Chief Investigator Checklist (before seeking approvals)

Sponsor(s) identified and agreements for allocation / delegation of responsibilities (if necessary) are in place	
Arrangements for appropriate Patient and Public Involvement	
Input from a statistician secured	
Peer review complete	
Arrangements for a data monitoring committee, steering group and/or management group in place (with consent from members)	
Trial risk assessment carried out, trial management systems and monitoring plan/arrangements in place	
Funding secured	
Unique trial number and EudraCT number obtained	
R&D and local NHS support departments (e.g. pharmacy, labs, radiology etc.) consulted and capacity available	
Contracts and agreements in place including third party agreements where outsourcing of any trial specific test/services is required	
Insurance and indemnity arrangements in place (non NHS)	
CVs of investigators (signed and dated)	
Arrangements for trial supplies in place	
Arrangements for pharmacovigilance considered	
Systems in place to ensure trial will be conducted the principles of GCP and Clinical Trials Regulations	
Trial Master File established	
Protocol and associated documents (see relevant stations):	
• EudraCT number on all documentation	
• End of trial defined	
• Safety reporting section of the protocol outlining definitions and reporting requirements	
• All written information provided to/viewed by subjects (e.g. Participant information sheets, consent forms, patient diaries, recruitment advertisements) finalised and version controlled	
• All other relevant trial documentation finalised and version controlled e.g. questionnaires, case report forms, trial specific SOPs	
• Investigator's brochure or SmPC developed/identified	