

Researcher's Checklist

Clinical Trial of an Investigational Medicinal Product

not being sponsored by LTHT / UoL

Incomplete applications will mean a delay in R&D approval of the trial

	Tick if submitted
<p>➤ Site Specific Information Form (SSIF) Signed / dated by the Leeds Principal Investigator Please send both XML and PDF format via e-mail</p>	<input type="checkbox"/>
<p>➤ CMT Approval CMT signature on Q39 of the SSIF (Or) written confirmation of CMT Approval</p>	<input type="checkbox"/>
<p>➤ Main REC approved trial protocol</p>	<input type="checkbox"/>
<p>➤ Main REC approved patient information and consent form Submitted on headed paper that will be used at this research site</p>	<input type="checkbox"/>
<p>➤ Parts A and B of the NRES form Please send both XML and PDF format via e-mail</p>	<input type="checkbox"/>
<p>➤ Main REC letter confirming favourable opinion for the trial Incorporating a list of approved study documents</p>	<input type="checkbox"/>
<p>➤ Main REC letter confirming favourable opinion of the local SSA</p>	<input type="checkbox"/>
<p>➤ 3 Copies of the Indemnity (if separate from the clinical trials agreement) May not be applicable for an NHS / Academic / Public Body sponsored trial</p>	<input type="checkbox"/>
<p>➤ 3 Copies of the Clinical Trials Agreement / Sponsor Agreement If applicable, letter from a UK Legal Representative confirming sponsorship arrangements, if the Research Sponsor is based out of the European Union.</p>	<input type="checkbox"/>
<p>➤ MHRA Clinical Trial Authorisation letter If there are Remarks on the Notice of Acceptance, then please forward a copy of the response and the MHRA acknowledgement of the response. Repeat for further Remarks.</p>	<input type="checkbox"/>
<p>➤ Investigational Medicinal Product GMP Compliance documents For certain CTIMPs we may need to ask for a confirmation letter from the sponsor that the IMP(s) used in the trial are imported / manufactured to GMP standards</p>	<input type="checkbox"/>
<p>➤ Documentary evidence of GCP training for CI and the PI within the last 2 years (if employed by LTHT). <i>This evidence may be a training or attendance certificate</i> Please contact R&D for information on course availability or look on the R&D website http://www.leedsth.nhs.uk/sites/research_and_development/trainings.php</p>	<input type="checkbox"/>

Please note that there is an R&D Admin Fee for all commercially sponsored trials

For further information please contact Quality Assurance, R&D, LGI - tel. (0113) 39 26473 or visit our website: www.leedsth.nhs.uk/sites/research_and_development