## 1. Introduction

This Standard Operating Procedure (SOP) describes the procedure to ensure that all regulatory and Sponsor processes have been completed and therefore confirm the end of Sponsor Green Light.

**1.1)**
At the end of research activity there are a number of procedures that must be undertaken as part of the regulatory / statutory requirements. UHL as Sponsor is required to ensure that Chief Investigators (CI) carry out all tasks within 12 months of the declared end of study date.

## 2. Scope

This SOP applies to all research sponsored by University Hospitals of Leicester (UHL) NHS Trust.

## 3. Outcome

The outcome of following this SOP will be that UHL as an organisation can be assured that all relevant processes and regulatory / statutory requirements have been successfully completed prior to archiving.

## 4. Procedure

**4.1)** This process will commence at the declared 'end of study'. The definition of the End of Study will be used as the study end. When a definition is not provided, the date of the End of Study Declaration will be used. This date will be added to the EDGE database and will be considered as the start of 12 months' timeframe.

**4.1.1**
The Sponsor will send an acknowledgement, and a check list (Appendix 1) detailing required activities to be completed within 12 months of the End date stated on the End of Study Declaration (EoS) to the CI or their delegate

**4.1.2**
The Sponsor will send a reminder notification (Appendix 2), at 6 months from EoS asking for progress update, with further emails if no response received

**4.1.3**
The Sponsor will send a reminder notification (Appendix 3), at 9 months from EoS asking for progress update, with further emails if no response received

**4.1.4**
The Sponsor will send a reminder notification (Appendix 4), at 10 months from EoS asking for progress update, with further emails if no response received

**4.1.5**
The Sponsor will send a reminder notification (Appendix 5), at 11 months from EoS asking for progress update, with further emails if no response received

**4.2)**
In cases where there has been no response or updates, the research activity will be discussed at the R&I Governance meeting and a resolution sought in line with the Non-Compliance SOP S-1016 UHL.

## 5. End of Sponsor Green Light Process Checklist

**5.1)** Single site
On receipt of a completed End of Sponsor Green Light check list ( Appendix 1A), the Sponsor will acknowledge receipt (Appendix 6), complete the EDGE Attribute lists and workflows.

**5.2)** Multi Site
On receipt of End of Sponsor Green Light check list CI Site (Appendix 1A) and collaborating site end of Sponsor Green Light checklist (1B), the Sponsor will acknowledge receipt (Appendix 6), and complete EDGE Attribute lists and workflows.

## 6. Non Compliance

Failure to demonstrate compliance to this SOP will result in implementation of the SOP S-1016 UHL Non Compliance SOP, and may affect the decision to sponsor future trials.

### 6.1) Trial Steering Committees & Data Monitoring Committees

To maintain strict independence, independent members of the trial steering committee and /or independent monitoring committee members should not gain any academic credit by being a co-author on study publications.

## 7. Submission of Publication

The CI or delegate (Lead Author) must on acceptance of publication to a journal, provide a copy of all publications to the Sponsor and file a copy in the Trial Masterfile/Investigator site file.

## 8. Responsibilities

| | Responsibility | Undertaken by | Activity |
|---|---|---|---|
| 1 | Sponsor | Chief Investigator / Delegate | Complete End of Green Light Process Check List |
| 2 | Sponsor | Sponsor | Remind CI of requirement |
| 3 | Chief Investigator | Chief Investigator / Delegate | Notify Sponsor of completion of tasks within 12 months of EoS |

## 9. Who Guideline Applies To

All staff within UHL and external to UHL who are delivering research.

## 10. Guideline Standards and Procedure

The SOP is detailed so the process can be clearly followed. No flowchart is provided / required.

## 11. Education and Training

**None**

## 12. Monitoring Compliance

| What will be measured to monitor compliance | How will compliance be monitored | Monitoring Lead | Frequency | Reporting arrangements |
|---|---|---|---|---|
| Sponsor Audit | Randomly chosen for audit | Carolyn Maloney | As and when | A report will be produced |

## 13. Supporting Documents and Key References

SOP S-1045 Appendices 1, 2, 3, 4, 5 & 6

SOP S-1016

## 14. Key Words

Research, Innovation, EDGE, REC, MHRA, HRA, Sponsor, Green Light

## 15. Contact and Review Details

| CONTACT AND REVIEW DETAILS | |
|---|---|
| **Guideline Lead (Name and Title)**<br>Lisa Wann R&I Manager | **Executive Lead**<br>**Medical director** |
| **Details of Changes made during review:**<br>**Review and update** | |

**16.**

This line signifies the end of the document

**16.1)**

This table is used to track the development and approval and dissemination of the document and any changes made on revised / reviewed versions

**16.2)**

| DEVELOPMENT AND APPROVAL RECORD FOR THIS DOCUMENT | | |
|---|---|---|
| **Author / Lead Officer:** | Carolyn Maloney | **Job Title:** Head of Research Operations |
| **Reviewed by:** | UHL R&I Management Meeting | |
| **Approved by:** | Professor Nigel Brunskill | **Date Approved: PGC 19 March 2021** |

| REVIEW RECORD | | | |
|---|---|---|---|
| **Date** | **Issue Number** | **Reviewed By** | **Description Of Changes (If Any)** |
| Feb 2021 | 2 | CM LW JJ | Update and consistency check |
| June 2021 | 3 | LW JJ | Update single and multi centre |
| | | | |

| DISTRIBUTION RECORD: | | | |
|---|---|---|---|
| **Date** | **Name** | **Dept** | **Received** |
| | | | |
| | | | |

Appendix 1 - End of Sponsor Green Light Checklist

| | | | |
|---|---|---|---|
| **Sponsor Number [EDGE number]:** | | | |
| **Study Name:** | | | |
| **Chief Investigator Name:** | | | |
| | | | |
| **Actions to be verified:** | | | |
| Please confirm the date of submission of the final study report | / / | | |
| Please confirm that you have received an acknowledgement of the final study report submission from the following: | YES | NO | |
| REC (copy sent to Sponsor) | ☐ | ☐ | |
| MHRA (copy sent to Sponsor) where applicable N/A ☐ | ☐ | ☐ | |
| Sponsor | ☐ | ☐ | |
| Please confirm that you have uploaded a copy of the final study report/study publication to the regulatory databases e.g. ISRCTN, clinical trials.gov. Where appropriate please confirm that you have completed full submission on EudraCT database | ☐ | ☐ | |
| Please confirm that all study participants have been thanked for their participation, as agreed | ☐ | ☐ | |
| Please confirm that all study participants have been given a copy of/access to the final study results/invited to study result dissemination event (as agreed) | ☐ | ☐ | |
| Please confirm if any samples are to be held for future research | YES ☐ | NO ☐ | N/A ☐ |
| If YES: please confirm where ALL samples are to be stored and give details of the point of contact: | | | |
| Locally: | | | |
| Externally: | | | |
| If NO: please confirm sample destruction for ALL samples has been undertaken: | YES ☐ | NO ☐ | N/A ☐ |

| | | | |
|---|---|---|---|
| Where appropriate, please confirm that ALL investigational medicinal product has been destroyed/returned to the manufacturer for destruction | YES ☐ | NO ☐ | N/A ☐ |
| Where appropriate, please confirm that all devices have been returned by the participants. | YES ☐ | NO ☐ | N/A ☐ |
| Please confirm that all devices have been returned | YES ☐ | NO ☐ | N/A ☐ |
| Please confirm that all personal identifiable data not held within the TMF/ISF has been removed from:<br><br>Paper documents<br><br>Electronic documents | YES<br><br>☐<br><br>☐ | NO<br><br>☐<br><br>☐ | N/A<br><br>☐<br><br>☐ |
| Please confirm that full anonymisation of ECRFs and ALL relevant study documentation has occurred | YES ☐ | NO ☐ | N/A ☐ |
| Please confirm location of paper/electronic records prior to archiving | | | |
| Location: | | | |
| For multicentre studies - Please confirm that all centres have been closed down | YES ☐ | NO ☐ | N/A ☐ |
| Please confirm all study specific (electronic/software) have been returned/disabled | YES ☐ | NO ☐ | N/A ☐ |
| Have all support services /third party vendors been notified of study closure | YES ☐ | NO ☐ | N/A ☐ |

| | |
|---|---|
| Name of person completing checklist | |
| Role | |
| Signature | |
| Date | |

| CI sign off: | |
|---|---|
| I confirm that I have reviewed the checklist and that the information provided is accurate | |
| Name of CI | |
| CI signature | |
| Date | |

Appendix 1B - End of Sponsor Green Light Checklist – Collaborating site

| | | | |
|---|---|---|---|
| **Sponsor Number [EDGE number]:** | | | |
| **Study Name:** | | | |
| **Site:** | | | |
| **Principal Investigator Name:** | | | |
| **Actions to be verified:** | | | |
| Please confirm the following: | YES | NO | |
| End of study Declaration and acknowledgement from REC/Sponsor. Confirm filed in Investigator site file | ☐ | ☐ | |
| REC Final report. Confirm filed in Investigators site file | ☐ | ☐ | |
| Please confirm that the Investigator site file has been updated to reflect study closure | ☐ | ☐ | |
| Please confirm that the Pharmacy folder has been updated to reflect study closure and that any IMP has been returned/destroyed as per the Sponsor requirements | YES ☐ | NO ☐ | N/A ☐ |
| Please confirm that all personal identifiable data not held within the ISF has been removed from:<br><br>Paper documents<br><br>Electronic documents | YES<br><br>☐<br><br>☐ | NO<br><br>☐<br><br>☐ | N/A<br><br>☐<br><br>☐ |
| Please confirm that all study participants have been thanked for their participation | ☐ | ☐ | |
| Please confirm that all study participants have been given a copy of/access to the final study results/invited to study result dissemination event (as agreed) | ☐ | ☐ | |
| Please confirm if any samples are to be held at your site for future research? | YES ☐ | NO ☐ | N/A ☐ |
| If YES: please confirm where ALL samples are to be stored and give details of the point of contact for personnel responsible for sample/specimen maintenance.<br>***Please be aware that once specimens /samples are not covered by this ethical application, they must be stored in a HTA licensed area.**<br>Contact Details:<br><br>Location: | | | |

| | | | |
|---|---|---|---|
| If NO: please confirm sample destruction for ALL samples has been undertaken: | YES ☐ | NO ☐ | N/A ☐ |
| Where appropriate, please confirm that all devices have been returned by the participants. | YES ☐ | NO ☐ | N/A ☐ |
| Please confirm that all devices have been returned | YES ☐ | NO ☐ | N/A ☐ |
| Please confirm that all personal identifiable data not held within the ISF has been removed from:<br><br>Paper documents<br><br>Electronic documents | YES<br><br>☐<br><br>☐ | NO<br><br>☐<br><br>☐ | N/A<br><br>☐<br><br>☐ |
| Please confirm that full anonymisation of ECRFs and ALL relevant study documentation has occurred | YES ☐ | NO ☐ | N/A ☐ |
| Please confirm contact details and location of paper/electronic ISF/ Pharmacy records | | | |
| Contact Details:<br><br>Location: | | | |
| Please confirm all study specific equipment/supplies (electronic/software) have been returned/disabled | YES ☐ | NO ☐ | N/A ☐ |
| Have all support services /third party vendors been notified of study closure | YES ☐ | NO ☐ | N/A ☐ |

| | |
|---|---|
| Name of person completing checklist | |
| Role | |
| Signature | |
| Date | |

| PI sign off: | |
|---|---|
| I confirm that I have reviewed the checklist and that the information provided is accurate | |
| Name of PI | |
| PI signature | |
| Date | |

Appendix 2 – 6 Month Reminder

*(6 month reminder)*
The Sponsor will send a reminder notification (Appendix 2), at 6 months from EoS asking for progress update, with further emails if no response received.

---

Dear (*insert name)*

As you will be aware there is a requirement for researchers to submit a final study report/publication and update EudraCT/ISRCTN/Clinicaltrials.com within 12 months of the End of Study Declaration.

As you submitted your End of Study Declaration for **EDGE ********* (*Insert study title*) on ****/**/******, you now have **180 days** left and we would like to take this opportunity to ask for an update on how your Final Study Report/Publication is progressing.

If you have already produced your Final Study Report/Publication, we would be grateful if you could forward a copy to the UHL Research & Innovation Department for our Sponsor records please, via UHLSponsor@uhl-tr.nhs.uk. We will then ensure submission to the appropriate Regulatory bodies/agencies. If you have not finalised the report/publication, we would be grateful if you could advise the UHL Research & Innovation Department, via UHLSponsor@uhl-tr.nhs.uk as to when you anticipate the report/publication being completed.

Once you have submitted your Final Study Report/Publication you need to ensure that EudraCT/ISRCTN/Clinicaltrials.com and any other relevant public databases are updated and upload a copy of the Final Study Report/Publication.

If you have already updated all relevant databases and uploaded your Final Study Report/Publication we would be grateful if you could confirm this to the UHL Research & Innovation Department for our records please, via UHLSponsor@uhl-tr.nhs.uk

If you have not yet had the opportunity to update all relevant databases and/or upload you Report/Publication can we ask that you do so within the next **180 days** and provide the UHL Research & Innovation Department with confirmation when this has occurred please, via UHLSponsor@uhl-tr.nhs.uk.

Please do not hesitate to contact us if you have any queries or concerns regarding this.

Many thanks for your continued help and support in this matter

Appendix 3 – 6 Month Reminder

*(9 month reminder)*
The Sponsor will send a reminder notification (Appendix 3), at 9 months from EoS asking for progress update, with further emails if no response received.

---

Dear (*insert name)*

As you will be aware there is a requirement for researchers to submit a Final Study Report/Publication and update EudraCT/ISRCTN/Clinicaltrials.com within 12 months of the End of Study Declaration.

As you submitted your End of Study Declaration for **EDGE ********* (*Insert study title*) on ****/**/******, you now have **90 days** left and we would like to take this opportunity to ask for an update on how your Final Study Report/Publication is progressing.

If you have already produced your Final Study Report/Publication, we would be grateful if you could forward a copy to the UHL Research & Innovation Department for our Sponsor records please, via UHLSponsor@uhl-tr.nhs.uk. We will then ensure submission to the appropriate Regulatory bodies/agencies. If you have not finalised the Report/Publication, we would be grateful if you could advise the Research & Innovation Department via UHLSponsor @uhl-tr.nhs.uk as to when you anticipate the Report/Publication being completed.

Once you have submitted your Final Study Report/Publication you need to ensure that EudraCT/ISRCTN/Clinicaltrials.com and any other relevant public databases are updated and upload a copy of the Final Study Report/Publication.

If you have already updated all relevant databases and uploaded your Final Study Report/Publication we would be grateful if you could confirm this to the UHL Research & Innovation Department for our records please, via UHLSponsor@uhl-tr.nhs.uk.

If you have not yet had the opportunity to update all relevant databases and/or upload you Report/Publication can we ask that you do so within the next **90 days** and provide the UHL Research & Innovation Department with confirmation when this has occurred please, via UHLSponsor@uhl-tr.nhs.uk.

Please do not hesitate to contact us if you have any queries or concerns regarding this.

Many thanks for your continued help and support in this matter

Appendix 4 – 10 Month Reminder

*(10 month reminder)*
The Sponsor will send a reminder notification (Appendix 4), at 10 months from EoS asking for progress update, with further emails if no response received.

---

Dear (*insert name)*

As you will be aware there is a requirement for researchers to submit a final study report/publication and update EudraCT/ISRCTN/Clinicaltrials.com within 12 months of the End of Study Declaration.

As you submitted your End of Study Declaration for **EDGE ********* (*Insert study title*) on ****/**/******, you now have **60 days** left and we would like to take this opportunity to ask for an update on how your Final Study Report/Publication is progressing.

If you have already produced your Final Study Report/Publication, we would be grateful if you could forward a copy to the UHL Research & Innovation Department for our Sponsor records please, via UHLSponsor@uhl-tr.nhs.uk. We will then ensure submission to the appropriate Regulatory bodies/agencies. If you have not finalised the report/publication, we would be grateful if you could advise the UHL Research & Innovation Department via UHLSponsor@uhl-tr.nhs.uk as to when you anticipate the report/publication being completed.

Once you have submitted your Final Study Report/Publication you need to ensure that EudraCT/ISRCTN/Clinicaltrials.com and any other relevant public databases are updated and upload a copy of the Final Study Report/Publication.

If you have already updated all relevant databases and uploaded your Final Study Report/Publication we would be grateful if you could confirm this to the UHL Research & Innovation Department for our records please, via UHLSponsor@uhl-tr.nhs.uk.

If you have not yet had the opportunity to update all relevant databases and/or upload you Report/Publication can we ask that you do so within the next **60 days** and provide the UHL Research & Innovation Department with confirmation when this has occurred please, via UHLSponsor@uhl-tr.nhs.uk.

Please do not hesitate to contact us if you have any queries or concerns regarding this.

Many thanks for your continued help and support in this matter

Appendix 5 – 11 Month Reminder

*(11 month reminder)*
The Sponsor will send a reminder notification (Appendix 5), at 11 months from EoS asking for progress update, with further emails if no response received.

---

*MARK EMAIL AS URGENT*

Dear (*insert name)*

As you will be aware there is a requirement for researchers to submit a final study report/publication and update EudraCT/ISRCTN/Clinicaltrials.com within 12 months of the End of Study Declaration.

As you submitted your End of Study Declaration for **EDGE ********* (*Insert study title*) on ****/**/******, you now have only **30 days** left to submit the Final Study Report/Publication within the required regulatory timeframe.

If you have already produced your Final Study Report/Publication, we would be grateful if you could forward a copy to the UHL Research & Innovation Department for our Sponsor records, via UHLSponsor@uhl-tr.nhs.uk as a matter of urgency please. We will then ensure submission to the appropriate Regulatory bodies/agencies. If you have not finalised the Report/Publication, please contact the UHL Research & Innovation Department, via UHLSponsor@uhl-tr.nhs.uk as a matter of urgency to discuss when you anticipate the Report/Publication being completed.

Once you have submitted your Final Study Report/Publication you need to ensure that EudraCT/ISRCTN/Clinicaltrials.com and any other relevant public databases are updated and upload a copy of the Final Study Report/Publication.

If you have already updated all relevant databases and uploaded your Final Study Report/Publication we would be grateful if you could confirm this to the UHL Research & Innovation Department for our records please, via UHLSponsor@uhl-tr.nhs.uk.

If you have not yet had the opportunity to update all relevant databases and/or upload you Report/Publication can we ask that you do so within the next **30 days** and provide the UHL Research & Innovation Department with confirmation when this has occurred please, via UHLSponsor@uhl-tr.nhs.uk

Please do not hesitate to contact us if you have any queries or concerns regarding this.

Many thanks for your continued help and support in this matter

Appendix 6 – Receipt of Completed Sponsor Green Light Checklist

*(Receipt of Completed Sponsor Green Light Checklist)*

*MARK EMAIL AS URGENT*

Dear *(insert name)*

Thank you for submitting your completed End of Sponsor Greenlight check list. Our Sponsor records/EDGE database will be updated to reflect this information.

We will be in touch if we require any further information.