

MRAM

MAY 11 Meeting Q&A

Greetings Colleagues,

The <u>May 11 MRAM materials</u> are published for your review. Q&A from our session are included here for reference and will be available with the other meeting materials shortly.

PAFC Hot Topic: Travel on Federal Awards

Q1: Do we have to make travelers book the "below economy" class some airlines offer, for example, "basic economy" that doesn't allow a carry on bag, doesn't allow people to choose their seat, etc.?

A1: The federal regulations state that the "basic least expensive accommodations class" ticket is the allowable charge. The name of the class is not as important as the fact that it's the least expensive class of ticket.

2 CFR 200.475(e)

Q2: Medical needs - is approved by DSO and what does the documentation look like on the expense report?

A2: A documented medical need (a note from a doctor) to fly business/first class could be attached with the expense report or retained with other approval documentation for the award. The medical-need documentation is not required to be part of the expense report but the documentation must be available and retained.

Q3: What if traveler qualifies for a free upgrade?

A3: Yes, a traveler may use a free upgrade as that does not result in any additional costs to the sponsor above the least expense accommodations class.

Q4: If part of a multi-year award but UW has different budgets for each year. Can travel be purchased for future trips using the current budget year as it is still within the Award period not UW budget period?

A4: Yes, if the travel is occurring within the same competitive segment or project period, the cost could be charged in the current budget year. As always, review the terms and conditions of your award to understand any specific restrictions that may apply.

Q5: We have a visitor coming for two months. The first month of his stay is covered by a federal grant, and the second month is covered by dept. funds. That is, he is working on two unrelated projects, which, for efficiency, have been arranged in a single visit. We want to charge the outbound flight to Seattle to the federal award and the return flight to Spain to the dept. budget. We can fully document why this is useful. Any concerns about allowability doing it this way?

A5: If travel benefits more than one funding source (sponsored or non-sponsored funding), the cost of the travel must be allocated in relation to the proportional benefit to each source. The documentation should be clear and easy to follow – anyone should be able to look at the documentation and understand the reasons for the charges to the award. Additionally, any math involved in determining the amount to charge to each funding source should be simple and easy to follow.

We have additional resources on documentation guidelines and allocation of costs across multiple funding sources on the PAFC website:

https://finance.uw.edu/pafc/documentation-guidelines#additional-info https://finance.uw.edu/pafc/cost-allocation#best-practices

Scope of UW Clinical Trial Office Budget Review

Q1: Normally, we don't know how many periods a clinical trial will last, so we just choose 5 years in order to prevent having to repeatedly request extensions. Should we still do that?

A1: You may choose to do either of the following:

- Enter five separate periods of 12 months each
- One 60 month period

In the Award Setup Request, the periods selected will be used to create the award schedule periods in Workday. SAGE will use the first start date and last end date of the selected periods to create the Workday Award Line Start and End dates.

Q2: Does all of this apply only to clinical trials taking place in a UW Medicine setting?

What about a clinical trial taking place in a non-UW Medicine setting?

A2: This change is applicable to all studies where both are true:

- (1) Procedures, items or services are billable through Epic EMR (UWMC, HMC, FHCC, UWP), and
- (2) UW receives the funding/award (agreement signed by UW OSP).

Q3: Does the CTO provide a coverage analysis for pre-award budget development? **A3**: Assuming the question is about grant budgeting prior to submitting an application.

CTO has received infrequent requests to evaluate what services would not be covered by patient insurance for grant budgeting purposes. We are happy to provide this consult but if we have to engage our 3rd party vendor (depends on complexity of the protocol), a fee may be assessed, which we would, of course, disclose upfront before engaging the vendor.

For fixed-price contract budgets, Coverage analysis is a required step before budgeting and is done for every such study.

Upcoming Changes to HSD Administrative Fee and Processes

Q1: Can we get a memo to share with sponsors for the HSD fee increase as justification for our negotiations?

A1: I would point sponsors to our published content on our website that discusses the <u>fee increase and rationale</u>.

Q2: Do we need to budget for the Industry Clinical Trial Fee in our budget proposals to sponsors?

A2: Yes. This is true in the current state so there is no change in this requirement. If you are working through the Clinical Trial Office they automatically include this fee when preparing the billing grid for applicable industry sponsored and initiated clinical trials. CTO has the new fee rate and effective date and will be provided any future rate updates months in advance so they can work with researchers to include it in their budget proposals.

Q3: This new rate for HSD is most reasonable. Can you clarify this does not apply for NIH trials where we are asking for determination for an external institution to be the IRB of record for a multi-site trial?

A3: Correct. This fee does not apply to NIH-funded trials. It only applies to industry

sponsored and initiated clinical trials where the contract has been negotiated by UW Office of Sponsored Programs (OSP).

Q4: Do you anticipate charges for NIH multi-site trial where UW is asked to be the IRB of record?

A4: Presently we do not charge a flat fee for UW IRB review of multi-center trials, though we are exploring this. Instead, for these studies we request that a portion of our FTE be written into the grant to cover our effort. The amount is dependent on the size and complexity of the trial. We encourage researchers to contact our office (<a href="https://nxeduc.org/nseduc

Q5: Is the 29% increase in the external IRB fee set to because the fee hasn't been increased in 13 years?

A5: Yes.

Q6: Can we expect yearly increases at a similar % increase? Or, will the yearly increase expected to be less?

A6:Going forward you can expect yearly increases to be much smaller. Increased costs will usually be commensurate with increases in salaries resulting from merit or cost of living adjustments. We would anticipate 2-4% increases annually effective July 1st of the new fiscal year. Any changes in our fee will be communicated to CRBB and announced in our newsletter several months in advance. Subscribe to our monthly HSD newsletter.

We hope to see you next Friday May 19, at 9 a.m. for our bonus UWFT-focused MRAM.

Thank you, MRAM



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