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21 September 2021

Dear Professor Whittaker,

**HRA and Health and Care
Research Wales (HCRW)
Approval Letter**

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

I am pleased to confirm that [HRA and Health and Care Research Wales \(HCRW\) Approval](#) has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications received. You should not expect to receive anything further relating to this application.

Please now work with participating NHS organisations to confirm capacity and capability, in line with the instructions provided in the “Information to support study set up” section towards the end of this letter.

How should I work with participating NHS/HSC organisations in Northern Ireland and Scotland?

HRA and HCRW Approval does not apply to NHS/HSC organisations within Northern Ireland and Scotland.

If you indicated in your IRAS form that you do have participating organisations in either of these devolved administrations, the final document set and the study wide governance report (including this letter) have been sent to the coordinating centre of each participating nation. The relevant national coordinating function/s will contact you as appropriate.

Please see [IRAS Help](#) for information on working with NHS/HSC organisations in Northern Ireland and Scotland.

How should I work with participating non-NHS organisations?

HRA and HCRW Approval does not apply to non-NHS organisations. You should work with your non-NHS organisations to [obtain local agreement](#) in accordance with their procedures.

What are my notification responsibilities during the study?

The standard conditions document “[After Ethical Review – guidance for sponsors and investigators](#)”, issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

The [HRA website](#) also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures.

Who should I contact for further information?

Please do not hesitate to contact me for assistance with this application. My contact details are below.

Your IRAS project ID is **279078**. Please quote this on all correspondence.

Yours sincerely,
Laura Greenfield

Approvals Specialist

Email: approvals@hra.nhs.

Copy to: *Ms Rachel Beaton*

List of Documents

The final document set assessed and approved by HRA and HCRW Approval is listed below.

<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 RELATIONS STUDY]	1.0	08 February 2021
Covering letter on headed paper [Covering Letter RELATIONS STUDY]	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]	279078/1476 514/37/930	09 February 2021
Letter from funder [Award letter]	1.0	15 July 2019
Letter from sponsor [Sponsor letter]	1.0	16 September 2020
Letters of invitation to participant [Invitation letter - Referrers]	1.0	01 November 2020
Letters of invitation to participant [Invitation letter - Site Manager]	1.0	01 November 2020
Letters of invitation to participant [Invitation letter - Practitioners]	1.0	01 November 2020
Letters of invitation to participant [Invitation letter - 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
Organisation Information Document	1	20 May 2021
Participant consent form [Consent form Young People]	1.0	01 November 2020

Participant consent form [Assent form Children]	1.0	01 December 2020
Participant consent form [Consent form Significant Others]	1.0	01 November 2020
Participant consent form [Consent form Guardian]	1.0	01 November 2020
Participant consent form [Consent form Site Manager]	1.0	01 November 2020
Participant consent form [Consent form Practitioners]	1.0	01 November 2020
Participant consent form [Consent form Senior Managers]	1.0	01 November 2020
Participant consent form [Consent form Parents]	v2.0	16 March 2021
Participant information sheet (PIS) [PIS for YOUNG PEOPLE]	1.0	04 December 2020
Participant information sheet (PIS) [PIS for Children]	1.0	03 November 2020
Participant information sheet (PIS) [PIS for SIGNIFICANT OTHERS]	1.0	01 December 2020
Participant information sheet (PIS) [PIS for SITE MANAGERS]	1.0	01 December 2020
Participant information sheet (PIS) [PIS for SENIOR MANAGERS COMMISSIONERS POLICYMAKERS]	1.0	01 December 2020
Participant information sheet (PIS) [PIS for GUARDIAN CORPORATE PARENT LEGAL PARENTS]	1.0	01 December 2020
Participant information sheet (PIS) [PIS for PARENTS]	v2.0	16 March 2021
Research protocol or project proposal [Protocol_Relations_Study]	v2.0	16 March 2021
Summary CV for Chief Investigator (CI) [CV 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

Information to support study set up

The below provides all parties with information to support the arranging and confirming of capacity and capability with participating NHS organisations in England and Wales. This is intended to be an accurate reflection of the study at the time of issue of this letter.

Types of participating NHS organisation	Expectations related to confirmation of capacity and capability	Agreement to be used	Funding arrangements	Oversight expectations	HR Good Practice Resource Pack expectations
This is a multicentre non-commercial organisation sponsored study where research sites are to undertake the same research activities	Research activities should not commence at participating NHS organisations in England or Wales prior to their formal confirmation of capacity and capability to deliver the study.	An Organisation Information Document has been submitted and the sponsor is not requesting and does not expect any other site agreement to be used.	Funding arrangements outlined in the Organisation Information Document	A Principal Investigator is expected to be in place at the participating NHS site	Should prior contractual arrangements with the host NHS site(s) not be in place, the researchers undertaking research activities at the NHS trusts would be expected to obtain Letters of Access on the basis of Research Passports if University employed, or NHS to NHS confirmation of pre-engagement checks letters if they are NHS employed, or have already Honorary Research Contracts. Standard DBS checks and occupational health clearance would be appropriate.

Other information to aid study set-up and delivery

This details any other information that may be helpful to sponsors and participating NHS organisations in England and Wales in study set-up.

1. The applicant has indicated that they do not intend to apply for inclusion on the NIHR CRN Portfolio.
2. The CAG requested changes to patient facing documents (patient/staff notification flyers)
3. Please update the Participant Information and Informed Consent Documents with the IRAS ID