East of England - Cambridge East Research Ethics Committee
The Old Chapel
Royal Standard Place
Nottingham
NG1 6FS

Telephone: 0207 972 2503

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

17 March 2020

Professor Peter Horby
University of Oxford
New Richards Building, Old Road Campus, Headington
Oxford
OX3 7LG

Dear Professor Horby

Study title:	**Randomised Evaluation of COVID-19 Therapy (RECOVERY)**
REC reference:	**20/EE/0101**
Protocol number:	**NDPHRECOVERY**
EudraCT number:	**2020-001113-21**
IRAS project ID:	**281712**

Thank you for your response to the Committee's request for further information on the above research.

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.

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

It is a condition of the REC favourable opinion that **all clinical trials are registered** on a publicly accessible database. For this purpose, 'clinical trials' are defined as the first four project categories in IRAS project filter question 2. Registration is a legal requirement for clinical trials of investigational medicinal products (CTIMPs), except for phase I trials in healthy volunteers (these must still register as a condition of the REC favourable opinion).

Registration should take place as early as possible and within six weeks of recruiting the first research participant at the latest. Failure to register 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/

As set out in the UK Policy Framework, research sponsors are responsible for making information about research publicly available before it starts e.g. by registering the research project on a publicly accessible register. Further guidance on registration is available at:
https://www.hra.nhs.uk/planning-and-improving-research/research-planning/transparency-responsibilities/

You should notify the REC of the registration details. We will audit these as part of the annual progress reporting process.

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/

Clinical trial authorisation must be obtained from the Medicines and Healthcare products Regulatory Agency (MHRA).
[Please remove the following sentence for HRA Approval studies as the CTA status will be checked by the assessor]:
The sponsor is asked to provide the Committee with a copy of the notice from the MHRA, either confirming clinical trial authorisation or giving grounds for non-acceptance, as soon as this is available.

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

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 listed in the application 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).

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
Confirmation of Clinical Trial Authorisation from MHRA and relevant correspondence	1	17 March 2020
Covering letter on headed paper		13 March 2020
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Sponsor letter]		13 March 2020
Investigator Brochure [IB for interferon]	11	05 March 2020
Investigator's brochure / IMP Dossier		20 August 2019
IRAS Application Form [IRAS_Form_13032020]		13 March 2020
IRAS Application Form XML file [IRAS_Form_13032020]		13 March 2020
IRAS Checklist XML [Checklist_13032020]		13 March 2020
Letter from sponsor		13 March 2020
Other [SmPC for dexamethasone]		16 May 2018
Other [poster]	1	16 March 2020
Participant consent form [PIS & ICF]	V1.0	13 March 2020
Participant information sheet (PIS) [Legal representative information sheet]	V1.0	13 March 2020
Participant information sheet (PIS) [PIS clean]	1.3	17 March 2020
Participant information sheet (PIS) [PIS Tracked]	1.3	17 March 2020
Research protocol or project proposal [Protocol]	V1.0	13 March 2020
Summary CV for Chief Investigator (CI) [CI CV]		12 March 2020
Summary of any applicable exclusions to sponsor insurance (non-NHS sponsors only)		13 March 2020
Summary of product characteristics (SmPC)		09 March 2020

Statement of compliance

This Committee is recognised by the United Kingdom Ethics Committee Authority under the Medicines for Human Use (Clinical Trials) Regulations 2004, and is authorised to carry out the ethical review of clinical trials of investigational medicinal products.

The Committee is fully compliant with the Regulations as they relate to ethics committees and the conditions and principles of good clinical practice.

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: 281712 Please quote this number on all correspondence

With the Committee's best wishes for the success of this project.

Yours sincerely

Catherine Adams
Approvals Manager on behalf of

Dr Alan Lamont
Chair

Email:CambridgeEast.REC@hra.nhs.uk

Enclosures: List of names and professions of members who were present at the meeting and those who submitted written comments

Copy to: CTRG

East of England - Cambridge East Research Ethics Committee

Attendance at Committee meeting on 17 March 2020

Committee Members:

Name	*Profession*	*Present*	*Notes*
Dr Philip Bedford	Retired Study Responsible Scientist	Yes	
Dr Helen Burns	Retired GP	Yes	
Dr Alan Calverd	Scientific Consultant	Yes	
Mr John Chandler	Former Chief Executive PSP Association	No	
Mrs Ann Colvill	Retired Employment Tribunal Service	Yes	
Mr Edward Gibbes	Freelance journalist	Yes	
Dr Sinead Healy	Research Governance Facilitator	No	
Mrs Victoria Hollamby	Research Governance Advisor	Yes	
Dr Alan Lamont	Retired Consultant Oncologist	No	
Mr Trevor McCann	Retired Strategic Development Consultant	Yes	
Miss Sophie Newton	Hearing Implant Research Nurse	Yes	
Dr Derek Prater	Pharmacist	Yes	
Dr Wendi Qian	Senior Statistician	No	
Dr Jessica Santos	Global Compliance & Quality Director	Yes	
Dr Joyce Whittington	Psychologist	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Tad Jones	Approvals Officer