

Dr David Pinato
Consultant Medical Oncologist, MD
Room 138 ICTEM Building Level 1, Hammersmith
Hospital
Du Cane Road
London
W12 0HS

Email: approvals@hra.nhs.uk
HCRW.approvals@wales.nhs.uk

26 March 2020

Dear Dr Pinato

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

Study title:	ONCOVID: natural history and outcomes of cancer patients during the COVID19 epidemic.
IRAS project ID:	282140
Protocol number:	1
REC reference:	20/HRA/1608
Sponsor	Imperial College London

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 “[After HRA Approval – guidance for sponsors and investigators](#)” document on the HRA website gives detailed guidance on reporting expectations for studies with HRA and HCRW Approval, 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 **282140**. Please quote this on all correspondence.

Yours sincerely,

Christie Ord

Approvals Specialist

Email: approvals@hra.nhs.uk

Copy to: *Becky Ward, Imperial College Healthcare NHS Trust/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>
Covering letter on headed paper [Coverletter]		24 March 2020
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Insurance]	1	24 March 2020
IRAS Application Form [IRAS_Form_26032020]		26 March 2020
IRAS Application Form XML file [IRAS_Form_26032020]		26 March 2020
IRAS Checklist XML [Checklist_26032020]		26 March 2020
Letter from sponsor [Sponsor]	1	24 March 2020
Referee's report or other scientific critique report [Referee]	1	24 March 2020
Research protocol or project proposal [Protocol]	v1.1	24 March 2020
Summary CV for Chief Investigator (CI) [CV]	1	24 March 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 non-commercial study with two sites, where both sites are sponsored by a university who has a partnership with the NHS organisation. Therefore there is only one site type.	This study has two sites, where both sites are sponsored by a university who has a partnership with the NHS organisation. You should work with your sponsor R&D office to make arrangements to set up the study. The sponsor R&D office will confirm to you when the study can start following issue of HRA and HCRW Approval.	This study has two sites, where both sites are sponsored by a university who has a partnership with the NHS organisation therefore no agreements are expected.	External study funding has not been sought.	A Principal Investigator should be appointed at study sites	The sponsor has stated that local staff in participating organisations in England who have a contractual relationship with the organisation will undertake the expected activities. Therefore no honorary research contracts or letters of access are expected for this study.

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 do not intend to apply for inclusion on the NIHR CRN Portfolio.