JRES Clinical Study Support Process:

Phase	Study Stage	What will the HRA[1] do?	What will the sponsor should do?	What will the JRES do?	What will the researcher do?	Metric Target Timeline	What will be documented on EDGE?[2]
IDENTIFICATION	**"Early Engagement"- initial identification of potential study sites/Researcher(s).**		Provide a Confidentiality Disclosure agreements (CDA) and or study Expression of Interest (EOI)/feasibility form- Directly	**Review and authorise any confidentiality agreements** **Create an Edge record**	Forward any new study interest/sponsor communication to the JRES team asap Notify the JRES team of any pre-site selection visits asap		Date Site Invited
			Request EOI via NIHR CRN South London	**Liaise with the researcher to review study request**			
			Provide a protocol/draft protocol / synopsis	**Work with researcher/research team to review study feasibility (ideally via meeting/call) incorporating relevant support teams – CRF, Pharmacy. Radiology** **<u>Initiate</u> local support department reviews- CRF, Pharmacy, Radiology, Pathology** **Support appropriate target setting**	Provide early feasibility feedback Where relevant meet with the JRES and Research support teams to discuss feasibility		
STUDY SET-UP	Assess		Request Site Intelligence (SI) review via NIHR Clinical Research Network (CRN) Confirm site selection Submission to HRA/Regulatory bodies	**Early opportunity to identify support required to ensure effective study delivery.** **Support organisational agreement to undertake study** **Support completion of all/any feasibility forms**	Complete Sponsor and or NIHR CRN EOI/SI		
	Arrange	**HRA Initial Assessment Letter Issued** And/ or **HRA Approval Letter Issued** (*once all regulatory reviews complete including MHRA if applicable*)	Email (submission) Local HRA documentation package to Principle Investigator (PI), JRES (researchgovernance@sgul.ac.uk) and CRN London South (if NIHR study) (gst-tr.LSCLRN@nhs.net)	**Review and Acknowledge submission** **Update Edge record** **<u>Finalise</u> relevant organisation reviews (CRF, Pharmacy. Radiology, Pathology)**	Review submission Where relevant meet/discuss with the JRES and Research support teams to discuss study arrangements	40 days	Date site selected
			Provide additional supporting study specific documents- Investigator Brochure / Laboratory Manual/ Imaging protocols	**Liaise and work with the researcher(s) and research teams to put in place practical requirements to deliver the study** **Review Budget costings and or Schedule of Events** **Review contract and or Statement of Activities**	Confirm appropriate target Confirm appropriate costings Confirm appropriate Site initiation date with sponsor		Date site confirmed by sponsor
			Provide HRA Approval letter & MHRA approval letter when issued	**Seek Divisional Directorate approval**			
	Confirm			**Authorise site contract and or Statement of Activities**	Ensure site file is created Add authorised site contract to site file		**Date site confirmed** or Non Confirmation
STUDY DELIVERY	**Opening**		Hold SIV- Open the site	**Ensure all study teams are added to EDGE**	Start recruitment	30 days	Date site ready to start
	1st Patient			**Provide study team EDGE training**	Recruit first patient		1st Patient Recruited
	On-going		Identify any issues with delivery of the study onsite to the PI and JRES	**Regular review of recruitment** **Recruitment trouble-shooting for poorly recruiting studies** **Review funding allocation**	Register all recruitment on EDGE on a regular/real time basis Update JRES on study progress		Ongoing recruitment progress- Recruitment Time to Target
	Ending		Close the site	**Archive site study file(s)**	End recruitment		Total number of recruits & Last Patient Recruited

[1] http://www.hra.nhs.uk/resources/hra-approval-guidance-for-sponsorschief-investigators-working-collaboratively-with-nhs-organisations-in-england/
[2] https://www.nihr.ac.uk/research-and-impact/nhs-research-performance/hra-approvals-and-nihr-metrics.htm