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31 October 2019

Dear Professor Holti

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

Study title:	**Before, During and After Gender Identity Specialist Services: improving the integration of care for trans adults**
IRAS project ID:	**262467**
Protocol number:	**661833**
REC reference:	**19/EM/0289**
Sponsor	**The Open University**

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 **262467**. Please quote this on all correspondence.

Yours sincerely,

Barbara Cuddon

Approvals Specialist

Email: hra.approval@nhs.net

Copy to: *Prof Richard W Holti*

List of Documents

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

Document	*Version*	*Date*
Copies of advertisement materials for research participants	1.0	05 August 2019
Copies of advertisement materials for research participants	2.1	05 August 2019
Covering letter on headed paper [Cover letter from chief investigator]		08 August 2019
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Confirmation of Sponsor's insurance]		17 December 2018
HRA Schedule of Events [HRA Assessed]	1.0	10 September 2019
Interview schedules or topic guides for participants [Topics to be covered in interviews with Leeds GIS staff]	1.0	24 July 2019
Interview schedules or topic guides for participants [Topics to be covered in Leeds GIS service user interviews]	3.0	24 July 2019
Interview schedules or topic guides for participants [Topics to be covered in national sample qualitative interviewss GIS service user interviews]	2.0	21 June 2019
IRAS Application Form [IRAS_Form_09082019]		09 August 2019
IRAS Application Form XML file [IRAS_Form_09082019]		09 August 2019
IRAS Checklist XML [Checklist_09082019]		09 August 2019
Letter from funder [Confirmation of funds]		
Letters of invitation to participant [Invitation to offer a follow up interview, from the screening survey]	1.0	05 August 2019
Letters of invitation to participant [Letter and email to be sent to Leeds GIS clinic list and waiting list]	3.0	06 August 2019
Letters of invitation to participant [Leaflet inviting Leeds GIS staff to participate]	2.1	05 August 2019
Non-validated questionnaire [Screening survey as piloted online, as pdf]	1.0	05 August 2019
Non-validated questionnaire [Guide for paper survey]	1.2	18 October 2019
Non-validated questionnaire [Paper version of survey as previously reviewed by REC]	1.2	30 October 2019
Organisation Information Document	1.1	06 September 2019
Other [Applicant Responses to Ethical and Governance Review]		27 October 2019
Other [Liability insurance]		31 December 2018
Other [Prof indemnity ins.]		21 December 2018
Other [Draft agenda for feedback workshops within each organisational case study of integrated care]	1.0	07 August 2019
Other [Draft agenda for national workshop in November 2020 to review findings and outputs from the whole project]	1.0	21 June 2019
Participant consent form [Consent form for paper survey]	1.2	18 October 2019
Participant consent form [Consent form for all interviews]	1.1	08 August 2019
Participant consent form [Consent form for participating in feedback workshops]	1.0	08 August 2019
Participant information sheet (PIS) [PIS for national screening survey]	4.3	16 October 2019
Participant information sheet (PIS) [PIS for interviews with national qualitative sample]	3.1	16 October 2019
Participant information sheet (PIS) [PIS for service user interviews in Leeds GIS case study]	2.0	18 October 2019
Participant information sheet (PIS) [PIS for staff interviews in Leeds	2.2	18 October 2019

GIS case study]		
Referee's report or other scientific critique report [Review by funder]		19 June 2019
Referee's report or other scientific critique report [Response to funder]		17 July 2019
Research protocol or project proposal [ICTA Protocol]	1.0	15 May 2019
Schedule of Events or SoECAT [Schedule of events for Leeds GIS case study]	1.0	08 August 2019
Summary CV for Chief Investigator (CI) [Short research CV]		08 August 2019

IRAS project ID	262467

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
All sites will perform the same research activities therefore there is only one site type.	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.	No study funding will be provided to sites as per the Organisation Information Document. This needs to be checked when right OID submitted.	It is expected that a Principal Investigator would be appointed at study sites	The activities at the participating NHS organization will be undertaken by local staff therefore it is expected that adequate contractual relationship with the host organization are already in place. Where arrangements are not already in place, research staff not employed by the NHS host organisation undertaking any of the research activities listed in the research application would be expected to obtain a Letter of Access based on standard DBS checks and occupational health clearance.

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.

The applicant has indicated that they intend to apply for inclusion on the NIHR CRN Portfolio.