Checklist (CTIMP / PI-led)

Following is a list of documents, approvals and stage markers that define the route taken by a healthcare research study for an Investigational Medicinal Product, where an Imperial College/Trust principal investigator is responsible for a local site.

Item	Description	Required for CTIMP-PI?
Funding letter	Funding agreement	Yes (via main study)
Sponsorship letter	Sponsorship agreement (external or College)	Yes (via main study)
Protocol	Objectives, design, methodology, statistical considerations	Yes (via main study)
Peer review	Expert consideration of design quality, feasibility, acceptability and importance (study-wide, sponsor to arrange)	Yes (via main study)
Feasibility study	Assessment of resource capacity, staffing, locations	Yes
ICHT Clinical Division review	Assessment of value to portfolio	Yes
Registration with JRCO	Entry on to Documas	Yes
Chief Investigator's CV	CV	Yes
CVs of study team mentioned on SSI form	CVs	If applicable
Investigator's brochure	Dose, frequency, method, safety monitoring etc of IMP	Yes (via main study)
Participant information sheet	To outline the study's aims and the participant's involvement	Yes
Consent form	To obtain consent from the participant (or parent/carer)	Yes
GP Letter	Letter to GP from research team about participant	Yes
Study specific documentation (eg patient diary cards)	To monitor progress on the trial	Yes
Evidence of sponsor insurance		Yes (via main study)
Contract	May include standards, roles and responsibilities, procedures, lines of communication, IP	Yes (via main study)
Costing/budget (InfoEd)	Accurate costing of research and services	Yes
Grant	Submission procedure	Yes (via main study)
Intellectual Property agreement	To enable the originator of a creative work to benefit	Yes (via main study)
Model agreement eg mCTA	Agreements between stakeholders (roles and responsibilities)	Yes (via main study)
Material Transfer Agreement	For transfer of tangible research materials between organisations	Yes (via main study)

Authorised Legal Representative letter	For non-CTIMP studies, ALR must be nominated if sponsor is ex-EU	Yes (via main study)
Imaging Research Proposal Form (v3)	Imaging requirement	If applicable
Site surveys (Imaging)	To determine a site's imaging capabilities and media required	If applicable
Imaging manuals	Parameters and guidelines for imaging to be performed	If applicable
ISAF form	Imaging support	If applicable
Pathology	Pathology support (test names, special reqs)	If applicable
Pharmacy MF14 Trial Notification form (v2)	Pharmacy support	If applicable
Technical agreement	Covers manufacture of IMP	If applicable
Investigational Medicinal Product Dossier	Information related to quality, manufacture and control of IMP	If applicable
Pharmacy manual	Covers IMP formulation, storage, labelling, admin	If applicable
Pharmacy Agreement with external sites		If applicable
Tissue Bank registration		If applicable
Additional peer review	Through Peer Review Service	Yes (via main study)
REC favourable opinion letter	Issued by REC following satisfactory review	Yes (via main study)
New Interventions Committee		Yes (via main study)
Good Clinical Practice (evidence of)		Yes
Information governance (Caldicott)		Yes
CPG authorisation (for IRAS submission)	CPG authorises study submission	Yes
IRAS REC form (inc MHRA/GTAC/NGIB)	For ethical approval	Yes (via main study)
IRAS NHS R&D form	For NHS R&D approval	Yes (via main study)
IRAS Site Specific Information (SSI) form	For local site approval	Yes
Local Allocation Service (for REC)	To request REC slot	Yes (via main study)
CSP application form (NIHR Portfolio)	For NIHR Portfolio	Yes (via main study)
NHS Permission/R&D Approval	Written permission for research involving human participants hosted through the NHS	Yes