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The Leeds Teaching Hospitals NHS
NHS Trust

Updates to the Amendment Submission and Approval Process for UoL/LTHT Sponsored Trials

1) Introduction

From 2nd June 2020, the amendment submission and approval process has changed significantly across all regulatory bodies. Additionally, following the end of the EU Exit transition period on 1st January 2021, changes have been made to the submission process for amendments requiring MHRA review.

This bulletin will provide further information on the updates made and provide guidance on how to ensure your amendment is processed correctly.

2) Changes in the Amendment Document Pack: Introduction of The Amendment Tool

From 2nd June 2020, the "Notification of Substantial Amendment Form" (NoSA's) and the "Non-Substantial Amendment Form" were replaced with an **"Amendment Tool"** which must now be used for all amendments. The current version of the "Amendment Tool" can be found here: https://www.myresearchproject.org.uk/help/hlpamendments.aspx#Amendment-Tool

For all amendments: Sections 1 and 2 of the "Amendment Tool" tab must be fully completed. Section 1 relates to general information regarding your trial and a brief summary of the amendment. Section 2 of this tab should include information regarding all the proposed changes.

For amendments also requiring submission to the MHRA: The "Annex 2" tab must also be completed. Some information in Annex 2 will auto-complete based on the information provided in the "Amendment Tool" tab.

Once the above sections have been completed, Section 4 of the "Amendment Tool" tab will provide an automated categorisation for the amendment and will suggest which regulatory bodies this amendment should be submitted to (**please note** that the HRA will therefore no longer issue categorisation emails). You should review this section upon completion of the Amendment Tool to inform you of the categorisation requirements.

Once you have completed the "Amendment Tool", this must be included within the submission pack to Sponsor QA for review alongside the internal "CTT05: LTHT/UoL Sponsor Notification of a CTIMP Amendment" form and any other supporting documentation.

Once your amendment has been approved, Section 3 of the Amendment Tool will be signed by the Sponsor Representative (or delegate) and locked for submission. This will generate a PDF version of the form for you to submit to the required regulatory bodies.

3) Changes in Submission of the Amendment to the Regulatory Bodies

All amendments requiring submission to the REC and/or HRA must be submitted via IRAS. **Please do not submit any amendment documentation to a REC and/or HRA email address unless instructed to do so.**

From 1st January 2021, amendments requiring submission to the MHRA must now be submitted via the new **"MHRA Submissions"** portal. Please refer to QA Bulletin #9 for further information.

Once your amendment has been submitted, you will receive automated confirmation of submission emails from IRAS and/or MHRA Submissions. Please ensure these emails are forwarded to QA when received and are filed appropriately with the rest of your amendment documentation.

You should then await approvals or further communications from the regulatory bodies, **ensuring all correspondence is forwarded to QA in real time.**

4) Changes to the Approvals Received from Regulatory Bodies

Several significant changes have been made to the approval process depending on the type of amendment submitted. The below table provides a brief outline of the documents you should expect to receive from the relevant regulatory bodies for different types of amendments. **Please note** that regulatory guidance is subject to change and any alternative approvals should be forwarded to QA immediately.

Type of Amendment	Acknowledgment/Validation	Approvals
Substantial Amendment (requiring REC and MHRA review)	REC: Validation Email/Letter MHRA: Acknowledgement Letter	REC: Favourable Opinion Letter MHRA: Acceptance of Amendment Letter HRA: HRA and HCRW Approval Email
Substantial Amendment (requiring MHRA review/ HRA notification)	MHRA: Acknowledgement Letter	MHRA: Acceptance of Amendment Letter HRA: HRA and HCRW Approval Email
Substantial Amendment (requiring REC review only) **(not including New Site/PI Change)**	REC: Validation Email/Letter	REC: Favourable Opinion Letter HRA: HRA and HCRW Approval Email
Substantial Amendment (requiring REC review **for New Site/PI Change only**)	N/A	REC: Favourable Opinion Letter HRA: HRA and HCRW Approval Email
Substantial Amendment- for REC/HRA's information only	REC: Acknowledgement Letter	HRA: HRA and HCRW Approval Email
Non-Substantial Amendment for HRA review only	N/A	HRA: HRA and HCRW Approval Email
Non-Substantial Amendment for notification only (not requiring review)	N/A	No formal approval will be issued, the automated email received following IRAS submission documents the approval.
Non-Substantial Non-Notifiable Amendment that do not require notification to a regulatory body.	N/A	On these occasions, the Sponsor will provide amendment approval via email correspondence.

5) What Happens Next?

As per the normal process, once all required approvals have been received by the Research Team and forwarded to QA for our records, the QA team will check the approvals and, if no queries are raised, issue a *Sponsor Authorisation for Implementation of the Amendment* email.

Once received, you may then proceed to implement your amendment in line with the amendment categorisation listed on your locked Amendment Tool.

Key Resources & Further Reading:

IRAS Help	IRAS (REC/HRA)	https://www.myresearchproject.org.uk/help/hlpamendments.aspx
HRA Amending an Approval	HRA/REC	https://www.hra.nhs.uk/approvals-amendments/amending-approval/
Clinical Trials for Medicines: Manage Your Authorisations	MHRA	https://www.gov.uk/guidance/clinical-trials-for-medicines-manage-your-authorisation-report-safety-issues

Good Clinical Practice Guide	MHRA	https://www.tsoshop.co.uk/MHRA/Good-Clinical-Practice-Guide/
Sponsor CTIMP SOPs and Bulletins	Sponsor QA office	http://www.leedsth.nhs.uk/research/information-for-researchers/key-documents/

*** Should you have any queries or concerns, or would like further information regarding the content of this bulletin, * then please do not hesitate to contact the Sponsor Quality Assurance Office on Tel: 0113 30 60465**