

Amendment Tool

v1.2 11 Jun 2020

For office use

QC: No

Section 1: Project information

Short project title*:	RECOVERY Trial			
IRAS project ID* (or REC reference if no IRAS project ID is available):	281712			
Sponsor amendment reference number*:	Substantial Amendment 10			
Sponsor amendment date* (enter as DD/MM/YY):	24 October 2020			
Summary of amendment including justification*:	We wish to add a further randomisation to the RECOVERY trial to assess whether aspirin may improve outcomes in people hospitalised with COVID-19.			
Project type:	<input checked="" type="radio"/> Specific study <input type="radio"/> Research tissue bank <input type="radio"/> Research database			
Has the study been reviewed by a UKECA-recognised Research Ethics Committee (REC) prior to this amendment?:	<input checked="" type="radio"/> Yes		<input type="radio"/> No	
What type of UKECA-recognised Research Ethics Committee (REC) review is applicable?:	<input checked="" type="radio"/> NHS/HSC REC <input type="radio"/> Ministry of Defence (MoDREC)			
Is all or part of this amendment being resubmitted to the Research Ethics Committee (REC) as a modified amendment?	<input type="radio"/> Yes		<input checked="" type="radio"/> No	
Where is the NHS/HSC Research Ethics Committee (REC) that reviewed the study based?:	England	Wales	Scotland	Northern Ireland
	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Was the study a clinical trial of an investigational medicinal product (CTIMP) OR does the amendment make it one?:	<input checked="" type="radio"/> Yes		<input type="radio"/> No	
Was this clinical trial of an investigational medicinal product (CTIMP) processed under the Combined Ways of Working (CWoW) pilot?:	<input type="radio"/> Yes		<input checked="" type="radio"/> No	
Did the study receive Pharmacy Assurance?:	<input checked="" type="radio"/> Yes		<input type="radio"/> No	
Was the study a clinical investigation or other study of a medical device OR does the amendment make it one?:	<input type="radio"/> Yes		<input checked="" type="radio"/> No	
Did the study involve the administration of radioactive substances, therefore requiring ARSAC review, OR does the amendment introduce this?:	<input type="radio"/> Yes		<input checked="" type="radio"/> No	
Did the study involve the use of research exposures to ionising radiation (not involving the administration of radioactive substances) OR does the amendment introduce this?:	<input type="radio"/> Yes		<input checked="" type="radio"/> No	
Did the study involve adults lacking capacity OR does the amendment introduce this?:	<input checked="" type="radio"/> Yes		<input type="radio"/> No	
Did the study involve access to confidential patient information without consent OR does the amendment introduce this?:	<input type="radio"/> Yes		<input checked="" type="radio"/> No	
Did the study involve prisoners OR does the amendment introduce this?:	<input type="radio"/> Yes		<input checked="" type="radio"/> No	
Did the study involve NHS/HSC organisations prior to this amendment?:	<input checked="" type="radio"/> Yes		<input type="radio"/> No	
Did the study involve non-NHS/HSC organisations OR does the amendment introduce them?:	<input type="radio"/> Yes		<input checked="" type="radio"/> No	
	England	Wales	Scotland	Northern Ireland
Lead nation for the study:	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Which nations had participating NHS/HSC organisations prior to this amendment?	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Which nations will have participating NHS/HSC organisations after this amendment?	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

Section 2: Summary of change(s)

What do you want to update?:	<input checked="" type="radio"/> Project information <input type="radio"/> New site/PI only
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Please note: Each change being made as part of the amendment must be entered separately. For example, if an amendment to a clinical trial of an investigational medicinal product (CTIMP) involves an update to the Investigator's Brochure (IB), affecting the Reference Safety Information (RSI) and so the information documents to be given to participants, these should be entered into the amendment tool as three separate changes. A list of all possible changes is available on the "Glossary of Changes" tab. To add another change, tick the "Add another change" box.

Change 1				
Area of change (select)*:	Study Design			
Specific change (select - only available when area of change is selected first)*:	New arm - Addition of a study arm or placebo/control group			
Further information (free text):	We wish to add a further randomisation for eligible participants between aspirin and usual care in order to assess whether aspirin may improve outcomes (through its antiplatelet and anti-inflammatory effects). This arm has been recommended by the UK COVID-19 Therapeutics Advisory Panel.			
Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Will all participating NHS/HSC organisations be affected by this change, or only some?:	<input checked="" type="radio"/> All		<input type="radio"/> Some	

Add another change: ☒

Change 2				
Area of change (select)*:	Study Documents			
Specific change (select - only available when area of change is selected first)*:	Other minor document change that can be implemented within existing resource in place at participating organisations - Please specify in the free text below			
Further information (free text):	We have amended the PIS/ICF accordingly. We have also added a sentence (at our sponsor's request) to inform participants that they may receive newsletters from the study team. The children's PIS/ICF has been updated to handle children aged >=16 appropriately.			
Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Will all participating NHS/HSC organisations be affected by this change, or only some?:	<input checked="" type="radio"/> All		<input type="radio"/> Some	

Add another change: ☒

Change 3				
Area of change (select)*:	Study Documents			
Specific change (select - only available when area of change is selected first)*:	Other minor document change that can be implemented within existing resource in place at participating organisations - Please specify in the free text below			
Further information (free text):	We have clarified the inclusion criterion "SARS-CoV-2 infection" to "SARS-CoV-2 disease". This is not a material change because our guidance to sites has always been to recruit people who have symptomatic SARS-CoV-2 infections, but we would like to take this opportunity to clarify the text.			
Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Will all participating NHS/HSC organisations be affected by this change, or only some?:	<input checked="" type="radio"/> All		<input type="radio"/> Some	

Add another change: ☒

Change 4	
Area of change (select)*:	Study Documents

Specific change (select - only available when area of change is selected first)*:	Other minor document change that can be implemented within existing resource in place at participating organisations - Please specify in the free text below			
Further information (free text):	We have made some changes to the protocol to improve clarity and readability for users, by improving the flow and avoiding unnecessary duplication.			
Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Will all participating NHS/HSC organisations be affected by this change, or only some?:	<input checked="" type="radio"/> All		<input type="radio"/> Some	

Add another change: ☒

Change 5				
Area of change (select)*:	Study Management			
Specific change (select - only available when area of change is selected first)*:	Non-UK countries - Inclusion or withdrawal of an EU Member State or third country			
Further information (free text):	Further to V9.1 of the protocol which included possibility of non-UK countries, V9.2 provides some specific details of coordinating centres (and which interventions will be available where).			
Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Will all participating NHS/HSC organisations be affected by this change, or only some?:	<input checked="" type="radio"/> All		<input type="radio"/> Some	

Add another change: ☐

Section 3: Declaration(s) and lock for submission

Declaration by the Sponsor or authorised delegate	
<ul style="list-style-type: none">I confirm that the Sponsor takes responsibility for the completed amendment toolI confirm that I have been formally authorised by the Sponsor to complete the amendment tool on their behalf	
Name [first name and surname]*:	Heather House
Email address*:	ctrg@admin.ox.ac.uk

Lock for submission
<p>Please note: This button will only become available when all mandatory (*) fields have been completed. When the button is available, clicking it will generate a PDF copy of the completed amendment tool that can be included in the amendment submission. Please ensure that the amendment tool is completed correctly before locking it for submission.</p>
<div>Lock for submission</div>
After locking the tool, refer to the "Submission Guidance" tab for further information about the next steps for the amendment.

Section 4: Review bodies for the amendment

Please note: This section is for **information only**. Details in this section will complete automatically based on the options selected in Sections 1 and 2.

Review bodies															
UK wide:				England and Wales:				Scotland:				Northern Ireland:			
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	REC	Competent Authority MHRA - Medicines	Competent Authority MHRA - Devices	ARSAC	Radiation Assurance	UKSW Governance	REC (MCA)	CAG	HMPPS	HRA and HCRW Ap	REC (AWIA)	PBPP	SPS (RAEC)	National coordinating	HSC REC	HSC Data Guardians	Prisons	National coordinating	Category:
Change 1:	Y	Y				(Y)				(Y)				(Y)				(Y)	A
Change 2:	N	N				(Y)				(Y)				(Y)				(Y)	C
Change 3:	N	N				(Y)				(Y)				(Y)				(Y)	C
Change 4:	N	N				(Y)				(Y)				(Y)				(Y)	C
Change 5:	N	N				(Y)				(Y)				(Y)				(Y)	C
Overall reviews for the amendment:																			
Full review:	Y	Y				N				N				N				N	
Notification only:	N	N				Y				Y				Y				Y	
Overall amendment type:	Substantial for review																		
Overall Category:	A																		