Great Western Hospitals NHS

NHS Foundation Trust

Standard Operating Procedure: Amendments

SOP NUMBER: 007 Version Number & Date: v1 01/04/2017 Superseded Version Number & Date(if applicable):	Effective Date: 01/04/2017 Review Date: 01/04/2019

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1. BACKGROUND

During the course of a study, a Chief Investigator (CI) and/or trial team may wish to change certain aspects of a study protocol and other study documentation following receipt of approval from the regulatory authorities, such as, the Research Ethics Committee (REC), Health Research Authority (HRA) and the Medicines and Healthcare products Regulatory Agency (MHRA). This may be for various reasons; to ensure safety, to better inform participants, to allow the study to run more efficiently, to increase recruitment and such like.

For all studies, it is the responsibility of the Sponsor to determine whether an amendment is substantial or minor.

The Health Research Authority (HRA) defines a substantial amendment as:

An amendment to the terms of the application, or to the protocol or any supporting documentation, that is likely to affect to a significant degree:

- The safety or physical or mental integrity of the subjects in the study;
- The scientific value of the study;
- The conduct or the management of the study;
- Or the quality or safety of any investigational medicinal product used in the trial

The Health Research Authority (HRA) defines a non-substantial amendment as:

An amendment made to any of the trial documentation including the application forms, protocol or supporting documentation which do not fall into the categories above.

As a participating site, amendments may affect us in a number of ways, including the resources/staff required to support the study amendment, the role of local support departments (e.g. pharmacy, pathology, and radiology), subjects eligible for inclusion into the study, study end-points and more.

The impact of amendments must therefore be carefully reviewed and considered before confirmation of continued capacity and capability can be given.

2. PURPOSE

The purpose of this document is to describe the Standard Operating Procedures for amendments received from Sponsor's for studies in which Great Western Hospital NHS Foundation Trust as a participating site. To ensure they are processed appropriately and undergo the necessary review to ensure continued capacity and capability.

3. APPLICABLE TO

The CI/Sponsor remains responsible for ensuring that amendments and any supporting documentation are passed to the local Principal Investigators (PIs) and their research team including the R&I department.

4. PROCEDURE

The Sponsor should submit their amendment to the HRA (in England) who will categorize the amendment A, B or C and inform the Sponsor within 5 days. It is the Sponsors responsibility to send the amendment and categorization information to us as a participating site in order that arrangements can be put in place to continue the site' s capacity and capability to deliver the study. Studies undertaken in Scotland, Wales and Northern Ireland will not go through the HRA. Sponsors in these countries should notify us of an amendment in parallel with ethical and regulatory review so that the implications of the amendment can be assessed and necessary arrangements made.

The Sponsor should notify us of any amendments via the official generic R&I email address (researchapporovals@gwh.nhs.uk) in order for us to conduct our capacity and capability review of the amendment within 35 days. The 35 day review will not commence unless the amendment has been received appropriately as stated. As soon as the R&I department are made aware of any amendments not coming via this route, a member of the R&I team will notify the Sponsor with a request to redirect their notification to the generic email address.

Amendments will be categorized into one of three categories, A, B or C.

- ***Category A*** *– Amendment to a research study that ALL participating NHS organisations are expected to consider*

  This category includes any amendment to a research study that has implications for, or affects, ALL participating NHS organisations hosting the research study.
  All participating NHS organisations will be informed of, and have access to the amendment.
  All participating NHS organisations are expected to consider the amendment to determine whether they are able to continue NHS research permission.

- ***Category B –*** *Amendment to a research study that only those participating NHS organisations affected by the amendment are expected to consider*

  This category includes any amendment to a research study that has implications for, or affects, SPECIFIC participating NHS organisations hosting the research study.
  Only those participating NHS organisations affected by the amendment will be informed of the amendment. However, all participating NHS organisations will have access to the amendment through the relevant national co ordinating function.
  Only those participating NHS organisations affected by the amendment are expected to consider the amendment to determine whether they are able to continue NHS research permission.

- ***Category C*** *– Amendment to a research study that participating NHS organisations are not expected to consider*

  This category includes any amendment to a research study that has no implications that require management or oversight by the participating NHS organisations hosting the research study.

All participating NHS organisations will have access to the amendment.
Participating NHS organisations are NOT expected to consider the amendment or give continued permission for these amendments.
There may be amendments of a confidential nature that the Sponsor is required to submit to the MHRA. Such amendments will have no implications for, or affect, the participating NHS organisations hosting the research study. Therefore these amendments will not be notified to the NHS organisations.

It is the responsibility of the R&I team to ensure that the Principal Investigator, together with any other support departments are notified. Any potential additional time and /or cost implications should be identified and a decision will be made as to whether the amendment can be accommodated.

Once the amendment review has been carried out and accepted within the 35 day period, an email will be sent to the Sponsor to confirm we have no objection to the amendment being implemented at site subject to receipt of HRA approval (if not already received). **No** amendments may be implemented until the HRA approval has been received.

Occasionally after carrying out a review a decision may be made that the amendment cannot be accommodated at this site due to capacity and capability issues. The Sponsor will be notified of this decision within the 35 day time frame.

If a longer time frame than 35 days is required to review an amendment, then an email must be sent to the Sponsor to notify them and request extra time to review the amendment.

Once the 35 day period elapses, the CI/Sponsor may assume continuing permission (subject to other regulatory approvals) at the site unless a request has previously been made for additional time to review the amendment.