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# Annual Reporting SOP

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| Distribution: | HHP R&D internet<br>Click on GCP SOPs for HHP-sponsored CTIMPs<br>https://www.hey.nhs.uk/research/researchers/gcp-sops-for-hey-sponsored-ctimps/ |

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This page details the version history and the main changes made for each new version.

| Version Log | | |
|---|---|---|
| **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/ |
| Version 5, 26.06.2024 | L Cox | New wording is in red<br>Amendment of wording from R&D to RDI throughout the SOP.<br>Amendment of wording from REC Manager to the REC throughout the SOP.<br><br>In 1.1 the addition of HRA guidance in terms of when an APR is due for a clinical trial. New guidance from the HRA confirms that there are specific requirements for when an APR is required for a clinical trial. In 1.6 the addition of when a trial has been submitted through CWOW (Combined Review) process<br><br>In1.7 the addition of the cost to now submitted an APR or DSUR as per HRA guidelines<br><br>In 4.1 amendment from EudraCT number to IRAS Number, as well as the addition of 'as well as a receipt confirming the fee has been paid'. |
| Version 6, DRAFT | L Cox | Updated terminology throughout SOP from R&D to RDI and from REC Manager to REC, ensuring consistency with current organisational structure.<br><br>Added new HRA guidance in Section 1.1 clarifying when an Annual |

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| | | Progress Report (APR) is required, including exemptions and conditions under the updated HRA framework.<br>Added wording in Section 1.6 to reflect that APRs and DSURs for trials approved under the Combined Review (formerly CWoW) process must be submitted via the IRAS platform only.<br>Added new requirement in Section 1.7 detailing the £248 submission fee for APRs and DSURs, including the move to mandatory online payment from 1 June 2024 and internal RDI Finance processes for payment and evidence submission.<br>Updated Section 4.1 to replace EudraCT number with IRAS number, and added requirement to include evidence of fee payment with the APR when used in place of a DSUR.<br>Added ICH E6(R3)-aligned wording across Sections 1–4 to incorporate:<br>• proportionality and risk-based approaches,<br>• Sponsor oversight expectations,<br>• protection of critical-to-quality (CtQ) factors,<br>• strengthened data governance requirements for electronic filing (eTMF/eSSF).<br>Updated Sections 3.6 and 3.7 to clarify expectations for completion, signature, submission, and validated storage of APRs, including electronic governance requirements.<br><br>Updated Section 4.2–4.14 to strengthen Sponsor oversight language, clarify delegated responsibilities, and ensure alignment with MHRA expectations for DSUR content, timelines, and submission pathways.<br>Added explicit requirement in Section 4.14 for submission of the CTIMPs Safety Report Form alongside the DSUR to the REC.<br>General formatting updates, removal of outdated references, and alignment with current HRA/MHRA terminology and processes.<br>Trust name changed from Hull University Teaching Hospitals NHS Trust (HUTH) to Humber Health Partnership (HHP- Hull University Teaching Hospitals NHS Trust and Northern Lincolnshire and Goole NHS Foundation Trust). |

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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 must be submitted by the Chief/Principal Investigator one year after the date of the favourable opinion and annually thereafter, unless exempt under HRA proportionate review guidance. Annual reporting forms part of the sponsor's ongoing oversight and proportionate risk-based monitoring responsibilities. However, progress reports are not required in the following instances:

- if the study is expected to run for less than two years in duration
- if the study received a proportionate review
- if the study received a favourable ethics opinion from a REC in England or Wales.

In addition, the MHRA requires an annual safety report that summarises all new safety information and provides an updated risk–benefit assessment in line with ongoing safety evaluation.

1.3 For single-site Type A trials, authorised under the Notification Scheme, the APR will also serve as the annual safety update, consistent with the proportionate approach.

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

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Sponsor before RDI approval is given. The RDI Monitor will remind the CI/PI to complete the APR and DSUR when due and will help with completion and submission.

1.6 Where a CTIMP has been approved through the Combined Review process, the APR and DSUR must be submitted via the IRAS platform, in accordance with the HRA/MHRA harmonised submission - (https://myresearchproject.org.uk/CWOW).

1.7 The current fee for submitting an APR or DSUR is £248. Evidence of payment must accompany the submission. The sponsor retains responsibility for ensuring appropriate resources are available for regulatory reporting.
Guidance for this can be found here https://products.payments.service.gov.uk/pay/abbc9729dc244d2c82b02e25420454f8?_ga=2.165827070.1119410353.1718615281-538129580.1717657388. The MHRA ask that payment for the DSUR is made prior to submission and evidence of the payment is submitted with the DSUR. Payment should be requested by HHP RDI QA to the RDI Finance manager to be paid for by the departmental credit card (other payment options are satisfactory to the discretion of the RDI Finance manager).

1.8 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 HHP-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 HHP RDI staff who manage the sponsorship of HHP-sponsored CTIMPs.
- Research staff involved with clinical trials sponsored by an external organisation where the sponsor has no SOP for safety reporting. HHP RDI SOPs are defaulted to in this case.

## 3 Annual safety reporting

3.1 For single-site Type A trials authorised under the Notification Scheme, the APR will be used to report annual safety information. This is consistent with a risk-proportionate approach. A covering letter will need to be submitted which includes the IRAS number and CTA reference number and that the APR is in place of a full DSUR, as well as a receipt confirming the fee has been paid.
A list of all the SARs will need to be added to section 6 of the APR.

3.2 For Type B and multi-site Type A trials, the DSUR must be completed and submitted annually. Administrative sections may be completed by the RDI Monitor; however, the CI/PI remains responsible for the clinical safety assessment. The sponsor must maintain oversight of all delegated reporting activities.

3.3 The Reference Safety Information must be reviewed annually as part of the ongoing safety evaluation. This review must be documented in the APR or DSUR.

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3.4 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.

3.5 The DSUR must be submitted to the MHRA **within 60 days** from the end of the reporting year. 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.

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

3.7 The DSUR must provide a concise summary of all new safety information and include an updated risk–benefit evaluation.

3.8 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 that have been appropriately evaluated since the start of the study (if any).

3.9 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 from HHP R&D QA.

3.10 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.

3.11 The signed DSUR must be filed in the TMF/eTMF as an essential record in Section 11.

3.12 A copy of the signed DSUR should be sent to the RDI Monitor or QA Manager who will submit the DSUR to the MHRA.

# 4 Implementation

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