

**ANNEX B****Checklist of documents required for R&D submission**Study Title: R&D Ref: **All documents must be submitted if relevant to the application. If not, please state not applicable (N/A)**

<b>Documents:</b>	<b>Yes/No/ N/A</b>	<b>Version no. and date</b>	<b>Date submitted to R&amp;D</b>
IRAS parts A-D (in xml and pdf format)			
IRAS signed declaration pages			
SSI (NOTE: For any studies deemed as Site Specific Exempt an SSI is still required by R&D for each site involved within GG&C, with all support department signatures if applicable) (in xml and pdf format)			
SSI signed declaration pages			
Protocol			
CV ( for all personnel named on the SSI )			
GP/Consultant Information sheet			
Letters of invitation to participants			
Investigator Brochure			
Participant Information Sheet			
Consent Form			
Questionnaire			
Letter from Sponsor (not required if Sponsor is NHS GG&C)			
Funding Application			
Letter from Statistician			
Evidence of Peer review			
Funding Award Letter			
ARSAC Authorisation			
MHRA Clinical Trial authorisation			
REC acknowledgment letter			
REC favourable opinion and all correspondence			
Site Specific Approval letter			
Trial Agreements			
Evidence of Insurance or Indemnity			
Confirmation of REC favourable opinion for any substantial amendments			
Confirmation of authorisation from MHRA for any substantial amendments			
Evidence of GCP training ( for all personnel named on the SSI )			
Completed copy of this checklist			

**Please Note: Applications with blank signatory sheets unfortunately cannot be accepted as valid document set.**