IRAS Checklist for REC and R&D

Documentation	REC	R&D
Covering letter on headed paper	Y	
REC application form (signed/authorised)	Y	
R&D Form XML file		Y
Research protocol or project proposal	Y	Y
Investigator's brochure / IMP Dossier	Y	Y
Costing template (commercial projects)		Y
Contract/Study Agreement		Y
Summary CV for supervisor (student research)	Y	Y
Summary of product characteristics (SmPC)	Y	Y
Summary CV for student	Y	Y
Summary CV for Chief Investigator (CI)	Y	
Participant information sheet (PIS)	Y	Y
Letters of invitation to participant	Y	Y
GP/consultant information sheets or letters	Y	Y
Evidence of Sponsor insurance or indemnity (non-NHS Sponsors only)	Y	Y
Participant consent form	Y	Y
Letter from sponsor	Y	
Letter from funder	Y	
Letter from statistician	Y	
Referee's report or other scientific critique report	Y	
Summary, synopsis or diagram (flowchart) of protocol in non-technical language	Y	
Details of any Data Monitoring Committee	Y	
Interview schedules or topic guides for participants	Y	Y
Sample diary card/patient card	Y	Y
Validated questionnaire	Y	Y
Non-validated questionnaire	Y	Y
Copies of advertisement materials for research participants	Y	Y
Instructions for use of medical device	Y	Y
REC favourable opinion letter and all correspondence		Y
Confirmation of clinical trial authorisation from MHRA and relevant correspondence		Y
MHRA ‘Notice of No Objection’ Letter (Medical Devices) and relevant correspondence		Y
Confirmation of any other regulatory approvals (eg NIGB) and all correspondence		Y
Notice of Substantial Amendment XML file		Y
Notice of no objection letter (Medical Devices) for any substantial amendments and related correspondence		Y
Notice of Non-substantial Amendment		Y

Confirmation of REC favourable opinion for any substantial amendments and all correspondence		Y
Laboratory Manual		Y
Confirmation of authorisation from MHRA for any substantial amendments and relevant correspondence		Y