Completing studies on the Local Portfolio Management System

NJRO-INF-WI-006

Relates to SOP: End of Study Procedures – NJRO-REG-SOP-003

Document Tree for LPMS - NJRO-REG-GUIDE-003

Background

This Working Instruction sets out procedures carried out by members of Research & Development (R&D) Informatics Team for completing studies.

Procedure/Method

1. Completion Notification – all studies

- Completed Notification received
- If no end of study documentation is included in closure notification, send an e-mail response confirming receipt and request that any end of study or closeout documents are forwarded once available.
- Use information in the email notification to identify the study on the Local Portfolio Management System (LPMS).
- Notify Research Information Manager that the study is in process of completing to enable study status change to 'Completed'.
- If study is already complete on LPMS, upload email to relevant study folder in R: drive and add to LPMS-End of Study folder following the NJRO-REG-GUIDE-003 **Document Tree for LPMS**.

2. End of Study Documents and Closure

- End of study declaration form – be aware that there are two separate forms: one for all studies and another for Clinical Trial of an Investigational Medicinal Product (ctIMP) & Advanced Therapy Medicinal Products (ATMP). The forms can be found here on the HRA Website.
- For ctIMP studies, once the 'final summary report' has been received change the 'Site Study Status' on the LPMS to 'Archived'. Most ctIMP studies have 12 months to submit the final report after the end of study declaration form; a paediatric ctIMP should submit their final report within 6 months of the end of study declaration form.

- For all other studies, the study can be Archived on LPMS once the end of study declaration form or closeout form have been received
- Notify the Information Manager of study completion.
- Send a study closure e-mail to the PI/Coordinator/Team Lead to inform them R&D file is being archived by Trust R&D. Research Finance (nuth.researchfinance@nhs.net) and Newcastle Laboratories (tnu-tr.newcastlelaboratories@nhs.net) should both be copied in to the closure email

"As the study is now complete, please can you contact the appropriate member of the finance team to ensure all outstanding invoicing is undertaken and the cost centre closed. If you are unsure of the correct contact please email the R&D Finance Team generic email address and your email will be directed to the correct individual (nuth.Researchfinance@nhs.net). Final invoicing for commercial studies must be complete within 60 days of study close, it is therefore important that you contact the finance team as soon as possible to ensure this can be complete within the period.

In addition, please ensure that all collected samples are managed in line with the protocol and terms of the consent from donors. If samples are to be retained, appropriate permission should be in place to comply with Human Tissue Authority (HTA) as required by the Human Tissue Act 2004. Any queries can be directed to NJRO Quality Assurance Team via nuth.HumanTissueResearch@nhs.net or HumanTissueResearch@ncl.ac.uk for Newcastle University"

- Notify the appointed staff member in the NJRO responsible for archiving.
- Staff might receive a sponsor 'close out letter' or 'site closure visit follow-up letter' as a closure document. If appropriate, follow the sponsor's instructions for when to archive. Sponsor may instruct staff to archive before the final report is ready however, ensure we have received documented evidence before confirming archiving. See below:
    - Final study report
    - Site closure letter
    - Site closure visit follow-up letter
    - Written confirmation from Sponsor to archive
- Do not complete if Sponsor advises not to or if there are outstanding actions from close out visit.
- Upload the closure documents to the relevant study folder in the R: drive and the LPMS following the NJRO-REG-GUIDE-001 **Document Naming Convention.**