

Registration should take place as early as possible and within six weeks of recruiting the first research participant at the latest. Failure to register is a breach of these approval conditions, unless a deferral has been agreed by or on behalf of the Research Ethics Committee (see here for more information on requesting a deferral: https://www.hra.nhs.uk/planning-and-improving-research/research-planning/research-registration-research-project-identifiers/

As set out in the UK Policy Framework, research sponsors are responsible for making information about research publicly available before it starts e.g. by registering the research project on a publicly accessible register. Further guidance on registration is available at: https://www.hra.nhs.uk/planning-and-improving-research/research-planning/transparency-responsibilities/

You should notify the REC of the registration details. We will audit these as part of the annual progress reporting process.

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).

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, including early termination of the study
- Final report

The latest guidance on these topics can be found at https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/.

Ethical review of research sites

NHS/HSC sites

The favourable opinion applies to all NHS/HSC sites listed in the application subject to confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or management permission (in Scotland) 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/HSC sites

I am pleased to confirm that the favourable opinion applies to any non-NHS/HSC sites listed in the application, subject to site management permission being obtained prior to the start of the study at the site.

Approved documents

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

Document	*Version*	*Date*
Covering letter on headed paper [Cover letter]		09 August 2019
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only)	V1.0	01 April 2019
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [UCO 2018 Insurance Policy]		01 November 2018
GP/consultant information sheets or letters	V1.0	07 August 2019
Instructions for use of medical device [Osteopath Protocol]	V1.2	13 June 2019
Letter from funder [Contract for funding]		28 August 2019
Letter from funder [NCOR CUTIES Agreement]		27 February 2019
Letters of invitation to participant	V1.1	18 May 2019
Non-NHS/HSC Site Assessment Form [Osteopath Agreement form]	V1.0	15 April 2019
Non-NHS/HSC Site Assessment Form [Osteopath Consent and Agreement form]	V1.0	15 April 2019
Other [Follow up questionnaire]	V1.3	11 June 2019
Other [CUTIES protocol]	V1.4	30 October 2019
Other [Participant Inforamtion Leaflet]	V1.2	30 October 2019
Other [Protocol for osteopaths]	V1.3	30 October 2019
Other [CryingDiaryCUTIES]	V1.2	30 October 2019
Other [Baseline Questionnaire]	V1.4	30 October 2019
Other [Participant consent form]	V1.2	30 October 2019
Other [Recruitment flow chart]	V1.3	30 October 2019
Other [Recruitment poster]	V1.2	30 October 2019
REC Application Form [REC form]	2	17 September 2019
Referee's report or other scientific critique report [Peer Review See expert 3]		14 June 2019
Summary CV for Chief Investigator (CI)		26 July 2019

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.

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 Learning

We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities– see details at:
https://www.hra.nhs.uk/planning-and-improving-research/learning/

19/LO/1620	**Please quote this number on all correspondence**

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

Yours sincerely

pp

Mrs Chrissie Lawson
Chair

Email:nrescommittee.secoast-surrey@nhs.net

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

Copy to: Mr Steven Vogel, University College of Osteopathy