Required documentation	Notes	External links
IRAS R&D Application form (Parts A –D, as applicable)	Contains structured information about the study and sets out the responsibilities of the Sponsor and Chief Investigator (CI). • Must be signed by the Sponsor and the Chief Investigator and, where applicable, by Medical Physics and Clinical Radiation Experts • Generated via the IRAS system	www.myresearchproject.org.uk
Sponsor Letter	Confirms responsibilities of Sponsorship, as required by Research Governance Framework. • Required for all non-NHS GG&C Sponsored studies	http://www.dh.gov.uk/en/Researchanddevelopment/A-Z/Researchgovernance/DH_4002112
Protocol	Outlines the overall research plan • Must be version number and date controlled.	
Site-specific Information form (SSI).	Outlines site specific research team activities and individual responsibilities at the site. • Information used for financial assessment	www.myresearchproject.org.uk

Fully signed	• Required for each site • Generated via the REC or R&D form within IRAS system. • Must be signed by Principal Investigator and authorised at Question 23 by the management of Clinical specialities and support departments (Biochemistry, pathology).
Insurance certificate / statement of indemnity arrangements	Evidence of appropriate insurance/indemnity required for all non NHS GG&G sponsored studies.
Agreements/contracts	May be required for both commercial & Non-commercial studies and include: • Clinical Trial Agreements • Sponsorship agreements • Third party agreements • University Indemnities • Equipment indemnities (loaned equipment)

Funder Letter	Confirms funding arrangements and whether peer-review has occurred. • If there is no external funding, peer review will be arranged by the R&D Office • For student projects review is assumed to have been made by the educational supervisor.	
Participant Information sheets & Consent forms	• Must be version number and date controlled	
Researcher CVs	A signed and dated CV is required for the CI and every member of the research team listed on the SSI.	
Research Passports / Honorary Contracts for Researchers	Required by all researchers with direct access to patients or patient identifiable data who: • are not employed by NHS GG&C • do not hold an honorary clinical contract with NHS GG&C	http://www.nihr.ac.uk/systems/Pages/systems_research_passports.aspx

Favourable Opinion Letter from REC	Researchers must submit a favourable opinion letter along with all documents approved by the REC committee.	
MHRA Clinical Trial Authorisation (CTA) Letter	Required for all trials regulated by the Medicines for Human Use (Clinical Trials) Regulations 2004, 2006 as amended	http://www.mhra.gov.uk/index.htm http://www.opsi.gov.uk/si/si2004/20041031.htm
Good Clinical Practice (GCP) Training Certificate	Required for all staff listed on the delegation log for trials regulated by the Medicines for Human Use (Clinical Trials) Regulations 2004, 2006 as amended	http://www.glasgowcrf.org.uk/courses.htm
Study-specific Regulatory Documentation	An ARSAC licence is required for studies when radioactivity is administered to patients beyond that delivered in routine care; Medical devices documentation	http://www.arsac.org.uk/
Additional documentation	Maybe required. Please discuss with the Commercial	

for commercial studies	Research Coordinator