

Research and Development SOP012 Income from Clinical Trials and Research Studies

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Table of Contents

1. Introduction.....	4
1.7. Scope	4
1.8. Definitions and Glossary	5
2. Purpose of this Standard Operating Procedure	8
3. Ownership and Responsibilities.....	8
3.1. Role of the Research and Development Clinical Director	8
3.2. Role of the Finance Director	8
3.3. Role of the Senior Management Team (SMT).....	9
3.4. Role of the Head of Research and Development	9
3.5. Role of the Lead Research Nurse	10
3.6. Role of the Contracts Manager	10
3.7. Role of the Research Accountant.....	11
3.8. Role of the Industry Operations and Quality Improvement Manager.....	11
3.9. Role of the Research Operations Service Manager (ROSM)	12
3.10. Role of the Team Leader and Research Nurse.....	13
3.11. Role of the Admin Team	13
3.12. Role of the Data Team	14
3.13. Role of the Pharmacy Research Staff.....	14
3.14. Role of Individual Staff.....	15
4. Standards and Practice	15
4.1. Study Set-Up Team (SST)	15
4.2. Research Accountant and Finance Team.....	18
4.3. Industry Operations and Quality Improvement Manager (IOM) and Data Team	20
4.4. Research Operations and Service Manager (ROSM).....	20
4.5. Clinical Research Teams	21
4.6. Data Team	21
4.7. Research Admin Team.....	21

4.8. Pharmacy Team	22
4.9. Aged Debt.....	22
5. Dissemination and Implementation	23
6. Monitoring compliance and effectiveness	24
7. Updating and Review.....	25
8. Equality and Diversity	25
Appendix 1. Governance Information	26
Appendix 2. Quality and Equality Impact Assessment (QEIA) Form	29

Data Protection Legislation

The Trust must comply with the UK GDPR, Data Protection Act 2018, and Data (Use and Access) Act 2025 by ensuring all personal data is processed lawfully, fairly, transparently, and for a defined purpose.

Before processing personal data, an appropriate Article 6 UK GDPR lawful basis must be identified and recorded. Where special category data is involved, a relevant Article 9 condition must also be documented.

All staff, contractors, students, volunteers, agency workers, and third parties working on behalf of the Trust are responsible for complying with data protection legislation.

Further guidance is available in the Trust's Information Use Framework and Information Governance policies. Advice can also be obtained from the Information Governance Team.

1. Introduction

- 1.1. Commercially funded clinical research is research sponsored and financed by private sector organisations, primarily pharmaceutical and life sciences companies, to test new treatments, drugs and medical interventions. This funding is essential for supporting clinical trials for investigational products and other health and social care research. Clinical Trials are defined in the Medicines in Human Use (Clinical Trials) Regulation 2004 (“the Clinical Trials Regulations”) Part 2 Regulation 2 (1).
<https://www.legislation.gov.uk/uksi/2004/1031/regulation/2/made> and the Medicines in Human Use (Clinical Trials) (Amendment) Regulations 2025 (referred to as the “amended Clinical Trials Regulations”) Part 2 Regulation 3.
<https://www.legislation.gov.uk/uksi/2025/538/regulation/3>
- 1.2. Non-commercial research is primarily sponsored and funded by public bodies such as the NHS, local authorities, universities, charities and non-profit organisations. These studies may cover a much broader range of study types, including surgical, observational, diagnostic and screening studies, as well as CTIMPs. This research may be funded by a commercial organisation through a grant.
- 1.3. International Council for Harmonisation (ICH) Good Clinical Practice (GCP) Guidelines E6 (R3) paragraph Annex 1 Paragraph 3.5 states that “The financial aspects of the trial should be documented in an agreement between the sponsor and the investigator/institution.”
[ICH E6\(R3\) Step4 FinalGuideline 2025 0106.pdf](#)
- 1.4. The National Contract Value Review (NCVR) was introduced in the UK in October 2023 and is a standardised, national approach to costing for commercial contract research. The NCVR uses a standardised pricing and contract terms for commercial research across the whole of the NHS, providing transparent and predictable research delivery prices.
- 1.5. Contracts and agreements should be in place prior to the initiation of any trial and be subject to periodic review to ensure that they remain up to date and relevant. A clinical trial agreement (CTA) contains details of all the clinical trial or study activity, the associated cost to the sponsor and the contract payment terms and agreements.
- 1.6. Research and Development (R and D) procedures required to accurately cost and recover clinical trial or research study income, to ensure the funds support the capability and growth of research at Royal Cornwall Hospitals NHS Trust (RCHT). Processes for capturing and invoicing sponsors for completed research activity should align with the appropriate contractual requirements.
- 1.7. **Scope**
 - 1.7.1. This Standard Operating Procedure (SOP) applies to all clinical trials and studies, hosted by Royal Cornwall Hospitals NHS Trust (RCHT).
 - 1.7.2. This SOP applies to all staff involved in research activities being conducted for RCHT.

1.8. Definitions and Glossary

- 1.8.1. **Attributing the Costs of Health and Social Care Research and Development (AcoRD)** is a framework for the NHS and its partners to identify, recover and attribute the costs of health and social care research. AcoRD makes a clear distinction between the three costs: research costs, NHS support costs and treatment Costs and describes how these costs should be met.
<https://www.gov.uk/government/publications/guidance-on-attributing-the-costs-of-health-and-social-care-research>
- 1.8.2. **National Contract Value Review (NCVR)** is a standardised, national approach to costing for commercial contract research.
- 1.8.3. **Interactive Costing Tool (iCT)** is a web-based tool through which the UK's standardised methodology is access and applied to commercial trials, used to review the National Contract Value Review (NCVR) process. <https://www.nihr.ac.uk/guidance-using-interactive-costing-tool-ict>
- 1.8.4. **SoECAT (Schedule of Events Cost Attribution Template)** is required by the Health Regulation Authority for all non-commercial studies. The study sponsor is required to submit this document, which details the support service costs, treatment and excess treatment costs and research costs. This information is required to populate RaDICO workbooks for the collection of non-commercial income.
- 1.8.5. **Model Clinical Trial Agreement (mCTA)** is a standardised template used to streamline the contracting process for clinical trials, ensuring compliance and efficiency in industry sponsored research.
- 1.8.6. **Model Non-commercial Agreement (mNCA)** is the standardised template used to agree the relationship between and the responsibilities of non-commercial commercial sponsors and the research site.
- 1.8.7. **Organisation Information Document (OID)** is a key component of the UK Local Information Pack (LIP) for non-commercial research projects and forms part of the core documents required by the Health Research Authority (HRA) as part of the review process for providing approval. The OID defines the study terms and can provide an alternative to a formal contract for non-commercial studies.
- 1.8.8. **Research and Development Industry Costings (RaDICO)** is a bespoke, web-based electronic database, facilitating the management and collection of income from clinical research activity at RCHT.
- 1.8.9. **RaDICO Workbook** refers to the costings provided for a particular study or arm of a study.
- 1.8.10. **Case Report Form (CRF)** is a document used to record the required data as defined by the protocol for each participant throughout their participation in the trial or study.

- 1.8.11. **Scheme of Delegation** outlines the authorities, limits and processes by which delegated financial decisions are made, detailing the levels of approval, monetary thresholds, and accountability for expenditure and governance.
- 1.8.12. **Levels of access:** RaDlCo has four levels of access. Each level of access enables a specific function. Some staff may require more than one level of access depending on roles and responsibility.
- Trust IT administration level access enables the management of other users including assigning users the appropriate access.
 - R and D level access enables the import and management of RaDlCo Workbooks.
 - Study Team level access enables the recording of activity into the RaDlCo Workbooks.
 - Finance level access enables the finance team the access and provides the information for them to raise invoices and confirm payment as well as the redistribution of income.
- 1.8.13. **Aged debt** refers to any outstanding invoices unpaid after 45 days or longer.
- 1.8.14. **Unit 4 Business World or Unit 4** is a professional procurement and accounting system used by RCHT for financial management.
- 1.8.15. **Capacity and Capability** is the local procedure undertaken to assess and confirm that RCHT has the resources, policies and potential participants required to deliver the research trial or study to time and target.
- 1.8.16. **Hosted** refers to an externally sponsored study for which the RCHT is acting as a research site.
- 1.8.17. **EDGE** is a dedicated, web-based research database which is used within, and managed by, the R and D department at RCHT as a document repository.
- 1.8.18. **The Director of the Corporate Care Group** under which the finance and research departments reside and acts as the executive signatory for this document.
- 1.8.19. **Sponsor** is an individual, company, institution or organisation which takes responsibility for the initiation, management and/or financing of a clinical trial. A group of individuals and/or organisations may take on sponsorship responsibilities and distribute them by agreement among the members of the group, provided that, collectively, they make arrangements to allocate all the responsibilities that are relevant to the study in line with the UK Policy Framework for Health and Social Care Research.

1.8.20. **Standard Operating Procedure (SOP)** is a procedure document detailing a specific sequence of events that must be followed for an activity.

1.8.21. **Glossary of Terms** (R and D 07) is a glossary of the terms and the definition of the acronyms and can be found in the Associated Documents folder in EDGE.

1.9. Acronyms

- **AcoRD:** Attributing the Costs of Health and Social Care Research and Development.
- **ARID:** Account Receivable Identification Code.
- **C and C:** Capacity and Capability.
- **CRF:** Case Report Form.
- **CTA:** Clinical Trial Agreement.
- **eCRF:** Electronic Case Report Form.
- **HRA:** Health Research Authority.
- **iCT:** Interactive Costing Tool.
- **IOM:** Industry Operations Manager.
- **IRAS:** Integrated Research Application System.
- **IVRS:** Interactive voice response.
- **LIP:** Local Information Pack.
- **mCTA:** Model Clinical Trial Agreement.
- **mNCA:** Model Non-commercial Agreement.
- **NCVR:** National Contract Value Review.
- **NIHR:** National Institute for Health and Care Research.
- **OID:** Organisation Information Document.
- **PIC:** Patient Identification Centre.
- **RECIST:** Response evaluation criteria in solid tumours.
- **ROSM:** Research Operations Service Manager.
- **R and D:** Research and Development.
- **RCHT:** Royal Cornwall Hospitals NHS Trust.

- **REC:** Research Ethics Committee.
- **RaDICO:** Research and Development Industry Costings.
- **SMT:** Senior Management Team.
- **SoECAT:** Schedule of Events Cost Attribution Template.
- **SOP:** Standard Operating Procedure.
- **SST:** Study Set-up Team.

1.10. This version supersedes any previous versions of this document.

2. Purpose of this Standard Operating Procedure

The purpose of this SOP is to describe the processes all staff at RCHT are required to follow to ensure the income is claimed for all the contracted research activity in respect of hosted clinical trials and research studies.

3. Ownership and Responsibilities

3.1. Role of the Research and Development Clinical Director

The R and D Clinical Director or delegate is responsible for:

- Having oversight to ensure that there are robust arrangements in place for research staff to follow the processes described in [Section 4](#), Standards and Practice.
- Gaining assurance from the Senior Management Team (SMT) to ensure compliance with the processes outlined in [Section 4](#), Standards and Practice.
- Awareness of income and expenditure and responding accordingly to ensure the viability of the department and service.

3.2. Role of the Finance Director

The Finance Director is responsible for:

- Having oversight of the provision of training for finance staff to perform their roles and responsibilities in association with the processes described in [Section 4](#), Standards and Practice.
- Ensuring staff have the appropriate access to the financial systems to perform their roles and responsibilities.
- Providing assurance that the finance staff are compliant with the processes outlined in [Section 4](#), Standards and Practice.
- Reviewing and signing the commercial contracts on behalf of the Trust or delegating the duty to an appropriately qualified person, in line with the scheme of delegation.

- Having oversight to ensure that there are robust arrangements in place for timely invoicing to the sponsor or funder in accordance with the contractual arrangements.
- Ensuring financial systems are backed up and contingency plans are in place for any system interruptions.
- Having oversight of income and expenditure and responding accordingly to ensure the viability of the department and service.

3.3. **Role of the Senior Management Team (SMT)**

The SMT is responsible for:

- Providing assurance to the R and D Clinical Director of the compliance with the processes outlined in [Section 4](#), Standards and Practice.
- Ensuring adequate provision of training for staff to perform their roles and responsibilities in association with the processes described in Section 4, Standards and Practice.
- Supporting all staff to fulfil the duties, responsibilities and obligations in executing the processes described in [Section 4](#), Standards and Practice.
- Ensuring the research activity is accurately costed and all costs are captured in the appropriate contract.
- Ensuring the sponsor and funder is invoiced in accordance with the contractual arrangements.
- Ensuring staff have the appropriate access to the systems to perform their roles and responsibilities.
- Supporting the Head of Research and Development (R and D) to ensure RaDlCo is backed up and a contingency plan in place for systems interruptions.
- Monitoring income and expenditure and responding accordingly to ensure the viability of the department and service.
- Arranging and auditing of the systems and processes associated with the standards and practices described in [Section 4](#).

3.4. **Role of the Head of Research and Development**

The Head of Research and Development is responsible for:

- Ensuring there is a process in place to accurately cost and recover and distribute commercial clinical trial or research study income.
- Having oversight of the provision of training for research staff to perform their roles and responsibilities in association with the processes described in [Section 4](#), Standards and Practice.

- Supporting all staff to fulfil the duties, responsibilities and obligations in executing the processes described in [Section 4](#), Standards and Practice.
- Ensuring the systems operated by research staff are backed up and contingency plans are in place for systems interruptions.
- Oversight of research activity and that it is accurately costed and all costs are captured on the Clinical Trial Agreements (CTAs).
- Monitoring income and expenditure and responding accordingly to ensure the viability of the department and service.
- Signing off the contracts for non-commercial, non-CTIMPs on behalf of the Trust, or delegating the duty to an appropriately qualified person.
- Chairing monthly finance meetings with key personnel to review and direct actions for the recovery of debt.

3.5. **Role of the Lead Research Nurse**

The Lead Research Nurse is responsible for:

- Ensuring adequate provision of training for staff to perform their roles and responsibilities in association with the processes described in [Section 4](#), Standards and Practice.
- Supporting all staff to fulfil the duties, responsibilities and obligations in executing the processes described in [Section 4](#), Standards and Practice.
- Ensuring staff have the appropriate access to the systems to perform their roles and responsibilities.
- Supporting the Research Operations Service Manager (ROSM) to ensure all activity for clinical trials is updated in RaDlCo, and that the data is accurate and verified.
- Monitoring income and expenditure and responding accordingly to ensure the viability of the department and service.

3.6. **Role of the Contracts Manager**

The Contracts Manager is responsible for:

- Providing training to the Study Set-Up Team (SST) to allow them to efficiently and effectively reconcile the Interactive Costing Tool (iCT) with the protocol, and model clinical trial agreement (mCTA).
- Negotiating the study costs with the sponsor to ensure all research activity has been costed appropriately.
- Populating the clinical trial or research study details in RaDlCo.

- Supporting the SST in populating the clinical trial or research study details in RaDlCo by importing the data from the iCT for commercial clinical trials or adding the information provided for non-commercial research after the appropriate checks have been completed, and updating the study information page as required.
- Providing appropriate guidance to the SST for informing the wider department of any new RaDlCo workbooks that have been created.
- Overseeing the SST when updating or populating new costing templates for studies that have undergone a modification and have incurred a cost implication.
- Ensuring the data in RaDlCo is accurate, and any modifications are clearly identified, version controlled and clearly marked to supersede any earlier versions of the workbooks.

3.7. **Role of the Research Accountant**

The Research Accountant is responsible for:

- Providing adequate support to staff to ensure they perform their roles and responsibilities in association with the processes described in [Section 4](#), Standards and Practice.
- Providing adequate training for the Research Finance Team to allow them to efficiently and effectively process invoices and payments in line with the activity recorded in RaDlCo.
- Supporting staff to ensure that all research activity is fully and accurately captured in RaDlCo.
- Ensuring the sponsor or funder is invoiced in accordance with the contractual arrangements and appropriate processes.
- Investigating, escalating and/or resolving invoice discrepancies raised by the sponsor or research staff, tracking progress at monthly finance meetings or sooner if immediate action is required.
- Attending monthly finance meetings and presenting details of unpaid invoices which contribute to the aged debt.
- Tracking income and expenditure and providing regular reports to the SMT to assist in department financial planning.

3.8. **Role of the Industry Operations and Quality Improvement Manager**

The Industry Operations and Quality Improvement Manager has overall responsibility and oversight for the income generated for commercial trials:

- Providing adequate training and support to allow the Data Team to perform their roles and responsibilities in relation to the standards and processes

described in [Section 4](#), Standards and Practice, ensuring research activity is captured accurately and in full to RaDlCo in a timely manner.

- Overseeing that all commercial research activity is updated into RaDlCo in real time or as soon as possible after the event.
- Having processes in place that provide assurance that all commercial research activity is added to RaDlCo correctly and recorded to the correct workbook and where necessary, put in place processes to support the Data team to achieve this.
- Implementing quality checks and systems to ensure the integrity of the data recorded for research activity is accurate and verified.
- Supporting the resolution of overdue invoicing including communication with commercial companies and supporting the finance team with reconciliation reviews where needed.
- Attending monthly finance meetings and undertaking appropriate actions of unpaid invoices which contribute to the aged debt.

3.9. Role of the Research Operations Service Manager (ROSM)

The ROSM has overall responsibility and oversight for income generated for non-commercial trials and studies:

- Providing adequate training and support to allow Admin Team staff to perform their roles and responsibilities in relation to the standards and processes described in [Section 4](#), Standards and Practice.
- Overseeing that all non-commercial research activity is updated into RaDlCo in real time or as soon as possible after the event.
- Having processes in place that provide assurance that all costs for non-commercial studies and trials have been added to RaDlCo correctly and have been recorded to the correct workbook and where necessary, put in place processes to support the teams achieve this.
- Implementing quality checks and systems to ensure the integrity of the data recorded for research activity is accurate and verified.
- Supporting resolution of overdue invoicing including communication with sponsors and supporting the finance team with reconciliation reviews where needed.
- Attending monthly finance meetings and undertaking appropriate actions of unpaid invoices which contribute to the aged debt.
- Ensuring systems are in place to update the Study Set-up Team when a modification has been received that will have an effect on the costs of a trial or study to allow them to update RaDlCo as necessary.

3.10. **Role of the Team Leader and Research Nurse**

The Team Leader and Research Nurse are responsible for:

- Ensuring the Capacity and Capability (C and C) form is accurately and fully completed, capturing all research activity.
- Ensuring all research activity is recorded on EDGE in real time or as soon as possible after the event, understanding that it cannot be invoiced until it is on RaDICO.
- Undertaking adequate training to perform their roles and responsibility for the standards and processes described in [Section 4](#), Standards and Practice.
- Liaising with the Study Set-up Team to ensure the relevant trial activities have been costed accurately.
- Supporting other staff to ensure RaDICO and EDGE are updated in real time or as soon as possible after the event.
- Ensuring the Admin Team are aware of continued C and C and any cost implications for modifications to the clinical trial or research study, ensuring that the Study Set-Up and Admin teams are aware of the changes.
- Liaising with the Research Accountant to ensure the invoices for all activity have been raised.
- Attending monthly finance meetings and undertaking appropriate actions of unpaid invoices which contribute to the aged debt.
- Supporting monitors and auditors addressing queries relating to activity verification.

3.11. **Role of the Admin Team**

The Admin Team is responsible for:

- Undertaking adequate training to perform the roles and responsibility in relation to the standards and processes described in [Section 4](#), Standards and Practice.
- Ensuring costs are recorded on RaDICO in real time or as soon as possible after the event, understanding that it cannot be invoiced until it is on RaDICO.
- Cross checking data recorded on different systems as required to ensure all data entered in RaDICO is accurate and verifiable.
- Ensuring all chargeable monitoring visits are recorded on RaDICO.
- Supporting other staff to ensure RaDICO is updated in real time or as soon as possible after the event.

- Ensuring the Study Set-up Team are made aware of cost implications for modifications.
- Supporting the auditor and monitor with access to the study files and documents for activity verification.
- Liaising with staff as required to resolve data queries to the sponsor's satisfaction in a timely fashion.

3.12. **Role of the Data Team**

The Data Team is responsible for:

- Ensuring all research activity is recorded in the case report forms (CRFs) or electronic case report forms (eCRFs) in real time or as soon as possible after the event and that RaDlCo is updated in parallel.
- Cross checking data recorded on different systems as required to ensure all data entered in RaDlCo is accurate and verifiable.
- Supporting other staff to ensure RaDlCo is updated in real time or as soon as possible after the event.
- Undertaking adequate training to perform the roles and responsibility in relation to the standards and processes described in [Section 4](#), Standards and Practice.
- Supporting the auditor and monitor with access to the study files and documents for activity verification.
- Liaising with staff as required to resolve data queries to the Sponsor's satisfaction in a timely fashion.

3.13. **Role of the Pharmacy Research Staff**

The Pharmacy Research staff are responsible for:

- Liaising with the SST to ensure all pharmacy activity has been costed accurately.
- Ensuring all research activity is recorded on RaDlCo in real time or as soon as possible after the event, understanding that it cannot be invoiced until it is on RaDlCo.
- Supporting the auditor and monitor with access to the study files and documents for activity verification.
- Liaising with staff as required to resolve data queries to the sponsor's satisfaction in a timely fashion.

3.14. **Role of Individual Staff**

The individual, in other words, any person involved in the trial or study but not listed above, is responsible for:

- Supporting all staff to ensure all research activity is undertaken in accordance with the protocol and recorded on RaDICO where applicable in real time or as soon as possible after the event.
- Undertaking adequate training to perform the roles and responsibility in relation to the standards and processes described in [Section 4](#), Standards and Practice.
- Escalating concerns or problems which prevent the undertaking of activities described in [Section 4](#), Standards and Practice.
- Supporting the auditor and monitor with access to files and documents for audit and monitoring purposes.

4. Standards and Practice

4.1. Study Set-Up Team (SST)

- 4.1.1. The National Institute for Health and Social Care Research (NIHR) interactive Costing Tool (iCT) is populated by the study sponsor to provide a breakdown of funded activity. The iCT is a web-based tool through which the UK's standardised costing methodology is accessed and applied to commercial clinical trials. It is possible for a clinical trial to have an iCT for each arm of a clinical trial. The Study Set-up Team (SST) use this document to agree and finalise the trial or study costs with the sponsor prior to completion of the Clinical Trial Agreement (CTA).
- 4.1.2. The SST should receive the local information pack (LIP) from the sponsor after the Royal Cornwall Hospitals NHS Trust (RCHT) involvement in a clinical trial or research study has been confirmed. The contract will be documented as follows:
 - Commercial trials and studies will include a Model Clinical Trial Agreement (mCTA).
 - Non-commercial studies could include an Organisation Information Document (OID) or Model Non-clinical Trial Agreement (mNCA).
- 4.1.3. The contract or national model equivalent defines the terms of the payments for the activity undertaken at RCHT. The SST must check the contract and ensure it confirms the process and timeframe for invoices to be paid. In accordance with the payment terms for the mCTAs, invoices should be paid within 45 days of being issued, interest could be applied for any delayed payments. [PC mCTA Guidance May 2025.pdf](#)

- 4.1.4. The details of the research costs which can be claimed for non-commercial studies should be provided in the contract or the Organisation Information Document (OID) and should correlate with the Schedule of Events Cost Attribution Template (SoECAT). The SST will reconcile the contract with the SoECAT form and resolve any differences with the sponsor.
- 4.1.5. Sponsor self-billing is only acceptable in exceptional circumstances, for example, if it would otherwise result in loss of business. In such instances the SST must receive assurances that the sponsor will provide sufficient details with the payments to enable cross-referencing with the activity entered in RaDlCo. The process must be approved by the Finance Director by signing the contract.
- 4.1.6. The SST should reconcile the costs attributed to the research activities captured on the iCT with the contract. To do this effectively the SST will require the clinical research team to provide a fully completed capacity and capability (C and C) form. The clinical research team must reconcile the C and C form with the protocol requirements.
- 4.1.7. RCHT will comply with the nationally adopted National Contract Value Review (NCVR) principles and only escalate for exceptional variations. Upon receiving the iCT and ideally the draft contract, the SST should request a meeting with the senior research nurse or research nurse, and where possible the team leader, to undertake the following:
- Check activity is correctly identified and costed.
 - Check the activity allocated times are correct.
 - Check the activity has been allocated to the correct member of staff.
 - Check the frequency of visits is correct.
 - Determine what is additional.
 - Check the costings match the protocol activities.
 - Check the costings match the patient pathway at RCHT.
- 4.1.8. After receiving the request from the SST, the senior research nurse, research nurse or delegate has 14 days to ensure the capacity and capability (C and C) form is completed and meet with the SST as soon as practicable.
- 4.1.9. The SST will advise the sponsor during contract negotiations that the Trust confirms capacity and capability when the set-up process is complete and the contract has been signed. Once the contract has been signed, any set up fees can be claimed, this is the case even if the trial or study does not progress past this point.
- 4.1.10. The SST should ensure the appropriate set-up fees for applicable departments and supporting services, archiving per box and any additional items are included in the contracts.

- 4.1.11. Before the contract is signed on behalf of the Trust, it must be updated to reflect any agreed changes and the final costs. It should contain sponsor or funder contact details (name, email and postal address) along with clear details for raising invoices and the frequency with which invoices can be raised.
- 4.1.12. Commercial clinical trial contracts must be signed by an Associate Finance Director or as per scheme of delegation. The Research Clinical Director can sign non-commercial research contracts providing there are no conflicts of interest. In such instances the Medical Director or deputy should sign. The Head of R and D can sign non-commercial, non-CTIMP research contracts.
- 4.1.13. The SST will add the details of the clinical trial or research study to RaDICO and import the details from the costing template. Quality checks to be carried out by the SST for the information input into RaDICO, ensuring the total and per-patient costs on the iCT and RaDICO match.
- 4.1.14. The SST must create a RaDICO Workbook for the study in accordance with the SST Non-Commercial Costings and RaDICO Workflow (see the Management folder on EDGE) which should be added to the study workflow tab on EDGE (at the project site level). In the absence of an iCT to pre-populate parts of the workbook, the SST must manually upload all entries, as required.
- 4.1.15. It is important to ensure the study identifiers and all fields in the cover page are fully completed with all available information. The study title should have been imported, and the SST should include a retention rate of up to 10% if requested by the sponsor. They should also ensure the contact details are included and a purchase order number added if provided.
- 4.1.16. The SST must provide as much detail as possible to facilitate invoicing. For example, the sponsor may provide specific instructions, and the contract will define the frequency of when invoices can be raised. These details must be captured in the notes on the cover page.
- 4.1.17. It is also very important that the SST references other RaDICO entries for the same study to prevent double charging. For example, there may be a separate RaDICO workbook for each arm of the study. The information should be provided in the notes on the cover page.
- 4.1.18. The SST should email the Research Accountant, Admin Team, Data Team, relevant clinical research team and pharmacy to inform them of all new RaDICO workbooks for commercial and non-commercial studies.
- 4.1.19. The SST will organise Study Catch Meetings where at least one member of the clinical research team should attend. At these meetings, the SST will provide details of how RaDICO workbooks have been populated and how the admin or data teams should be completing the workbooks for each trial or study.

- 4.1.20. When a modification is made to the trial or study protocol which results in additional activities and costs, the SST will request a costings breakdown, and action as appropriate. The sponsor must agree to the revised costs and the contract should be updated to reflect the changes. The SST should inform the Research Accountant, Admin team, Data Team, Clinical Research Team and Pharmacy, as required, of the details of the changes made to the RaDlCo workbooks following the modification.

4.2. Research Accountant and Finance Team

- 4.2.1. The formal requirements for the collection of income are set out in the Royal Cornwall Hospitals NHS Trust Standing Orders document, Annex 1, Section 7 (Income, including contracts for the provision of healthcare, fees and charges) [Standing Orders, Standing Financial Instructions, Schedule of Matters Reserved to the Trust Board and Scheme of Delegation](#). (Document available in the Trust Document Library).
- 4.2.2. Once a trial or study has been uploaded to RaDlCo by the SST, the Research Finance Team will add a budget code and an account receivable identification code (ARID). The ARID identifies the sponsor in Unit 4 and enables tracking of invoices. Each study has its own unique budget code so any invoices raised can be matched back to an individual study.
- 4.2.3. The Research Finance Team must ensure all invoices are raised in accordance with the contractual arrangements. Delayed invoices can result in aged debt which may never be recoverable.
- 4.2.4. The Research Finance Team must follow a system in which the research activity for all open studies is invoiced. Refer to R and D W110 Finance Raising Invoices in RaDlCo (see Documents library in EDGE) which provides the process for tracking the activity for all open studies.
- 4.2.5. The Research Accountant should check the activity entered in RaDlCo matches with invoices raised. Any discrepancies must be investigated and resolved or explained in the notes for audit purposes.
- 4.2.6. The Research Accountant and Team Leader or deputy must meet each month to reconcile the data entered in RaDlCo with the raising of invoices. The meetings should explore the following points:
- Reconciliation between recruitment, activity and invoices.
 - Discrepancies raised by the sponsor with outstanding invoices.
 - Reasons why sponsors have not paid invoices.
 - The study end-date and the raising of final invoice before the deadline.

- 4.2.7. The Research Finance Team must keep a record of invoices raised. The number of days each invoice is outstanding should be tracked. Every effort should be made to resolve issues early and to establish why invoices remain outstanding.
- 4.2.8. Finance Escalation and Resolution Meeting will be held monthly. Actions should be taken by the appropriate person to resolve issues or seek further information. It is anticipated that the actions will be distributed as follows:
- Head of R and D will resolve capacity issues.
 - Depending on the type of activity, the IOM or the ROSM will resolve unresolved financial data queries.
 - Team Leaders will resolve delivery issues.
 - Research Accountant will resolve financial issues.
- 4.2.9. Unpaid invoices should be escalated at the earliest opportunity, either through monthly finance meetings or at the SMT held monthly.
- 4.2.10. The RaDICO workbook cover page has a tick-box which should be checked when the study has closed. For the purposes of RaDICO, this is after the final invoice has been raised for the study and should be undertaken by the Research Finance Team. Every effort must be made to ensure all activity is invoiced before the study has closed.
- 4.2.11. **Unit 4**
- 4.2.11.1. Unit 4 will facilitate tracking of invoices raised but in all instances the Research Accountant must follow a system which ensures all outstanding invoices are chased and problems identified early. The system should include an escalation process whereby unanswered emails are followed up with telephone calls.
- 4.2.11.2. The Research Accountant should roll out Unit 4 training to key senior personnel involved in the collection of income to enable individual teams to proactively track invoices. This training should include:
- Head of Research and Development.
 - Lead Research Nurse.
 - Industry Operations and Quality Improvement Manager (IOM).
 - Research Operations Service Manager (ROSM).
 - Team Leaders.

- 4.2.11.3. Whilst Unit 4 can be used to track invoices it is the responsibility of everyone involved in research to ensure all income is claimed and paid.

4.3. Industry Operations and Quality Improvement Manager (IOM) and Data Team

- 4.3.1. Industry Operations and Quality Improvement Manager (IOM) will ensure that the Data Team are adequately trained to undertake activities in RaDICO for commercial trials.
- 4.3.2. RaDICO should be updated with activity in real time or as soon as practicable after the event, in accordance with R and D WI11 Capturing Research Activity in RaDICO (see Documents folder on EDGE). The expectation is that RaDICO will be updated within five working days of the activity.
- 4.3.3. The IOM or suitable delegate will reconcile the contract and commercial RaDICO workbooks during study close out in accordance with R and D WI11 Capturing Research Activity in RaDICO (see Documents Folder in EDGE). The IOM or suitable delegate will ensure all activity has been uploaded and instruct the Research Accountant to raise the final invoices.
- 4.3.4. The IOM or suitable delegate will undertake quality checks of the information entered onto RaDICO for commercial trials to provide assurance of accuracy and completeness. Refer to the R and D WI11 Capturing Research Activity in RaDICO (see Documents Folder in EDGE).

4.4. Research Operations and Service Manager (ROSM)

- 4.4.1. The Research Operations and Service Manager (ROSM) will ensure that the Admin Team are adequately trained to undertake activities in RaDICO for non-commercial trials and studies.
- 4.4.2. RaDICO should be updated with activity in real time or as soon as practicable after the event, in accordance with R and D WI11 Capturing Research Activity in RaDICO (see Documents folder on EDGE). The expectation is that RaDICO will be updated within five working days of the activity.
- 4.4.3. The ROSM will reconcile the contract and non-commercial RaDICO workbooks during study close out in accordance with R and D WI11 Capturing Research Activity in RaDICO (see Documents Folder in EDGE). The ROSM or suitable delegate will ensure all activity has been uploaded and instruct the Research Accountant to raise the final invoices.
- 4.4.4. The ROSM or suitable delegate will undertake quality checks of the information entered onto RaDICO for non-commercial trials and studies, to provide assurance of accuracy and completeness. Refer to the R and D WI11 Capturing Research Activity in RaDICO (see Documents Folder in EDGE).

- 4.4.5. The ROSM will run weekly reports from EDGE for the weekly finance review process, to identify participant payments, reconsent visits, Patient Identification Centre (PIC) visits and any visits not covered by the Data Team. The relevant information is circulated to the Admin Team to update RaDICO with the relevant activity.

4.5. Clinical Research Teams

- 4.5.1. The clinical research teams should accurately record activities for clinical trials and research studies in EDGE in accordance with the protocol schedule of activities and for any additional activities, refer to R and D WI06 EDGE Workflow for Adding and Appointment (see Documents folder in EDGE).
- 4.5.2. Every effort must be made to ensure all fields of the corresponding Case Report Forms (CRFs) or electronic Case Report Forms (eCRFs) are complete and accurate. Any discrepancies must be explained to the satisfaction of the sponsor. In some instances, the sponsor will not pay invoices until the data has been verified, which could involve a monitoring visit.
- 4.5.3. The clinical research staff must ensure EDGE is updated in real time or as soon as practicable with participant recruitment, visits and activities completed during the visits.
- 4.5.4. Where the participant identifies the GP as the referral source, the clinical research staff conducting the visit will add 'PIC' in the participant appointment commentary on EDGE.
- 4.5.5. All staff must make every effort to support the resolution of issues involving invoices to ensure aged debt does not accrue. The aged debt should also be reviewed at the monthly finance SMT meetings with action plans to reduce the debt agreed.

4.6. Data Team

- 4.6.1. The Data Team receive the participant packs and completed CRFs from the clinical teams and enter the details of the participant visits onto the relevant eCRFs.
- 4.6.2. RaDICO should then be updated with the details of the participants' visits, ensuring all relevant activities are recorded.
- 4.6.3. Corresponding EDGE appointment will be updated to record that the eCRF and RaDICO have been completed.

4.7. Research Admin Team

- 4.7.1. The Admin Team receive weekly reports from the ROSM, which identifies the participant payments, reconsent visits, PIC visits and any visits not covered by the Data Team. RaDICO should then be updated with the details of the participants' visits, ensuring all relevant activities are recorded.

- 4.7.2. The Admin Hub will identify eligible PIC payments through the weekly finance review process using EDGE data and add the necessary PIC payment information to RaDlCo. Where PIC payments are due the Admin Team will:
- Email GP Practice requesting an invoice.
 - Copy the RDN Primary Care email address into the correspondence to facilitate payment processing.
 - Process payment via Research Finance when invoice received.
- 4.7.3. The sponsor may provide a date by which all final invoices must be raised, which is very likely to be before the study has been archived. To ensure all costs are invoiced, the clinical research team must ensure all activity has been recorded in RaDlCo and the tick-box checked to facilitate invoicing.
- 4.7.4. When recruitment has closed and the study is nearing completion the Admin Team should ensure the costs of archiving the physical files are claimed. At this stage the Admin Team should estimate the number of archiving boxes required for all studies which have a per box fee. In all instances this should be in accordance with R and D SOP043 Closure Process for Hosted Studies (see Documents folder in EDGE).
- 4.7.5. The Admin Team will make the SST aware of any modifications affecting the research activities and costs of the clinical trial or research study.

4.8. Pharmacy Team

- 4.8.1. The Pharmacy Team will be consulted by the SST during the negotiations of the contracts for the clinical trials and will identify the relevant costs including receiving, storing, dispensing and destroying investigational products.
- 4.8.2. The Pharmacy Team will enter the details directly into RaDlCo, for the relevant costs relating to investigational products used in clinical trials.

4.9. Aged Debt

- 4.9.1. Royal Cornwall Hospitals NHS Trust Standing Orders document, Annex 1, Section 16 (Management of debtors) sets the formal requirements for the debt management [Standing Orders, Standing Financial Instructions, Schedule of Matters Reserved to the Trust Board and Scheme of Delegation](#) (Document available in the Trust Document Library).
- 4.9.2. The process for the collection of outstanding debts is described in the Guidance to Staff Responsible for the Collection of Income Following the Supply of Goods or Services, Sections 6.5 Outstanding Debts and 6.6 Debt Queries [Guidance to Staff Responsible for the Collection of Income Following the Supply of Goods or Services](#) (Document available in the Trust Document Library).

- 4.9.3. Invoices should be paid within the allocated timeframe listed within the research contract, usually 45 days. Any that exceed this timeline will be processed in accordance with the procedures described in section 6.5 of the Guidance to Staff Responsible for the Collection of Income Following the Supply of Goods or Services document [Guidance to Staff Responsible for the Collection of Income Following the Supply of Goods or Services](#) (Document available in the Trust Document Library). In effect, the Accounts Receivable Team will chase unpaid debts which could result in the debt being passed on to a debt collection agency.
- 4.9.4. The aged debt should also be reviewed and discussed at the monthly Finance SMT. The Research Accountant should escalate concerns or issues affecting individual payment of invoices. SMT must address the issues and act accordingly.

5. Dissemination and Implementation

- 5.1. Trust-wide Research and Development (R and D) procedural documents will be stored on the Trust's Document Library, and a working copy will be accessible through EDGE providing alternative access for research staff.
- 5.2. The Research Governance Manager or delegate will arrange for documents to be published on the Trust Documents Library and EDGE.
- 5.3. The Research Governance Manager or delegate will ensure that any previous versions of the document are made inaccessible to general EDGE users, in accordance with the EDGE document archiving procedure.
- 5.4. R and D SMT to define any training requirements prior to the implementation of any procedural documentation. There will be appropriate time allowed for such training prior to the publishing of the SOP or WI.
- 5.5. Relevant research staff registered on EDGE will be notified by email of the new or reviewed document. Relevant staff will be identified from the ownership and responsibilities ([Section 3](#)) of this procedural document and the R and D AD19 Training Matrix (see Documents folder in EDGE).
- 5.6. Details of how to access EDGE is available by contacting the Research Systems Officer via rch-tr.edge@nhs.net.
- 5.7. It is the responsibility of all staff to check the website regularly, in order to see if SOPs have been added or amended. R and D will endeavour to notify research staff of any SOP developments that may be relevant to them via staff communications, for example, R and D Newsletters, Leadership Huddle and Workstream Huddles. A list of any new or updated SOPs will be reviewed and ratified at the R and D Senior Management Team Governance and Performance monthly meetings.
- 5.8. Consideration must be given at study set up as to which SOPs will not apply to a specific study, with agreement from the R and D Senior Management Team (SMT). Full details must be included as a written statement in the study site file.

5.9. Whilst SOPs may be printed, the electronic version maintained on R and D internet page is the controlled copy. Any printed copies are not controlled documents.

5.10. Chief and Principal Investigators will be notified as per the Trust's process for notifying all staff of new procedural documents.

5.11. Training and Development

5.11.1. When a new SOP is authorised, or when an existing SOP is revised, self-directed training as specified and detailed by the SMT must be carried out by all staff to which the SOP is relevant, and this training documented on EDGE.

5.11.2. Staff should take time to read and fully understand the SOP and relevant documents, ensuring that they are able to implement the SOP as required. If clarification is needed, the staff member should approach the Research Governance Manager, or another member of the SMT, who will arrange additional training. All staff are responsible for maintaining their own training logs and copies must be made available to study monitors on request.

5.12. SOP Deviations

5.12.1. If a process deviates from an approved SOP, a risk assessment will be undertaken to determine the consequences and identify any remedial action(s) that needs to be taken. It may also be appropriate to submit an incident report via the Datix system.

5.12.2. The author of the risk assessment must submit the risk assessment to SMT.

6. Monitoring compliance and effectiveness

Information Category	Detail of process and methodology for monitoring compliance
Element to be monitored	Successful implementation of the procedures described in this SOP ensures that there is a clear understanding of how the Research and Development Industry Costing (RaDICO) system is used in research studies and clinical trials by staff conducting research studies and clinical trials.
Lead	Research Governance Manager.
Tool	Internal monitoring of RaDICO and the associated systems and documents will ensure compliance with this SOP and the relevant processes.
Frequency	Compliance with this procedural document will be monitored as part of the R and D risk-based, audit and monitoring process directed through the R and D SMT Governance and Performance meetings.

Information Category	Detail of process and methodology for monitoring compliance
Reporting arrangements	The Research Governance Manager will provide monthly reports at the R and D SMT Finance meetings.
Acting on recommendations and Lead(s)	The Finance SMT meetings will provide effective oversight and ensure corrective actions are undertaken.
Change in practice and lessons to be shared	The Finance SMT meetings will identify non-compliance and appoint a member of the SMT to provide support and advice to identify training needs and improve practice. Required changes to practice will be implemented as soon as practically possible.

7. Updating and Review

The R and D procedural documents will be reviewed no less than every three years by the R and D SMT unless an earlier review is required, in accordance with Section 9 of the Trust Policy for the Development and Management of Knowledge, Procedural and Web Documents (The Policy on Policies).

8. Equality and Diversity

8.1. This document complies with the Royal Cornwall Hospitals NHS Trust service Equality and Diversity statement which can be found in the [Equality Diversity And Inclusion Policy](#) or the [Equality and Diversity website](#).

8.2. Equality Impact Assessment

The Initial Equality Impact Assessment Screening Form is at Appendix 2.

Appendix 1. Governance Information

Information Category	Detailed Information
Document Title:	Research and Development SOP012 Income from Clinical Trials and Research Studies V2.0
This document replaces (exact title of previous version):	Income from Clinical Trials RD and I Standard Operating Procedure V1.0
Date Issued / Approved:	July 2026
Date Valid From:	August 2026
Date Valid To:	August 2029
Directorate / Department responsible (author/owner):	Caroline Phillips, Research Governance Manager.
Contact details:	rcht.researchqualityassurance@nhs.net
Brief summary of contents:	This SOP outlines the requirements and the processes for collecting income for research activity in accordance with the contractual arrangements for hosted research.
Suggested Keywords:	Standard Operational Procedure (SOP) Research and Development (R and D) Research and Development Industry Costings (RaDlCo)
Target Audience:	RCHT: Yes CFT: No CIOS ICB: No
Executive Director responsible for Policy:	Chief Strategy Officer.
Approval route for consultation and ratification:	R and D Senior Management Team (SMT).
Manager confirming approval processes:	Lisa Trembath, Interim Head of Research and Development.
Name of Governance Lead confirming consultation and ratification:	Caroline Phillips, Research Governance Manager.
Links to key external standards:	Good Clinical Practice for Clinical Trials.

Information Category	Detailed Information
	https://www.gov.uk/guidance/good-clinical-practice-for-clinical-trials
Related Documents:	The Medicines for Human Use (Clinical Trials) Regulations 2004 The Medicines for Human Use (Clinical Trials) Regulations 2004 The Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025 The Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025 International Council for Harmonisation Guideline for Good Clinical Practice E6 (R3) (06 January 2025) ICH E6(R3) Step4 FinalGuideline 2025 0106.pdf Guidance: Using the interactive Costing Tool (iCT) https://www.nihr.ac.uk/guidance-using-interactive-costing-tool-ict Attributing the costs of health and social care research https://www.gov.uk/government/publications/guidance-on-attributing-the-costs-of-health-and-social-care-research Royal Cornwall Hospitals NHS Trust Standing Orders V12.0 June 2025 http://doclibrary-rcht-intranet.cornwall.nhs.uk/DocumentsLibrary/RoyalCornwallHospitalsTrust/Finance/FinanceGeneral/StandingOrdersStandingFinancialInstructionsScheduleOfMattersReservedToTheTrustBoardAndSchemeOfDelegation.pdf RCHT Guidance for the Collection of Income Following the Supply of Goods and Services V6.0 October 2023 http://doclibrary-rcht-intranet.cornwall.nhs.uk/DocumentsLibrary/RoyalCornwallHospitalsTrust/Finance/FinancialServices/GuidanceToStaffResponsibleForTheCollectionOfIncomeFollowingTheSupplyOfGoodsOrService.pdf R and D SOP001 Preparation, Approval and Review of Standard Operating Procedures (SOPs) and Work Instructions (WIs). R and D SOP043 Closure Process for Hosted Studies. R and D WI06 EDGE Workflow for Adding and Appointment.

Information Category	Detailed Information
	R and D WI10 – Finance Raising Invoices in Radico. R and D WI11 – Capturing Research Activity in RaDlCo. R and D AD07 Glossary of Terms. R and D AD19 Training Matrix.
Training Need Identified:	Yes – Details provided in Section 5.
Publication Location (refer to Policy on Policies – Approvals and Ratification):	Internet and Intranet
Document Library Folder/Sub Folder:	Research and Development.

Version Control Table

Date	Version Number	Summary of Changes	Changes Made by
26/02/2020	V1.0	New document.	Dr N Morley, Quality Management System Manager
23/07/2026	V2.0	Changes from RD and I to R and D. Review of SOP in line with changes to R and D procedures. Review and update in accordance with Trust policies.	Caroline Phillips, Research Governance Manager.

All or part of this document can be released under the Freedom of Information Act 2000.

All Policies, Strategies and Operating Procedures, including Business Plans, are to be kept for the lifetime of the organisation plus six years.

This document is only valid on the day of printing.

Controlled Document.

This document has been created following the Royal Cornwall Hospitals NHS Trust [The Policy on Policies \(Development and Management of Knowledge Procedural and Web Documents Policy\)](#). It should not be altered in any way without the express permission of the author or their Line Manager.

Appendix 2. Quality and Equality Impact Assessment (QEIA) Form

The QEIA process allows RCHT to monitor the impact of changes to its policies and services, ensuring that nobody is unduly disadvantaged.

Please ensure you have completed a Quality and Equality Impact Assessment (QEIA) using this link to complete the form:

[E11 QEIA Policy](#)

For guidance, please see the [QEIA Essentials – Quick Reference Guide](#) or contact as required below:

Equality, Diversity and Inclusion guidance, please contact: rcht.inclusion@nhs.net

Quality Governance guidance, please contact Jillian Tozer: jillian.tozer3@nhs.net