

Amendment Sponsor Green Light Checklist

Study Title:	
Reference No:	
Amendment No:	

PI:		Site:	
Point of Contact:		R&D/R&I Contact:	
Email:		Email:	

All amendments (except NSA No Study-wide Review)	N/A	Date Completed
Confirmation of Funding for End Date Extension <i>(i.e., from the funder, budget holder, the grants team etc.)</i>	<input type="checkbox"/>	
Contracts Fully Executed <i>(i.e., Collaboration, Funder(s), Data/Material Sharing)</i>	<input type="checkbox"/>	
Renewed Indemnity Certificate Issued	<input type="checkbox"/>	
MHRA Approval	<input type="checkbox"/> <input type="checkbox"/>	Valid Application: Approval:
REC Approvals	<input type="checkbox"/> <input type="checkbox"/>	Valid Application: Favourable Opinion:
HRA Approval	<input type="checkbox"/>	Approval:
Research Passport/Letter of Access	<input type="checkbox"/>	
Confirmation of Capacity & Capability <i>(inc. updated mNCA and/or OID issued)</i>	<input type="checkbox"/>	
Pharmacy Green Light <i>(if not part of C&C)</i>	<input type="checkbox"/>	
Other Approvals <i>(i.e., CAG, ARSAC, Uni Ethics; please list)</i>	<input type="checkbox"/>	
Risk Assessment Updated	<input type="checkbox"/>	
Monitoring Plan Updated	<input type="checkbox"/>	
Study Tracker Updated	<input type="checkbox"/>	

CRN Notified	<input type="checkbox"/>	
EDGE End Date Updated	<input type="checkbox"/>	
Study Documents Moved on X:Drive	<input type="checkbox"/>	
Protocol Version & Signature Page	<input type="checkbox"/>	
Sponsor Green Light		

NSA No Study-wide Review (NSA-NSWR) <ul style="list-style-type: none"> • Category A <input type="checkbox"/> • Category B <input type="checkbox"/> • Category C <input type="checkbox"/> 	N/A	Date Completed
Confirmation of Funding for End Date Extension <i>(i.e., from the funder, budget holder, the grants team etc.)</i>	<input type="checkbox"/>	
Contracts Fully Executed <i>(i.e., Collaboration, Funder(s), Data/Material Sharing)</i>	<input type="checkbox"/>	
Study Tracker Updated	<input type="checkbox"/>	
CRN Notified	<input type="checkbox"/>	
R&I Notified <i>(NB. IAS to be informed of any new site)</i>	<input type="checkbox"/>	
EDGE End Date Updated	<input type="checkbox"/>	
Other <i>(please detail)</i>	<input type="checkbox"/>	
Document(s) Approved	Version	Date
Sponsor Approval of Amendment		

NSA-NSWR email template

<<DELETE >>Admin Steps:

1. Subject: XXXX_ACRONYM_IRAS_NSAXX_NSWR **Extend end date of study to XX/XX/XXXX *delete if not relevant**
2. Add details after Dear

3. Add the NSA number to the first sentence.
4. Delete text as appropriate in relation to the amendment categorisation
5. If not portfolio adopted remove bullet 5
6. If portfolio adopted amend bullet 5 and CC the CRN as necessary
7. Turn all text black
8. Attached the locked amendment tool
9. For Category C amendments complete the Sponsor Green Light Checklist and attach to the email

Dear <insert detail>

Please see attached the signed and PDF'd amendment tool for NSAXX ready for submission via IRAS.

NSA-NSWR Amendments – Instructions to the study team:

1. Upload the amendment form and the tracked and clean versions of your document (where relevant) to the IRAS submission portal and select 'NSA-no study wide review required'.
2. You will receive an automated email when you submit to confirm the amendment **does not** require REC, HRA or MHRA approval. **Please forward a copy of this acknowledgement to us for our records.**
3. Please inform the CRN of this amendment/The CRN have been notified of this amendment (they are cc'd). The amendment does not affect the original outcomes of the trial.

<<Delete as appropriate>>

As this is a Category A/B NSA-NSWR amendment please forward the amendment tool, tracked and clean versions of amendment documents and the IRAS submission email to all relevant participating sites. Once confirmation of capacity and capability has been received please forward to rgosponsor@le.ac.uk and we will issue Sponsor Green Light for this amendment.

As this is a Category C NSA-NSWR amendment please accept this email as Sponsor approval for the immediate implementation of the amendment once relevant participating sites have been notified. Please forward the amendment tool, tracked and clean versions of amendment documents (where relevant) and the IRAS submission email to all relevant participating sites.

Use the table below to understand when you can implement your amendment.

Amendment Category	When can I implement the amendment?	What do you need to do?
A	Once Sponsor Green Light has been issued (per site)	<p>Where site confirmation of capacity and capability has been received; forward a copy of the site approval to rgosponsor@le.ac.uk</p>
B		<p>OR</p> <p>Where site confirmation of capacity has not been received but it has been ≥ 35 days since the site was notified of the amendment and there has been no objection or request for additional time, forward a copy of the notification email sent to any relevant R&D/I offices to rgosponsor@le.ac.uk</p>
C	Once Sponsor confirmation that the amendment can be implemented has been issued	<p>Some sites will acknowledge these types of amendments, where this occurs, please forward the response to rgosponsor@le.ac.uk.</p> <p>For relevant sites which do not acknowledge these types of amendments, please forward a copy of the email notification of the amendment which was sent to any relevant R&D/I offices.</p>