



## PRESSURE INVESTIGATOR SITE FILE – Checklist

Please complete this form and keep the original in the front of your site file to be used as part of the content index (if a hard copy of the ISF is being maintained).

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Centre Name:	Centre No:	Activation Date:	PRESSURE Principal Investigator:			
SITE FILE SECTION	DOCUMENT	VERSION	DATE	IN SITE FILE		
				Yes	File Note	N/A
<b>1. ISF checklist</b>	PRESSURE Investigator Site File - checklist	Version 6.1	19 April 2023	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>2. Trial Management Contact Information</b>	<b>CURRENT</b>	Version 2.0	15 November 2022	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<b>SUPERSEDED</b>	Version 1.0	06 August 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>3. Trial Specific Standard Operating Procedures</b>	SOP 001 Guidance on the use of the Investigator Site File	Version 2.0	23 November 2022	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	SOP 002 Delegation of trial duties	Version 1.0	10 June 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	SOP 003 Patient Screening and Enrolment	Version 4.0	23 November 2022	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	SOP 004 Patient Randomisation	Version 2.0	23 November 2022	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	SOP 005 Consent Procedures	Version 4.0	11 March 2022	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	SOP 006 Delivery of Trial Treatment	Version 4.0	04 July 2022	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	SOP 007 Guidance for completion of Case Report Forms	Version 5.0	23 November 2022	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	SOP 008 MACRO User Guide	Version 7.0	23 November 2022	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	SOP 009 Safety Monitoring	Version 5.0	11 April 2023	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	SOP 010 Site Monitoring	Version 1.0	02 July 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	SOP 011 Archiving	Version 1.0	21 June 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	SOP 012 Research Costs	Version 1.0	21 June 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<b>SUPERSEDED</b>					
	SOP 001 Guidance on the use of the Investigator Site File	Version 1.0	30 June 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	SOP 003 Patient Screening and Enrolment	Version 3.0	11 March 2022	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	SOP 003 Patient Screening and Enrolment	Version 2.0	17 December 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	SOP 003 Patient Screening and Enrolment	Version 1.0	12 July 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	SOP 004 Patient Randomisation	Version 1.0	29 July 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	SOP 005 Consent Procedures	Version 3.0	15 December 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	SOP 005 Consent Procedures	Version 2.0	13 October 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	SOP 005 Consent Procedures	Version 1.0	01 July 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	SOP 006 Delivery of Trial Treatment	Version 3.0	14 April 2022	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
SOP 006 Delivery of Trial Treatment	Version 2.0	30 September 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
SOP 006 Delivery of Trial Treatment	Version 1.0	02 August 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	



	SOP 007 Guidance for completion of Case Report Forms	Version 4.0	10 May 2022	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	SOP 007 Guidance for completion of Case Report Forms	Version 3.0	17 December 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	SOP 007 Guidance for completion of Case Report Forms	Version 2.0	13 October 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	SOP 007 Guidance for completion of Case Report Forms	Version 1.0	02 August 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	SOP 008 MACRO User Guide	Version 6.0	16 May 2022	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	SOP 008 MACRO User Guide	Version 5.0	10 May 2022	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	SOP 008 MACRO User Guide	Version 4.0	24 January 2022	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	SOP 008 MACRO User Guide	Version 3.0	17 December 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	SOP 008 MACRO User Guide	Version 2.0	08 November 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	SOP 008 MACRO User Guide	Version 1.0	03 August 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	SOP 009 Safety Monitoring	Version 4.0	23 November 2022	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	SOP 009 Safety Monitoring	Version 3.0	10 May 2022	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	SOP 009 Safety Monitoring	Version 2.0	17 December 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	SOP 009 Safety Monitoring	Version 1.0	02 August 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>4. Trial Protocol</b>	<b>CURRENT</b>	Version 4.0	25 August 2022	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<b>SUPERSEDED</b>					
		Version 3.3	14 April 2022	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		Version 3.2	17 December 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		Version 3.1	28 October 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		Version 2.2	04 August 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	(Approved but never implemented)	Version 2.0	28 April 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
<b>5. Documents for participants</b>	<b>CURRENT</b>					
	<b>Patient Information Sheets</b>					
	PRESSURE Bereaved-Participant Information Sheet (Parents or Guardians)	Version 1.1	28 April 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	PRESSURE Participant Information Sheet (Parents or Guardians)	Version 2.0	25 August 2022	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	PRESSURE PIS less than 8 years	Version 1.0	09 February 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	PRESSURE PIS 8-10 years	Version 1.0	09 February 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	PRESSURE PIS 11+ years	Version 1.0	09 February 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<b>Consent Forms</b>					
	PRESSURE Consent Form (Parent or Guardian)	Version 2.0	25 August 2022	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	PRESSURE Bereaved Consent Form (Parent or Guardian)	Version 1.1	28 January 2022	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	PRESSURE Study Assent form	Version 1.0	10 February 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



	<b>Other</b>					
	PRESSURE Participant Information Leaflet (Parents or Guardians)	Version 1.1	19 April 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	PRESSURE Family Room Poster	Version 1.0	10 February 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Newsletter (Parents or Legal Guardians)	Version 1.0	10 February 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Enrolment Covering Letter (1)	Version 1.0	10 February 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Enrolment Follow-Up Covering Letter (2)	Version 1.0	10 February 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Bereaved-Enrolment Covering Letter (1)	Version 1.0	10 February 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Bereaved-Enrolment Follow-Up Covering Letter (2)	Version 1.0	10 February 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Follow-Up Email for questionnaire	Version 1.0	10 November 2020	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Follow-Up Letter for questionnaire	Version 1.0	10 November 2020	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	CHU-9D-Questionnaire	Version 1.0	18 January 2008	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	PedsQL-Infant(1-12Months)_AU1.0_eng-GB1	Version 1.0	13 March 2017	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	PedsQL-Infant(13-24Months)_AU1.0_eng-GB1	Version 1.0	13 March 2017	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	PedsQL-4.0-Core-PT_AU4.0_eng-GB2 (age 2-4)	Version 4.0	15 March 2016	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	PedsQL-4.0-Core-PYC_AU4.0_eng-GB2_(age 5-7)	Version 4.0	15 March 2016	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	PedsQL-4.0-Core-PC_AU4.0_eng-GB2 (age 8-12)	Version 4.0	15 March 2016	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	PedsQL-4.0-Core-PA_AU4.0_eng-GB2 (age 13-18)	Version 4.0	15 March 2016	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<b>SUPERSEDED</b>					
	PRESSURE Consent Form (Parent or Guardian)	Version 1.1	28 January 2022	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	PRESSURE Participant Information Sheet (Parents or Guardians)	Version 1.1	28 April 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	PRESSURE Consent Form (Parent or Guardian)	Version 1.0	10 February 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PRESSURE Bereaved Consent Form (Parent or Guardian)	Version 1.0	10 February 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>6. Screening and Enrolment</b>	<b>CURRENT</b>					
	PRESSURE Screening and Enrolment log	Version 3.0	22 November 2022	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	PRESSURE Screening Tool	Version 2.1	22 March 2023	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Screening and Enrolment log file path	Version 1.0	02 July 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<b>SUPERSEDED</b>					
	PRESSURE Screening and Enrolment log	Version 2.0	17 December 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	PRESSURE Screening and Enrolment log	Version 1.0	05 July 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	PRESSURE Screening Tool	Version 2.0	22 November 2022	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	PRESSURE Screening Tool	Version 1.0	06 July 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Signed consent forms	<i>Please keep a copy of signed consent form</i>				
<b>CURRENT</b>						



7. Data Collection (formerly named CRFs)	Baseline: Demographics/Observations	Version 1.1	16 November 2022	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Baseline: Comorbidities	Version 1.0	02 August 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Functional Status Prior to PICU Admission	Version 1.1	16 November 2022	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Observations Day 1 (Part 1)	Version 2.2	18 April 2023	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Observations Day 1 (Part 2)	Version 2.2	18 April 2023	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Observations (Part 1 additional pages)	Version 2.2	18 April 2023	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Observations (Part 2 additional pages)	Version 2.2	18 April 2023	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Daily Values_v1.2	Version 1.2	16 November 2022	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Organ Support Daily Observations	Version 2.0	16 November 2022	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	E Organ Support Daily Observations (Part 2)	Version 1.0	16 November 2022	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Functional Status at PICU Discharge	Version 1.1	16 November 2022	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Outcomes at hospital discharge	Version 1.0	02 August 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Outcomes Survival Status	Version 1.1	11 March 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Consent/Assent	Version 2.0	13 October 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Safety Monitoring	Version 2.0	14 April 2022	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Withdrawal of Consent	Version 1.0	13 October 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	SAE Reporting Form	Version 3.0	04 April 2023	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Randomisation Form	Version 3.0	26 September 2022	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<b>SUPERSEDED</b>						
	Baseline: Demographics / Observations	Version 1.0	02 August 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Baseline: Comorbidities	Version 1.0	02 August 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Functional Status prior to PICU admission	Version 1.0	02 August 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Observations Day 1 (Part 1)	Version 2.1	16 November 2022	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Observations Day 1 (Part 1)	Version 2.0	30 September 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Observations Day 1 (Part 1)	Version 1.0	02 August 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Observations Day 1 (Part 2)	Version 2.1	16 November 2022	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Observations Day 1 (Part 2)	Version 2.0	30 September 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Observations Day 1 (Part 2)	Version 1.0	02 August 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Observations (Part 1 additional pages)	Version 2.1	16 November 2022	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Observations (Part 1 additional pages)	Version 2.0	30 September 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Observations (Part 1 additional pages)	Version 1.0	02 August 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Observations (Part 1 additional pages)	Version 2.1	16 November 2022	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Observations (Part 2 additional pages)	Version 2.0	30 September 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Observations (Part 2 additional pages)	Version 1.0	02 August 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Daily Values	Version 1.1	28 January 2022	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Organ Support Daily Observations	Version 1.0	02 August 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		



	Functional Status at PICU discharge	Version 1.0	02 August 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Outcomes at hospital discharge	Version 1.0	02 August 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Outcomes Survival Status	Version 1.1	11 March 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Consent/Assent	Version 2.0	13 October 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Safety Monitoring	Version 2.0	14 April 2022	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Withdrawal of Consent	Version 1.0	13 October 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Daily Values	Version 1.0	02 August 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Outcomes Survival Status	Version 1.0	02 August 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Consent/Assent	Version 1.0	02 August 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Safety Monitoring	Version 1.1	17 December 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Safety Monitoring	Version 1.0	02 August 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	SAE Reporting Form	Version 2.1	24 January 2022	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	SAE Reporting Form	Version 2.0	30 September 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	SAE Reporting Form	Version 1.0	03 August 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Randomisation Form	Version 2.0	30 September 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Randomisation Form	Version 1.0	16 June 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Site completed paper Data Collection Worksheets	<i>File note to location of any completed paper CRFs</i>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>8. Quality Assurance</b>	Monitoring Log	Version 1	09 June 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Monitoring reports	<i>Monitoring reports should be filed here</i>				
	Site File Note template	Version 1	09 June 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>9. Finance and Agreements</b>	PRESSURE Research Team acknowledgement	Version 2.0	28 January 2022	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	PRESSURE Principal Investigator Statement	Version 2.0	28 January 2022	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Signed Clinical Trial Sites Agreement (mNCA template V2.1 July 2018)	Version 1.0	26 February 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Organisation Information Document	Version 1.0	13 January 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	NIHR128895 PRESSURE Grant Award Letter	-	03 December 2019	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<b>SUPERSEDED</b>					
	PRESSURE Research Team acknowledgement	Version 1.0	06 August 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PRESSURE Principal Investigator Statement	Version 1.0	06 August 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>10. Ethics/Regulatory Documentation</b>	IRASForm_PRESSURE_08-03-2021	08 March 2021		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	East of England-Cambridge South PRESSURE_IRAS-289545_ Application valid for REC review (email)	11 March 2021		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	PRESSURE_IRAS-289545 SLO2_HRA Initial Assessment Letter	11 March 2021		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	PRESSURE_IRAS-289545_HRA & HCRW Approval Status Update - Provisional Outcome (email)	12 April 2021		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	PRESSURE_IRAS 289545_Ethics re-submission cover letter	05 May 2021		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



East of England-Cambridge South REC favourable opinion letter	10 May 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PRESSURE_IRAS-289545_(Approval)_Letter_of_HRA_Approval	10 May 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Non-Substantial Amendment 1</b>				
Amendment tool	26 May 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IRAS 289545_ HRA Non Substantial Amendment 1 confirmation (email)	26 May 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Non-Substantial Amendment 2</b>				
Amendment tool	04 August 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IRAS 289545_ HRA & HCRW Approval for Non Substantial Amendment 2 (email)	06 August 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Substantial Amendment 1</b>				
Amendment tool	30 September 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IRAS 289545_ HRA & HCRW Confirmation of favourable opinion for Substantial Amendment 1 (email)	09 November 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IRAS 289545_REC Favourable Opinion of Substantial Amendment	09 November 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Non-Substantial Amendment 3</b>				
Amendment tool	26 November 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IRAS 289545_ HRA Approval for Non-Substantial Amendment 3 (email)	29 November 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Non-Substantial Amendment 4</b>				
Amendment tool	17 December 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IRAS 289545_ HRA Approval for Non-Substantial Amendment 4 (email)	21 December 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Non-Substantial Amendment 5</b>				
Amendment tool	28 January 2022	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IRAS 289545_ HRA Approval for Non-Substantial Amendment 5 (email)	02 February 2022	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Non-Substantial Amendment 6</b>				
Amendment tool	14 April 2022	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IRAS 289545_ HRA Approval for Non-Substantial Amendment 6 (email)	14 April 2022	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Non-Substantial Amendment 7</b>				
Amendment tool	14 June 2022	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IRAS 289545_ HRA Approval for Non-Substantial Amendment 7 (email)	15 June 2022	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Local Confirmation of Capacity and Capability	-	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Substantial Amendment 2</b>				
Amendment Tool	01 September 2022	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IRAS 289545HRA Approval for Substantial Amendment 2 (email)	14 November 2022	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



<b>11. Site Staff Information</b> <i>(Please send copies to ICNARC CTU)</i>	PRESSURE Delegation Log	Version 1.0	01 June 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	PRESSURE Staff Contact Form	Version 1.0	01 June 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	PRESSURE Training Log	Version 1.0	01 June 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	CVs <i>Signed &amp; dated within the last two years</i>	<i>Store and send where appropriate</i>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	GCP Certificates	<i>Store and send where appropriate</i>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>12. Correspondence / Information</b>	<i>Other important correspondence / information documents or emails (e.g. site activation, study updates)</i>					

<b>I confirm that the above documents are stored in the Local Investigator Site File</b>	
<b>Signature:</b>	<b>Date:</b>
<b>Print Name:</b>	<b>Job Title:</b>