

Pharmacy Clinical Trials – Pharmacy Modification Review Checklist

Pharmacy Review Checklist	Pharmacy Approval Required	Information Only - email approval to Portfolio Pharmacist and Technician(s)	No Action Required
IMP change in how it is administered	X		
Reformulation of IMP	X		
IMP change in dose	X		
Changes to cycle/length of supply	X		
Modification with an updated IMP Dossier	X		
Change to Study Documents - Patient Information Sheet (PIS) or Consent Form (CF)	X		
Change to Study Documents - Protocol (<i>changes affecting IMP</i>), IB, Pharmacy Manual or IWRS Manual	X		
Extension of a study	X		
Issue of an updated Investigator's Brochure	X		
New NHS GG&C Location (hosted study)	X		
Inclusion/exclusion criteria	X		
Updated safety profile of IMP	X		
Change in funding arrangements		X	
Changes to the radiation dose given to a participant		X	
Temporary halt to recruitment of a study		X	
Re-start to recruitment of a study		X	
Any modification which includes an MHRA approval		X	
Change to Study Documents - Protocol (excluding IMP)		X	
Change to the design methodology of a study		X	
Change to the definition of the end of the study (e.g. 10 year follow-up changed to 'until death')		X	

Addition to local study team		X	
Change in Sponsor		X	
Change in Sponsor contact details		X	
Change in Chief Investigator		X	
Change in Principal Investigator at one of our locations		X	
Change of number of patients recruited		X	
New researcher/SSI form for location already approved			X
Changes in the logistical arrangements for storing samples			X
Changes in the logistical arrangements for transporting samples			X
Changes to the requirement of an ARSAC certificate			X

Modifications should be sent to the relevant Portfolio Pharmacist for their review or information based on modification categorisation. For reference, contact and location details of Portfolio Pharmacists are listed in the 'GL52.003A Modification Approval Checklist - Pharmacy Portfolios' which will be updated as and when required to reflect staff changes.

Guideline signatories

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Document history

Version	Date	Description	Retrospective Implementation
1.0	14/07/2016	Released to staff	No
2.0	27/07/2026	Updated 'amendment' to 'modification'	Yes – 28/04/2026

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