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Essential documents version checklist

ISF Section 1 – Trial contact Information

Document	Present
Oxy-PICU contact information	<input type="checkbox"/>

ISF Section 2 – Trial-specific Standard Operating Procedures (SOPs)

SOP No.	Name of SOP	Version(s)	Date	Present
001	Use of the Investigator Site File (ISF)	1.0	21/01/2020	<input type="checkbox"/>
002	Delegation of study duties	1.0	21/01/2020	<input type="checkbox"/>
003	Patient Screening	1.1	12/08/2020	<input type="checkbox"/>
		1.0	21/01/2020	<input type="checkbox"/> N/A* <input type="checkbox"/>
004	Patient Randomisation	1.1	19/08/2020	<input type="checkbox"/>
		1.0	21/01/2020	<input type="checkbox"/> N/A* <input type="checkbox"/>
005	Trial treatment	1.2	26/10/2020	<input type="checkbox"/>
		1.1	19/08/2020	<input type="checkbox"/> N/A* <input type="checkbox"/>
		1.0	27/01/2020	<input type="checkbox"/> N/A* <input type="checkbox"/>
006	Consent procedures	1.0	27/01/2020	<input type="checkbox"/>
007	Entering data onto the web portal	1.0	17/02/2017	<input type="checkbox"/>
008	Safety monitoring	1.2	16/02/2021	<input type="checkbox"/>
		1.1	12/08/2020	<input type="checkbox"/>
		1.0	21/01/2020	<input type="checkbox"/> N/A* <input type="checkbox"/>
009	Guidance for completion of Case Report Forms	1.0	03/01/2017	<input type="checkbox"/>
010	Site monitoring	1.0	27/01/2020	<input type="checkbox"/>
011	Archiving	1.0	27/01/2020	<input type="checkbox"/>

**Mark N/A if document was superseded prior to your original approval or was introduced after you closed to recruitment.*

ISF Section 3 – Trial Protocol

Document	Version	Date	Present
Oxy-PICU Protocol	1.4	04/11/2022	<input type="checkbox"/>
	1.3	01/02/2021	<input type="checkbox"/>
	1.2	07/08/2020	<input type="checkbox"/>
	1.1	18/12/2019	<input type="checkbox"/> N/A* <input type="checkbox"/>
Protocol Signature Page – signed by PI	N/A	-	<input type="checkbox"/>

ISF Section 4 – Information sheets / leaflets

Copies of localised, sample versions of information sheets/leaflets should be filed in the ISF.

Document	Version	Date	Present
Parent Information Sheet	1.2	07/08/2020	<input type="checkbox"/>
	1.1	18/12/2019	<input type="checkbox"/> N/A* <input type="checkbox"/>
Parent Information Sheet (Bereaved)	1.2	07/08/2020	<input type="checkbox"/>
	1.1	18/12/2019	<input type="checkbox"/> N/A* <input type="checkbox"/>
Participant Information Leaflet (Parents or Guardians)	1.1	07/08/2020	<input type="checkbox"/>
	1.0	06/11/2019	<input type="checkbox"/> N/A* <input type="checkbox"/>
PIS sheet (8-10 years)	1.0	06/11/2019	<input type="checkbox"/>
PIS sheet (11+ years)	1.0	06/11/2019	<input type="checkbox"/>
Postal Consent Covering Letter	1.1	09/12/2020	<input type="checkbox"/>
	1.0	06/11/2019	<input type="checkbox"/>
Postal Consent Covering Letter (Bereaved)	1.0	06/11/2019	<input type="checkbox"/>
Postal Consent Follow-Up Covering Letter	1.1	09/12/2020	<input type="checkbox"/>
	1.0	06/11/2019	<input type="checkbox"/>
Postal Consent Follow-Up Covering Letter (Bereaved)	1.0	06/11/2019	<input type="checkbox"/>

ISF Section 5 – Consent/Assent Forms

Copies of localised, sample versions of consent/opinion forms should be filed in the ISF.

Document	Version	Date	Present
Consent Form (Parent or Guardian)	1.2	09/12/2020	<input type="checkbox"/>
	1.1	07/08/2020	<input type="checkbox"/> N/A* <input type="checkbox"/>
	1.0	06/11/2019	<input type="checkbox"/> N/A* <input type="checkbox"/>
Bereaved consent Form (Parent or Guardian)	1.1	07/08/2020	<input type="checkbox"/>
	1.0	06/11/2019	<input type="checkbox"/> N/A* <input type="checkbox"/>

Assent Form	1.0	06/11/2019	<input type="checkbox"/>
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ISF Section 6 – Screening and enrolment

Document	Version	Date	Present
Screening and Enrolment log (Excel) - Electronic Version	1.3	02/11/2020	-
Screening and Enrolment Log location – <i>indicating where the electronic version of the Log can be found on the local computer system</i>	-	-	<input type="checkbox"/>
Screening Tool – <i>this is an optional Tool, and is not essential to be filed in the ISF</i>	1.0	14/08/2020	-

ISF Section 7 – Case Report Form(s)

Document	Version	Date	Present
Randomisation Form	1.4	07/08/2020	<input type="checkbox"/>
Case Report Form	2.2	16/02/2021	<input type="checkbox"/>
	2.1	02/11/2020	<input type="checkbox"/>
	2.0	18/08/2020	<input type="checkbox"/> N/A* <input type="checkbox"/>
	1.9	27/07/2020	<input type="checkbox"/> N/A* <input type="checkbox"/>
MACRO User Guide	1.0	09/02/2017	<input type="checkbox"/>

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ISF Section 8 – Safety Monitoring

Document	Version	Date	Present
Serious Adverse Event Reporting Form	1.2	25/02/2022	<input type="checkbox"/>
	1.1	27/10/2020	<input type="checkbox"/>
	1.0	18/02/2020	<input type="checkbox"/> N/A* <input type="checkbox"/>

ISF Section 9 – Agreements / Approvals

Document	Date	Present
Clinical Trial Site Agreement		<input type="checkbox"/>

HRA initial assessment letter	12/11/2019	<input type="checkbox"/>
REC favourable opinion letter	23/12/2019	<input type="checkbox"/>
HRA and HCRW approval letter	23/12/2019	<input type="checkbox"/>
Local Confirmation of Capacity and Capability		<input type="checkbox"/>
Non-Substantial Amendment 1 categorisations and approvals <i>(affects: Nottingham University Hospitals NHS Trust, Birmingham Women's and Children's NHS Foundation Trust, University Hospital Southampton NHS Foundation Trust, University Hospitals Bristol NHS Foundation Trust, and Oxford University Hospitals NHS Foundation Trust only)</i>	06/01/2020	<input type="checkbox"/> N/A <input type="checkbox"/>
Non-Substantial Amendment 2 categorisations and approvals <i>(affects Alder Hey Children's NHS Foundation Trust, Guy's and St Thomas' NHS Foundation Trust, NHS Greater Glasgow and Clyde, King's College Hospital NHS Foundation Trust, Royal Manchester University NHS Foundation Trust, St George's University Hospitals NHS Foundation Trust, Imperial College Healthcare NHS Trust, Newcastle upon Tyne Hospitals NHS Foundation Trust, Cardiff and Vale University Health Board only)</i>	26/02/2020	<input type="checkbox"/> N/A <input type="checkbox"/>
Non-Substantial Amendment 3 categorisations and approvals <i>(affects Imperial College Healthcare Trust only)</i>	19/06/2020	<input type="checkbox"/> N/A <input type="checkbox"/>
Non-Substantial Amendment 4 categorisations and approvals	07/08/2020	<input type="checkbox"/>
Non-Substantial Amendment 5 categorisations and approvals	11/08/2020	<input type="checkbox"/>
Non-Substantial Amendment 6 categorisations and approvals <i>(affects Oxford University Hospitals NHS Foundation Trust only)</i>	07/09/2020	<input type="checkbox"/> N/A <input type="checkbox"/>
Non-Substantial Amendment 7 categorisations and approvals <i>(affects University Hospital Southampton NHS Foundation Trust only)</i>	18/09/2020	<input type="checkbox"/> N/A <input type="checkbox"/>
Non-Substantial Amendment 8 completed amendment tool	11/12/2020	<input type="checkbox"/>
Non-Substantial Amendment 9 completed amendment tool and confirmation of submission email	09/02/2021	<input type="checkbox"/>
Non-Substantial Amendment 10 completed amendment tool and confirmation of submission email	11/08/2021	<input type="checkbox"/>
Non-Substantial Amendment 11 completed amendment tool and confirmation of submission email	01/04/2022	<input type="checkbox"/>
Non-Substantial Amendment 12 completed amendment tool and confirmation of submission email	04/11/2022	<input type="checkbox"/>
Non-Substantial Amendment 13 completed amendment tool and confirmation of submission email	17/11/2022	<input type="checkbox"/>

(It is optional to file a Non-Substantial Amendment that did not affect your site.)

ISF Section 10 – Staff Information

Document	Version	Date	Present
Delegation Log	1.0	04/12/2019	<input type="checkbox"/>
Site Staff CVs	-	-	<input type="checkbox"/>
Staff Contacts Form	1.0	04/12/2019	<input type="checkbox"/>
Site Staff GCP certificates – <i>for PI and all staff members delegated the tasks of seeking consent/assent</i>	-	-	<input type="checkbox"/>
Training Log – <i>all staff members randomising patients should be recorded</i>	1.0	04/12/2019	<input type="checkbox"/>

ISF Section 11 – Routine Monitoring

Document	Present
Monitoring Log	<input type="checkbox"/>
Routine Monitoring Visit report	<input type="checkbox"/> N/A* <input type="checkbox"/>

**Mark N/A if a monitoring visit has not been conducted at your site.*

ISF Section 12 – Other materials

Document	Version	Date	Present
Bedside postcards	1.0	22/01/2020	<input type="checkbox"/>
Family Room Poster A3	1.0	06/11/2019	<input type="checkbox"/>
Labels 14 per sheet	1.1	08/10/2020	<input type="checkbox"/>
	1.0	22/01/2020	<input type="checkbox"/> N/A* <input type="checkbox"/>
Labels Transport 14 per sheet	1.1	08/10/2020	<input type="checkbox"/>
	1.0	05/02/2020	<input type="checkbox"/> N/A* <input type="checkbox"/>
Pocketcards	1.2	13/08/2020	<input type="checkbox"/>
Staff sign – A5 arm think reminder	1.1	08/10/2020	<input type="checkbox"/>
	1.0	24/01/2020	<input type="checkbox"/> N/A* <input type="checkbox"/>
Staff sign – exclusion	1.0	19/02/2020	<input type="checkbox"/>
Staff sign – inclusion	1.0	13/08/2020	<input type="checkbox"/>

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ISF Section 13 – Important correspondence

Document	Present
Correspondence with Chief Investigator/ICNARC CTU, including Site Activation Checklist, updates and other study specific correspondence	<input type="checkbox"/>
R&D correspondence	<input type="checkbox"/>
Ethics correspondence	<input type="checkbox"/>