NSW Health

Ref: H240002845

TO: Chief Executives

CC: Directors of Finance

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**Change to Financial Management of Clinical Trials in Restricted Financial Assets**

Dear Chief Executives

This letter is to advise of a change in relation to Clinical Trials financial management options.

Currently clinical trials across NSW Health are managed both in General Fund (GF) and Restricted Financial Assets (RFA).

The Accounts and Audit Determination for public health entities in NSW Health currently provides conditions for trials that meet certain criteria to be managed in RFA - primarily that clinical trials revenue is received in advance. However, this is not how sponsored clinical trials work in the industry.

The change takes into account that sponsored clinical trials can extend over multiple years and revenue may be paid upon achievement of agreed milestones in arrears rather than in advance of work to be done.

NSW Health benefits significantly from clinical trials which can significantly improve treatments, outcomes and future clinical protocols for treatment of patients, and so participation in trials is a key target for NSW Health medical facilities. Industry sponsored trial revenue can also allow support for Clinician initiated trials and research which are similarly critical for future outcomes for patients.

In order to support these trials in a way that does not result in revenues being lost within annual General Fund activities and that funds do not expire at end of financial year, it is proposed to expand the criteria to allow Trials to be managed in RFA where funds are received in arrears, provided the overall RFA funds held within Clinical Trials and Research purposes in the Health entity RFA cover the annual spend. This change has been reflected in the Accounts and Audit Determination for public health entities in NSW Health and PD2023_017 Research Agreements in NSW Health Organisations.

A specific set of eligibility criteria and operational requirements (attached) will ensure that governance is strong and supports the building of NSW Health Clinical Trials capability over time and enables the sharing the capability across metro and regional sites in the future. The approach also supports the Office of Health and Medical Research (OHMR) initiative to implement the standard Clinical Trials Management Systems (CTMS) and supporting and investing in clinical trials and research in the future.

Attached also is a Responsibility, Accountable, Consulted, Informed and Supporting (RACIs) matrix to assist with implementation and ongoing management.

Questions on set up of clinical trials in RFA should be directed to Sandra Mulder, Director Cash and Financial Systems Governance at Sandra.Mulder@health.nsw.gov.au.

Further information on the monitoring and reporting in relation to the requirement in the operational requirements outlined below will be issued in due course.

Yours sincerely

**Adjunct Professor Alfa D'Amato**
Deputy Secretary, Financial Services and Asset Management and
Chief Financial Officer, NSW Health
14/11/2024

## Eligibility for trials to be managed within RFA

Summary

- Clinical Trial Research Agreement (CTRA) requires funds to be used for Clinical Trials and Research
- Trial is sponsored by an external third party
- Trial meets the requirements for WHO definition of Clinical Trial
- Trial approved in line with NHMRC requirements
- Budget for revenue and expense is established for the trial for the duration
- In year spend is able to be covered by available funds within local RFA for clinical trials and research cost centres
- Trials are managed via the CTMS system as per the Ministry of Health Office of Health and Medical Research (OHMR) branch requirements
- Billing and receipting for trial is managed via StaffLink AR (including RCTI)
- Full cost recovery for Trial costs is made against revenue
- New trials only - clinical trials already running may not be rolled into or switched to be managed in RFA.

Detail

| Criteria | Action | Impact |
|---|---|---|
| New Clinical Trials with specific contract conditions - standard Clinical Trials contracts are in place for each trial undertaken and include a clause that states that any funds received should be used for Clinical Trials and Research | The accounting for a clinical trial in RFA requires that the contract contains the following requirement:<br>Any funds/payments received should be used for Clinical Trials and Research. | The conditions of use for an RFA are set to allow use of funds received for Clinical Trials and for Research purposes. This sets the restriction for the funds and allows cash to be held within the RFA bank account, and accounting to be within RFA. |
| The trial or research is sponsored/funded by a third party and does not use appropriation from the NSW Government Consolidated fund | The revenue received is from a third party and not part of NSW Treasury funding | GSF Act compliance in relation to ability to hold funds for use in a future year |
| Trials undertaken meet the World Health Organisation's definition of a clinical trial as "any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes" | Trials meet the definition of WHO for Clinical Trials | Governance of Clinical Trials |
| All trials are approved in line with the National Health and Medical Research Council requirements as published. | Trial approvals comply with the National requirements | Governance of Clinical Trials |

| Criteria | Action | Impact |
|---|---|---|
| An annual budget for revenue and costs is established for clinical trials activity within the RFA entity for the duration of the clinical trial | An approved budget for revenue and expense is established in the RFA fund entity.<br>Where Clinical Trials were previously part of GF budget, these can be transferred to RFA. Where no budget exists, new budget must be requested as per standard practise. | Compliance with GSF Act requiring expenditure to be approved and in line with budget. Also ensures that GF budget is not utilised for RFA activities. |
| Funds spent in year on clinical trials are assessed to ensure they do not exceed net cash funds held and received for the combined total of Clinical Trials and Research purposes held in RFA | Monthly reporting to review and ensure this measure is adhered to. Where spend is exceeding in year cash available, action should be taken to ensure this is ceased and funds received before further expenditure is incurred | Ensures that RFA is fully funding the Clinical Trials held in RFA. |
| Clinical trials are set up and managed via the Clinical Trials Management System | CTMS system is available at all NSW Health sites for clinical trials management.<br>Use of the system is governed via the Office of Health and Medical Research (OHMR) Ministry branch. | Traceability and standard practices, costing, cost recover, revenue billing and reporting and processes are in place for governance and visibility over Clinical Trials activity. |
| No rollover of existing Clinical Trials | Rollover of existing Clinical Trials is not permitted | Only new clinical trials can be set up and managed in RFA. |

## Operational Requirements for trials managed in RFA

Summary

- eCTRA system configuration requirements covering how clinical trial cost centres are to be established
- Full cost recovery requirements covering how all costs associated with the trial are to be managed
- Administrative overhead recovery covers the cost of administering trials in RFA
- Requirements to properly apply accounting standards
- Requirements for using StaffLink Receivables for billing/receipting of clinical trials revenue
- Requirements for review of coverage for clinical trials costs by combined RFA Clinical Trial and Research cost centres available funds.
- Budget establishment for duration of the clinical trial
- Close out of clinical trial
- Management of interest earned on any clinical trial funds held in RFA.

Detail

The following details the operational requirements to ensure proper accounting and cash management for Clinical Trials and to support standard practice and reporting across all NSW Health entities conducting Clinical Trials. In order to maintain Clinical Trials in RFA, these practices must also be followed.

*Note: eCTRA is the Electronic Custodial Trust and Restricted Asset system which is the only place cost centres for RFA can be established.*

| Requirement | Action | Impact |
|---|---|---|
| Registration of Clinical Trials in eCTRA system | • Cost centres are established within eCTRA system including documentation – copy of Clinical Trials contracts.<br>• Single Cost centre per trial or grouped under a cost centre – depending on the local management of Clinical Trials<br>• All RFA cost centres for Clinical Trials use the naming convention of CT-xxxxx<br>• RFA cost centre purpose must be 'RFA Clinical Trials'<br>• Industry sponsored trials must have the source of funds of 'Grant from private or other industry organisation' (must not use 'State Government Grant')<br>• Conditions of use must include the requirement Any funds/payments received should be used for Clinical Trials and Research. This must be able to be proven via the contract or other documentation from the funding organisation | All RFA cost centres are managed via the eCTRA system. This assist with reporting and fiduciary requirements as well as ensuring the statutory financial accounting reporting schedules are correct. |

| Requirement | Action | Impact |
|---|---|---|
| Full cost recovery | All costs associated with running sponsored Clinical Trials is to be fully recovered from the revenue/funding received from the sponsor.<br>This includes all direct staff costs and oncosts, all goods and services and allowance for depreciation and amortisation of equipment used as appropriate.<br>PHEs should also recover oncosts where the work is performed by employees normally costed under General Fund. Recovery of employee oncosts for staff not directly expensed to RFA should be recovered at a rate of 21.2% of the actual employee related cost.<br>Standard costs within the CTMS system should be used to calculate billing to the sponsor and should incorporate an assumption of full cost recovery. | Costs associated with the trial will typically be paid for via General Fund through Central Creditor or Central Payroll bank accounts.<br>Where costs are directly expensed to RFA cost centres, these will automatically settle the cash back from RFA to reimburse GF.<br>Where costs are expensed to GF directly, a cost recovery journal must be processed to trigger cash settlement back to GF. |
| Clinical Trial administrative overhead recovery | PHEs should levy an administrative charge to Clinical Trials to ensure recovery of costs associated with the management of Restricted Financial Assets.<br>This is separate from any other Clinical Trials fees levied as part of the contract.<br>As per conditions of subsidy overhead charges applied to RFA is transferred as an expense offset to the General Fund. This allows coverage of administrative costs for management of RFA. | As per the 2024/25 Conditions of Subsidy the maximum administrative charge is 7.5% |
| Follow accounting standards | Accounting for Clinical Trials must be in alignment with the Australian accounting standards as in place during the relevant financial year. This includes proper recording of Revenue received in advance. | Refer to issued Financial Accounting instructions to ensure compliance. |
| Billing and receipting must be via standard StaffLink billing and payment processes | All billing for Clinical Trials must be passed through the StaffLink AR billing process and follow the requirements for registering debtors to enable payments received to be identified and receipted via the Central Receipting process (refer process for requesting ARM bank account for new and existing contracts).<br>This includes where a sponsor pays on a RCTI or based on an acquittal in their own systems. | Billing and receipt of payments managed through standard system processes will ensure appropriate and timely crediting of revenue |

| Requirement | Action | Impact |
|---|---|---|
| Review and ensure spend is maintained within RFA cash held for Clinical Trials and Research | A regular assessment of combined Clinical Trials and Research net cash funds held in RFA against expected spend must be conducted regularly to ensure full coverage from RFA held funds within the FY.<br>Reporting for this measure will be developed for this review. Review is required monthly | Cash must be held in RFA bank account that covers the spend incurred. Cash calculation is for net available cash, and excludes creditor liabilities and income billed but not received. |
| Initial and ongoing annual budget for clinical trials | PHEs must ensure that an initial and ongoing annual budget in RFA for Clinical Trials is established to cover the expected revenue and expense for each financial year during the duration of the trial. | Cash is not budget. Budget must cover the expected accounting for Clinical Trials over the course of the financial year for each year of the trial duration. |
| Completion and close out of trial | Clinical trials are expected to have a defined duration and completion date. Budgets are set at the beginning and expected to be closed out and all excess funds moved to CE controlled research fund at the conclusion of the trial. | Funds will support research and clinician initiated trials via the RFA research funds maintained for this purpose. |
| Clinical Trial funds earning interest are to be allocated to Research as directed. | Clinical Trials funds held in RFA may earn interest. Where interest is earned, it will be allocated to research purposes as directed by the Ministry of Health | Clinical Trials funds are not investments and are to be used for the purpose of paying for the trial activities. Any interest earnings are to be directed to Research activities as directed by the Ministry. |

# Responsibility Matrix for setup, implementation, ongoing and compliance management of Clinical Trials in RFA

| Task | CFO | DEP CFO/SFP Branch | RFA MOH Team | FDARG Branch | FAPIR Branch | OHMR Branch MOH | Health Entity CE/DOF | Health Entity Finance | Health Entity Clinical |
|---|---|---|---|---|---|---|---|---|---|
| **Set-Up** | | | | | | | | | |
| Initiation - Brief and Letter | A | I | C | R | A | C | I | I | I |
| Reporting Design (EPM) | I | I | C | R | C | S | | | |
| Systems Design/Config (eCTRA) | I | I | A | R | C | | | | |
| **Implementation** | | | | | | | | | |
| Assess eligible trials to move to RFA | | | I | C | | S | A | R | R |
| Update CT contracts (if required) | | | I | C | | S | A | R | R |
| Set-up cost centres in eCTRA | | | C | | | | A | R | R |
| Set up Trials in CTMS | | | I | | | C | A | C | R |
| Request Budget | A | C | I | S | | | R | C | C |
| Request Reporting Hierarchies | | | | C | | | | R | |
| Update Reporting Hierarchies | | I | I | R | C | | I | I | |
| **Ongoing** | | | | | | | | | |
| Correct accounting of trials in RFA (including Accg Stds) | | | C | | C | | A | R | |
| Full cost recovery to RFA CC | | | I | | I | S | A | R | R |
| Billing via StaffLink AR including RCTI | | | I | C | I | R | A | R | R |
| Run trial via CTMS | | | I | | I | C | A | | R |
| **Compliance/Review** | | | | | | | | | |
| Performance against budget | | I | | | | | A | R | R |
| Assessment of within Research/CT cash in RFA | | I | R | | I | I | A | R | R |
| Key decisions on issues with compliance | I | I | C | C | R | C | A | C | C |

RACIs

R - Responsible

A - Accountable

C - Consulted

I - Informed

S - Supporting