UNIVERSITY OF LEICESTER, LOUGHBOROUGH UNIVERSITY
&
UNIVERSITY HOSPITALS OF LEICESTER NHS TRUST

JOINT RESEARCH SUPPORT OFFICE

STANDARD OPERATING PROCEDURES

UHL Research Support Office
SOP S-1045 UHL V1 November 2019

Standard Operating Procedure for End of Sponsor Green Light Process for all research sponsored by University Hospitals of Leicester NHS Trust (UHL)

PGC Reference No:

OFFICE BASE
Research & Innovation
Leicester General Hospital
Gwendolen Road
Leicester
LE5 4PW
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.

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

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 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

4.2 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

4.3 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

4.4 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

4.5 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

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

5. End of Sponsor Green Light process checklist

On receipt of a completed End of Sponsor Green Light check list, the Sponsor will acknowledge receipt (Appendix 6), complete the 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.
7. Responsibilities

<table>
<thead>
<tr>
<th>Responsibility</th>
<th>Undertaken by</th>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Sponsor</td>
<td>Chief Investigator /</td>
<td>Complete End of Green Light</td>
</tr>
<tr>
<td></td>
<td>Delegate</td>
<td>Process Check List</td>
</tr>
<tr>
<td>2 Sponsor</td>
<td>Sponsor</td>
<td>Remind CI of requirement</td>
</tr>
<tr>
<td>3 Chief</td>
<td>Chief Investigator /</td>
<td>Notify Sponsor of completion of</td>
</tr>
<tr>
<td>Investigator</td>
<td>Delegate</td>
<td>tasks within 12 months of EoS</td>
</tr>
</tbody>
</table>

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

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**DEVELOPMENT AND APPROVAL RECORD FOR THIS DOCUMENT**

<table>
<thead>
<tr>
<th>Author / Lead Officer:</th>
<th>Carolyn Maloney</th>
<th>Job Title: Head of Research Operations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reviewed by:</td>
<td>UHL R&amp;I Management Meeting</td>
<td></td>
</tr>
<tr>
<td>Approved by:</td>
<td>Professor Nigel Bradskiil</td>
<td>Date Approved: 9/12/2019</td>
</tr>
</tbody>
</table>

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**REVIEW RECORD**

<table>
<thead>
<tr>
<th>Date</th>
<th>Issue Number</th>
<th>Reviewed By</th>
<th>Description Of Changes (If Any)</th>
</tr>
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**DISTRIBUTION RECORD:**

<table>
<thead>
<tr>
<th>Date</th>
<th>Name</th>
<th>Dept</th>
<th>Received</th>
</tr>
</thead>
</table>
### End of Sponsor Green Light Checklist

**Sponsor Number [EDGE number]:**  
**Study Name:**  
**Chief Investigator Name:**

**Actions to be verified:**

<table>
<thead>
<tr>
<th>Please confirm the date of submission of the final study report</th>
<th>/  /</th>
</tr>
</thead>
<tbody>
<tr>
<td>Please confirm that you have received an acknowledgement of the final study report submission from the following:</td>
<td>YES  NO</td>
</tr>
<tr>
<td>REC (copy sent to Sponsor)</td>
<td>☐      ☐</td>
</tr>
<tr>
<td>MHRA (copy sent to Sponsor) where applicable</td>
<td>☐      ☐</td>
</tr>
<tr>
<td>Sponsor</td>
<td>☐      ☐</td>
</tr>
<tr>
<td>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</td>
<td>☐      ☐</td>
</tr>
<tr>
<td>Please confirm that all study participants have been thanked for their participation, as agreed</td>
<td>☐      ☐</td>
</tr>
<tr>
<td>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)</td>
<td>☐      ☐</td>
</tr>
<tr>
<td>Please confirm if any samples are to be held for future research</td>
<td>YES   NO  N/A</td>
</tr>
<tr>
<td>If YES: please confirm where ALL samples are to be stored and give details of the point of contact:</td>
<td></td>
</tr>
<tr>
<td>Locally:</td>
<td></td>
</tr>
<tr>
<td>Externally:</td>
<td></td>
</tr>
<tr>
<td>If NO: please confirm sample destruction for ALL samples has been undertaken:</td>
<td>YES   NO  N/A</td>
</tr>
</tbody>
</table>

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Appendix 1 SOP S-1045 End of Sponsor Greenlight checklist version 1 November 2019
<table>
<thead>
<tr>
<th>Question</th>
<th>YES</th>
<th>NO</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>Where appropriate, please confirm that ALL investigational medicinal product has been destroyed/returned to the manufacturer for destruction</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Where appropriate, please confirm that all devices have been returned by the participants</td>
<td>YES</td>
<td>NO</td>
<td>N/A</td>
</tr>
<tr>
<td>Please confirm that all devices have been returned</td>
<td>YES</td>
<td>NO</td>
<td>N/A</td>
</tr>
<tr>
<td>Please confirm that all personal identifiable data not held within the TMF/ISF has been removed from:</td>
<td>YES</td>
<td>NO</td>
<td>N/A</td>
</tr>
<tr>
<td>Paper documents</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Electronic documents</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Please confirm that full anonymisation of ECRFs and ALL relevant study documentation has occurred</td>
<td>YES</td>
<td>NO</td>
<td>N/A</td>
</tr>
<tr>
<td>Please confirm location of paper/electronic records prior to archiving</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Location:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>For multicentre studies - Please confirm that all centres have been closed down</td>
<td>YES</td>
<td>NO</td>
<td>N/A</td>
</tr>
<tr>
<td>Please confirm all study specific (electronic/software) have been returned/disabled</td>
<td>YES</td>
<td>NO</td>
<td>N/A</td>
</tr>
<tr>
<td>Have all support services /third party vendors been notified of study closure</td>
<td>YES</td>
<td>NO</td>
<td>N/A</td>
</tr>
</tbody>
</table>

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
Dear (insert names)

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 your 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 2 SOP 5-1045 6 month email reminder  v1 November 2019
(9 month reminder)

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 UHL Sponsor @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 UHL Sponsor @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 UHL Sponsor @uhl-tr.nhs.uk.

If you have not yet had the opportunity to update all relevant databases and/or upload your 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 UHL Sponsor @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.
(10 month reminder)

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 we can 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.
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.
(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.