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| Authorized by | | Sign | Date |
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This page details the version history and the main changes made for each new version.
The new changes are in red font.

| Version Log | | |
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| **Version number and date** | **Author** | **Details of significant changes** |
| Version 1, 06.11.12 | J Pacynko and J Illingworth | Original SOP approved by R&D Committee on 01.11.12 |
| Version 2, 31.03.16 | H L Bexhell | Links checked<br>New wording is in red font |
| Version 3, 18.03.19 | J Pacynko | For single-site Type A trials, submitted under the Notification Scheme, the APR will now be used to submit annual safety updates to the MHRA and REC. Multi-site Type A and Type B trials will continue to use the DSUR. |
| Version 4, 19.03.21 | S Moffat | In 3.7 and 4.12 the addition of saving a scanned copy of the Annual Progress Report and DSUR respectively to the eTMF or the eSSF.<br><br>Addition of point 4.14 A CTIMPs Safety Report Form must be completed and sent with the DSUR to REC. This form can be found on the HRA website https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/safety-reporting/ |

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**Please note for definitions of acronyms refer to Appendix 1 of Management of SOPs. Refer to Appendix 2 of Management of SOPs for the standards to which clinical trials that investigate the safety and/or efficacy of a medicinal product are conducted.**

**All the R&D GCP SOPs are available at:**
**https://www.hey.nhs.uk/research/researchers/gcp-sops-for-hey-sponsored-ctimps/**

# 1 Background and purpose

1.1 NHS Research Ethics Committees (RECs) are required to monitor research that has received a favourable opinion. A progress report should be submitted by the Chief/Principal Investigator to the REC which gave the favourable opinion, one year after the date on which the favourable opinion was given. Annual progress reports (APR) should be submitted thereafter until the end of the study.

1.2 In addition, the Medicines and Healthcare products Regulatory Agency (MHRA) require a safety report to be sent to the MHRA and REC once a year throughout the clinical trial. The annual safety report should take into account all new available safety information received during the reporting period.

1.3 For single-site Type A trials, authorised under the MHRA's Notification Scheme, the APR will also be used to submit annual safety updates to the MHRA and REC.

1.4 For multi-site Type A and Type B trials the MHRA's annual safety report will be the Development Safety Update Report (DSUR).

1.5 The responsibility to complete and submit APRs and DSURs is delegated to the Chief/Principal Investigator (CI/PI) in the Formal Agreement signed by Investigator and Sponsor before R&D approval is given. The R&D Monitor will remind the CI/PI to complete the APR and DSUR when due and will help with completion and submission.

1.6 This SOP describes how to produce and submit the APR and DSUR.

# 2 Who should use this SOP

2.1 This SOP should be used by:

- All research staff involved with HUTH-sponsored CTIMPs – Chief/Principal Investigator, co-investigators, research nurses, clinical trial assistants, trial managers, clinical trial co-ordinators, data managers, administrators etc.
- Clinical trials pharmacy staff – technicians and pharmacists.
- All HUTH R&D staff who manage the sponsorship of HUTH-sponsored CTIMPs.
- Research staff involved with clinical trials sponsored by an external organisation where the sponsor has no SOP for safety reporting. HUTH R&D SOPs are defaulted to in this case.

# 3 Annual progress reporting

3.1 The first APR is due one year from the date of the REC favourable opinion for the study. APRs are then due on the same date each consecutive year for the duration of the study.

3.2 The APR link and reminders of what to include in the form are available from the R&D Monitor or QA Manager. This is Working Instruction 21 available on the ClinicalGov Y Drive in Research\GCP SOPs & forms\Working instructions.

3.3 The form title is 'Annual progress report form for clinical trials of investigational medicinal products (CTIMPs)'.

3.4 The APR is a short form and asks for up-to-date information on the start and end date of the study, the number of sites involved, the number of patients recruited, safety reports, amendments and serious breaches.

3.5 The R&D monitor will help with the completion and submission of the APR. If the trial is being managed by a Clinical Trials Unit, the CTU will help with the completion and submission.

3.6 The APR needs to be completed electronically then printed and signed off by the CI/PI. A copy should be scanned and emailed to the REC Manager **within 30 days** of the end of the reporting period.

3.7 The original, signed APR should be filed in the REC section of a paper Trial Master File or a scanned copy saved in the electronic TMF or SSF**.**

# 4 Annual safety reporting

4.1 For single-site trials, authorised under the MHRA's Notification Scheme (Type A trials), the Annual Progress Report will be used to report the safety information. A covering letter will also need to be submitted which includes the EudraCT number and CTA reference number and that the APR is in place of a full DSUR. A list of all the SARs will need to be added to section 6 of the APR.

4.2 For Type B trials and multi-site Type A trials, the Development Safety Update Report (DSUR) will be completed. The R&D monitor will complete the administrative parts of the DSUR and then send to the CI/PI for completion of the clinical safety information and assessments. The R&D monitor will submit the DSUR to the MHRA and REC. If the trial is being managed by a Clinical Trials Unit, the CTU will submit the DSUR.

4.3 The Reference Safety Information will need to be reviewed for updates annually at the time the APR or DSUR is completed. This check will be documented in the APR or DSUR.

4.4 The first DSUR is due one year from the date of the MHRA Clinical Trial Authorisation for the study. DSURs are then due on the same date each consecutive year for the duration of the study.

4.5 The DSUR must be submitted to the MHRA **within 60 days** from the date it was due. During MHRA inspections the inspectors check whether timelines have been respected and if not class this as a 'finding'. If there is a large volume of findings from an inspection, this could be classed as a critical finding which involves re-inspection of the Trust.

4.6 If there is a failure to submit the DSUR within 60 days then this will be escalated to the R&D Director who will raise the issue with the CI/PI to take appropriate action.

4.7 A copy of the signed DSUR should be sent to the REC responsible for the study at the same time as submitting to the MHRA.

4.8 The aim of the DSUR is to describe concisely all new safety information relevant for the clinical trial and to assess the safety of subjects included in these studies.

4.9 The DSUR should include the following:

- A covering letter.
- An overall safety assessment with an evaluation of the risk:benefit and a summary of the important risks.
- A line listing of SARs (including SUSARs) during the reporting period (if any).
- A cumulative summary tabulation of all SAEs since the start of the study (if any).

4.10 A template for the DSUR and guidance on how to complete the DSUR is available from the R&D Monitor or QA Manager. This is Working Instruction 22 available on the \\hri_data3\clinicalgov\Research\GCP SOPs & forms\SOPs & WIs.

4.11 It is very much recommended that the guidance is used because there are many sections of the DSUR that are not relevant for Trust-sponsored CTIMPs and the guide indicates those sections.

4.12 The original, signed DSUR should be filed in the MHRA section of a paper Trial Master File or a scanned copy saved in the electronic TMF or SSF**.**

4.13 A copy of the signed DSUR should be sent to the R&D Monitor or QA Manager who will submit the DSUR to the MHRA and email a copy to the REC Manager.

4.14 A CTIMPs Safety Report Form must be completed and sent with the DSUR to REC. This form can be found on the HRA website https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/safety-reporting/

# 5 Implementation

5.1 Implementation of this SOP will conform to the process outlined in R&D SOP 01 Management of SOPs.