

Dr Matthew Williams
Consultant Clinical Oncologist
Imperial College Healthcare NHS Trust
Dept. Clinical Oncology - Charing Cross Hospital
Fulham Palace Road
London
W6 8RF

Email: approvals@hra.nhs.uk

12 July 2023

Dear Dr Williams

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

Study title:	INDIGO Community: Investigating DIGital Outcomes in a community setting for patients living with and beyond a diagnosis of cancer. To understand more about the long-term outcomes and service use of patients living with and beyond a diagnosis of cancer Phase II randomised feasibility research administering questionnaires in a mixed methods study.
IRAS project ID:	324034
REC reference:	23/PR/0405
Sponsor	Imperial College London, Head of Research Governance and Integrity

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 **324034**. Please quote this on all correspondence.

Yours sincerely,

Sarah Prothero
Approvals Specialist

Email: approvals@hra.nhs.uk

Copy to: *Keith Boland, Imperial College London*

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 [Indigo Community - Adverts (overall)]	1.1	21 February 2023
Copies of materials calling attention of potential participants to the research [Indigo Community - Facebook]	1.0	10 February 2023
Copies of materials calling attention of potential participants to the research [Indigo Community - Instagram]	1.0	10 February 2023
Copies of materials calling attention of potential participants to the research [Indigo Community - Twitter]	1.0	10 February 2023
Covering letter on headed paper [Indigo Community - Covering letter]	1.0	27 March 2023
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Indigo Community - Verification certificate]	1.0	01 August 2022
IRAS Application Form [IRAS_Form_03042023]		03 April 2023
Letter from funder [Indigo Community - Award letter]	0.1	11 August 2022
Letter from sponsor [Indigo Community - College non CTIMP sponsor letter]	0.1	10 March 2023
Non-validated questionnaire [Indigo Community - Block - Non-validated questionnaires]	1.2	23 March 2023
Organisation Information Document [Indigo Community - Organisation Information Document - Data-Processing]	1.0	23 March 2023
Organisation Information Document [Indigo Community - Organisation Information Document - NonCommercial]	1.0	23 March 2023
Other [Indigo Community - end of survey message]	0.4	23 March 2023
Other [Indigo Community - 1. initial questionnaire]	1.2	23 March 2023
Other [Indigo Community - 2. follow-up questionnaire]	1.0	23 March 2023
Other [Indigo Community - Transparency notice]	0.1	23 March 2023
Other [Indigo Community - Ethical Review - Response - 2023.05.16]	1.0	16 May 2023
Other [Indigo Community - Patient Information Sheet_2023.05.16]	1.2	16 May 2023
Other [Indigo Community - Ethical Review - Response - 2023.07.11.pdf]	1.0	11 July 2023
Other [Indigo Community Protocol - v1.3 - 2023.02.28.pdf]	1.3	11 July 2023
Participant consent form [Indigo Community - Block - 1. Initial consent]	1.2	23 March 2023
Participant consent form [Indigo Community - Block - 2. Consent to linkage]	1.2	23 March 2023
Participant consent form [Indigo Community - Block - 3. Consent to future contact]	1.2	23 March 2023
Participant information sheet (PIS) [Indigo Community - Patient Information Sheet]	1.1	23 March 2023
Referee's report or other scientific critique report [Indigo Community - Peer Review Certificate]	1.0	22 February 2023
Referee's report or other scientific critique report [Indigo Community - Peer Review 1]	1.0	22 February 2023
Referee's report or other scientific critique report [Indigo Community - Peer Review 2]	1.0	22 February 2023
Referee's report or other scientific critique report [Indigo Community - Extra Peer Review]	1.0	23 February 2023
Summary CV for Chief Investigator (CI) [Indigo Community - Matt Williams - CV]	1.0	20 January 2023
Summary, synopsis or diagram (flowchart) of protocol in non technical	1.0	10 February 2023

language [Indigo Community - Process time]		
Summary, synopsis or diagram (flowchart) of protocol in non technical language [Indigo Community - survey flow]	1.0	10 February 2023
Summary, synopsis or diagram (flowchart) of protocol in non technical language [Indigo Community - data flowchart]	1.0	10 February 2023
Validated questionnaire [Indigo Community - Block - Validated questionnaires]	1.1	23 March 2023

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 non-commercial single site study taking place in the NHS where that single NHS organisation's partner University is the study sponsor therefore there is only one site type.	<p>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.</p> <p>This is a single site study sponsored by that single NHS organisation's partner University. You should work with the sponsor/JRO R&D office to make arrangements to set up the study. The sponsor/JRO R&D office will confirm to you when the study can start following issue of HRA and HCRW Approval.</p>	This is a non-commercial single site study taking place in the NHS where that single NHS organisation's partner University is the study sponsor. Therefore, no study agreements are required.	External study funding has been sought via Brain Tumour Research Campaign	A Principal Investigator should be appointed at participating NHS organisations of this type.	Where an external individual will be conducting any of the research activities that will be undertaken at this site type then they would be expected to hold a Letter of Access. This should be issued be on the basis of a Research Passport (if university employed) or an NHS-to-NHS confirmation of pre-engagement checks letter (if NHS employed). These should confirm Occupational Health Clearance. These should confirm standard DBS checks and appropriate barred list checks.

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.