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REPORTING AND TRANSPARENCY REQUIREMENTS FOR CARDIFF AND VALE HEALTH BOARD AND CARDIFF UNIVERSITY SPONSORED RESEARCH: STANDARD OPERATIONAL PROCEDURE

This SOP will be implemented from the 28th of Apr 2026 to align with The Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025 coming into force.

INTRODUCTION AND AIM

The purpose of this procedure is to outline the periodic progress and safety reporting requirements for research studies sponsored by Cardiff and Vale University Health Board (CAVUHB) and Cardiff University (CU). It also details transparency requirements for CTIMPs and the activities and reporting requirements for closing, suspending and terminating research.

After a research study has received all necessary approvals to proceed, various bodies and organisations will be interested in its progress. This is particularly the case for Clinical Trials of Investigational Medicinal Products (CTIMPS). From 1 August 2024 the HRA removed the requirement to submit annual progress reports to RECs for studies with a final REC opinion across the UK; for CTIMPs an annual Development Safety Update Report (DSUR) must still be submitted to the MHRA (and not to the REC).
The Sponsor is accountable for ensuring periodic reports are submitted within appropriate timelines. Where CAVUHB or CU is the Sponsor, responsibility for compiling and submitting these reports has been delegated to the Chief Investigator and the CTU.

The Sponsor is accountable for notifying the REC, MHRA, and other relevant bodies of the end of a trial. There are also a number of circumstances when it may be necessary to suspend or terminate research trials. This procedure explains the steps to be taken in such situations.

Under the amended UK Clinical Trials Regulations (coming into force on 28 April 2026), terminology and processes change in several areas. It is a legal requirement to publish a summary of results in the same public registry used for registration within 12 months of trial completion and to offer an accessible summary of results to participants; details of where the results are published should be provided to the MHRA and REC. For trials previously registered on EU systems, sponsors should ensure results are posted in the relevant public registry in line with transparency requirements.

OBJECTIVES

To outline reporting and transparency requirements for research studies, incorporating changes introduced by the Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025 (in force from 28 April 2026) in particular: -.

- To outline the periodic reporting requirements for research studies
- To outline the end of trial reporting requirements and activities for research studies
- To describe the procedure for suspending and terminating research studies
- To outline transparency requirements for CTIMPs
- To ensure compliance with regulatory requirements

SCOPE

This procedure applies to Chief Investigators and research staff in all locations including those with honorary contracts. This procedure is applicable for all studies that are sponsored by Cardiff and Vale University Health Board or Cardiff University.

Equality Health Impact Assessment	An equality impact assessment has been carried out on the Research Governance Policy under which this Procedure falls. No adverse impact has been identified.
Documents to read alongside this Procedure	Research Governance Policy (UHB 099) Managing breaches of GCP or the study protocol (UHB 235) Archiving of Clinical Trials Data and Research Study Data SOP *(UHB 121)*
Approved by	Joint Research Governance Group (JRGG)
Accountable Executive or Clinical Board Director	Medical Director
Author(s)	Research Governance Team

Disclaimer

If the review date of this document has passed please ensure that the version you are using is the most up to date either by contacting the document author or the Governance Directorate.

SUMMARY OF REVIEWS/AMENDMENTS

Version Number	Date of Review Approved	Date Published	Summary of Amendments
1	24/04/18	21/06/18	New document
2	28/04/21	24/06/21	Updates to reflect new guidance information following end of transition period including submission procedures for DSURs.

			Clarification that progress reports for REC are only required for studies that are more than two years in duration and for Research Tissue Bank and Research Databases. There is no requirement for a Progress Report for Proportionate Review studies. Information added regarding the use of shortened DSURs Reporting requirements for CAG Update on end of study reporting to the MHRA
3	18/04/2024		Minor changes – to reflect national updates
4	15/04/2026	24/04/2026	**Addition of Cardiff University to reflect this is a joint SOP** **Removal of REC Annual Progress Reports** The HRA removed the requirement to submit annual progress reports to RECs across the UK (effective 1 Aug 2024). REC APRs no longer required; CAG annual review remains. **Introduction of New Terminology from 28 April 2026** 'Amendments' replaced with 'modifications', categorised as substantial modification, modification of an important detail (MOID), or minor modification. ***DSUR Reporting Updated*** Annual DSURs must be submitted to MHRA only (not REC). Submission route depends on whether trial used combined review (IRAS) or standard route (MHRA Submissions).

			Shortened DSUR Withdrawn The option to submit an Annual Progress Report in lieu of a DSUR is removed; DSURs now required in all CTIMPs. **End-of-Trial Reporting Requirements Updated** Sponsors must notify MHRA and REC of trial end within statutory timelines (90 or 15 days). Routing clarified: IRAS for combined review, MHRA Submissions and REC email otherwise. ***Transparency Requirements -CTIMPs*** Sponsors must register trials in a public registry, publish summary results within 12 months, and offer an accessible lay summary to participants. Sponsors must report that the first participant has been recruited to a trial (CTIMPs only) and must end a trial where no participants have been recruited within 2 years of the CTIMP being approved. **Suspension / Restart Process Updated** Temporary halt and restart must be notified/submitted as a 'modification' under amended Regulations, replacing substantial amendment terminology. ***Transitional Arrangements*** Trials submitted before 28 Apr 2026 operate under 'old rules'; applications submitted on/after this date are 'new rules clinical trials'.

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1. SOP FLOWCHART

Periodic reporting requirements summary

CTIMP Study	Non-CTIMP Study
Submission of Annual Progress Reports (APR) to REC– requirement removed (from 1 August 2024) Approvals supported by section 251 (via CAG) still require the submission of an annual review report (to maintain approval) An annual DSUR must be submitted to the MHRA. From 28 April 2026, DSURs are not submitted to the REC (for combined review and non-combined review trials). .	Submission of Annual Progress Reports (APR) to REC– requirement removed (from 1 August 2024) Approvals supported by section 251 (via CAG) require an annual review report (to maintain approval)

2. DEFINITIONS/ABBREVIATIONS

APR	Annual Progress Report
CAVUHB	Cardiff and Vale University Health Board
CAG	Confidentiality Advisory Group
CI	Chief Investigator
CTIMP	Clinical trials of Investigational Medicinal Products
CTU	Clinical Trials Unit
CU	Cardiff University
DSUR	Development Safety Update Report
EudraCT	European Union Drug Regulating Authorities Clinical Trials. This is the European Clinical Trials Database of all clinical trials commencing in the European Union after 1 May 2004
HCRW	Health and Care Research Wales
HRA	Health Research Authority
JRO	Cardiff Joint Research Office
R&D	Research and Development
REC	Research Ethics Committee
MHRA	Medicines and Healthcare Products Regulatory Agency
SOP	Standard Operating Procedure
Sponsor	The individual, company, institution or organisation, which takes on ultimate responsibility for the initiation, management (or arranging the initiation and management) of and/or financing (or arranging the financing) for that research
Suspension or temporary halt	Suspension is a temporary cessation of some or all of the research activities at a particular location or across all research locations. A decision not to recommence a suspended trial amounts to termination of the trial.
Termination	Termination is a permanent cessation of all research activities across all research locations.

3. PROCEDURES

3.1 PERIODIC REPORTING PROCEDURES IN RESEACH STUDIES- WHERE CAVUHB OR CU IS THE STUDY SPONSOR

The CI and CTU where applicable is delegated the responsibility for compiling and submitting periodic reports
If the CI fails to provide a copy of the reports submitted within the regulatory timeframes, this will constitute a breach of Good Clinical Practice and the procedure Managing breaches of GCP or the study protocol (UHB 235) will be followed accordingly, Detailed guidance regarding how to prepare and submit reports is outlined in the remainder of this SOP.

3.3.1 **Reporting the recruitment of the first participant- CTIMPs only**

For CTIMPs approved on or after the 28th April 2026, the Sponsor is required to confirm the date that the first UK participant in a trial is recruited via the Submission of a Modification of an Important Detail (please refer to the JRO SOP for Managing Modifications SOP-003-06). In CU and CAVUHB Sponsored CTIMPs, this responsibility is delegated to the Sponsor-appointed CTU.

There are exceptions to this reporting requirement and this should be discussed with the JRO Sponsor representative during the Sponsor Approval Process (SAP) (please refer to SOP-012-01).

CU and CAVUHB Sponsored CTIMPs approved before 28th April 2026 do not need to report the recruitment of the first UK participant.

3.3.2 Annual Progress Reporting to REC -

Annual progress reports – requirement removed (from 1 August 2024)

The HRA has removed the requirement to submit annual progress reports to RECs for studies with a final REC opinion across the UK. This applies to studies in England, Wales, Scotland and Northern Ireland.

3.3.2 Projects requiring only HRA/HCRW Approval

For projects requiring only HRA/HCRW Approval (e.g. projects involving NHS staff participants only), progress reports are not required.

3.3.3 Confidentiality Advisory Group (CAG) annual review

Approvals supported by section 251 (via CAG) continue to require an annual review report (submitted ~11 months after approval) to maintain approval.

All approvals are reviewed annually to assess the need for continuing approval and to ensure that progress towards, or achievement of, any conditions of approval is in place. This review is carried out following submission of an annual review report.

At this stage consideration should be given to whether it is possible to reduce the amount of confidential patient information being processed.

To allow sufficient time for processing, an annual review report should be submitted to the Confidentiality Advice Team by email **four weeks** before the approval expires (i.e. no later than 11 months following the final approval date) using the report template found in the IRAS Help function. This will be assessed by the Confidentiality Advice Team in the first instance. Please refer to HRA website and to the Help section of IRAS for further guidance and templates**.** The CAG remit only extends to England and Wales. If studies process confidential patient information generated within Scotland, Investigators should follow guidance from the Public Benefit and Privacy Panel https://www.informationgovernance.scot.nhs.uk/
For Northern Ireland, contact the Northern Ireland Public Data Panel (NIPDP) r.j.mcclelland@qub.ac.uk **/** info@nipdp.org

3.3.4 Development Safety Update Report (DSURs) -CTIMPs only

For CTIMPs, an annual DSUR must be submitted to the MHRA. From 28 April 2026, DSURs are submitted to the MHRA only and do not need to be submitted to the REC (for combined review and non-combined review trials).

In the case of CU and CAVUHB-Sponsored CTIMPs, the preparation and submission of the DSUR is delegated to the Sponsor-appointed CTU. The JRO Sponsor Representative(s) may provide input into the DSUR upon request.

The DSUR should consider all new available safety information received during the reporting period. The main objective of a DSUR is to present a comprehensive annual review and evaluation of pertinent safety information collected during the reporting period related to a drug under investigation, regardless of whether it is marketed.

The DSUR must be compiled annually for the duration of the clinical trial until the regulator has been notified of the end of the trial.

The DSUR due date is the anniversary of the first international regulatory approval sometimes referred to as the 'Development International Birth Date' (DIBD) regardless of the approval status in the UK. For CTIMPs only taking place in the UK, this will be the date of the MHRA Clinical Trial Authorisation (CTA).

The DSUR must be submitted **within 60 days** of the due date.
The data lock point of the DSUR should be the last day of the one-year reporting period.
If a Sponsor oversees several CTIMPs involving the same IMP(s), one DSUR should be submitted for the IMP rather than the Sponsor submitting individual reports for each trial including that IMP. If there is a valid reason for submitting separate reports this should be clearly explained on the DSUR. DSURs are IMP specific therefore for trials involving multi-drug therapy (i.e. combinations of drugs that are not fixed) the JRO , in conjunction with the CI or CTU will need to decide to either prepare a DSUR for the multi-drug therapy, or DSURs for one or more of the individual components; in this case information on the multi-drug therapy trials can be included in the DSURs of one or all of the components. This should be determined during the CTIMP set-up period.

The DSUR should include:

- an analysis of the subjects' safety in the concerned clinical trial(s) with an appraisal of its ongoing risk/benefit
- a line listing of all suspected serious adverse reactions (including all SUSARs) that occurred in the trial(s), including all SUSARs from third countries
- an aggregate summary tabulation of SUSARs that occurred in the concerned trial(s)
- Region-specific information on how to increase transparency

3.3.5 Submission of the DSUR and payment- for CU and CAVUHB Sponsored CTIMPs

The submission of the DSUR is delegated to the Sponsor-appointed CTU. CTU processes and procedures for the preparation and submission of the DSUR should be adhered to.

DSURs are not considered valid unless proof of payment is provided.
Payment for a DSUR submission must be made by a credit or debit card,

through the MHRA's DSUR Submission page: Make a payment - Pay for a DSUR submission

A proof of payment receipt will be generated by the MHRA, and this must be uploaded with the completed DSUR as part of the DSUR submission. To ensure that CTUs meet the DSUR submission deadline, it is recommended that the payment process is initiated at least one month prior to the date the DSUR is due.

Submit DSURs to the MHRA either via MHRA Submissions (for non-combined review projects) or via IRAS (for projects where at least one trial was approved through combined review). DSURs do not need to be reported to the REC. Provide a copy to the applicable JRO governance team (CAVUHB or CU). The submission of the DSUR must be accompanied by a cover letter which lists:

- all IRAS numbers (and/or EudraCT references if the trial was registered prior to 1st January 2021 or is conducted at trial locations in the European Union) of trials covered by the DSUR, including any trials approved via the Voluntary Harmonisation Procedure (VHP) process including an email address for correspondence.

- an email address for correspondence
- the DSUR payment reference number in the format: 'DSUR- [5-digit MHRA company number]- [IMP name]- [Payment date DD/MM/YYYY]'

At the end of the DSUR reporting period the CI on behalf of the Sponsor may assess the new safety information that has been generated and submit any proposed safety changes to the Investigator's Brochure as a modification. This modification must be supported by the DSUR and approved before the reference safety information (RSI) is changed.

Use of the HRA Annual Progress Report in lieu of a DSUR for trials meeting the MHRA's criteria for a Type A risk categorisation, is no longer applicable, as annual progress reports to REC have been withdrawn. All CTIMPs are required to submit an annual DSUR to the MHRA, regardless of risk categorisation. The CI/CTU on behalf of the Sponsor must submit a DSUR to the MHRA.

3.2 PROCEDURE FOR CLOSING, SUSPENDING AND TERMINATING RESEARCH

3.2.1 End of Trial Definition The definition of the end of a trial should be described in the protocol (and any subsequent modifications). For most trials, this will be the date of the last patient's last visit (LPLV) or the completion of any follow-up monitoring and data collection described in the protocol. For international studies, this is the end of study in all participating countries, not just in the UK.

For studies involving human tissue, the analysis of the samples should be undertaken as part of the data collection **before** the end of study is declared.

Any retained tissue for possible future evaluation after the end of study has been declared should be with the appropriate licence and should be undertaken as described in the protocol and within the terms of consent from the donors. Otherwise, a new proposal for REC review would need to be submitted.

Any change to the end of study definition after approval has been given for the research should be notified as a modification to the appropriate review bodies.

There are several actions that need to be completed upon trial completion. For CAVUHB or CU sponsored trials, responsibility for undertaking these actions is delegated to the CI or CTU.

3.2.2 Notifying MHRA and REC

(a) both the MHRA (licensing authority) and the REC must be notified that a clinical trial has ended within 90 calendar days of the end of the trial, or within 15 calendar days if the trial ended prematurely.

- For combined review trials, the CI should complete and submit the end of trial form in the new part of Integrated Research Application System (IRAS). This automatically submits the notification to the REC and MHRA.

- For CTIMP and IMP/Device trials that were not submitted through combined review, the CI will need to complete the form available on the MHRA website and email this to the MHRA and REC.

For all other research, the end of study declaration form should be completed and emailed to the REC.

Where a project has HRA/HCRW Approval and has been reviewed by a REC the CI needs only inform the REC when the study has ended.

Where a project has HRA/HCRW Approval only and was not reviewed by an NHS REC, the CI (or their delegate) will need to inform the HRA/HCRW when the project has ended:

- For studies where the lead NHS location was in England- the CI will need to notify the HRA directly approvals@hra.nhs.uk

For studies where the lead location was in Wales- Send this notification to HCRW- Research-permissions@wales.nhs.uk iThe CI should include the study IRAS ID and their contact details when information the HRA/HCRW of the end of a study.

3.2.3 Notifying the MHRA (medical devices)

Manufacturers or sponsors are required to email the MHRA at ctdhelpline@mhra.gov.uk when a clinical investigation of a medical device comes to an end.

3.2.4 Notifying the Confidentiality Advisory Group (CAG)

For studies which have an application with the Confidentiality Advisory Group (CAG), when the study is complete, the CI or CTU should email the confidentiality advice team as soon as possible. The confidentiality advice team will review the information provided; update the approval register and email to confirm they have received the notice.

The application will remain on the approval register on the website for at least 12 months following notification of closure.

3.2.5 Notifying Stakeholders and Closedown Activities

The CTU or CI should notify other stakeholders of trial completion, including R&D departments of other NHS Trusts where the trial took place and any other bodies, as required under separate agreements (such as funding bodies, universities or specialist committees).

At the end of trial, the CTU or CI must ensure close-out monitoring activities are conducted. For CAVUHB or CU Sponsored CTIMPs, close-down activity is delegated to the appointed CTU, and the CI should work with the appointed CTU to complete all close-down activity with trial locations. Support departments (e.g. pharmacy) should also be notified in order that they can prepare for close-out. For CTIMPs and Clinical Investigations of Medical Devices JRO staff (or CTU staff if trial monitoring has been delegated) will undertake close-out activities with the appointed CTU including:

- Checking that the Trial Master File (TMF) and/or Site file is organised and ensuring all necessary documents are present.
- Ensuring that archiving procedures have been initiated by the CTU or CI in line with the Archiving of Clinical Trials Data and Research Study Data SOP *(UHB 121) for CAVUHB sponsored studies* or in line with the Archiving SOP/procedures of the appointed CTU in the case of CU Sponsored studies (including the Cardiff University Records Retention Policy)
- Ensuring pharmacy close-out has been undertaken in accordance with Pharmacy procedures, if applicable.

For non CTIMPs it is the CIs responsibility to ensure the necessary close out activities are conducted.

The CI should also ensure arrangements are made for the following:

i. Data-lock of the database prior to analysis.

ii. Resolving any outstanding financial obligations including ensuring any outstanding invoices payable or to be raised.

Documents should be archived in accordance with the Archiving of Clinical Trials Data and Research Study Data SOP *(UHB 121) for CAVUHB sponsored studies or the Cardiff University Records Retention Policy and Schedules for CU Sponsored studies*

3.2.6 Reporting a Temporary Halt in a Research Study

Sometimes it is necessary to temporarily halt or suspend a research study. A temporary halt is normally implemented in order to resolve an immediate problem or threat to the study, and it is normally made on the assumption that the study will resume in the future.

The decision to temporarily halt or suspend a research study or trial may be based on:

- an immediate need to protect participants (e.g. following an Urgent Safety Measure or a Serious Breach).
- a major safety event arising in the study (e.g. an Urgent Safety Measure, or in the case of certain SUSARs).
- emerging data (either from the study or from other studies) which may impact upon the safety and/or efficacy of the trial IMP/NIMP or scientific validity of the study.
- the recommendation of a trial location.

- the recommendation(s) of the funder.
- the recommendation(s) of the Independent Data Monitoring Committee (IDMC) as recommended to the Trial Steering Committee, based on emerging evidence around the trial data or as a result of information arising from other trials and studies.
- the request of the REC, HRA and/or MHRA.
- the outcome of monitoring or audit activity.
- the recommendation of the Sponsor.
- a decision made by the Chief Investigator or Principal Investigator, with the Sponsor's agreement.

In CU or CAVUHB Sponsored research studies, the CI and/or the appointed CTU should discuss any plans to implement a temporary halt in a study with the Sponsor representative in the JRO. Temporary halts may be implemented across all study locations or at one location, depending on the circumstances.

When it has been agreed that a temporary halt is required, the CI and/or CTU should:

- follow the Sponsor-appointed CTU's processes.
- prepare a Route A Substantial Modification to submit to the REC and/or MHRA (in the case of CTIMPs and Medical Device Trials). The Route A Substantial Modification must be authorised by the Sponsor representative and should be accompanied by a covering letter clearly explaining which aspects of the trial have been stopped and the reason(s) for the suspension. In the case of CTIMPs and Medical Device Trials it must be submitted within 15 calendar days of the decision to implement a temporary halt.
- promptly inform any study participants remaining on the trial and implement appropriate follow-up procedures to ensure participants continue to receive adequate medical care and treatment required to enable them to complete their involvement in the study safely. Participants should be provided with options to withdraw from the study where it is deemed safe to do so or continue to be managed in line with the study protocol until their involvement in the study is completed.
- During the temporary halt, participants should continue to be monitored or followed up.

Where a temporary halt is being made as part of an urgent safety measure (USM) in a CTIMP, the notification of the temporary halt of a trial should be reported directly to the MHRA via the USM reporting process by calling the Clinical Trial Helpline to discuss the USM within 3 days of implementing the USM (please also refer to the Joint SOP for *Safety Reporting SOP-012-01*). A follow-up written report is then required to be submitted by the Sponsor (or the

Sponsor's appointed CTU) within 7 calendar days. Failure to notify the licensing authority of the implementation of a temporary halt for safety reasons may be considered a serious breach.

While the trial is halted, the issues of concern should be assessed and revisions to be made to the clinical trial protocol should be considered. The CI and/or CTU should ensure that the JRO Sponsor representative remains updated throughout the duration of the temporary halt (e.g. via the Trial Management Group, or other regular forms of communication). Together with the CI and/or CTU, the Sponsor should reach a decision about whether to restart or end the study.

To resume a research study following a temporary halt, a further Route A Substantial Modification is required to be submitted to the REC and/or the MHRA and must be approved by the REC and/or MHRA before any study activity may recommence. The Substantial Modification to restart a study must be authorised by the Sponsor. This application should include evidence that it is safe to restart the trial, including conclusions of the analysis, any mitigation measures if applicable and an updated risk assessment should be provided by the CI or CTU.

3.2.7 Reporting a Premature Termination of a Research Study

Occasionally, a research study or trial may need to be closed ahead of the planned end date (prematurely terminated). Premature termination of a research study normally (but not always) occurs after the decision has been made to temporarily halt the study and may occur as a result of:

- a major safety event.
- emerging data which may impact upon the safety and/or efficacy of the IMP/NIMP or the scientific validity of the trial.
- slow recruitment rates, or extreme challenges with recruitment.
- a decision made by the funder.
- A decision made by the Independent Data Monitoring Committee (IDMC) as recommended to the Trial Steering Committee, based on emerging evidence around the trial data or as a result of information arising from other trials and studies.
- a decision made by the Sponsor.
- a decision made by the Chief Investigator, with the Sponsor's approval.
- findings from auditing or monitoring activity.

3.2.8 Reporting process in the event of a premature termination of CAVUHB or CU Sponsored CTIMPs and Medical Device Trials

In accordance with section 2.6 of ICH GCP E6(R3), where the decision is made to prematurely terminate a CTIMP, the Chief Investigator should:

- follow the processes in place at the Sponsor-appointed CTU.
- Prepare a Route A Substantial Modification and include a Covering Letter detailing the reasons for the Premature Termination of the study.
- promptly inform any study participants remaining on the trial and implement appropriate follow-up procedures to ensure participants continue to receive adequate medical care and treatment required to enable them to complete their involvement in the study safely. Participants should be provided with options to withdraw from the study where it is deemed safe to do so or continue to be managed in line with the study protocol until their involvement in the study is completed.

- Suspended or terminated by the Sponsor (where CAVUHB or CU is the Sponsor):
  Where CAVUHB or CU is the Sponsor, all the rights, powers and duties of a Sponsor will be exercised in relation to the suspension and termination of any research study where necessary. Decisions to suspend or terminate a study may only be taken by the JRO Director (or delegated authority in their absence).

- Suspended or terminated by the CI/PI: For CTIMPs- while the Medicines for Human Use (Clinical Trials) Regulations 2025 (Amendment) (as amended) do not expressly provide a CI/PI with the legal power to suspend or terminate a clinical trial, ICH-GCP E6 (R3) paragraph 3.17.1 sets out the process for doing so. If a trial is prematurely terminated or suspended for any reason by the CI/PI, then participants should be provided with options to withdraw from the study where it is deemed safe and appropriate to do so, or continue to be managed in line with the study protocol until their involvement in the study is completed.

- If the study is suspended or terminated without the prior agreement of the Sponsor (e.g. at the request of a trial location), then the CI/PI must inform the JRO immediately with a detailed written explanation of the reasons for termination or suspension. The CI/PI would not be expected to terminate or suspend a study without prior discussion with the JRO unless in an emergency, where there are immediate safety concerns.

3.2.9 Restarting research - If the JRO Director is satisfied that any concerns or issues have been appropriately addressed then permission may be given to continue with suspended studies. Research must not re-start without this permission. To restart a temporarily halted trial, the CI must submit a further modification with evidence that it is safe to restart. JRO staff will liaise with the CI regarding submission of these.

3.2.10 Terminating Research - If the JRO decides not to recommence a suspended study, the MHRA (for CTIMPs) and REC should be notified by the CI within 15 days of the decision. In particular, the following information must be provided:

- Justification of the premature ending of the study and the number of patients still receiving treatment at the time of termination
- Proposed management of patients receiving treatment at the time of termination
- Consequences for the evaluation of results.

3.2.11 CTIMPs which fail to recruit a participant within 2 years of receiving approval

All CTIMPs (including those involving Advanced Therapy Medicinal Products/ATMPS) submitted under the new UK Regulations (on or after 28th April 2026) will be expected to recruit their first participant in the UK within 2 years of the trial being approved (meaning when the trial received both authorisation from the MHRA and a favourable opinion from the Research Ethics Committee).

From CTIMPs approved on or after 28th April 2026, if no participants are recruited within 2 years, the approval for the trial will lapse. Where this occurs, the Sponsor is required to end the trial and submit a notification in writing by the date that the approval lapsed (e.g. 2 years from the date of approval). Continuing to run a CTIMP after the approval has lapsed would be considered an offence under the UK Clinical Trial Regulations.

Where it is anticipated that a CU or CAVUHB Sponsored CTIMP will not recruit a participant by the 2-year approval anniversary, a discussion will be facilitated with the JRO Director, the CTU and the CI and the closedown process will be initiated. In certain scenarios it may be possible for the Sponsor to request an extension to the 2-year timeframe.

This reporting requirement does not apply to CTIMP applications submitted before 28 April 2026. This means the approval for these CTIMPs will not lapse if the trial does not recruit its first participant within 2 years.

3.3 TRANSAPARENCY REQUIREMENTS FOR CTIMPs

The updated Clinical Trial Regulations introduce new legal requirements for research transparency in clinical trials of investigational medicinal products (CTIMPs) in the UK.

They will require sponsors of CTIMPs in the UK to:

- register a clinical trial in a public registry before the recruitment of the first participant or within 90 days of approval of the clinical trial (whichever is sooner)

- publish a summary of the results within 12 months of the end of the trial. If a deferral or waiver is required (e.g. Phase I trials), follow HRA guidance. Where a suitable public registry is not used, submit a summary of results via MHRA Submissions

- offer to share a summary of the results with participants or relevant individuals (this should be in a suitable format and in a manner that's understandable to participants or those who may have provided consent on behalf of the participant or other relevant people.

Failure to comply with the requirements to register or publish a summary of results (without any deferral or waiver) will constitute an offence under the new legislation and, if not corrected, may result in action being taken by the Medicines and Healthcare products Regulatory Agency (MHRA).

For trials Sponsored by either CU or CAVUHB, responsibility for registering a trial on an appropriate registry and regularly maintaining the entry is delegated to the CI/CTU.

CTIMPs and Medical Device Trials Sponsored by Cardiff University and CAVUHB taking place in the UK must be registered on ISRCTN. Cardiff University does not support the use of ClinicalTrials.gov as a suitable clinical trials registry.

It is the responsibility of the CI and/or CTU to ensure registration entries remain up to date, accurate and complete.

3.4 TRANSITIONAL ARRANGEMENTS

Trials with initial applications submitted before 28 April 2026 are 'old rules clinical trials'. Applications submitted on/after 28 April 2026 are 'new rules clinical trials'. Sponsors should follow MHRA transitional guidance, including how to apply modifications and fulfil transparency and pharmacovigilance requirements during transition. Clinical trials regulations: transitional arrangements - GOV.UK

4. DISSEMINATION AND TRAINING

SOPs are reviewed by the JRO Quality Management Group (QMG) and presented to the JRGG for information. Once approved, they are published on the CAVUHB Intranet, AMAT and sent to the R&D Leads and JRGG members to disseminate appropriately. The Clinical Board R&D Leads should facilitate implementation by ensuring that all relevant research active personnel within their Boards are aware of the Procedure and the implications for their practice. Education and support should be available from the R&D Office for researchers who are involved in conducting clinical research studies.

5. RELATED SOPS AND DOCUMENTS

Health Research Authority
Progress Reports
https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/progress-reports

Medicines & Healthcare products Regulatory Agency (MHRA)
Clinical trials for medicines: manage your authorisation, report safety issues
www.mhra.gov.uk/Howweregulate/Medicines/Licensingofmedicines/Clinicaltrials/Safetyreporting-SUSARSandASRs/index.htm

Health Research Authority
Ending your project
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