Policy announcement - NSW Health Research Fee Policy

SESLHD researchers are set to benefit from a new Fee Policy launched by the Office of Health Medical Research (OHMR).

With the aim to ensure consistency in the application of fees for research ethics and governance review across the NSW public health system, OHMR released the new Research Fee policy earlier this year. The policy is intended to provide researchers with certainty in the fees they expect to be charged for ethics and governance submissions and to ensure that fees are passed on to trial sponsors.

After months of planning, SESLHD, will commence this policy roll-out on 1 November 2023.

Key Changes

- NSW Health Fee Policy [PD2023_015] will replace the existing SESLHD Fee Policy [SESLHDPD/332], for applications received on or after 1 November 2023.
- Research Ethics and Governance Review fees described in the new policy apply to clinical trial research only
- The price design undertook a systematic process of comparing fees and offerings of service providers in other jurisdictions to maintain relevance and sustainability.
- Fees set out in the Policy Directive represent part of the cost of conducting research and are expected to be passed on to the sponsor of the trial
- No fees will be charged for research applications other than for clinical trials

What you need to do

1. All research personnel must read and understand the NSW Health Fee Policy and Information Bulletin prior to submitting a research application or amendment.
2. Researchers must ensure that relevant research invoicing details are included as part of research project budget planning, obtain appropriate clearances for the expenditure of any projects funds, and abide by provisions outlined within the Policy.
3. The study team must ensure appropriate invoicing details are provided when submitting their research applications.
4. A grace period upto 31 December 2023 is available to allow trial coordinators and sponsors to adjust budgets and contracts for existing trials.
5. We recommend using standard wording on CTRAs, i.e. 'Research review fees are payable in accordance with the NSW health fee policy.'
6. Ensure the invoice is paid in accordance with details included.

Q & A

Q1. Where can I find this policy and the fee schedule?

The **Policy Directive** and **Information Bulletin** can be found in the NSW Health website under Policy Directives, guidelines and information bulletins.

Policy Directive: Fee Schedule for Research Ethics and Governance Review of Clinical Trial Research (nsw.gov.au)
Fee Schedule Information Bulletin: Fees for Research Ethics and Governance Review of Clinical Trial Research (nsw.gov.au)

Q2. Are fees set out in this policy GST inclusive?
A: Fees outlined in the NSW Health Fee Policy is exclusive of GST.

Q3. Is a study approved prior to 1 July 2023 subject to application of the new schedule of fees?

A: For multi-centre studies submitted before 1st of July that anticipate numerous site amendments, OHMR (author branch) has considered this scenario and allowed a grace period until 31 December 2023 for trial coordinators and sponsors to adjust budget and contracts as appropriate.

Q4. Definition of Institution Sponsor

The Policy defines an Institution Sponsor as **"***A NSW Health Organisation which is the sponsor of a clinical trial. For the purposes of this Policy Directive, such entities include those public health organisations from other Australian jurisdictions as well as other government agencies and departments"*

In response to some queries received, we would like to share the following clarifications:

Cancer Australia:

- Acting as Sponsor for a trial, we would consider them a government entity and therefore an 'institution-sponsor' and fee-exempt;
- Funds a trial that is sponsored by the health organisation (SESLHD), then it is fee-exempt;
- Funds a collaborative/cooperative group that sponsors a trial, then it is a non-commercial trial and the relevant fees apply.

MRFF grants: While MRFF grants originate from a Commonwealth department, the key is to identify the entity taking on the role of the sponsor, which involves not just financing but also initiating and managing the trial.

Hospital Foundations: The classification would depend on the entity taking on the sponsor role. The source of funds (e.g., donations) doesn't determine the sponsor type. The Policy Directive's fee is applied based on the sponsor type, not the funding source.

The above changes will be applicable to all applications including amendments of an existing study, from 1 November 2023.