

Name	Version number	Document Date	Submission Date	REC Approval Date	Main reason for change	Summary of changes made
<b>PROTOCOL</b>						
Protocol	4.0	29/05/2020	01/06/2020	01/06/2020 (SA_3)	Northern Ireland regulations and secondary outcomes	<ul style="list-style-type: none"> <li>• Secondary outcomes updated.</li> <li>• Inclusion criteria updated to include inpatients with suspected or proven covid-19, not just admitted patients.</li> <li>• Update to consent process for NI</li> <li>• Clarification of SAEs for reporting</li> <li>• Added socioeconomic status and the use of data linkage</li> <li>• Update to interim analysis time points</li> </ul>
Protocol	3.1	24/04/2020	24/04/2020	N/A - (NSA_08)	Scottish approvals and consent pathway	<ul style="list-style-type: none"> <li>• Remove reference to an application for ethical approval from a Scottish REC</li> <li>• Clarify that adults without capacity will not be recruited from Scotland.</li> </ul>
Protocol	3.0	21/04/2020	21/04/2020	21/04/2020 (SA_1)	Update to consent model, eligibility criteria	<ul style="list-style-type: none"> <li>• Consent process updated to enable consent prior to enrolment where patient has capacity</li> <li>• Eligibility criteria update to clarify that patients will be eligible with FiO<sub>2</sub> more than or equal to 0.4 and SpO<sub>2</sub> less than or equal to 94%.</li> <li>• Update to protocol to include process for Scottish sites</li> <li>• All Patient documentation updated to include reference to collection of race and ethnicity data</li> <li>• New information sheets and consent forms added for obtaining verbal informed consent from patients with capacity, prior to randomisation</li> </ul>
Protocol	2.0	03/04/2020	03/04/2020	03/04/2020	N/A	N/A
<b>INFORMATION FOR PARTICIPANTS – **PLEASE NOTE: VERSIONS AVAILABLE IN FRENCH, PORTUGUESE, POLISH, BENGALI, PUNJABI AND URDU**</b>						
Patient Information Sheet on Commencement	2.0	29/05/2020	01/06/2020	01/06/2020	NI regulations	Secretary of State’s for Health and Social Care (England) advice is not applicable to data from Northern Ireland patients
Patient Information Sheet on Commencement	1.1	24/04/ 2020	24/04/2020	N/A	Minor amendment – sponsor approval only	Remove reference to Scotland A REC.
Patient Information Sheet on Commencement	1.0	20/04/2020	21/04/2020	21/04/2020	Amendment to consent process	New information sheets for obtaining verbal informed consent from patients with capacity, prior to randomisation.

(Current versions in use highlighted in yellow)

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<b>Short Patient Information Sheet on Commencement</b>	<b>2.0</b>	<b>29/05/2020</b>	<b>01/06/2020</b>	<b>01/06/2020</b>	<b>NI regulations</b>	<b>Secretary of State's for Health and Social Care (England) advice is not applicable to data from Northern Ireland patients</b>
Short Patient Information Sheet on Commencement	1.1	24/04/2020	24/04/2020	N/A	Minor amendment – sponsor approval only	Remove reference to Scotland A REC.
Short Patient Information on Commencement	1.0	20/04/2020	21/04/2020	21/04/2020	Amendment to consent process	New information sheets for obtaining verbal informed consent from patients with capacity, prior to randomisation.
<b>Patient Information Sheet</b>	<b>4.0</b>	<b>29/05/2020</b>	<b>01/06/2020</b>	<b>01/06/2020</b>	<b>NI regulations</b>	<b>Secretary of State's for Health and Social Care (England) advice is not applicable to data from Northern Ireland patients</b>
Patient Information Sheet	3.0	20/04/2020	21/04/2020	21/04/2020	Updates to data collection	Updated documents to include reference to collection of race and ethnicity data.
Patient Information Sheet	2.1	17/04/2020	17/04/2020	N/A	Remove localisation	
Patient Information Sheet	2.0	03/04/2020	03/04/2020	03/04/2020	N/A	N/A
<b>Short Patient Information Sheet</b>	<b>4.0</b>	<b>29/05/2020</b>	<b>01/06/2020</b>	<b>01/06/2020</b>	<b>NI regulations</b>	<b>Secretary of State's for Health and Social Care (England) advice is not applicable to data from Northern Ireland patients</b>
Short Patient Information Sheet	3.0	20/04/2020	21/04/2020	21/04/2020	Updates to data collection	Updated documents to include reference to collection of race and ethnicity data.
Short Patient Information Sheet	2.1	17/04/2020	17/04/2020	N/A	Remove localisation	
Short Patient Information Sheet	2.0	03/04/2020	03/04/2020	03/04/2020	N/A	N/A
Northern Ireland Assent Form	<del>3.0</del>	<del>20/04/2020</del>	<del>21/04/2020</del>	<del>21/04/2020</del>	Updates to data collection	Updated documents to include reference to collection of race and ethnicity data. <b>No longer required as not suitable for use in Northern Ireland.</b>
Northern Ireland Assent Form	2.1	17/04/2020	17/04/2020	N/A	Remove localisation	
Northern Ireland Assent Form	2.0	03/04/2020	03/04/2020	03/04/2020	N/A	N/A
<b>Consultee Cover Letter</b>	<b>2.0</b>	<b>29/05/2020</b>	<b>01/06/2020</b>	<b>01/06/2020</b>	<b>Clarification of use</b>	<b>Document is only applicable for use in England, Wales and Northern Ireland</b>
Consultee Cover Letter	1.0	01/04/2020	01/04/2020	03/04/2020	N/A	N/A
<b>Consent Form on Commencement</b>	<b>1.0</b>	<b>20/04/2020</b>	<b>21/04/2020</b>	<b>21/04/2020</b>	<b>Amendment to consent process</b>	<b>New consent forms for obtaining verbal informed consent from patients with capacity, prior to randomisation.</b>
<b>Patient Deferred Consent Form</b>	<b>2.0</b>	<b>20/04/2020</b>	<b>21/04/2020</b>	<b>21/04/2020</b>	<b>Updates to data collection</b>	<b>Updated documents to include reference to collection of race and ethnicity data.</b>

Name	Version number	Document Date	Submission Date	REC Approval Date	Main reason for change	Summary of changes made
Patient Deferred Consent Form	1.2	17/04/2020	17/04/2020	N/A	Remove localisation	
Patient Deferred Consent Form	1.1	08/04/2020	08/04/2020	N/A	Minor amendment to a word	
Patient Deferred Consent Form	1.0	03/04/2020	03/04/2020	03/04/2020	N/A	N/A
<b>Consultee Deferred Consent Form</b>	<b>3.1</b>	<b>08/06/2020</b>	<b>10/06/2020</b>	<b>N/A</b>	<b>Minor amendment to add space for names.</b>	<b>Addition of space to write the consultee and patient's name. Also removed space to insert hospital name in clause 7 as this is documented at the top of the form.</b>
Consultee Deferred Consent Form	3.0	29/05/2020	01/06/2020	01/06/2020	Clarification of use	<ul style="list-style-type: none"> <li>5. formatting update</li> <li>7. To include NHS digital and electronic Data Research &amp; Innovation Service (eDRIS)</li> <li>Document is only applicable for use in England, Wales and Northern Ireland</li> </ul>
Consultee Deferred Consent Form	2.0	20/04/2020	21/04/2020	21/04/2020	Updates to data collection	Updated documents to include reference to collection of race and ethnicity data.
Consultee Deferred Consent Form	1.1	17/04/2020	17/04/2020	N/A	Remove localisation	
Consultee Deferred Consent Form	1.0	01/04/2020	01/04/2020	03/04/2020	N/A	N/A
<b>Easy Read PIS (screen)</b>	<b>1.0</b>	<b>29/05/2020</b>	<b>01/06/2020</b>	<b>01/06/2020</b>	<b>New document</b>	<b>N/A</b>
<b>Easy Read PIS (print)</b>	<b>1.0</b>	<b>29/05/2020</b>	<b>01/06/2020</b>	<b>01/06/2020</b>	<b>New document</b>	<b>N/A</b>
<i>STUDY AIDS &amp; TRAINING MATERIALS</i>						
<b>Trial Participation Checklist / Trial Flow Diagram</b>	<b>4.0</b>	<b>02/06/2020</b>	<b>N/A</b>	<b>N/A</b>	<b>Updates to protocol</b>	<b>Update to inclusion criteria and secondary outcomes</b>
Trial Participation Checklist	3.0	06/05/2020	N/A	N/A	Updates to data collection	Remove reference to NHS encryption service and updated flowchart in align with protocol.
Trial Participation Checklist	2.0	22/04/2020	N/A	N/A	Update to consent model	Consent can be obtained from patient if they have mental capacity prior to randomisation
Trial Participation Checklist	1.0	06/04/2020	N/A	N/A	N/A	N/A
<b>Inclusions/Exclusion Cards ppt.</b>	<b>3.0</b>	<b>02/06/2020</b>	<b>N/A</b>	<b>N/A</b>	<b>Protocol Amendment</b>	<b>Update to inclusion criteria</b>
Inclusions/Exclusion Cards ppt.	2.0	22/04/2020	N/A	N/A	Protocol Amendment	Update to inclusion criteria
Inclusions/Exclusion Cards ppt.	1.0	03/04/2020	N/A	N/A	N/A	N/A
<b>Quick Reference – Poster</b>	<b>2.0</b>	<b>22/04/2020</b>	<b>N/A</b>	<b>N/A</b>	<b>Protocol Amendment</b>	<b>Update to inclusion criteria</b>
Quick Reference – Poster	1.0	03/04/2020	N/A	N/A	N/A	N/A

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<b>Trial Assessments</b>	<b>2.0</b>	<b>22/04/2020</b>	<b>N/A</b>	<b>N/A</b>	<b>Updates to data collection processes</b>	<b>Removed reference to Day 2 data collection timepoint</b>
Trial Assessments	1.0	03/04/2020	N/A	N/A	N/A	N/A
<b>GCP training slides</b>	<b>1.0</b>	<b>04/04/2020</b>	<b>N/A</b>	<b>N/A</b>	<b>N/A</b>	<b>N/A</b>
<b>SIV slides</b>	<b>6.0</b>	<b>04/06/2020</b>	<b>N/A</b>	<b>N/A</b>	<b>Substantial Amendment 3</b>	<b>Updates throughout</b>
SIV slides	5.3	28/04/2020	N/A	N/A	N/A	N/A
<b>Infographic: Trial Flexibility</b>	<b>1.0</b>	<b>28/04/2020</b>	<b>N/A</b>	<b>N/A</b>	<b>N/A</b>	<b>N/A</b>
<b>Infographic: Quick Guide to consent in England, Wales &amp; NI</b>	<b>2.0</b>	<b>03/06/2020</b>	<b>N/A</b>	<b>N/A</b>	<b>Protocol Amendment</b>	<b>Removal of Assent Form from use in Northern Ireland</b>
Infographic: Quick Guide to consent in England, Wales & NI	1.1	28/04/2020	N/A	N/A	N/A	N/A
<b>Infographic: Quick Guide to consent in Scotland</b>	<b>1.1</b>	<b>29/04/2020</b>	<b>N/A</b>	<b>N/A</b>	<b>N/A</b>	<b>N/A</b>
<b>Infographic: Eligibility</b>	<b>2.0</b>	<b>03/06/2020</b>	<b>N/A</b>	<b>N/A</b>	<b>Protocol Amendment</b>	<b>Inclusion criteria</b>
Infographic: Eligibility	1.0	28/04/2020	N/A	N/A	N/A	N/A
<b>Infographic: Randomisation</b>	<b>1.0</b>	<b>27/04/2020</b>	<b>N/A</b>	<b>N/A</b>	<b>N/A</b>	<b>N/A</b>
<b>DATA COLLECTION</b>						
<b>Eligibility CRF</b>	<b>2.0</b>	<b>23/04/2020</b>	<b>N/A</b>	<b>N/A</b>	<b>Protocol Amendments</b>	<b>Update to inclusion criteria</b>
Eligibility CRF	1.0	03/04/2020	N/A	N/A	N/A	N/A
<b>Randomisation CRF</b>	<b>3.0</b>	<b>29/06/2020</b>	<b>N/A</b>	<b>N/A</b>	<b>Updates to data collection for Scotland</b>	<b>Addition of CHI number as alternative to NHS number for Scottish patients</b>
Randomisation CRF	2.0	26/04/2020	N/A	N/A	Updates to data collection	Remove reference to NHS encryption service as no longer required
Randomisation CRF	1.0	03/04/2020	N/A	N/A	N/A	N/A
<b>Baseline CRF</b>	<b>3.0</b>	<b>29/06/2020</b>	<b>N/A</b>	<b>N/A</b>	<b>Updates to data collection</b>	<b>Addition of patient ethnicity data</b>
Baseline CRF	2.0	26/04/2020	N/A	N/A	Updates to data collection	
Baseline CRF	1.0	03/04/2020	N/A	N/A	N/A	N/A
<b>Data Collection CRF</b>	<b>4.0</b>	<b>08/12/2020</b>	<b>N/A</b>	<b>N/A</b>	<b>Updates to data collection</b>	<b>Addition of 'pneumothorax' and 'pneumomediastinum' as adverse events</b>
Data Collection CRF	3.0	24/06/2020	N/A	N/A	Updates to data collection	Further questions added to collect information on where participants have been discharged to and if a participant is readmitted within 30 days of randomisation. Minor clarifications throughout.

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Data Collection CRF	2.0	23/04/2020	N/A	N/A	Updates to data collection	
Data Collection CRF	1.0	09/04/2020	N/A	N/A	N/A	N/A
<b>Withdrawal CRF</b>	<b>1.0</b>	<b>06/04/2020</b>	<b>N/A</b>	<b>N/A</b>	<b>N/A</b>	<b>N/A</b>
<b>Non-compliances CRF</b>	<b>1.0</b>	<b>03/04/2020</b>	<b>N/A</b>	<b>N/A</b>	<b>N/A</b>	<b>N/A</b>
<b>Death Notification Form</b>	<b>1.0</b>	<b>23/04/2020</b>	<b>N/A</b>	<b>N/A</b>	<b>N/A</b>	<b>N/A</b>
<b>Serious Adverse Event Form Initial</b>	<b>2.0</b>	<b>07/04/2020</b>	<b>N/A</b>	<b>N/A</b>	<b>Clarifications following QA feedback.</b>	
Serious Adverse Event Form Initial	1.0	03/04/2020	N/A	N/A	N/A	N/A
<b>Serious Adverse Event Continuation Form</b>	<b>2.0</b>	<b>07/04/2020</b>	<b>N/A</b>	<b>N/A</b>	<b>Clarifications following QA feedback.</b>	
Serious Adverse Event Continuation Form	1.0	03/04/2020	N/A	N/A	N/A	N/A
<b>Serious Adverse Event Follow Up Form</b>	<b>1.0</b>	<b>07/04/2020</b>	<b>N/A</b>	<b>N/A</b>	<b>N/A</b>	<b>N/A</b>
<i>SPECIFIC TRIAL WORKING INSTRUCTIONS</i>						
<b>SAE Handling Process working instruction</b>	<b>1.1</b>	<b>03/04/2020</b>	<b>N/A</b>	<b>N/A</b>	<b>Clarifications following QA feedback</b>	<b>N/A</b>
SAE Handling Process working instruction	1.0	02/04/2020	N/A	N/A	N/A	N/A
Data Transfer working instruction	1.0	02/04/2020	N/A	N/A	Updates to data collection processes	No longer required as not collecting randomisation CRF's via NHS encryption service.
<b>Patient interview publicity working instructions</b>	<b>1.0</b>	<b>27/05/2020</b>	<b>N/A</b>	<b>N/A</b>	<b>N/A</b>	<b>N/A</b>
<b>Twitter guidance</b>	<b>1.1</b>	<b>05/05/2020</b>	<b>N/A</b>	<b>N/A</b>	<b>N/A</b>	<b>N/A</b>
<i>SUBSTANTIAL AMENDMENT 2 - PUBLICITY</i>						
<b>GDPR compliant NIHR wide consent form</b>	<b>N/A</b>	<b>N/A</b>	<b>15/05/2020</b>	<b>15/05/2020</b>	<b>N/A</b>	<b>N/A</b>
<b>Publicity Information Sheet</b>	<b>1.0</b>	<b>15/05/2020</b>	<b>15/05/2020</b>	<b>15/05/2020</b>	<b>N/A</b>	<b>N/A</b>
<b>RECOVERY-RS Patient Questions</b>	<b>1.1</b>	<b>14/05/2020</b>	<b>14/05/2020</b>	<b>15/05/2020</b>	<b>N/A</b>	<b>N/A</b>