

**Partner Organisations:**

Health Research Authority, England

NHS Research Scotland

HSC Research &amp; Development, Public Health Agency, Northern Ireland

NIHR Clinical Research Network, England

NISCHR Permissions Co-ordinating Unit, Wales

**Notification of Non-Substantial/Minor Amendments(s) for NHS Studies**

This template **must only** be used to notify NHS/HSC R&D office(s) of amendments, which are **NOT** categorised as Substantial Amendments.

**If you need to notify a Substantial Amendment to your study then you MUST use the appropriate Substantial Amendment form in IRAS.**

**Instructions for using this template**

- For guidance on amendments refer to <http://www.hra.nhs.uk/research-community/during-your-research-project/amendments/>
- This template should be completed by the CI and optionally authorised by Sponsor, if required by sponsor guidelines.
- This form should be submitted according to the instructions provided for NHS/HSC R&D at <http://www.hra.nhs.uk/research-community/during-your-research-project/amendments/which-review-bodies-need-to-approve-or-be-notified-of-which-types-of-amendments/>. If you do not submit your notification in accordance with these instructions then processing of your submission may be significantly delayed.

**1. Study Information**

<b>Full title of study:</b>	Randomised Evaluation of COVID-19 Therapy
<b>IRAS Project ID:</b>	281712
<b>Sponsor Amendment Notification number:</b>	NSA1
<b>Sponsor Amendment Notification date:</b>	18-Mar-2020
<b>Details of Chief Investigator:</b>	
Name [first name and surname]	Peter Horby
Address:	NDM New Richards Building
Postcode:	
Contact telephone number:	
Email address:	peter.horby@ndm.ox.ac.uk
<b>Details of Lead Sponsor:</b>	
Name:	University of Oxford
Contact email address:	ctrng@admin.ox.ac.uk
<b>Details of Lead Nation:</b>	
Name of lead nation <i>delete as appropriate</i>	England
If England led is the study going through CSP? <i>delete as appropriate</i>	Yes
<b>Name of lead R&amp;D office:</b>	Oxford University Hospitals NHS Foundation Trust

**Partner Organisations:**

Health Research Authority, England

NIHR Clinical Research Network, England

NHS Research Scotland

NISCHR Permissions Co-ordinating Unit, Wales

HSC Research &amp; Development, Public Health Agency, Northern Ireland

**2. Summary of amendment(s)**

This template **must only** be used to notify NHS/HSC R&D office(s) of amendments, which are **NOT** categorised as Substantial Amendments.

**If you need to notify a Substantial Amendment to your study then you MUST use the appropriate Substantial Amendment form in IRAS.**

No.	Brief description of amendment (please enter each separate amendment in a new row)	Amendment applies to (delete/ list as appropriate)		List relevant supporting document(s), including version numbers (please ensure all referenced supporting documents are submitted with this form)		R&D category of amendment (category A, B, C) For office use only
		Nation	Sites	Document	Version	
1	Addition of details to PIS/ICF to support linkage with NHS Digital	England	All sites or list affected sites	RECOVERY PIS+ICF	V1.4	A
		Northern Ireland	All sites or list affected sites			
		Scotland	All sites or list affected sites			
		Wales	All sites or list affected sites			
2						
3						
4						
5						

[Add further rows as required]

**Partner Organisations:**

Health Research Authority, England

NHS Research Scotland

HSC Research &amp; Development, Public Health Agency, Northern Ireland

NIHR Clinical Research Network, England

NISCHR Permissions Co-ordinating Unit, Wales

**3. Declaration(s)****Declaration by Chief Investigator**

- I confirm that the information in this form is accurate to the best of my knowledge and I take full responsibility for it.
- I consider that it would be reasonable for the proposed amendment(s) to be implemented.

Signature of Chief Investigator:



Print name: Peter Horby .....

Date: 18-Mar-2020

**Optional Declaration by the Sponsor's Representative (as per Sponsor Guidelines)***The sponsor of an approved study is responsible for all amendments made during its conduct.**The person authorising the declaration should be authorised to do so. There is no requirement for a particular level of seniority; the sponsor's rules on delegated authority should be adhered to.*

- I confirm the sponsor's support for the amendment(s) in this notification.

Signature of sponsor's representative: .....

Print name:.....

Post: .....

Organisation:.....

Date:.....