

Site name:				Date of visit:	
Investigator Site File Review					
Check	Y	N	N/A	N/D	Details/Comments/Actions
Full review of Investigator Site File performed?					
Discussed site arrangements for archiving? (First visit only)					
Status of Investigator Site File					
File(s) appropriately labelled and stored in secure, appropriate place?					
Essential Documents					
All essential documents filed as per index?					
Old approved versions filed and marked as superseded?					
Trial Specific Logs					
Patients entered on the Master Subject List agree with information held at on PRISM database?					
Site completing Screening Log adequately?					
All records completed on the Delegation Log (Appropriate allocation of tasks, entries authorised by PI, all entries complete)?					
Copy of Delegation Log collected from site?					
Training Records and CVs					
All CVs present and up to date?					
All GCP certificates present and up to date?					
Trial Specific Requirements					

Investigator Site File – document version checklist.							
		Document Name	Version	Date	Present?		Comments
	1	ISF checklist	0.1	N/A	Y <input type="checkbox"/>	N <input type="checkbox"/>	
S1	2	Superseded contact page	1.1	06.01.2016	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	3	Contact page	2.0	20.01.2017	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	4	Version control log: protocol	1.0	23.09.2015	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	5	Version control log: PIS	1.0	23.09.2015	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	6	Version control log: informed consent	1.0	23.09.2015	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	7	Version control log: GP letter	1.0	23.09.2015	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	9	Version control log: other documents	1.0	23.09.2016	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	10	Current protocol	1.6	10.04.2017	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	11	Current protocol signature page	1.6	10.04.2017	Y <input type="checkbox"/>	N <input type="checkbox"/>	
S2	12	Superseded protocol	1.5	01.03.2016	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	13	Superseded protocol signature page	1.5	01.03.2016	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	14	Superseded protocol	1.4	18.08.2015	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	15	Superseded protocol signature page	1.4	18.08.2015	Y <input type="checkbox"/>	N <input type="checkbox"/>	
S3	16	Localised PIS	1.1	13.10.2015	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	17	Localised informed consent form	1.2	19.08.2015	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	18	Localised GP letter	1.0	02.07.2015	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	19	Localised patient information leaflet	1.0	29.06.2015	Y <input type="checkbox"/>	N <input type="checkbox"/>	
S4	20	REC form/IRAS	5.0.0	25.08.2015	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	21	Ethics cover letter		20.08.2015	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	22	REC acknowledgement		03.09.2015	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	23	REC approval		02.10.2015	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	24	Protocol/PIS change cover letter to REC		14.10.2015	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	25	REC acknowledgement for protocol/PIS change		16.11.2015	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	26	REC cover letter for substantial amendment 2		13.04.2017	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	27	IRAS form protocol amendment 2		25.04.2017	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	28	REC consideration letter for substantial amendment 2		04.05.2017	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	29	REC confirmation of amendment 2		12.05.2017	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	30	R&D approval for substantial amendment 2		27.07.2017	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	31	HRA approval of substantial amendment 2		19.06.2017	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	32	REC cover letter for substantial amendment 1		08.04.2016	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	33	IRAS form protocol amendment 1	V5.2.1	07.03.2016	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	34	REC consideration letter for substantial amendment 1		13.04.2016	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	35	REC confirmation of amendment 1		24.04.2016	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	36	R&D approval for substantial		27.04.2016	Y <input type="checkbox"/>	N <input type="checkbox"/>	

Investigator Site File – document version checklist.							
		Document Name	Version	Date	Present?		Comments
		amendment 1			<input type="checkbox"/>	<input type="checkbox"/>	
	37	SOE (for sites added with minor amendment)			Y <input type="checkbox"/>	N <input type="checkbox"/>	
	38	SOA (for sites added with minor amendment)			Y <input type="checkbox"/>	N <input type="checkbox"/>	
	39	HRA cover letter for minor amendment 1,2,3,4,5,6,7,8,9 (only for sites relating to the amendment)		27.05.2016 05.08.2016 30.09.2016 25.10.2016 10.02.2017 27.02.2017 24.04.2017 02.08.2017 17.08.2017	Y <input type="checkbox"/> Y <input type="checkbox"/> Y <input type="checkbox"/> Y <input type="checkbox"/> Y <input type="checkbox"/> Y <input type="checkbox"/> Y <input type="checkbox"/> Y <input type="checkbox"/> Y <input type="checkbox"/>	N <input type="checkbox"/> N <input type="checkbox"/> N <input type="checkbox"/> N <input type="checkbox"/> N <input type="checkbox"/> N <input type="checkbox"/> N <input type="checkbox"/> N <input type="checkbox"/> N <input type="checkbox"/>	
	40	Notification of non-substantial amendment 1,2,3,4,5,6,7,8,9 (only for sites relating to the amendment)		09.05.2016 05.08.2016 30.09.2016 25.10.2016 10.02.2017 27.02.2017 24.04.2017 02.08.2017 17.08.2017	Y <input type="checkbox"/> Y <input type="checkbox"/> Y <input type="checkbox"/> Y <input type="checkbox"/> Y <input type="checkbox"/> Y <input type="checkbox"/> Y <input type="checkbox"/> Y <input type="checkbox"/> Y <input type="checkbox"/>	N <input type="checkbox"/> N <input type="checkbox"/> N <input type="checkbox"/> N <input type="checkbox"/> N <input type="checkbox"/> N <input type="checkbox"/> N <input type="checkbox"/> N <input type="checkbox"/> N <input type="checkbox"/>	
	41	HRA approval		27.06.2016	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	42	Categorisation email for minor amendment 1,2,3,4,5,6,7,8,9 (all sites)		09.05.2016 05.08.2016 30.09.2016 25.10.2016 10.02.2017 27.02.2017 24.04.2017 02.08.2017 17.08.2017	Y <input type="checkbox"/> Y <input type="checkbox"/> Y <input type="checkbox"/> Y <input type="checkbox"/> Y <input type="checkbox"/> Y <input type="checkbox"/> Y <input type="checkbox"/> Y <input type="checkbox"/> Y <input type="checkbox"/>	N <input type="checkbox"/> N <input type="checkbox"/> N <input type="checkbox"/> N <input type="checkbox"/> N <input type="checkbox"/> N <input type="checkbox"/> N <input type="checkbox"/> N <input type="checkbox"/> N <input type="checkbox"/>	
S5	43	SSI form/IRAS form	5.1.0		Y <input type="checkbox"/>	N <input type="checkbox"/>	
	44	Local R&D approval/confirmation of C&C			Y <input type="checkbox"/>	N <input type="checkbox"/>	
	45	Local R&D approval for substantial amendment 1 (if applicable)			Y <input type="checkbox"/>	N <input type="checkbox"/>	
	46	Local R&D approval for substantial amendment 2			Y <input type="checkbox"/>	N <input type="checkbox"/>	
	47	Declaration of sponsorship		18.11.2015	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	48	Insurance certificate		2015/2016 2016/2017 2017/2018	Y <input type="checkbox"/> Y <input type="checkbox"/> Y <input type="checkbox"/>	N <input type="checkbox"/> N <input type="checkbox"/> N <input type="checkbox"/>	
	49	Feasibility (not required for all sites)			Y <input type="checkbox"/>	N <input type="checkbox"/>	
S6	50	-					
S7	51	Delegation log	1.0	23.09.2015	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	52	CVs and GCPs			Y <input type="checkbox"/>	N <input type="checkbox"/>	

Investigator Site File – document version checklist.							
		Document Name	Version	Date	Present?		Comments
S8	53	SOP 3 AE reporting	1.1	19.06.2017	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	54	SOP 3 AE reporting superseded	1.0	17.09.2015	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	55	List of AEs: file note to the database			Y <input type="checkbox"/>	N <input type="checkbox"/>	
	56	SOP 4 Protocol deviations	1.1	19.06.2017	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	57	SOP 4 Protocol deviations superseded	1.0	18.01.2016	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	58	SOP 1 CPAP	1.2	19.06.2017	Y <input type="checkbox"/>	N <input type="checkbox"/>	
S9	59	SOP 1 CPAP superseded	1.1	14.01.2016	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	60	Randomisation instructions	1.0	01.12.2015	Y <input type="checkbox"/>	N <input type="checkbox"/>	
S10	61	Screening log	1.0	23.09.2015	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	63	Enrolment log	1.0	23.09.2015	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	64	Completed consents/file note to the location			Y <input type="checkbox"/>	N <input type="checkbox"/>	
	65	Completed CRFs/file note to the location			Y <input type="checkbox"/>	N <input type="checkbox"/>	
	66	Current CRF	1.4	27.04.2017	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	67	Superseded CRF	1.3	10.10.2016	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	68	Superseded CRF	1.2	14.01.2016	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	69	Superseded CRF	1.1	03.12.2015	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	70	Deviations and breaches: file note to the database			Y <input type="checkbox"/>	N <input type="checkbox"/>	
S12	71	SIV presentation (if used)	6.0	15.05.2017	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	72	SIV presentation superseded			Y <input type="checkbox"/>	N <input type="checkbox"/>	
	73	Prism SIV attendance log	1.1	02.02.2016	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	74	File note for training after SIV			Y <input type="checkbox"/>	N <input type="checkbox"/>	
	75	SOP 2 Monitoring plan	1.3	20.10.2015	Y <input type="checkbox"/>	N <input type="checkbox"/>	

Training, CV and Delegation Log review				
Name	On Delegation Log (Y/N)	Date of CV	Date of GCP	Action required