

## Checklist (Observation / PI-led)

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

Item	Description	Required for Obs-PI?
<b>Funding letter</b>	Funding agreement	Yes (via main study)
<b>Sponsorship letter</b>	Sponsorship agreement (external or College)	Yes (via main study)
<b>Protocol</b>	Objectives, design, methodology, statistical considerations	Yes (via main study)
<b>Peer review</b>	Expert consideration of design quality, feasibility, acceptability and importance (study-wide, sponsor to arrange)	Yes (via main study)
<b>Feasibility study</b>	Assessment of resource capacity, staffing, locations	Yes
<b>ICHT Clinical Division review</b>	Assessment of value to portfolio	Yes
<b>Registration with JRCO</b>	Entry on to Documas	Yes
<b>Chief Investigator's CV</b>	CV	Yes
<b>CVs of study team mentioned on SSI form</b>	CVs	If applicable
<b>Investigator's brochure</b>	Dose, frequency, method, safety monitoring etc of IMP	No
<b>Participant information sheet</b>	To outline the study's aims and the participant's involvement	Yes
<b>Consent form</b>	To obtain consent from the participant (or parent/carer)	Yes
<b>GP Letter</b>	Letter to GP from research team about participant	Yes
<b>Study specific documentation (eg patient diary cards)</b>	To monitor progress on the trial	Yes
<b>Evidence of sponsor insurance</b>		Yes (via main study)
<b>Contract</b>	May include standards, roles and responsibilities, procedures, lines of communication, IP	Yes (via main study)
<b>Costing/budget (InfoEd)</b>	Accurate costing of research and services	Yes
<b>Grant</b>	Submission procedure	Yes (via main study)
<b>Intellectual Property agreement</b>	To enable the originator of a creative work to benefit	Yes (via main study)
<b>Model agreement eg mCTA</b>	Agreements between stakeholders (roles and responsibilities)	Yes (via main study)
<b>Material Transfer Agreement</b>	For transfer of tangible research materials between organisations	Yes (via main study)

<b>Authorised Legal Representative letter</b>	For non-CTIMP studies, ALR must be nominated if sponsor is ex-EU	Yes (via main study)
<b>Imaging Research Proposal Form (v3)</b>	Imaging requirement	No
<b>Site surveys (Imaging)</b>	To determine a site's imaging capabilities and media required	No
<b>Imaging manuals</b>	Parameters and guidelines for imaging to be performed	No
<b>ISAF form</b>	Imaging support	No
<b>Pathology</b>	Pathology support (test names, special reqs)	No
<b>Pharmacy MF14 Trial Notification form (v2)</b>	Pharmacy support	No
<b>Technical agreement</b>	Covers manufacture of IMP	No
<b>Investigational Medicinal Product Dossier</b>	Information related to quality, manufacture and control of IMP	No
<b>Pharmacy manual</b>	Covers IMP formulation, storage, labelling, admin	No
<b>Pharmacy Agreement with external sites</b>		No
<b>Tissue Bank registration</b>		No
<b>Additional peer review</b>	Through Peer Review Service	Yes (via main study)
<b>REC favourable opinion letter</b>	Issued by REC following satisfactory review	Yes (via main study)
<b>New Interventions Committee</b>		Yes (via main study)
<b>Good Clinical Practice (evidence of)</b>		Yes
<b>Information governance (Caldicott)</b>		Yes
<b>CPG authorisation (for IRAS submission)</b>	CPG authorises study submission	Yes
<b>IRAS REC form (inc MHRA/GTAC/NGIB)</b>	For ethical approval	Yes (via main study)
<b>IRAS NHS R&amp;D form</b>	For NHS R&D approval	Yes (via main study)
<b>IRAS Site Specific Information (SSI) form</b>	For local site approval	Yes
<b>Local Allocation Service (for REC)</b>	To request REC slot	Yes (via main study)
<b>CSP application form (NIHR Portfolio)</b>	For NIHR Portfolio	Yes (via main study)
<b>NHS Permission/R&amp;D Approval</b>	Written permission for research involving human participants hosted through the NHS	Yes