



PICnIC INVESTIGATOR SITE FILE – Checklist (Usual Care Period Two)

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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<https://www.icnarc.org/Our-Research/Studies/Picnic/For-Sites>

Centre Name:		Centre No:	Activation Date:	PICnIC Principal Investigator:		
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SITE FILE SECTION	DOCUMENT	VERSION	DATE	IN SITE FILE		
				Yes	File Note	N/A
1. ISF checklist	PICnIC Investigator Site File - checklist	Version 5.5	16 May 2022	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Contact Information	PICnIC Trial Management Contact Information	Version 2.0	01 September 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Trial Specific Standard Operating Procedures	CURRENT					
	SOP 001 Guidance on the use of the Investigator Site File	Version 1.0	10 March 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	SOP 002 Delegation of study duties	Version 1.0	10 March 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	SOP 003 Patient Screening and Enrolment	Version 2.1	04 October 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	SOP 004 Patient Co-enrolment	Version 1.0	10 March 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	SOP 005 Consent Procedures	Version 1.1	06 October 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	SOP 006 SDD Drug reconstitution and administration	For intervention sites only		<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	SOP 007 Guidance for completion of Case Report Forms	Version 3.2	02 December 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	SOP 008 Macro User Guide	Version 2.2	02 December 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	SOP 009 Safety Monitoring	Version 2.0	15 December 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	SOP 010 Site Monitoring	Version 1.0	09 December 2020	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	SOP 011 Archiving	Version 1.0	19 November 2020	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	SOP 012 PICnIC Samples	Version 2.2	02 December 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	SOP 013 Research Costs	Version 1.0	17 December 2020	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	SUPERSEDED					
	SOP 003 Patient Screening and Enrolment	Version 2.0	17 May 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	SOP 005 Consent Procedures	Version 1.0	19 March 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	SOP 007 Guidance for completion of Case Report Forms	Version 3.1	01 December 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	SOP 007 Guidance for completion of Case Report Forms	Version 3.0	24 November 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	SOP 007 Guidance for completion of Case Report Forms	Version 2.0	17 May 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	SOP 008 Macro User Guide	Version 2.1	01 December 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	SOP 008 Macro User Guide	Version 2.0	25 November 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	SOP 008 Macro User Guide	Version 1.0	19 May 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	SOP 009 Safety Monitoring	Version 1.1	02 December 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	SOP 009 Safety Monitoring	Version 1.0	16 May 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



	SOP 012 PICnIC Samples	Version 2.1	01 December 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	SOP 012 PICnIC Samples	Version 2.0	29 November 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	SOP 012 PICnIC Samples	Version 1.0	18 February 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	SUPERSEDED (never implemented)					
	SOP 003 Patient Screening and Enrolment	Version 1.0	10 March 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	SOP 007 Guidance for completion of Case Report Forms	Version 1.0	06 May 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
4. Study Protocol	CURRENT	Version 4.2	09 February 2022	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	SUPERSEDED	Version 4.1	17 December 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		Version 4.0	08 November 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		Version 3.1	10 September 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		Version 3.0	05 July 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		Version 2.1	23 November 2020	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	SUPERSEDED (approved but never implemented)	Version 2.0	02 October 2020	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
		Version 1.2	19 August 2020	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
		Version 1.1	10 March 2020	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
5. Documents for participants	CURRENT					
	Patient Information Sheets					
	PICnIC Baseline Parents_Guardians PIS (bereaved)	Version 1.2	10 September 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	PICnIC Baseline Parents_Guardians PIS (non bereaved)	Version 1.2	10 September 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	PICnIC Control Parent_Guardian PIS (bereaved)	Version 2.2	10 September 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	PICnIC Control Parent_Guardian PIS (non bereaved)	Version 2.2	10 September 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	PICnIC Ecology Parent_Guardian PIS (bereaved)	Version 2.2	10 September 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	PICnIC Ecology Parent_Guardian PIS (non bereaved)	Version 2.2	10 September 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	PICnIC Intervention Parent_Guardian PIS (bereaved)	<i>For intervention sites only</i>		<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	PICnIC Intervention Parent_Guardian PIS (non bereaved)	<i>For intervention sites only</i>		<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	PICnIC Participant Information Sheet age less than 8 years	Version 1.0	10 March 2020	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	PICnIC Pilot Trial information sheet 8-10 years	Version 1.1	10 March 2020	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	PICnIC Pilot Trial information sheet 11+ years	Version 1.1	10 March 2020	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Consent Forms					
	PICnIC Consent Form Parent or Legal Guardian (bereaved)	Version 1.1	10 September 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	PICnIC Consent Form Parent or Legal Guardian (non bereaved)	Version 3.1	25 September 2020	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	PICnIC Pilot Study Assent form	Version 1.0	09 June 2020	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Other					



PICNIC Parent Questionnaire	Version 1.0	30 January 2020	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PICnIC PICU Staff Questionnaire	Version 2.0	16 March 2022	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PICNIC Pilot Site Staff Questionnaire	Version 1.0	30 January 2020	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Ecological Poster	Version 1.2	06 October 2020	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
SUPERSEDED					
<i>Patient Information Sheets</i>					
PICnIC Baseline Parents_Guardians PIS (bereaved)	Version 1.1	23 November 2020	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PICnIC Baseline Parents_Guardians PIS (non bereaved)	Version 1.1	23 November 2020	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PICnIC Control Parent_Guardian PIS (bereaved)	Version 2.1	23 November 2020	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PICnIC Control Parent_Guardian PIS (non bereaved)	Version 2.1	23 November 2020	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PICnIC Ecology Parent_Guardian PIS (bereaved)	Version 2.1	23 November 2020	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PICnIC Ecology Parent_Guardian PIS (non bereaved)	Version 2.1	23 November 2020	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PICnIC Intervention Parent_Guardian PIS (bereaved)	<i>(for intervention sites only)</i>		<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
PICnIC Intervention Parent_Guardian PIS (non bereaved)	<i>(for intervention sites only)</i>		<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
<i>Consent Forms</i>					
PICnIC Consent Form Parent or Legal Guardian (bereaved)	Version 1.0	08 October 2020	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Other</i>					
Ecology Poster	Version 1.1	16 November 2020	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PICnIC PICU Staff Questionnaire	Version 1.0	30 January 2020	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
SUPERSEDED (approved but never implemented)					
<i>Patient Information Sheets</i>					
PICnIC Intervention Parent_Guardian PIS (non bereaved)	Version 2.1	23 November 2020	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
PICnIC Baseline Parents_Guardians PIS (bereaved)	Version 1.0	25 September 2020	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
PICnIC Baseline Parents_Guardians PIS (non bereaved)	Version 1.0	25 September 2020	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
PICnIC Control Parent_Guardian PIS (bereaved)	Version 2.0	25 September 2020	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
PICnIC Control Parent_Guardian PIS (non bereaved)	Version 2.0	25 September 2020	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
PICnIC Ecology Parent_Guardian PIS (bereaved)	Version 2.0	25 September 2020	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
PICnIC Ecology Parent_Guardian PIS (non bereaved)	Version 2.0	25 September 2020	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
PICnIC Intervention Parent_Guardian PIS (bereaved)	Version 2.0	25 September 2020	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
PICnIC Intervention Parent_Guardian PIS (non bereaved)	Version 2.0	25 September 2020	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
PICnC Pilot Trial Parent_Guardian Information Sheet (bereaved)	Version 1.1	10 March 2020	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>



	PICnC Pilot Trial Parent_Guardian Information Sheet (non bereaved)	Version 1.1	10 March 2020	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	PICnC Pilot Trial Control Arm Parent Guardian Information Leaflet	Version 1.1	10 March 2020	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	PICnC Pilot Trial Ecology Parent Guardian Information Leaflet	Version 1.1	10 March 2020	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	Consent Forms					
	PICnC Consent Form (Parent or Legal Guardian)	Version 3.0	19 August 2020	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	Participant Consent Form (Parent or Legal Guardian)	Version 2.0	19 June 2020	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	Other					
	Ecology Poster	Version 1.0	10 March 2020	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
6. Screening and Enrolment	Screening and Enrolment log file path	Version 1.0	30 October 2020	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	PICnC Ecology Surveillance Number List	Version 1.0	24 December 2020	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	PICnC Study Number List (Period One and Two)	Version 1.0	24 December 2020	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	PICnC Screening Tool	Version 1.0	14 May 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Signed consent forms	<i>Please keep a copy of signed consent form</i>				
7. SDD Intervention Management	Investigators Brochure (IB)	<i>For intervention sites only</i>		<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	PICnC SDD Kit Inventory Log	<i>For intervention sites only</i>		<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	PICnC SDD Patient Accountability Log	<i>For intervention sites only</i>		<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	PICnC Temperature Deviation Log	<i>For intervention sites only</i>		<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	PICnC SDD Intervention Acknowledgement	<i>For intervention sites only</i>		<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	SOP 006 SDD Drug reconstitution and administration	<i>For intervention sites only</i>		<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
8. Case Report Forms	PICnC Ecology Surveillance CRFs					
	Ecology Surveillance Part 1	Version 1.0	11 February 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Ecology Surveillance Part 2 (Outcomes)	Version 1.0	11 February 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	PICnC Period One Usual Care CRFs	Not required for patients in Period Two				
	Admission	Version 1.0	22 February 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Weekly Surveillance	Version 1.0	22 February 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Weekly Surveillance (Additional pages)	Version 1.0	22 February 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Outcomes	Version 1.0	22 February 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Outcomes (Additional pages)	Version 1.0	22 February 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Antibiotic Use	Version 2.0	23 November 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Discharge	Version 2.0	25 November 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	PICnC Period Two Usual Care CRFs					
	Admission	Version 1.0	22 February 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Weekly Surveillance	Version 1.0	22 February 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Weekly Surveillance (Additional pages)	Version 1.0	22 February 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Outcomes	Version 1.0	22 February 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Outcomes (Additional pages)	Version 1.0	22 February 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



	Antibiotic Use	Version 2.0	23 November 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Discharge	Version 2.0	25 November 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Safety Monitoring	Version 2.0	19 May 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	PiCnIC Intervention (SDD) CRFs					
	Admission	<i>For intervention sites only</i>		<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	Weekly Surveillance	<i>For intervention sites only</i>		<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	Weekly Surveillance (Additional pages)	<i>For intervention sites only</i>		<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	Outcomes	<i>For intervention sites only</i>		<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	Outcomes (Additional pages)	<i>For intervention sites only</i>		<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	SDD Administration	<i>For intervention sites only</i>		<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	SDD Administration (Additional pages)	<i>For intervention sites only</i>		<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	SDD Administration Deviation	<i>For intervention sites only</i>		<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	Antibiotic Use	<i>For intervention sites only</i>		<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	Discharge	<i>For intervention sites only</i>		<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	Safety Monitoring	<i>For intervention sites only</i>		<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	PiCnIC Safety CRFs					
	Serious Adverse Event Reporting Form	Version 2.0	21 May 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	SUPERSEDED CRFs					
	Antibiotic Use	Version 1.0	22 February 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Discharge	Version 1.0	22 February 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Site completed paper CRFs	<i>File note to location of any completed paper CRFs</i>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Quality Assurance	Monitoring Log	Version 1	29 October 2020	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Monitoring reports	<i>Monitoring reports should be filed here</i>				
	Archiving information	<i>File note to explain procedures</i>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Site File Note template	Version 1	15 December 2020	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. Finance and Agreements	PiCnIC Research Team acknowledgement	Version 1.0	30 October 2020	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	PiCnIC Principal Investigator Statement	Version 1.0	30 October 2020	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Signed Clinical Trial Sites Agreement	Version 1.0		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	PiCnIC Pharmacy Appendix	<i>For intervention sites only</i>		<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	Human Volunteer Study ref. HVS/2019/2780 – insurance cover confirmation	-	25 November 2020	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Organisation Information Document	Version 1.0	02 November 2020	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Sponsor Letter of Support	-	11 November 2019	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Pathan funding award NIHR	-	07 March 2018	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. Ethics/Regulatory Documentation	MHRA email confirming not CTMP	16 May 2019		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	IRAS application form 239324	04 February 2020		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	West Midlands – Black Country Research Ethics Committee Initial PiCnIC Valid Application	05 February 2020		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



Ethics Resubmission Covering Letter	23 June 2020	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
West Midlands – Black Country Research Ethics Committee Favourable Opinion of the REC with conditions	12 August 2020	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Ethics Resubmission Covering Letter	25 August 2020	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
West Midlands – Black Country Research Ethics Committee Favourable Opinion of the REC with conditions met	23 September 2020	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
HRA Initial Assessment Letter	09 October 2020	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Substantial Amendment 1				
Substantial Amendment 1 Cover Letter	08 October 2020	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
West Midlands – Black Country Research Ethics Committee Favourable Opinion of the REC for Substantial Amendment 1	03 November 2020	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
HRA and HCRW Approval for Substantial Amendment 1 (email)	06 November 2020	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Non-Substantial Amendment 1				
Non substantial amendment tool	26 November 2020	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
HRA email – Non Substantial Amendment 1	30 November 2020	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Non-Substantial Amendment 2				
Non substantial amendment tool	11 May 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
HRA email – Non Substantial Amendment 2	12 May 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Non-Substantial Amendment 3				
Non substantial amendment tool	11 May 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
HRA and HCRW Approval for Non Substantial amendment 3 (email)	13 May 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Non-Substantial Amendment 4				
Non substantial amendment tool	07 June 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
HRA email – Non Substantial Amendment 4	10 June 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Non-Substantial Amendment 5				
Non substantial amendment tool	14 June 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
HRA email – Non Substantial Amendment 5	16 June 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Substantial Amendment 2				
Substantial Amendment tool	30 July 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
HRA & REC approval_confirmation of favourable opinion (email)	10 August 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Favourable Opinion Substantial Amendment	10 August 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Non-Substantial Amendment 6				
Non substantial amendment tool	10 September 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
HRA email – Non Substantial Amendment 6	14 September 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Non-Substantial Amendment 7				
Non substantial amendment tool	07 October 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
HRA email – Non Substantial Amendment 7	08 October 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



	Non-Substantial Amendment 8					
	Non substantial amendment tool	25 November 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	HRA email – Non Substantial Amendment 8	26 November 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Substantial Amendment 3					
	Substantial Amendment tool	08 November 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Substantial Amendment 3 cover letter	08 November 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	HRA & REC approval confirmation of favourable opinion (email)	29 November 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Favourable Opinion Substantial Amendment	29 November 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Non-Substantial Amendment 9					
	Non substantial amendment tool	17 December 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	HRA email – Non Substantial Amendment 9	20 December 2021	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Non-Substantial Amendment 10					
	Non substantial amendment tool	09 February 2022	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	HRA email – Non Substantial Amendment 10	10 February 2022	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Non-Substantial Amendment 11					
	Non substantial amendment tool	17 March 2022	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	HRA email – Non Substantial Amendment 11	21 March 2022	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Non-Substantial Amendment 12					
	Non substantial amendment tool	12 May 2022	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	HRA & REC approval – Non Substantial Amendment 12 (email)	16 May 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"/>		
12. Site Staff Information <i>(Please send copies to ICNARC CTU)</i>	PICnIC Delegation Log	Version 1	05 November 2020	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	PICnIC Staff Contact Form	Version 1	05 November 2020	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	PICnIC Training Log	Version 1	05 November 2020	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	CVs <i>Signed & 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"/>
13. Correspondence / Information	<i>Other important correspondence / information documents or emails (e.g. site activation, study updates)</i>					

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