

# Amendment Tool

v1.1 22 May 2020

For office use

QC: Yes

## Section 1: Project information

Short project title*:	The RECOVERY Trial			
IRAS project ID* (or REC reference if no IRAS project ID is available):	281712			
Sponsor amendment reference number*:	Substantial Amendment 6			
Sponsor amendment date* (enter as DD/MM/YY):	18 June 2020			
Summary of amendment including justification*:	Removal of two IMPs from trial protocol following publication of results. Matching updates to PIS/ICF at request of REC.			
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)*:	CTIMP IMP

Specific change (select - only available when area of change is selected first)*:	Other - Please specify in the free text below			
Further information (free text):	Removal of hydroxychloroquine because results have been analysed and made public.			
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)*:	CTIMP IMP			
Specific change (select - only available when area of change is selected first)*:	Other - Please specify in the free text below			
Further information (free text):	Removal of corticosteroids for adults because results have been analysed and made public.			
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)*:	CRF/other study data records - Changes in the documentation used by the research team for recording study data			
Further information (free text):	Additional question on convalescent plasma safety case report form.			
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):	Clarification of statistical analysis details			
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 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):	Amendments to PIS/ICF to match the changes to the protocol described above and to include more information about PIMS-TS			

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 6				
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 wish to allow patients to be randomised between convalescent plasma and control even if none of the treatments in part A of the main randomisation are both available and suitable.			
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 7				
Area of change (select)*:	Study Documents			
Specific change (select - only available when area of change is selected first)*:	Correction of typographical errors			
Further information (free 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: ☐

Section 3: Declaration(s) and lock for submission

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

Lock for submission
<p><b>Please note:</b> 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>

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:	
	it Authority medicines	it Authority devices		Assurance	overnance				HCRW Approval				ordinating function		Guardians
															ordinating function

	REC	Competition MHRA - N	Competition MHRA - D	ARSAC	Radiation	UKSW Gc	REC (MC)	CAG	HMPPS	HRA and I	REC (AWI)	PBPP	SPS (RAE)	National c	HSC REC	HSC Data	Prisons	National c	Category:
Change 1:	Y	Y				Y				Y				Y				Y	A
Change 2:	Y	Y				Y				Y				Y				Y	A
Change 3:	N	N				(Y)				(Y)				(Y)				(Y)	A
Change 4:	N	N				(Y)				(Y)				(Y)				(Y)	C
Change 5:	N	N				(Y)				(Y)				(Y)				(Y)	C
Change 6:	N	N				(Y)				(Y)				(Y)				(Y)	C
Change 7:	N	N				N				N				N				N	N/A
Overall reviews for the amendment:																			
Full review:	Y	Y				Y				Y				Y				Y	
Notification only:	N	N				N				N				N				N	
Overall amendment type:	Substantial for review																		
Overall Category:	A																		