**End of Sponsor Green Light Checklist**

| **Information Requested** | **Response** |
| --- | --- |
| **Study Title:** |  |
| **Sponsor Reference Number:** |  |
| **Chief Investigator:** |  |
| **Study Contact:** | A valid email address must be provided for the person(s) responsible for completing the End of Study activities. |
| **End of Study date:** | DD/MM/YYYY - as listed in the End of Study Declaration form. |

It is expected that you **complete all the tasks listed in the checklist in full** prior to submitting the form back to the Research Governance Office. Incomplete forms, and/or forms that have incomplete tasks listed on them will not be accepted.

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| **End of Study Notification** | **Mark if N/A** | **Date Completed** |
| End of Study Declaration form submitted to the applicable REC according to the deadlines below:* **University Ethics = within 14 days of the end date**
* **NHS REC = within 90 days of the end date**
 |  | Submitted to REC: DD/MM/YYYY REC acknowledgement: DD/MM/YYYYSponsor Acknowledgement: DD/MM/YYYY |
| [End of Trial declaration form](https://www.gov.uk/guidance/clinical-trials-for-medicines-manage-your-authorisation-report-safety-issues) and covering letter submitted to the MHRA **within 90 days of the end date** (CTIMP/Device Study)For trials which have gone through the Combined Review process, the end of trial declaration should be submitted via [IRAS](https://www.myresearchproject.org.uk/CWOW).  |[ ]  Submitted to MHRA: DD/MM/YYYYMHRA automatic email confirmation: DD/MM/YYYYSponsor Acknowledgement: DD/MM/YYYYOrSubmitted via Combined Review: DD/MM/YYYY |
| Other applicable regulatory body notified that the study/trial has ended (e.g., ARSAC/CAG) |[ ]  Please list the regulator(s) and date(s) of notification |
| Please confirm that you have notified each participating NHS organisation - R&D/I office & local research team that the study has ended and where required provided copies of end of study forms. |[ ]  Please list the site(s) and date(s) of notification* SITE NAME: DD/MM/YYYY
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| Please confirm that you have notified the CRN(s) that the study/trial has ended. |[ ]  Please list the CRN(s) and date(s) of notification * CRN NAME: DD/MM/YYYY
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| Please confirm that you have notified relevant stakeholders that the study has ended and where required provided copies of end of study forms. |[ ]   |

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| **Actions that need to be completed within 12 months of the end date (as written above and on your End of Study Declaration Form):** | **Mark if** **N/A** | **Date Completed** |
| Please confirm a final summary report form has been submitted via REC [online form](https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/ending-your-project/final-report-form/).**Please note if you submitted via**[**combined review**](https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/clinical-trials-investigational-medicinal-products-ctimps/combined-ways-working-pilot/)**, you should complete and submit the final report form in the new part of Integrated Research Application System (IRAS).** |[ ]  Submitted to REC: DD/MM/YYYY REC acknowledgement: DD/MM/YYYYSponsor Acknowledgement: DD/MM/YYYY Or Submitted via Combined Review: DD/MM/YYYY |
| Please upload a copy of the final study/trial results and any publication(s) to the regulatory database(s) where your study/trial is registered (i.e., ISRCTN, clinicaltrials.gov, EudraCT). |[ ]  Please list the database(s) and date(s) of publication  |
| Please notify the MHRA that the End of Trial results have been uploaded to the public register (CTIMP/Device Study).  |[ ]  Submitted to MHRA: DD/MM/YYYYSponsor Acknowledgement: DD/MM/YYYY |
| Please confirm that all participants have been thanked for their participation. | [ ]  |  |
| Please confirm that all participants have been given a copy of/access to the final study results/invited to a dissemination event (where applicable), **OR** detail the plans that are being put in place for this to happen and the timelines. | ☐ |  |
| Please confirm that all stakeholders have been given a copy of/access to the final study results/invited to a dissemination event (where applicable), **OR** detail the plans that are being put in place for this to happen and the timelines. |[ ]   |
| Please confirm that the End of Study Sample Application form, or confirmation of destruction of samples, has been submitted to HTAenquiries@leicester.ac.uk  |[ ]  Date submitted: DD/MM/YYYY |
| Where applicable, please confirm that study supplies (e.g. equipment devices) have been returned/disabled by the participants.  |[ ]   |
| Personal identifiable data should only be stored in the TMF/ISF on documents such as consent forms/screening logs/enrolment logs. Paper CRFs and data collection forms, including blood and scan results etc. should be redacted and contain only the Participant ID number and study visit. Please confirm that you have removed all other sources of personal identifiable information from paper and/or electronic documents. **Unless otherwise agreed, no identifiable data must be transferred to the University of Leicester. Therefore, the above activity must be completed prior to data transfer.**  |[ ]  A confirmation is required per participating site.   |
| Please confirm the location of paper records (i.e., TMF/ISF/paper CRFs etc) prior to long-term archiving.  |  | A confirmation is required per participating site. |
| Please confirm the database arrangements for study data (i.e., does each site have their own local database, or is there a central database)? |  | A confirmation is required per participating site. |
| Please confirm the long-term archiving arrangements (i.e., will each site have to store the documents locally, or will they be stored centrally and how will this be arranged)? We recommend the use of **SOP S-1032** |  | A confirmation is required per participating site. |
| Please confirm that the site(s) have been closed down. We recommend the use of **SOP S-1024** |  | Please list the site(s) and date(s) of closed * SITE NAME: DD/MM/YYYY
 |
| Please state the anticipated date of transfer of research data to the University of Leicester.**Unless otherwise agreed, no identifiable data must be transferred to the University of Leicester. Therefore, anonymisation must be completed prior to data transfer.** |  | A confirmation is required per participating site. |
| Please confirm if you have REC approval to retain data for future ethically approved research?Have you reviewed the consent forms to ensure that consent for storage and future use is in place for all relevant participants (i.e., where this is an optional clause on your consent form)? |  |  |
| Other  |  |  |

**Chief Investigator sign-off: *I confirm that I have reviewed the checklist and that the information provided is accurate Notification to*** ***rgosponsor@le.uk******. If leaving the organisation what plans are in place?***

| **Information Requested** | **Response** |
| --- | --- |
| Name:  |  |
| Signature: |  |
| Date: |  |

**For Research Governance Office use:**

| **Action** | **N/A** | **Date Completed** |
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| Study Tracker complete |[ ]   |
| Sponsor database record complete |[ ]   |
| Final report form reviewed |[ ]  **Are there any outstanding actions from the final report form?** |
| End of study samples arrangements confirmed  |[ ]   |
| Study folder complete |[ ]   |
| End of Study Sponsor Green Light date |  |