

North of Scotland Research Ethics Committee

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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

30 March 2021

Professor Anne Whittaker
Professor
University of Stirling (seconded from NHS Lothian)
NMAHP Research Unit,
Pathfoot Building, University of Stirling
Stirling.
FK9 4LA

Dear Professor Whittaker

Study title:	Governing parental opioid use: a relational ethnography.
REC reference:	21/NS/0029
IRAS project ID:	279078

Thank you for your letter of 30 March 2021 , responding to the Research Ethics Committee's (REC) 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.

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.

Good practice principles and responsibilities

The [UK Policy Framework for Health and Social Care Research](#) sets out principles of good practice in the management and conduct of health and social care research. It also outlines the responsibilities of individuals and organisations, including those related to the four elements of [research transparency](#):

1. [registering research studies](#)
2. [reporting results](#)
3. [informing participants](#)
4. [sharing study data and tissue](#)

Conditions of the favourable opinion

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

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

All research should be registered in a publicly accessible database and we expect all researchers, research sponsors and others to meet this fundamental best practice standard.

It is a condition of the REC favourable opinion that **all clinical trials are registered** on a publicly accessible database within six weeks of recruiting the first research participant. For this purpose, 'clinical trials' are defined as the first four project categories in IRAS project filter question 2. Failure to register a clinical trial 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/>

If you have not already included registration details in your IRAS application form, you should notify the REC of the registration details as soon as possible.

Further guidance on registration is available at:

<https://www.hra.nhs.uk/planning-and-improving-research/research-planning/transparency-responsibilities/>

Publication of Your Research Summary

We will publish your research summary for the above study on the research summaries section of our website, together with your contact details, no earlier than three months from the date of this favourable opinion letter.

Should you wish to provide a substitute contact point, make a request to defer, or require further information, please visit:

<https://www.hra.nhs.uk/planning-and-improving-research/application-summaries/research-summaries/>

N.B. If your study is related to COVID-19 we will aim to publish your research summary within 3 days rather than three months.

During this public health emergency, it is vital that everyone can promptly identify all relevant research related to COVID-19 that is taking place globally. If you haven't already done so, please register your study on a public registry as soon as possible and provide the REC with the registration detail, which will be posted alongside other information relating to your project. We are also asking sponsors not to request deferral of publication of research summary for any projects relating to COVID-19. In addition, to facilitate finding and extracting studies related to COVID-19 from public databases, please enter the WHO official acronym for the coronavirus disease (COVID-19) in the full title of your study. Approved COVID-19 studies can be found at: <https://www.hra.nhs.uk/covid-19-research/approved-covid-19-research/>

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
- Reporting results

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 taking part in the study, 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:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Copies of materials calling attention of potential participants to the research Recruitment Poster	v2.0	16 March 2021
Covering letter on headed paper - Covering Letter	v2.0	30 March 2021
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) - Indemnity letter	1.0	16 September 2020
GP/consultant information sheets or letters GP notification letter	1.0	01 November 2020
Interview schedules or topic guides for participants - Interview schedule - Parents & Significant Others	1.0	01 November 2020
Interview schedules or topic guides for participants Interview schedule - Young People	1.0	01 November 2020
Interview schedules or topic guides for participants - Focus Group Topic Guide - Practitioners	1.0	01 November 2020
Interview schedules or topic guides for participants - Interview schedule - Senior Managers	1.0	01 November 2020
IRAS Application Form IRAS_Form_09022021	279078/1476514/37/930	09 February 2021
IRAS Checklist		30 March 2021
Letter from funder - Award letter	1.0	15 July 2019
Letter from sponsor	1.0	16 September 2020
Letters of invitation to participant - Referrers	1.0	01 November 2020
Letters of invitation to participant - Site Manager	1.0	01 November 2020
Letters of invitation to participant - Practitioners	1.0	01 November 2020
Letters of invitation to participant - Senior Managers	1.0	01 November 2020
Non-validated questionnaire - Participant Details Sheet - Parents	1.0	01 December 2020
Non-validated questionnaire - Participant Details Sheet - Significant Others	1.0	01 November 2020
Non-validated questionnaire - Participant Details Sheet - Practitioners	1.0	01 November 2020

Non-validated questionnaire - Participant Details Sheet - Managers	1.0	01 November 2020
Non-validated questionnaire - Alternative Contacts Form - Parents	1.0	01 November 2020
Non-validated questionnaire - Chronology - Parents	1.0	01 November 2020
Non-validated questionnaire - Ecomap - Parents	1.0	01 November 2020
Non-validated questionnaire - Diary Guide - Parents	1.0	01 November 2020
Non-validated questionnaire - Go-along interview guide - Parents	1.0	01 November 2020
Non-validated questionnaire - Workday debrief guide	1.0	01 December 2020
Non-validated questionnaire - Family-Researcher Contact Record	1.0	01 November 2020
Non-validated questionnaire - Fieldnote Template	1.0	01 November 2020
Non-validated questionnaire - NOTICE poster for service sites	1.0	01 November 2020
Non-validated questionnaire - Support Services for Families	1.0	01 November 2020
Non-validated questionnaire - Welfare Concern Form	1.0	01 November 2020
Non-validated questionnaire - Data Management Plan	1.0	08 February 2021
Participant consent form - Young People	1.0	01 November 2020
Participant consent form - Assent form Children	1.0	01 December 2020
Participant consent form - Significant Others	1.0	01 November 2020
Participant consent form - Guardian	1.0	01 November 2020
Participant consent form - Site Manager	1.0	01 November 2020
Participant consent form - Practitioners	1.0	01 November 2020
Participant consent form - Senior Managers	1.0	01 November 2020
Participant consent form - Parents	v2.0	16 March 2021
Participant information sheet – Young People	1.0	04 December 2020
Participant information sheet - Children	1.0	03 November 2020
Participant information sheet - Significant Others	1.0	01 December 2020
Participant information sheet - Site Managers	1.0	01 December 2020
Participant information sheet - Senior Managers Commissioners Policymakers	1.0	01 December 2020
participant information sheet - Guardian Corporate Parent legal parents	1.0	01 December 2020
Participant information sheet - Parents	v2.0	16 March 2021
Research protocol or project proposal	v2.0	16 March 2021
Summary CV for Chief Investigator	1.0	11 January 2021
Summary, synopsis or diagram (flowchart) of protocol in non technical language - Study Flowchart	1.0	01 December 2020

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/>

IRAS project ID: 279078 Please quote this number on all correspondence
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With the Committee's best wishes for the success of this project.

Yours sincerely



Dr Ruth Stephenson
Chair

Enclosures: "After ethical review – guidance for researchers" [\[SL-AR2\]](#)

Copy to: Ms Rachel Beaton