Standard Operating Procedure

Title:	**Amendments to Study Documentation**		
SOP Reference Number:	QUB-RGEI-010	Version Number:	FINAL v1.0
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	Name and Position	Signature	Date
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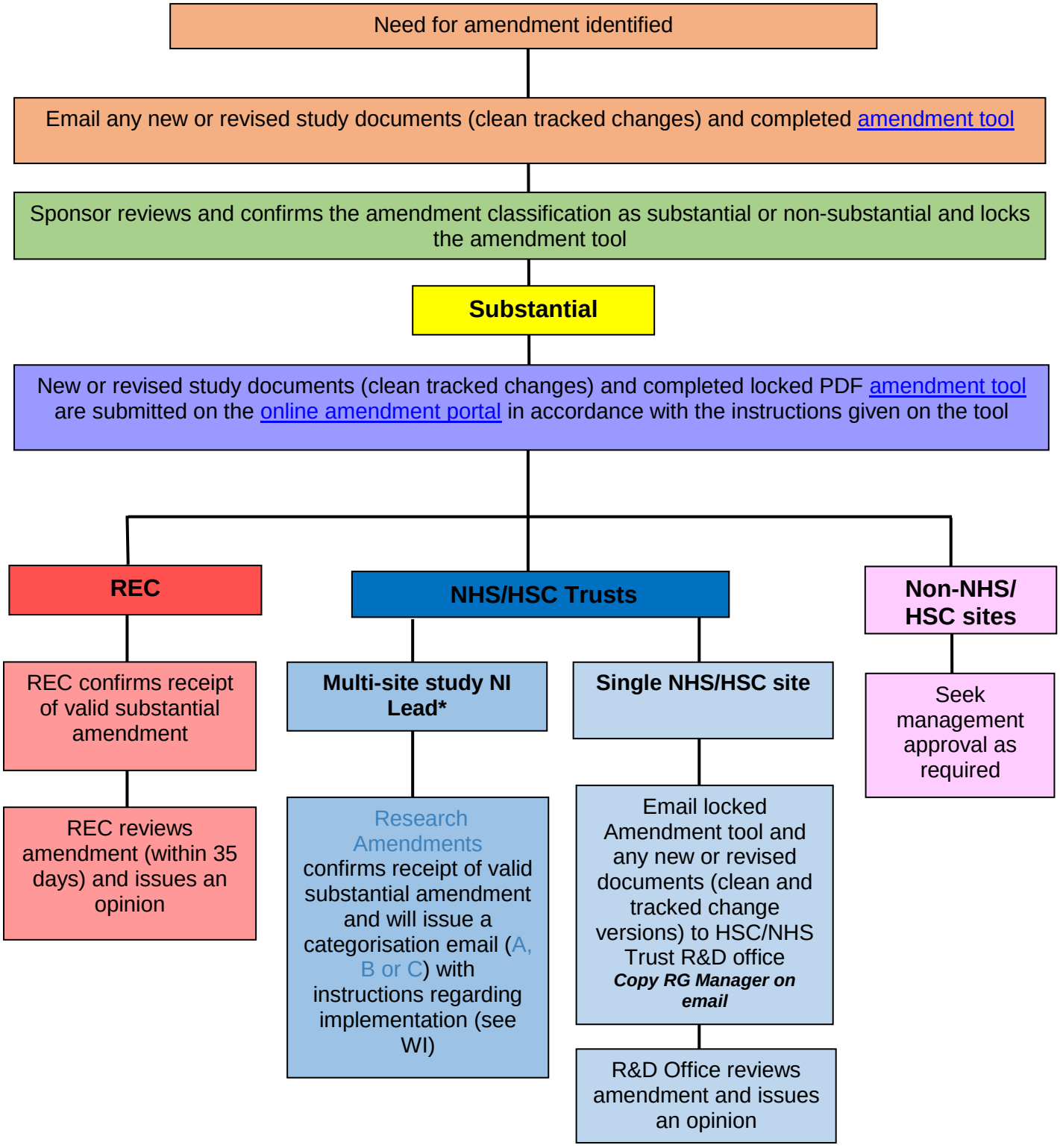
Revision Log

Previous Version number	Date of Review/Modification	Reason for Review/Modification	New Version Number

1. Purpose

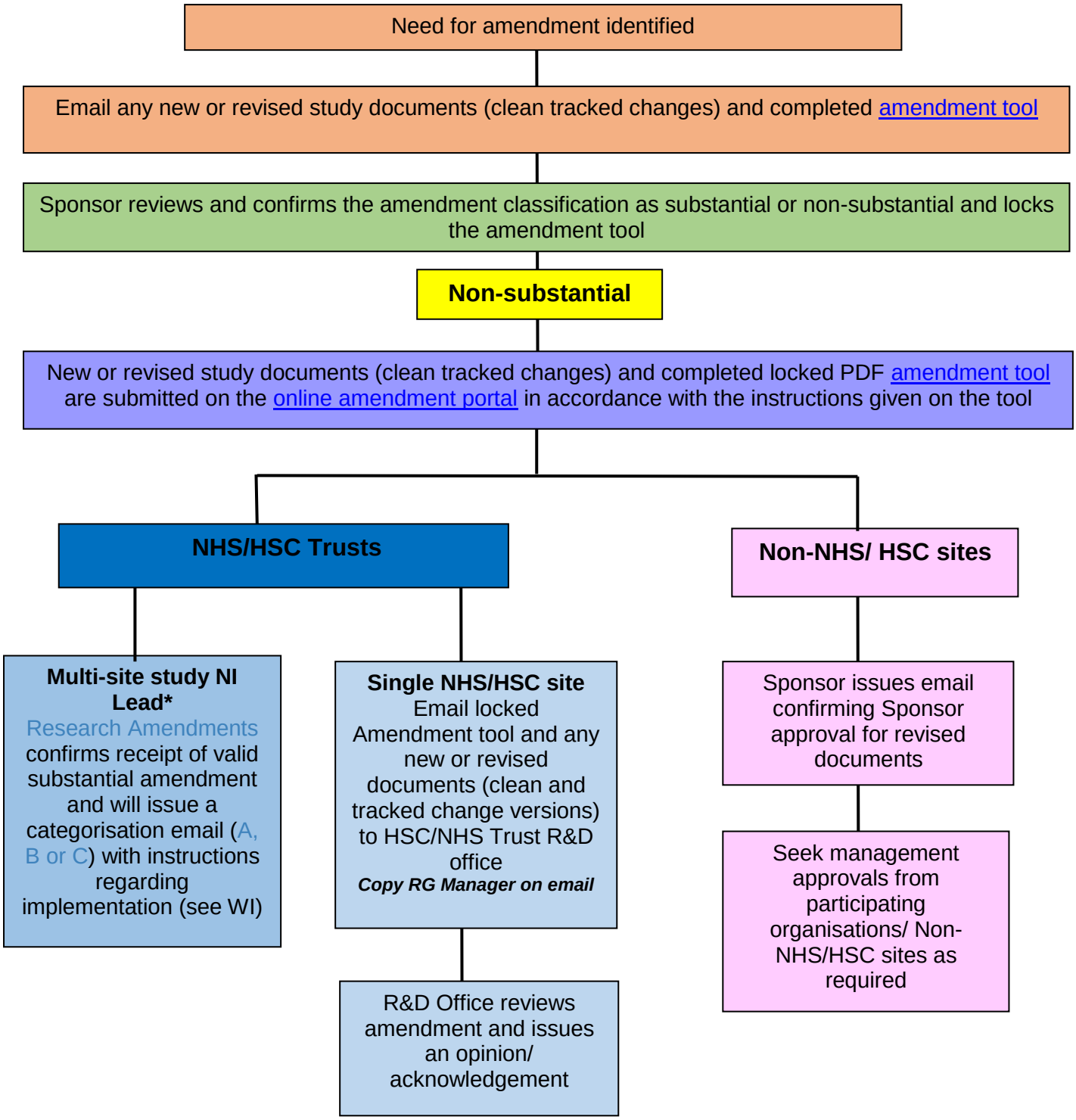
This Standard Operating Procedure (SOP) describes the procedure to be followed when amendments are made to a study protocol that has previously received a favourable opinion from an NHS/HSC Research Ethics Committee (REC), or has received approval from an NHS/HSC Trust.

2. Procedure – Category B studies Substantial



**For sites in other devolved nations additional approvals will be required eg HRA*

Procedure – Category B studies Non-Substantial



**For sites in other devolved nations additional approvals will be required eg HRA*

3. References

Health Research Authority Amendment tool
https://www.myresearchproject.org.uk/help/hlpamendments.aspx#Amendment-Tool (last accessed September 2021)
Online portal for Amendment submission
https://www.myresearchproject.org.uk/help/hlpamendments.aspx#Online-Submission (last accessed September 2021)
IRAS Amendments for projects conducted in NHS/HSC
https://www.myresearchproject.org.uk/help/hlpamendmentsresearch.aspx (last accessed September 2021)

4. Appendices

Work Instructions

Work Instructions

General

1. An amendment is any deviation from, or change(s) to the study protocol or other essential study documentation during the life of the study. An amendment can be either minor or substantial in nature.

   A non-substantial or minor amendment is one that has no significant implications for a research participant, or alters the management or conduct of the study. Examples of minor amendments include:
   - Correcting typing errors, minor clarifications of essential documents
   - changes to the research team (other than the Chief Investigator)
   - changes in funding arrangements
   - changes in the documents used by the research team to record study data
   - changes in the logistical arrangements for storing or transporting samples
   - extensions of the study period
   - inclusion of additional NHS/HSC research sites

   A substantial amendment is an amendment to the protocol or other supporting documentation, where they are likely to have a significant impact on one or more of the following:
   - changes to the design or methodology of the study, or to background information likely to have a significant impact on its scientific value
   - changes to the procedures undertaken by participants
   - changes likely to have a significant impact on the safety or physical or mental integrity of participants, or to the risk/benefit assessment for the study
   - significant changes to study documentation such as participant information sheets, consent forms, questionnaires, letters of invitation, letters to GPs or other clinicians, information sheets for relatives or carers
   - a change of sponsor(s) or sponsor's legal representative;
   - appointment of a new chief investigator
   - a change to the insurance or indemnity arrangements for the study
   - inclusion of a new trial site (not listed in the original application) in a CTIMP
   - appointment of a new principal investigator at a trial site in a CTIMP
   - temporary halt of a study to protect participants from harm, and the planned restart of a study following a temporary halt
   - a change to the definition of the end of the study
   - any other significant change to the protocol or the terms of the REC application

2. For studies approved by an NHS/HSC REC or involving an NHS/HSC Trust, the completed amendment tool should be emailed to the Sponsor's representative, along with any new or revised documents (clean and tracked changes).

3. The Sponsor, will review the documentation and amendment tool and lock the tool for submission. The researcher should complete the relevant documentation as detailed below.

Substantial Amendments

1. New or revised study documents (clean tracked changes) and completed locked PDF amendment tool are submitted on the online amendment portal in accordance with the instructions given on the tool.

2. The REC that approved the study will issue an acknowledgement of a valid substantial amendment and will review the amendment and issue an opinion within 35 days.

3. If the research involves NHS/HSC Trusts and NI is lead, Research Amendments confirm receipt of valid substantial amendment and issue a categorisation email (A, B or C) with instructions regarding implementation (see below).

Category:	This category includes any amendment to a research project that has:
A	Implications for, or affects, all participating NHS/HSC organisations hosting the research project.
B	Implications for, or affects, specific participating NHS/HSC organisations hosting the research project.
C	No implications that require management or oversight by the participating NHS/HSC organisations hosting the research project. However the amendment should still be provided for information.
New NHS/HSC site	Where the amendment is to add a new NHS/HSC site to the project, the set-up of this new site should proceed according to the process for local study set-up for the nation where the new site is located.

Non-Substantial/Minor Amendments

1. New or revised study documents (clean tracked changes) and completed locked PDF amendment tool are submitted on the online amendment portal in accordance with the instructions given on the tool.

2. If the research involves NHS/HSC Trusts and NI is lead, Research Amendments confirms receipt of valid substantial amendment and will issue a categorisation email (A, B or C) with instructions regarding implementation (see below).

Category:	This category includes any amendment to a research project that has:
A	Implications for, or affects, all participating NHS/HSC organisations hosting the research project.
B	Implications for, or affects, specific participating NHS/HSC organisations hosting the research project.
C	No implications that require management or oversight by the participating NHS/HSC organisations hosting the research project. However the amendment should still be provided for information.
New NHS/HSC site	Where the amendment is to add a new NHS/HSC site to the project, the set-up of this new site should proceed according to the process for local study set-up for the nation where the new site is located.

3. NHS/HSC REC approval is not required for non-substantial amendments

Implementation of Category A and B Amendments in NHS/HSC sites
(from Amendments for projects conducted in NHS/HSC https://www.myresearchproject.org.uk/help/hlpamendmentsresearch.aspx)

Participating NHS organisations in England and/or Wales:

For non-substantial amendments, requiring a study-wide review, you will receive confirmation of HRA and HCRW Approval via email if the amendment affects NHS sites in England and/or Wales.

For non-substantial no study-wide review required amendments you will not receive anything from the HRA. The automated acknowledgement email you receive when the amendment is submitted is your approval and the amendment can be implemented according to the categorisation information contained in the Amendment Tool.

After you have submitted your amendment, you should share your completed Amendment Tool with confirmation of amendment category and, if applicable, amended documents with relevant participating NHS organisations in England and/or Wales. In doing so, you should include the NHS R&D Office, LCRN (where applicable) as well as the local research team.

Template emails are used to notify participating NHS organisations in England and Wales of an amendment:

- Template email to share category A or B amendment documents with sites (regulatory approvals outstanding)
- Template email for Category A or B amendment documents with sites – where regulatory approvals in place
- Template email to share category C amendment documents with sites
- Template email to confirm implementation of an amendment

In Northern Ireland and/or Scotland

For multicentre studies there is no need for you to send the amendment to R&D offices of participating organisations in these nations as the National Coordinating Function will pass this on to them along with any amended documents on your behalf.

However, researchers must share these documents with the research teams at relevant participating NHS/HSC organisations in Northern Ireland and/or Scotland who should prepare to implement the amendment. When approval is received you may implement your amendment at all participating NHS/HSC organisations in Northern Ireland and/or Scotland 35 days after organisations have received the amendment and all supporting documentation as long as:

a. You have received all relevant regulatory approvals necessary for the amendment

   - If the last regulatory approval is received after the 35 day deadline, you may implement the amendment upon receipt of this approval, providing points (b) and (c) are satisfied.

b. A participating NHS/HSC organisation does not request additional time to assess.

- If you are notified that a participating organisation needs more time to assess the amendment you should not implement until they are ready to do so. You should work with the organisation to resolve any outstanding issues.

c. A participating NHS/HSC organisation does not decline to implement the amendment

- If a participating NHS/HSC organisation declines the amendment, you should discuss with that organisation and take appropriate actions in agreement with the NHS/HSC organisation.

Single centre study amendments should be sent directly to the R&D office and research team at the participating organisation.