UNIVERSITY OF LEICESTER

UoL Site Initiation Checklist

for studies NOT involving Investigational Medicinal Products

1.Site Information

Site	**Initiation Visit Method**	
Sponsor Reference Number:	On Site	☐
Study Name:	Teleconference	☐
Investigator:	Other (specify)	☐
Study Site:		
Date of Initiation		
Conducted by:		

2.Personnel in Attendance/Completing Report

Name	Title

3. Study Overview/Protocol Overview

Items discussed/verified	Comments
Background and purpose of study	

4. GCP and Regulatory Compliance

Items Discussed/verified	Yes	No	Comments
Investigator obligations	☐	☐	
Sponsor obligations	☐	☐	
Standard Operating Procedures	☐	☐	
Sponsor reporting requirements	☐	☐	
Amendments	☐	☐	
Annual reports	☐	☐	
Data Protection	☐	☐	
Study record storage requirements	☐	☐	
Archiving arrangements	☐	☐	

5. Trial Master File/Investigator Site File

Items Discussed/verified	Yes	No	Comments
TMF/ISF created and complete	☐	☐	
Delegated Individual for TMF/ISF maintenance	☐	☐	

Secure Location/limited Access	☐	☐	

6. Study Approval Status/Essential Documents

Items Discussed/verified	Yes	No	N/A	Version/ Comments
EC Favourable opinion/HRA approval	☐	☐	☐	
R&D/R&I/Host organisation approval/authorisation	☐	☐	☐	
Signed Sponsor/CI Agreement	☐	☐	☐	
Signed Financial Agreement	☐	☐	☐	
Protocol - Confirm protocol signed and dated by the PI	☐	☐	☐	
Protocol deviation/Serious Breach reporting	☐	☐	☐	
Patient Information Leaflet (document version no and date)	☐	☐	☐	
Consent (document version no and date)	☐	☐	☐	
Patient Invitation (document version and date)	☐	☐	☐	
GP Letter (document version and date)	☐	☐	☐	
Advertisement (document version and date)	☐	☐	☐	
CRF (document version and date)	☐	☐	☐	
Other: Are the contact numbers on the PIS correct/ been checked?	☐	☐	☐	

7. Investigator Site Personnel

Items Discussed/verified	Yes	No	Comments
Adequate site staff to conduct the study	☐	☐	
All study team members listed on Delegation of duties log/ all entries signed and dated by PI	☐	☐	
Signed and dated CVs for all study team members	☐	☐	
Documented evidence of GCP / consent/study specific training	☐	☐	

8. Recruitment

Items discussed/verified	Yes	No	N/A	Comments
Planned Number of Trial subjects	☐	☐	☐	
Methods for identifying Subjects	☐	☐	☐	
Research team aware of inclusion/exclusion criteria?	☐	☐	☐	
Requirement to complete Subject Screening and Enrolment logs	☐	☐	☐	

Procedure for withdrawn Subjects/Lost to follow-up	☐	☐	☐	

9. Informed Consent/Enrolment

Items Discussed/verified	Yes	No	Comments
Informed consent procedures/documentation requirements	☐	☐	
Eligibility criteria confirmed	☐	☐	

10. Randomisation/Blinding (check box if N/A ☐)

Items discussed/verified	Yes	No	Comments
Unblinding procedure/code break envelopes	☐	☐	
Randomisation procedures	☐	☐	

11. Safety Reporting/Pharmacovigilance (Check box if N/A ☐)

Items Discussed/verified	Yes	No	Comments
AE / SAE reporting procedures	☐	☐	
Notification process	☐	☐	

12. Data Collection

Items Discussed/verified	Yes	No	Comments
Format and timelines	☐	☐	
CRF completion guidelines	☐	☐	
Queries and corrections	☐	☐	
eDC training (for electronic case report forms)	☐	☐	
File notes	☐	☐	
Statistical Analysis Plan	☐	☐	

13. Source Documentation

Items Discussed/verified	Yes	No	Comments
Source Data agreement in place?	☐	☐	
CRFs as source	☐	☐	
Document retention	☐	☐	

14. Equipment List (Check box if N/A ☐)

Items Discussed/verified	Yes	No	Comments
Equipment list	☐	☐	
Calibration of equipment	☐	☐	
Maintenance/service record requirements	☐	☐	

Specimen collection (Check box if N/A ☐)

Items Discussed/verified	Yes	No	Comments
Specimen Collection	☐	☐	
Sample result verification/CS/NCS status and	☐	☐	

required actions			
Specimens to be obtained	☐	☐	
Specimen Storage	☐	☐	
Specimen storage and tracking logs	☐	☐	
Temperature monitoring	☐	☐	
Sample shipment	☐	☐	
Laboratory training/manual/SOPs	☐	☐	
Lab kits	☐	☐	
Lab Accreditation	☐	☐	
Lab Normal Values	☐	☐	

15. Communications

Items discussed/verified	Yes	No	Comments
Format and frequency	☐	☐	
Site contacts	☐	☐	
Recruitment updates to Sponsor	☐	☐	

16. Monitoring

Items discussed/verified	Yes	No	Comments
Site Monitoring response requirements	☐	☐	

17. SOP

Items discussed/verified	Yes	No	Comments
Do all members of the study team know how to access the Sponsor SOPs via the webpages?	☐	☐	
CI/PI confirmation of review and compliance with all Sponsor Standard Operating Procedures.	☐	☐	

18. Archiving

Items discussed/verified	Yes	No	Comments
Archiving at end of study discussed?	☐	☐	

Additional Comments/ Visit Overview

Study commencement must not occur until Sponsor Green Light process has been completed

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UoL Site Initiation Outstanding Issues Report

Sponsor Reference and Short Title:

Date of Visit: **Date of Report:** **Date Responses Due Back:**

No	Outstanding Issue	Action required	Action Taken	Signature & Date

SIV Report Completed By:

Monitor:
Telephone
e-mail:
Signature:
Date:

Completed Responses Approved by PI:

PI Name:
PI Signature:
Date:

Completed SIV Report Approved By:

Monitor:
Signature:
Date: