Queen's University Belfast

Research and Enterprise

Standard Operating Procedure
Research Governance

Title:	**Production of Progress, Safety and Final Reports**		
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* For all University sponsored research that has been approved by a National Research Ethics Committee
# For all other University sponsored research involving human participants

Revision Log

Previous Version number	Date of Review/Modification	Reason for Review/Modification	New Version Number
Final v 1.0	10/11/09	Annual Review	Final v 1.0
Final v 1.0	18/08/11	Annual Review/ Update following MHRA GCP Inspection and legislative changes	Final v 2.0
Final v 2.0	15/03/2012	Reviewed for clarity and accuracy.	Final v 3.0
Final v 3.0	21/08/2012	Periodic Review	Final v 4.0
Final v 4.0	21/10/2014	Periodic Review	Final v 5.0
Final v 5.0	01/01/2016	Periodic Review	Final v 6.0

1. Purpose

This Standard Operating Procedure (SOP) describes the process for the production and submission of annual progress, safety and final reports to the Medicines and Healthcare Regulatory Authority (MHRA), the main Research Ethics Committee (REC) and the University.

2. Introduction

The requirements for safety reporting are detailed in The Medicines for Human Use (Clinical Trials) Regulations 2004. In addition to expedited safety reporting as outlined in SOP-QUB-ADRE-006, sponsors are also required to submit an annual progress report, an annual Development Safety Update report and an end of study report.

The main REC that gave the favourable ethical opinion requires an annual progress report. This should be submitted annually, with the first report due 12 months after the date of the favourable opinion. This enables the REC to monitor the progress for any research to which they have given a favourable ethical opinion.

The Development Safety Update Report (DSUR) is designed to present a comprehensive, thoughtful annual review and evaluation of pertinent safety information collected during the reporting period related to a drug under investigation. The DSUR is submitted annually, to the MHRA and REC who provided approval. Although the full DSUR is submitted to REC they are only expected to review the Executive Summary. It is a formal legislative requirement to submit the DSUR.

At the end of the study a final safety report should be submitted to the MHRA and a report sent to the main REC advising them whether the project achieved its objectives, the main findings and arrangements for the dissemination of the research, including any feedback to participants.

3. Scope

This SOP applies to all studies where the University is acting in the capacity of Sponsor, or Co-Sponsor. It applies to all members of University staff; both academic and support staff as defined by Statute 1, including honorary staff, and students.

4. Responsibilities

4.1 Chief Investigator

The Sponsor is responsible for submitting the annual reports and final reports to the MHRA and REC. Where the University is acting in the capacity of Sponsor and/or Co-Sponsor this responsibility is delegated to the Chief Investigator (CI).

5. Procedure

An annual report should be prepared 12 months after the date on which the favourable ethical opinion was given and submitted annually thereafter until the end of the study.

5.1 Progress Report

The Main REC that provided the favourable ethical opinion is required to monitor the research. To facilitate this, a progress report should be submitted 12 months after the date on which the favourable opinion was given, and annual progress reports submitted

thereafter until the end of the study. The paper copy should be sent to the REC within 30 days of the end of the reporting period.

All progress reports should be completed in typescript and signed by the CI.

The first annual progress report should give the commencement date for the study. If the study has not started within 12 months of the favourable opinion, the first progress report should given an explanation for the delay. In the event that a study has a long period of follow-up with minimal participant involvement, the CI may make a written requested to the Chair of the REC to request the requirement of an annual progress report be waived.

A copy of the progress report and/or any requests for a waiver should be sent to the University's Research Governance Team.

5.2 Development Safety Update Reports

It is the responsibility of the CI to ensure that a DSUR is completed and submitted to the Sponsor and/or Co-sponsor, the MHRA and the REC who provided the favourable ethical opinion.

The DSUR must be completed annually for the duration of the clinical trial, the first report being due on the first anniversary of the first international regulatory approval. This time point is referred to as the Development International Birth Date (DIBD). Reports must be submitted within 60 days of the date of authorisation and every year, until completion of the trial.

In the event of more than one sponsored or co-sponsored trial involving the same IMP, the Sponsor or Co-Sponsor via the Research Governance Manager responsible for the study, will liaise with the CI/Ps involved to produce only one report for all concerned trials.

The DSUR has a standard format and requires all sections to be completed to be a valid report. If a section is not applicable to the clinical trial, or if the information is not currently available, this should be stated and explained where applicable.

Guidance on how to complete the DSUR can be found:
http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2010/09/WC500097061.pdf

A worked example of a completed DSUR can be found:
http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E2F/Examples_DSUR/E2F_Example_non-commercial_DSUR.pdf

The DSUR should be submitted, as an electronic document on a disk to:

Information Processing Unit
Area 6
Medicines & Healthcare products Regulatory Agency
151 Buckingham Palace Road
Victoria
London, SW1W 9SZ

When submitting the DSUR to the REC, from which the favourable ethical opinion was given, complete the Safety Report Form, found at:

http://www.hra.nhs.uk/resources/during-and-after-your-study/nhs-research-ethics-committee-rec-ctimp-safety-report-form/

5.3 End of Study Report

A summary of the final report on the research should be sent to the main REC within 12 months of the end of the project.

NRES guidance states that the end of study should be detailed in the 'protocol and any change to this definition should be notified as a substantial amendment. In most cases, it will be the date of the last visit of the last participant or the completion of any follow-up monitoring and data collection described in the protocol'.

The summary of the final report may be enclosed with the end of study declaration, or sent to the REC subsequently. However the end of study report should be sent to the main REC within 12 months of the end of study as defined in the protocol.

There is no standard format for final reports. As a minimum, the main REC should receive information on whether the project achieved its objectives, the main findings and arrangements for publication or dissemination of the research, including any feedback to participants.

A copy of the end of study report should be sent to the University's Research Governance Team for review.

6. References

Medicines and Healthcare products Regulatory Agency website, (last accessed December 2016).
http://www.mhra.gov.uk/Howweregulate/Medicines/Licensingofmedicines/Clinicaltrials/Safetyreporting-SUSARsandASRs/index.htm

Eudralex Volume 10: Detailed guidance on the collection, verification and presentation of adverse event/reaction reports arising from clinical trials on medicinal products for human use. http://ec.europa.eu/health/files/eudralex/vol-10/2011_c172_01/2011_c172_01_en.pdf (last accessed December 2106)

Health Research Authority (formerly National Patient Safety Agency), (last accessedDecember 2016)
http://www.hra.nhs.uk/research-community/during-your-research-project/progress-reporting/