Open to Recruitment Checklist

Sponsor ID no: **Site:** **Pharmacy:** **CI/PI name:** **Tick here if CI site ☐**	**Site Initiation date:** **Pharmacy Initiation date:** **SRA:** **COA:**

Items marked * may not be considered n/a

Item	Yes or n/a	Version/ Date
Trial Agreements/ Approvals		
Final Sponsorship letter*	**Yes**	
Funding Award confirmation	**Yes**	
MHRA approval*		
Ethics approval*		
ARSAC approval (if applicable)*	**N/A**	
Data Protection letter/ registration*	**Yes**	***TMF only***
Insurance certificate*	**Yes**	
Approved protocol*	**Yes**	
Central delegation log		***TMF only***
Finalised CRF* authorised by CI and Statistician		
eCRF User acceptance testing	**N/A**	***TMF only***
Finalised IDMC/TSC/TMG Charter		***TMF only***
Randomisation/ Unblinding SOP		
Data management SOP*		
Sample management SOP		
Monitoring Plan*		***TMF only***
Registration of trial on a publicly accessible database*		
TMF/ ISF review at site visit OR completion of UK Compliance Form Part 1*		
Trial Contracts signed* list below	**n/a**	***TMF only***
CI Agreement	**Yes**	
Funding agreement		
IMP supply Agreement		
Technical Agreement	**N/A**	
Laboratory Agreement	**N/A**	
SPONSOR FILE DOCUMENTS		
Registration on eSUSAR or equivalent		**SpF only** **Only for first SIV**
Signed Sourcing form *		**SpF only** **Only for first SIV**
Pharmacy questionnaire (within 2 years)		**SpF only**
Site feasibility questionnaire		**SpF only**
Sealed envelope registration		**SpF only**

Item		Yes or n/a	Version/ Date
IMP/ ATIMP			
Summary of Drug Arrangements/ ATIMP management plan*			
SPC/ IB			
IMP/ATIMP specific SOPs			
IMP order and receipt forms			
Master Prescription form			
Site specific documents			
R&D approval*			
Local genetic modification safety committee approval (if applicable)*			**Add other site specific approvals as applicable (eg HSE notification)**
CTSA*			
Approved Patient Information documents (on local headed paper)*:	**PIS**		
	ICF		
	GP letter		
	Patient card		
	Other		
Local Lab accreditations and reference ranges (as applicable)	**Haematology**		**if applicable**
	Biochemistry		**if applicable**
	Microbiology		**if applicable**
	Other		
	Other		
Personnel/ Training	**CI/PI CV- Signed and dated***		
	CI/PI GCP certificate*		Date:
	Completed delegation log*		
	Relevant Sponsor SOPs (see Investigator list) signed and filed*		
	Copy of Initiation slides (including Pharmacovigilance) filed*		
	Other trial specific training:		
Equipment (if applicable)	**Sample storage satisfactory**		
	All lab equipment/ lab kits available		
	Equipment calibration certificates		
	User names/ passwords issued for Randomisation/ Unblinding/ eCRF		
	Other:		
Pharmacy	**Local Dispensing procedure in place (or equivalent)**		
	IMP accountability logs in place		
	IMP storage reviewed *		
	Site specific prescription (if applicable)		
	SPCs for nIMPs filed		

Item	Yes or n/a	Version/ Date
Site documents (Tailored for the trial/ site if applicable)		
Source Data list signed by PI*		
Subject Screening log*		
Subject enrolment, withdrawal and completion log*		
Master Subject ID Code list*		
Trial contact sheet*		
CI/PI Log of Protocol/GCP Deviations/violations/potential serious breaches/USMs*		
Adverse Event Recording and Reporting Log*		
Pregnancy Reporting Form*		
Serious Adverse Event Reporting Form*		
Amendment log*		

All documents listed should be filed in the TMF/ISF prior to open to recruitment unless otherwise indicated (e.g. Sponsor file only documents).
TMF/ISF/Pharmacy files may be prepared by the site (JRO staff to send index in advance) or pre-prepared file may be sent to the site.
TMF and/ or ISF review may be completed prior to or on the day of the initiation visit, or documents can be verified on review of a complete JRO UK regulations compliance form (Part 1) (see monitoring plan for trial specific requirements).
A Sponsor file review should be completed prior to the initiation visit and documented (if a full file review is not available all essential documents on this checklist should be filed as a minimum).

The site initiation visit has been completed according to Initiation SOP (JBRU/SPON/S20), relevant training was given at the Site Initiation Visit and queries resolved (see IVR for details).

The signatures below confirm that all essential documents are in place at the Investigator site and that the ***Open to recruitment letter may be issued***.

Completed by (name):		Reviewed by (name):	
Role:		Role:	
Signature:		Signature:	
Date:		Date:	