# CLINICAL RESEARCH - FINANCIAL MANAGEMENT

## PROCEDURE ©

## DOCUMENT SUMMARY/KEY POINTS

- The purpose of this procedure is to outline the process for the appropriate financial management of clinical research, in compliance with NSW Health, SCHN, regulatory and Protocol requirements.
- The procedure must be followed by all personnel involved in financial management of clinical research.

## CHANGE SUMMARY

- Document due for mandatory review. Recommend to read the entire document.
- References updated.

## READ ACKNOWLEDGEMENT

- Read/Acknowledge Only – Personnel involved in the financial management of clinical research.



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| **Approved by:** | SCHN Policy, Procedure and Guideline Committee | |
| **Date Effective:** | 1st September 2021 | **Review Period**: 3 years |
| **Team Leader:** | Clinical Research Manager | **Area/Dept**: Kids Research |

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# Purpose/Scope

The purpose of this procedure is to ensure the appropriate financial management of clinical research, in compliance with NSW Health, SCHN, regulatory and Protocol requirements.

Adherence to this procedure will ensure that:

- Financial and operational risk to SCHN is reduced by ensuring that resources and funds are adequate to conduct the clinical research to a high standard of quality and safety and the Supporting Departments involved in the delivery of the research are reimbursed for costs incurred;
- There is appropriate stewardship of public and other resources whereby funding is used 'for purpose' and the receipt, investment and expenditure of funds complies with NSW Accounts and Audit Determinations for Public Health Organisations; and
- A high quality, efficient, sustainable and competitive service, delivered by experienced clinical and research personnel, is available to Investigators and Sponsors or Delegates, now and in the future.

The procedure must be followed by all personnel involved in the financial management of clinical research.

# Procedure

## Cost Centre

- Prior to commencement of clinical research, the Investigator or Delegate should setup a dedicated Cost Centre into which revenue is received and from which expenditure is incurred during conduct;
- **Note:** Due to the timing of receipt of clinical research income, expenditure often occurs within Departments initially, and is then transferred to clinical research Cost Centres.
- A General Fund/Clinical Trials Cost Centre type should be setup for commercially-sponsored clinical research. A Special Purpose and Trust/Restricted Financial Assets (SPT/RFA) Cost Centre type should be setup for non-commercially sponsored research (e.g. Investigator-initiated, grant funded, Collaborative Research Group etc.)
- The Cost Centre should be set up within the Department that will be managing the clinical research.
- At the completion of the clinical research, the dedicated Cost Centre should be reconciled in full and a request for closure lodged with Finance.

## Budget

- The Investigator or Delegate retains responsibility for constructing an appropriate budget for clinical research to ensure full cost-recovery with reference to the guidance provided by the SCHN Schedule of Fees for Clinical Research including detailing any in-kind or other untied support;

- The fees applicable to clinical research should be derived with consideration of the time required by personnel to perform protocol-specific tasks in a paediatric population to ensure that high standards of both safety and quality are maintained;
- The rate applied for study personnel must be fully-absorbed (i.e.: inclusive of mandatory oncosts, as per the applicable NSW Public Health System Award(s), and institutional overheads (as applicable);
- The basis for budgeted fees should be transparent and justifiable in that the fees pertain only to the costs incurred for involvement in the clinical research, either directly or indirectly, deemed to be above standard of care;
- It is the responsibility of the Investigator or Delegate to determine which procedures and assessments are deemed to be standard versus non-standard of care for a given study;
- Prior to drafting and negotiating the budget, the Investigator or Delegate should request the provision of all study-specific documentation of relevance from the Sponsor or Delegate for review;
- The active and direct involvement of the clinical research personnel who will be performing the tasks is recommended to ensure accurate estimates of time are derived;
- Quotes for the provision of services from Supporting Departments for clinical research should be obtained by request to nominated representative of the Supporting Department;
- Fee arrangements with each Supporting Department involved in the research, including in-kind contributions, must be documented in an Inter-Departmental Agreement prior to the initiation of a trial.
- A fully executed copy of the Inter-Departmental Agreement must be provided to each Supporting Department involved for their records;
- Fees for initial and subsequent review of clinical research by an NHMRC accredited Human Research Ethics Committee (HREC), where SCHN is acting as the only or lead site, and Research Governance Office (RGO), are payable directly to the HREC and RGO, as per the applicable fee policy;
- Any clinical research participant reimbursements being provided must be managed in accordance with the SCHN Procedure 2018-196 – Clinical Research - Participant Reimbursements.

## Payment Terms

- SCHN must provide the Sponsor or Delegate with a Tax Invoice and requires that payments are made within 30 days from the invoice date;
- In compliance with Australian Taxation Law, all invoices for taxable supplies are required to include Good and Services Tax (GST) of 10%, on top of the agreed fee.
- The invoice number must be referenced on remittance for all payments;

## Monitoring

- The Investigator or Delegate is responsible for monitoring of the Cost Centre with regard to the planned revenue and expenditure for the conduct of the clinical research and the appropriate use of funds as per the Agreement(s) with the Sponsor or Delegate or Administering Institution (as applicable);
- The Investigator or Delegate is responsible for preparing and approving any periodic reports and/or statements of acquittal to Parties prepared in consultation with the Business Manager;
- If the protocol or other requirements of the clinical research dictated by the Sponsor or Delegate change, it is recommended that the budget is reviewed and if appropriate, amended, and documented in the form of Agreement(s);
- If appropriate, a budget review will also be required three (3) years form the date of last signature of the Agreement(s) and on each anniversary thereafter. At this time the budget will be reviewed against expenses and the Sponsor or Delegate provided with an adjusted budget reflecting the inflation rates and other cost increases. Any changes will be documented in an amendment to the Agreement(s) with subsequent invoices reflecting the adjusted budget.

## Appendices

***SCHN Schedule of Fees for Clinical Research [External]***

***SCHN Inter-Departmental Agreement Template***

**Note:** Additional resources including the SCHN Schedule of Fees for Clinical Research [Internal] and SCHN Budget Template are accessible via: https://intranet.schn.health.nsw.gov.au/crc

## Abbreviations and Definitions

| | |
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| GL | Guideline |
| GST | Goods and Services Tax |
| HREC | Human Research Ethics Committee |
| NHMRC | National Health and Medical Research Council |
| NSW | New South Wales |
| PD | Policy Directive |
| RGO | Research Governance Office |
| SCHN | Sydney Children's Hospitals Network |
| SPT | Special Purpose and Trust |
| RFA | Restricted Financial Assets |

## Related Documents

1. NSW Health - Accounts and Audit Determination for Public Health Entities in NSW - https://www.health.nsw.gov.au/policies/manuals/Pages/accounts-audit-determination.aspx
2. NSW Health GL2011-001 - Research Governance in NSW Public Health Organisations; https://www1.health.nsw.gov.au/pds/Pages/doc.aspx?dn=GL2011_001
3. NSW Health PD2008_030 - HREC and Research Governance: Fee Policy for Review of Commercially Sponsored Research - https://www1.health.nsw.gov.au/pds/Pages/doc.aspx?dn=PD2008_030
4. NSW Health - Remuneration and Conditions NSW Public Health System Awards; http://www.health.nsw.gov.au/careers/conditions/pages/default.aspx
5. SCHN Policy – Clinical Research [DRAFT]
6. SCHN Policy 2014-9044 - Fees for the Review of Ethics and Site Specific Assessment Applications - http://webapps.schn.health.nsw.gov.au/epolicy/policy/3147
7. SCHN Procedure 2019-028 - Clinical Research – Personnel Roles and Responsibilities - http://webapps.schn.health.nsw.gov.au/epolicy/policy/4624
8. SCHN Procedure 2018-186 – Clinical Research - Participant Reimbursements - http://webapps.schn.health.nsw.gov.au/epolicy/policy/4619
9. SCHN Procedure 2019-145 – Clinical Research - Record Keeping - http://webapps.schn.health.nsw.gov.au/epolicy/policy/4661
10. SCHN Procedure 2019-045 – Research - Grants - http://webapps.schn.health.nsw.gov.au/epolicy/policy/4660