# REGU Fee Policy Q&A

## Highlights

- **Effective Date:** The new Policy Directive is in force from 1 July 2023.
- **Scope:** Fees may only be charged for clinical trials.
- **Comparative Fee Levels:** The fees are in line with levels in other jurisdictions.
- **Grace Period:** A 6-month grace period is being implemented for amendments to existing studies.
- **Review Period:** There will be a review after 12 months to evaluate the impact of the policy.
- **Administrative Items:** Safety notifications, DSURs, and general correspondence are considered administrative and do not attract fees.
- **Sponsor Responsibility:** The trial sponsor is responsible for financing the clinical trial, including any fees.
- **Student Research:** If a study is sponsored, the sponsor bears the financial responsibility, regardless of the investigator type (e.g., PhD students).
- **GST:** Goods and Services Tax (GST) is not included in the fees.
- **Non-Clinical Trials:** No fees are to be charged for non-clinical trials, as detailed on page 2, section 2 of the Policy Directive.
- **Sponsor Type:** The fee structure is based on the type of the sponsor, not the source of funds or the researcher's affiliations.
- **Consultation**: Extensive consultations were conducted with various stakeholders, including researchers from universities and collaborative groups, over a 2.5-year period.

## Amendments

### Question 1

For ethics-related site amendments, how is the fee determined? Specifically, if an amendment includes the addition of multiple sites, is the fee charged per amendment or per individual site?

### Answer

For commercial external sponsor, the fee for additional site is $1500. The fee for the addition of a site amendment is charged per amendment, not per site. If one amendment includes the addition of two sites, the fee would be $1500 for that single amendment. If you receive two amendments one for each site, then it would be $1500x2.

### Question 2

Why can Ethics charge a fee for the addition of sub-studies, but Governance cannot, especially when Governance may require a more comprehensive review than Ethics?

### Answer

The Policy Directive, on page 5, defines a sub-study as an ancillary study nested within a primary or "parent" study. It addresses a distinct research question while being related to the main study's objectives. It's understood that sub-studies might often necessitate new ethics approval, particularly if they introduce novel procedures or risks. The need for site approval hinges on the sub-study's specifics. For instance, if it introduces a new intervention not covered in the original site approval, a new or amended site approval might be required. If the primary study is observational and the sub-study is interventional, the site would need to evaluate the new intervention's feasibility and risks. Typically, site approvals should cover potential sub-studies, especially if foreseen during the initial application. However, if a sub-study diverges significantly from the original protocol, it would necessitate a new site application, incurring associated fees.

## Question 3

For Major Amendments, does "Contract Amendments" pertain to CTRA amendments?

## Answer

Yes, provided it only requires research office review.

## Question 4

Could you provide clarity on the application of Governance Review Fees for both Major and Minor Amendments? How often would the Governance Amendment Fee be applied, especially considering that most amendments receive Ethics approval before Governance Review? Would this mean that for changes like Personnel Adjustments or local site information updates on a PICF, the sponsor is charged both for the Ethics review and then again for the Governance Review of the same amendment?

## Answer

Governance fees apply to site-specific changes, even if previously reviewed by Ethics. Ethics assesses ethical considerations, while Governance evaluates site-specific implications. The policy does charge separately for Ethics and each Governance review. For multi-site studies, each site's review incurs a fee. However, if the amendments are administrative in nature and not explicitly defined in the Policy Directive, these changes do not attract any fee. For instance, RGOs noting CPI changes shouldn't attract a fee. We're actively evaluating feedback from our stakeholders and we will review the Policy after the first 12months.

## Question 5

How should we address older CTRAs that list outdated fees, especially when the amendment doesn't introduce a new CTRA?

## Answer

Fees effective from July 1st, 2023, will apply to new amendments, even for older studies.

## Question 6

Would it be beneficial to introduce a standard fee clause for CTRAs?

## Answer

Fees for ethics and governance submissions will be charged as per NSW Health Policy as that may be updated from time to time.

## Question 7

Will the new amendment fees apply to studies approved before 01/07/2023?

## Answer

Yes, they will apply. However, there is a grace period in place to accommodate such scenarios.

## Question 8

How are major and minor amendments categorized?

## Answer

The categories for major and minor amendments are detailed on Page 5 of the Policy Directive. Any item not explicitly mentioned in the PD will not incur a fee.

## Question 9

Who determines the correct categorization of amendments?

## Answer

The categorization is a joint discussion between the sponsor and the site. In cases of disagreement, the Ministry of Health can provide guidance.

### Question 10
Are the new fees relevant to Investigator-led clinical trials?
### Answer
The policy does not differentiate fees based on who conducts the trial. While non-clinical trial research is exempt from ethics and governance fees, clinical trials are charged based on the trial sponsor. Specifically, an investigator-led study sponsored by a NSW Public Health Organisation or its equivalent is not subject to review fees. In contrast, an investigator-led study with an external sponsor will be charged as outlined in Table 1 and 2 of the IB2023-026.

## Administrative Items

### Question 11
Should administrative changes, such as a change in the Principal Investigator or Development Safety Update Reports, incur charges?
### Answer
Administrative updates like the Development Safety Update report or annual reports are exempt from fees as per the Policy Directive. A change in the Principal Investigator is classified as a minor amendment, as detailed on page 5 of the PD.

### Question 12
Is there a governance fee associated with the "dear investigator" letter, annual report, and CoC?
### Answer
No, these administrative items are not specified in the Policy Directive, so they do not incur any fees.

### Question 13
Are we required to charge for safety notifications, DSURs, general correspondence, and changes to CPI/PI for ethics amendments?
### Answer
Safety notifications, DSURs, and general correspondence are deemed administrative and, according to the Policy Directive, are exempt from fees. However, for amendments involving CPI/PI changes, they are categorized as minor amendments. Thus, a fee should be applied for these as minor amendments. For SSA, if only acknowledging the CPI change without further actions, no fee is necessary.

### Question 14
Is there a fee associated with access requests?
### Answer
Access requests are not specified in the Policy Directive, and as such, no fee is applied to them.

## Financial Implications

### Question 15
How will CRGs, which may not have allocated funds for these fees and could have numerous sites, be affected?
### Answer
For multi-centre studies initiated before July 1st with multiple amendments across sites, a grace period of up to 6 months is available to facilitate negotiations between the sponsor and the Local Health District (LHD).

## Question 16

How will the RGO handle invoicing if the finalized contract doesn't clearly specify HREC/RGO fees? And if a non-commercial sponsor declines to include these fees in a contract amendment, what recourse does the LHD/researcher have?

## Answer

If the finalized contract doesn't clearly state HREC/RGO fees, the RGO should engage with the sponsor to seek clarity. The statewide policy directive is mandatory for all involved parties. The sponsor, responsible for initiating, managing, and funding the clinical trial, must adhere to and operate within the relevant policy framework when conducting their study at a NSW Public Health Organisation. If a non-commercial sponsor opts not to include fees in a contract amendment, the researcher has several alternatives, including seeking other funding sources or collaborating with other institutions or sponsors to distribute the costs.

## Question 17

How do the new fees influence the constraints in NHMRC Grant applications?

## Answer

Researchers must factor in these fees when preparing their grant applications. For those affiliated with a NSW Public Health Organisation (PHO), investigator-initiated studies won't incur these fees. However, for trials sponsored by non-commercial external entities or commercial entities, the onus is on the sponsor to adequately finance the trial, encompassing both ethics and governance fees.

## Question 18

Is there flexibility in charging fees for SSA for studies approved prior to the new policy, especially given that many haven't budgeted for these upcoming fees, and multicentre trials might face significant costs due to multiple sites?

## Answer

The new policy aims to provide clarity, transparency, and certainty to both researchers and sponsors. While multi-centre trials might incur higher review fees, sponsors will have a clear understanding of their budgetary requirements. For studies approved before 1st July, a 6-month grace period will be provided to allow for negotiations between involved parties.

## Question 19

Given that NHMRC & MRFF grant funding conditions specify that funds can't be used for administrative costs like ethics & governance, doesn't this new Policy Directive conflict with that, especially since many non-commercial sponsored trials rely on these funding sources?

## Answer

Ethics and governance review fees have been consistent for both commercial and non-commercial sponsors since before 2008, as per PD2008_030. These fees haven't increased over the past 15 years. However, our fees for non-commercial trials align with those in other jurisdictions. The primary goal of this policy is to standardize ethics and governance fees across NSW Health Organisations, ensuring clarity for researchers during budget preparations. It's crucial to note that the trial sponsor is responsible for initiating, managing, and financing the clinical trial, which includes covering these fees.

## Question 20

How should the following entities be categorized in terms of sponsor type?

- Cancer Australia, which is an Australian government entity and currently funds Multi-site Collaborative Cancer Clinical Trials Groups.
- Commonwealth funded studies.
- Studies funded by St George and Sutherland Medical Research Foundation, where the funding source is a donation but is managed through UNSW.
- Charity organizations.
- Non-profit organizations.

### Answer

For sponsor categorisation, please refer to Page 3 of the Policy Directive. The definition of an "institution sponsor" encompasses public health organisations from other Australian jurisdictions as well as other government agencies and departments. Nevertheless it is important to note that fees are determined based on the sponsor type, not the source of the funds.

## Sponsors

### Question 22

Is there a possibility of waiving fees for investigator initiated trials (IITs) conducted via CRG, given the significant impact on IITs?

### Answer

Currently, there is no provision for waiving fees specifically for IITs conducted via a CRG sponsor.

### Question 23

Could you provide further details on the fee associated with non-standard contracts?

### Answer

As outlined on page 6, section 4.6 of the Policy Directive, a non-standard contract fee is levied when a clinical trial contract does not conform to the standard contracts prescribed by the NSW Health Policy Directive. The fee amount varies based on the sponsor category, whether it's institution-sponsored, non-commercial external, or commercial external. This fee is designed to account for the extra administrative and legal scrutiny that non-standard contracts necessitate. Essentially, any contract that isn't part of the standard CTRA/CIRA suite is deemed non-standard.

### Question 24

Are NSWHP contracts classified as standard or non-standard?

### Answer

The Policy differentiates contracts based on their relation between a sponsor and a site or a commercial entity supporting a clinical trial. Contracts outside the standard CTRA/CIRA suite are deemed non-standard, as per PD-RA.

### Question 25

Could you clarify the fee implications for PhD students acting as investigators in clinical trials, especially when there's a protocol amendment? Would such an amendment be classified as major? And who bears the cost - the sponsor or the student?

### Answer

If a study has a sponsor, the financial responsibility for the study, including any amendment fees, lies with the sponsor, irrespective of the investigator's status, be it a PhD student or otherwise.

### Question 26

How will the new fees impact collaborative group studies, especially those by organizations like ALLG or Universities, particularly when they have limited or no funding? Is there a risk of these studies being abandoned, thereby affecting research in NSW?

### Answer

The primary intent of this policy is to provide clarity, transparency, and certainty to researchers and sponsors. While multi-centre trials might incur higher review fees, it's essential for sponsors to be aware of these costs upfront to budget appropriately for their trials.

### Question 27
How does the policy directive apply to researchers with dual affiliations, both academic and health-related?
### Answer
The policy directive primarily focuses on the trial sponsor. The categorization and associated fees are determined based on the type of the sponsor, irrespective of the researcher's affiliations.

## Consultation

### Question 21
Is there a plan to offer discounted fees for students? Additionally, were universities consulted during the decision-making process?
### Answer
We engaged in extensive consultations with the Health sector and conducted multiple rounds of discussions with researchers from Medical Research Institutes (MRIs), Universities, and Collaborative Groups. This consultation spanned approximately 2.5 years and prominently featured input from university researchers. It's crucial to understand that if universities choose to act as sponsors, they must meet all the obligations of a trial sponsor, including adequately funding the trial. This policy has exempted all research types that are not clinical trials from any fees. The onus of the fee is on the trial sponsor and not on the individual investigator.

## Other

### Question 28
Can HRECs levy charges for authorised prescriber applications?
### Answer
The policy directive does not cover charges for authorised prescriber applications. It's worth noting that the TGA seeks an "endorsement" from an HREC, not an outright approval. This policy directive is specifically tailored for clinical trials

### Question 29
How is a "Clinical trial" defined in the policy? Does it pertain solely to drug trials, or does it encompass any research that examines interventions, including non-pharmacological ones?
### Answer
The definition of "Clinical trial" can be found on page 2 of the Policy Directive. It is not limited to drug trials but includes various forms of research interventions.

### Question 30
Is the Goods and Services Tax (GST) incorporated in the fees, or should it be added separately?
### Answer
GST is not included in the fees mentioned.

### Question 31
I've heard that there are no fees for non-clinical trials. Could you direct me to the section in the policy directive that addresses this?
### Answer
You can refer to page 2, section 2 of the Policy Directive for details on the exemption of non-clinical trials from fees.