Humber Health Partnership

Submissions SOP

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Hull University Teaching Hospitals NHS Trust
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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, (24.03.2023)	G Constable	First generation of SOP
Version 2, 27.04.2026	L Cox	Added explicit reference to ICH E6(R3) principles • Inserted new text in Section 1 to clarify that the submission process supports participant protection, data reliability and quality-by-design expectations under ICH E6(R3). Clarified how this SOP fits within the Trust's wider Quality Management System • Added language in Section 2 explaining that SOP 21 covers regulatory submissions while other R&D GCP SOPs address informed consent, safety reporting, monitoring, data governance and other R3 requirements. Introduced quality-by-design and proportionate process statements • Added new wording in Section 3 emphasising that submission activities should be proportionate to trial risk and complexity, consistent with ICH E6(R3) principles. Strengthened expectations for qualified personnel and controlled access • Updated Section 4 to state that individuals with IRAS access must be appropriately trained and that access must be controlled to maintain data integrity and version control. Enhanced requirements for document quality and version control • Added text in Section 5 reinforcing that all documents submitted for combined review must be accurate, version-controlled and aligned with the Trust's Quality Management System. Expanded sponsor oversight language during regulatory review • Inserted new content in Section 6 confirming that sponsor QA review ensures accuracy, completeness and compliance with ICH E6(R3) during submissions and RFI responses. Added expectations for proportionate, timely and quality-controlled RFI responses • Updated Section 7 to emphasise clarity, accuracy and sponsor QA review of all amended documents before resubmission. Clarified integration with the Trust's Quality Management System • Added text in Section 8 confirming that this SOP

		contributes to overall ICH E6(R3) compliance when used alongside other R&D GCP SOPs Update from HUTH to HPP incorporating both HUTH and NLaG.

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

1 Introduction, purpose and who should use this SOP

1.1 This SOP describes the process of submitting a study to regulatory bodies for trials sponsored by Humber Health Partnership.

1.2 This SOP should be applied when a study has completed the trial set-up (highlighted in *R&D GCP SOP 04)*

1.3 It is a legal requirement to submit all studies to the relevant regulatory bodies in the UK.

1.4 This SOP supports the Trust's compliance with the principles of ICH E6(R3) Good Clinical Practice by ensuring that regulatory and ethics submissions are prepared, reviewed and authorised in a manner that protects participant rights, safety and well-being and supports the generation of reliable trial data.
The submission process described in this SOP forms part of the Trust's wider Quality Management System and contributes to quality-by-design by ensuring that documentation submitted for regulatory review is accurate, version-controlled, operationally feasible and proportionate to the risks and complexity of the clinical trial.

1.5 All supporting documentation must be ready and files clearly named with a version number (to the whole number) and date in line with *R&D GCP SOP 01 Version Control.*

1.6 It is strongly encouraged for investigators to read the general guidance provided on the HRA website covering the combined review process.

1.7 The approvals required (*where applicable*) before a clinical trial can commence are:

- Medicines and Healthcare products Regulatory Agency (MHRA) clinical trial authorization
- Research Ethics Committee (REC) favourable opinion
- Health Research Authority (HRA) approval (HCRW for Wales)
- *Confidentiality Advisory Group (CAG)*
- *Administration of Radioactive Substances Advisory Committee (ARSAC)*
- MHRA Medical Devices
- *His Majesty's Prison and Probation Service (HMPPS)*
- R&D approval (confirmation of Capacity and Capability)
- HUTH R&D QA as sponsor representative will send a 'green light' email to the CI/PI and research team to confirm that the trial can start.

Guidance for submission of the above can be found at https://www.myresearchproject.org.uk/help/hlphraapproval.aspx

1.7 This SOP should be used by any investigators and trial teams requesting sponsorship by HHP.

2 Scope

2.2 The SOP is applicable to all HHP sponsored research studies and clinical trials. Where HHP is co-sponsor on a clinical trials with another institution this SOP should be followed; any discrepancies between HHP and the other co-sponsors SOP should be highlighted in the co-sponsor agreement.

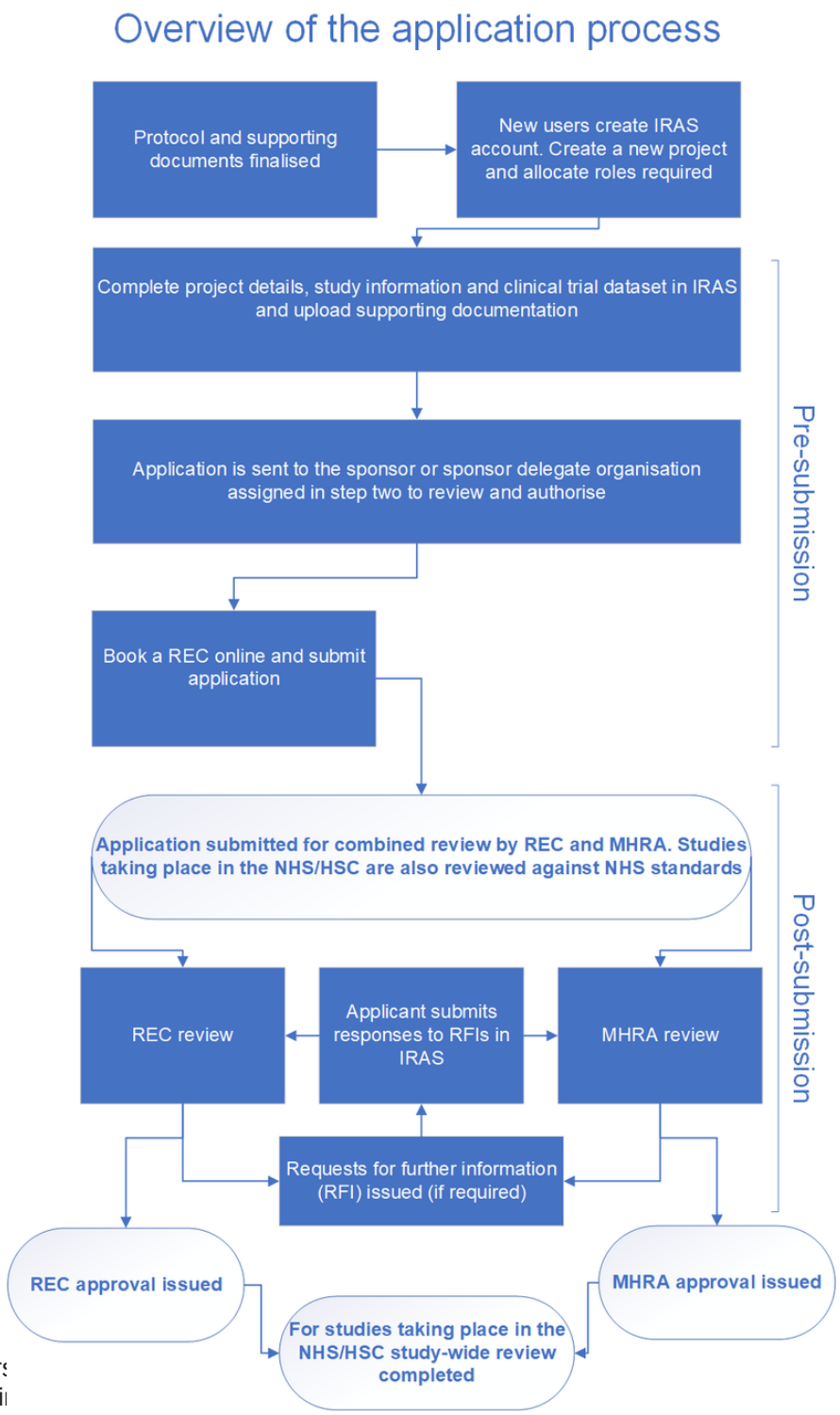
2.3 As of 1st January 2022 combined review is the way all applications for new Clinical Trials of Investigational Medicinal Products (CTIMPs) and combined IMP/device trials must be made. For all other types of research an application should be prepared and submitted using 'standard IRAS'.

2.4 Historically applications for clinical trials were sent separately to the MHRA for regulatory review, and to a Research Ethics Committee (REC) for ethics review. The combination of these applications into one portal will streamline the process as reviews are done in parallel. The application also goes for study wide review, such as HRA (and HCRW in Wales), if the study is to take place in the NHS or Northern Ireland HSC.

2.5 This SOP addresses the aspects relating to sponsor communication with regulatory authorities and independent ethics committees, and the preparation and control of essential documents required for initial review.
Other ICH GCP principles—including informed consent, safety reporting, monitoring, data governance, and risk-based quality management—are addressed in separate R&D GCP SOPs.

3 Overview of the application process

3.1 The following is taken from the HRA guide for IRAS applications for combined review.



3.2 The preparation and review of submission materials should be proportionate to the risks associated with the clinical trial and the importance of the data being collected. Trial teams should ensure that documentation submitted through IRAS is clear, concise and operationally feasible, reflecting the principles of quality-by-design and supporting efficient regulatory and ethics review.

4 User Roles

4.1 A change to the IRAS application (that now goes through combined review) is that every project must have a Chief Investigator and a Project Deputy assigned, so there is always two people with access to the study.

4.1.1 The Chief investigator must accept their role in IRAS before the project is submitted. The Project Deputy is a new role in IRAS and they will support the CI and often manage the project in IRAS.

4.1.2 The Project Deputy has full access to the project and can completed all project related tasks in IRAS.

4.1.3 Once a project has been set up, the CI or Project Deputy can add as many 'collaborators' as they would like to work on that project. Collaborators can be added and removed as required throughout the project lifetime.

4.1.4 All collaborators can have edit access meaning they are able to change, add or delete information held in the system. Collaborators will have the same user rights as a Project Deputy and can work on the project after Initial Submission, including booking the REC, responding to the RFI, creating amendments or reports and providing the end of trial notification.

4.1.5 When the project has been authorised the collaborators will automatically be removed by IRAS. The CI or Project Deputy can re add the collaborators if/when required in order to build a research team that works for the project.

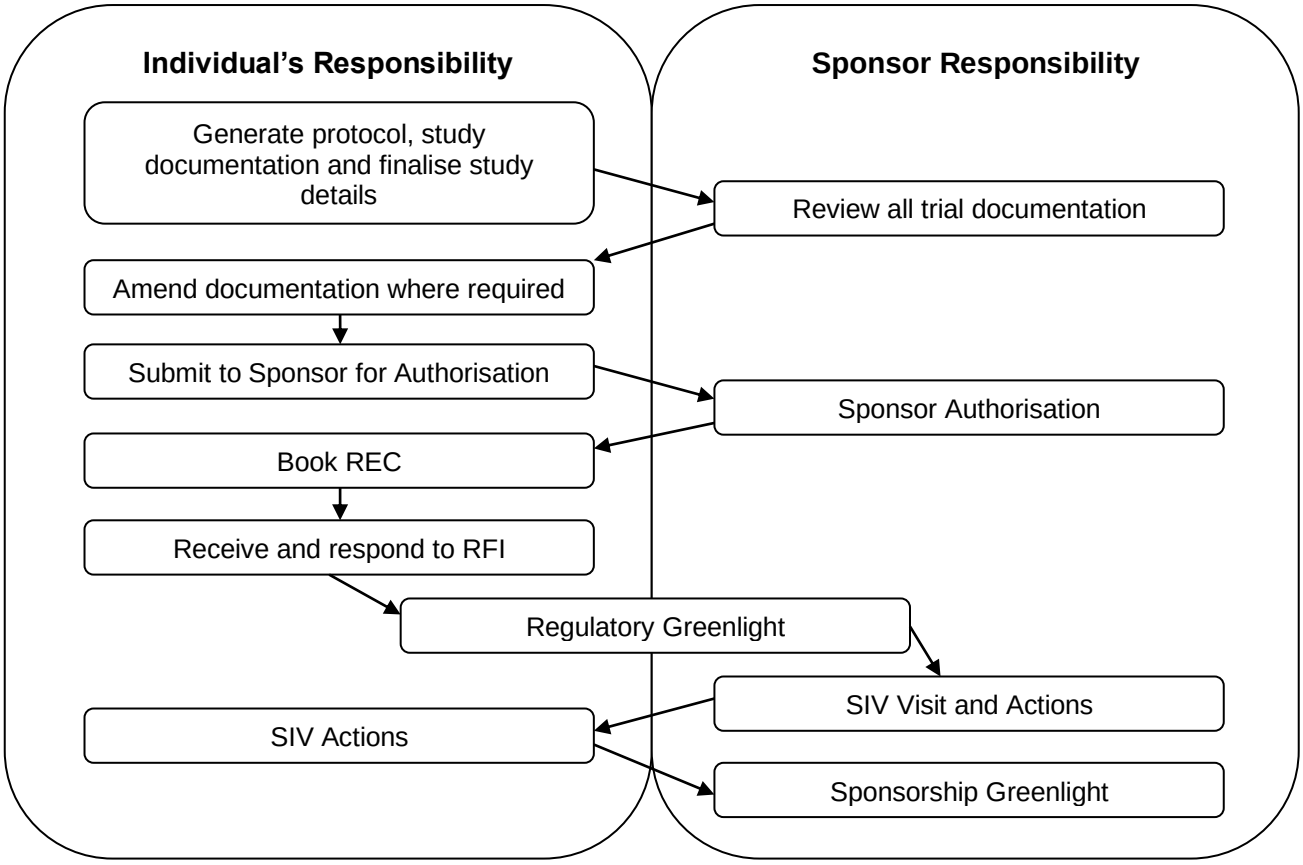
4.1.6 Collaborators can be from other departments, representatives from HHP as a sponsor organisation can be added.

4.1.7 It is a requirement to add members of HHP R&D QA team to assist in version controlling documents and finalising the submission.

4.1.8 Changes made by those with edit access will be stored once saved, so it is crucial that correct people have access to the project.

4.1.9 Individuals with access to the IRAS project must be appropriately trained and competent to perform their assigned tasks.
Access to IRAS must be controlled to maintain data integrity, ensure accurate version control and prevent unauthorised changes to essential documents submitted for regulatory review.

4.1.10 The person that sends the project to the Sponsor will receive the tasks in the system to book the REC and then to respond to any requests for further information (if needed). This is shown in a diagram below. This could be a collaborator so it is important to make sure this has been agreed within the trial team who will submit the study and respond to these follow-ups.



4.1.9 **NB Email correspondence about the project is ONLY sent to the contact listed in question C1, so do make sure the right person's contract details are listed. It is a requirement that the contact details of staff members of HHP R&D QA are added to this question to ensure the team is kept up-to-date with developments of the study.**

5 Submitting an application

5.1 When all study documents have been finalised the study is ready for submission.

5.2 To assist in accurate submissions to the regulatory bodies, there are a plethora of guides available to help investigators; it is strongly encouraged to use the HRA's step-by-step guide for using IRAS for combined review.

5.3 Ensure all supporting documents are finalised, free-from errors or comments and version controlled as mentioned in **1.4**.

5.4 All documents submitted for combined review must be version-controlled, accurate, free from inconsistencies and prepared in accordance with the Trust's Quality Management System.
This supports ICH GCP requirements for reliable data, essential document management and traceability throughout the clinical trial lifecycle.

5.5 If this is an investigators first time submitting through IRAS, the HRA will need to be contacted via cwow@hra.nhs.uk to set-up a user account. Guidance on the setting up of an IRAS account can be found here.

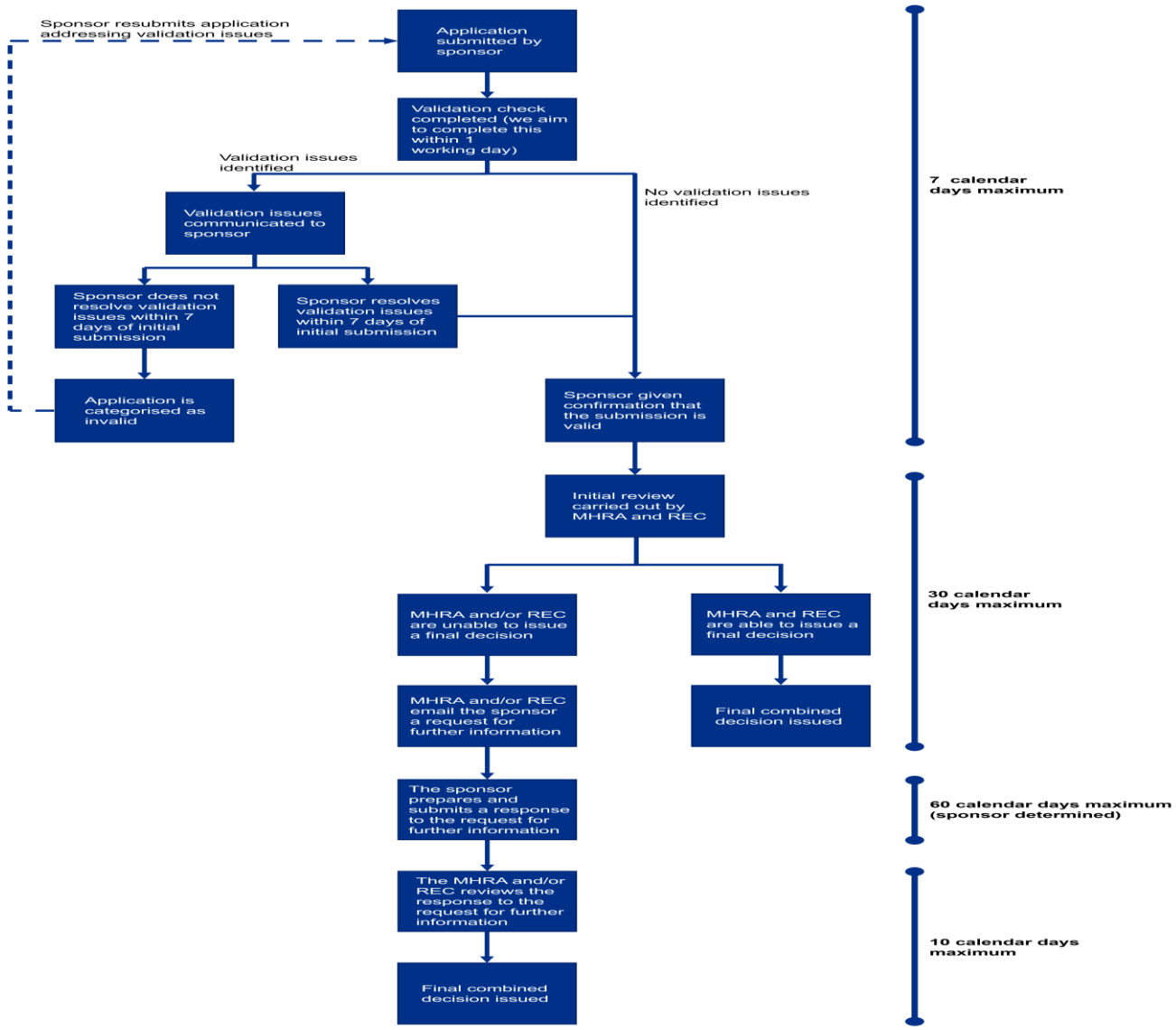
5.6 When you have an IRAS account and the study is ready for submission sign into your IRAS account here.

5.7 The process of making an initial submission can be found here.

5.8 For HUTH sponsored CTIMPs it is required that R&D QA team members are added to the study as a 'collaborator'. This can be done via the Project Dashboard, under 'key associates'. This will enable our QA department to be notified on responses from submission.

6 Regulatory Review

6.1 Once submitted the application will be sent to all relevant parties for review. The target timelines are shown on the following flowchart, taken from the HRA's website.



As shown in the flowchart **3.1** the REC review requires an in-person review to clarify points on the study for better understanding. Since the COVID-19 pandemic it has become favourable to perform REC reviews via online video platforms.

6.2 Once the MHRA and REC have reviewed the study they will issue and initial outcome and a Request for Further Information (RFI) may be issued.

6.3 The investigator team will respond to the RFI with any amended documentation or additional documents if requested. **All documentation should be reviewed by HHP R&D QA prior to submission**. The release of an RFI to Combined Review is performed by the R&D manager as a sponsor representative.

6.4 The sponsor retains responsibility for ensuring that submissions, responses to Requests for Further Information (RFIs) and any amended documents meet the standards of accuracy, completeness and quality required under ICH E6(R3).

6.5 Sponsor review prior to submission ensures that regulatory interactions are conducted in a manner that supports participant protection and the reliability of trial results.

7 Requests for Further Information

7.1 RFIs will be sent, as a task, to the user who initially submitted the application.

7.2 If more time is required to respond to an RFI, an extension can be formally requested by contacting clintrialhelpline@mhra.gov.uk, with a reference to how long over the 14 days is being requested.

7.3 To respond to an RFI log in to IRAS and follow My Tasks > My Personal Tasks > and select the project. Review and replies can then be made in the on-screen text box or submitted through an uploaded document if the replies are exceptionally long.

7.4 Once the RFI has been completed satisfactorily it can be submitted to 'request review'. The RFI will then go to the Sponsor or Sponsor Delegate's account under 'My tasks' > 'My organisational tasks' for a review and to make the final submission.

7.5 Responses to RFIs should be prepared in a timely manner and proportionate to the issues raised, ensuring clarity, accuracy and operational feasibility.
All revised documents must undergo sponsor QA review to maintain compliance with ICH GCP expectations for essential documents and quality oversight.

8 Implementation

8.1 Implementation of this SOP contributes to the Trust's overall compliance with ICH GCP by ensuring that regulatory submissions are controlled, traceable and aligned with quality-by-design principles. This SOP should be read alongside other R&D GCP SOPs that collectively implement the full set of ICH GCP principles across the clinical trial lifecycle.