Message from the ADR:

As the semester winds down, you may be gearing up to work on some grant applications or perhaps step up activities for some existing research projects. This newsletter contains information you need to know about the definition of clinical trials and inclusion in grant applications, budgeting around term limited employees and research incentive funds.

I want to take this opportunity to once again remind you of the new cost share guidelines and let you know that the cost share request form is now “live”. Therefore, if you wish to request a cost share for a grant application, please complete this form with the help of your pre-award team member and send to me after you submit your Notice of Intent to GRO.

Please know that my door is open for any discussions around what the UMSN Office of Research can do to facilitate your plans in addressing critical health care issues. I will be around this summer so feel free to come and talk.

Deb

Highlights from Research Day
April 9, 2019
As we just finished tax season, I am confident that what I am going to share with you about taxes will make a lot of sense. As you know, the University of Michigan provides numerous central services that are intended to meet the needs of our students, but also all of us who work here. Some of these things include the campus bus system, General Counsel services (lawyers), the library, museums, and core services such as the Office of Research and Sponsored Projects (ORSP) and grants and contracts.

Who pays for these services? In some way, every University stakeholder pays, including Units, Schools and Colleges. How do we pay for this?

Through a tax system - gee, that sounds familiar doesn’t it?

In 2014, the University went to a single tax model versus a multi-tax model. The multi-tax model that was previously in existence taxed different things at different rates. That system was also somewhat unstable as it was more vulnerable to changes in state appropriations to the University. The new single tax model taxes everything at the same rate, which in 2018, rose to the target rate of 21.4%. This means that the School of Nursing is taxed 21.4% on all expenditures that it has (which represents activities of the School), including research expenditures. This tax rate is IRREVERSIBLE of the indirects the grant generates.

The reason this is important for you to know is that it impacts the research incentive payments that Principal Investigators receive from UMSN. Research incentive payments are put into a research incentive fund, called RIF accounts. The payments are figured out through a formula that takes into account the indirect rate and the rate of the University tax. Through the current year, the tax rate that has been entered into the UMSN equation has been BELOW the actual University tax rate – so faculty have received somewhat larger incentive payments than they would otherwise have realized and the School has made up the cost to pay the tax. Eligibility to receive research incentive funds includes being the PI on the grant, the grant receiving at least 11% in indirect monies, and having UMSN as the administrative home for the grant or being a UMSN PI of a grant from another administrative home but with a subcontract/subaccount.

The bottom line “heads up” as a result of this important information is that next year, when research incentive payments are being calculated for faculty research accounts, the current tax rate of 21.4% will be figured into the equation. Therefore, for faculty whose grants may not have changed, you will see slightly lower research incentive payments. The difference is not a lot, but it is time to bring our accounting practices up to the current environment. If you have any questions, do not hesitate to reach out to me.

Do you know what the term “Vacation Pay out” means?

Vacation pay out is money paid for unused vacation time. At the end of your grant, any of your non-faculty, benefit eligible, term limited, research team members are entitled to all of their unused vacation pay if they leave the University.

Why this is important to be aware of is that as you approach the last year of grant, when reviewing the budget, you need to make sure you know what their remaining unused vacation hours are and that your budget includes the dollars for those hours. If the team member stays in the University system and starts another job, they take their unused vacation hours with them.

Beginning this summer and over the next year or so, there will be a new policy about grant submission deadlines from ORSP. The deadline policy will articulate the levels of central compliance review that will be done based on when the grant is submitted. If the grant is submitted within the deadlines, a full review would occur; if past the deadline, a limited review would take place. Very late submissions will be at risk for non-compliance and depending on the ORSP workload, grants submitted at the last minute may not get submitted at all.

The details and timing of all of the deadlines are still being negotiated and a “go live” date for these deadlines is not yet determined. However, this June, changes to the PAF (proposal approval form) will be implemented to be the first step in the process and to build awareness. For example, when a PAF is submitted, an email about the new policy and time of activation will be sent out. There will also be training for GRO team members before the new policy is activated.

One new feature is that the ORSP will keep records to be able to identify faculty who are chronically late submitters and the respective Associate Dean for Research will work with the Vice President of Research in the University of Michigan Office of Research to help those folks improve.

The entire UMSN GRO team will keep you updated on the specifics of any and all changes, but we wanted to bring this evolving change to your attention. Once the policy is enacted, it will be imperative to work closely with your UMSN GRO team to make sure your grant application gets submitted without a hitch. If you have an interest in meeting with me about best practices on getting your grant in on time, please know that I am open. Stay tuned….
Is Your Study a Clinical Trial?

Knowing whether your study fits the definition of a clinical trial is important because as of January, 2018, NIH started to indicate on various funding announcements whether an application in response to the funding announcement could or could NOT include a clinical trial. Language that is now included in a Funding Opportunity Announcement (FOA) includes the following: “Clinical Trial Required, “Clinical Trial Optional”, or “Basic Experimental Studies with Humans Required” (BESH) or “Clinical Trial Not Allowed”. These FOAs include new review criteria questions that focus on the rationale and study design and also include considerations for mechanistic studies, which will inform assessments of the proposed studies.

**Certain Career Development (K) awards, Fellowship (F) and Training (T) awards do not accept clinical trials but permit clinical trial research experience.** In these cases, the application is to propose research experience that involves activities within a clinical trial. It is possible that the trainee may still have a study but it cannot meet the definition of a clinical trial. The rationale behind this limitation is that trainees are not considered to have the skills required to conduct safe intervention trials. Therefore, close supervision and leadership of the sponsor (mentor) is being required with the mentee being able to obtain experience. New review criteria questions have also been added to these FOAs. See [this NIH webpage](#) for details.

So, is your study a clinical trial?

The NIH has defined a clinical trial as: a research study in which one or more human subjects are **prospectively assigned** to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

Seems simple enough but there are some nuances to this definition. Let’s dig in...

1) **Prospectively assigned:** “as related to the definition of a clinical trial, a pre-defined process (e.g., randomization) specified in an approved protocol that stipulates the assignment of research subjects (individually or in clusters) to one or more arms (e.g., intervention, placebo, or other control) of a clinical trial. In the case of the NIH definition, human subjects assigned to a single intervention in a single arm study would meet the criteria of “prospectively assigned”. Essentially, any study that uses an intervention with human beings will satisfy criteria 1 and 2. Below is an example of a case study taken from the NIH website to illustrate this point. All case studies are from the NIH website.

Case 18F: Prior to a study of the effects of interference on working memory and brain function, an investigator wishes to test the study procedures and adjust the difficulty of the memory tasks for a range of individuals.

To do so, the investigator runs a few healthy volunteers through the procedures and adjusts and finalizes the procedures prior to initiating the formal study.

- Does the study involve human participants? **Yes.**
- **Are the participants prospectively assigned to an intervention?** Yes, the participants are prospectively assigned to different interference conditions.
- Is the study designed to evaluate the effect of the intervention on the participants? **No,** the purpose of these preliminary of practice runs is to evaluate and refine the study procedures, not the effect of the intervention on the participants.

**This study is NOT a clinical trial because it is not evaluating the effects of the intervention in any way.**

Case #16: The study involves the recruitment of individuals to receive a new behavioral intervention for sedentary behavior. It is designed to measure the effect of the intervention on hypothesized differential mediators of behavior change.

- Does the study involve human participants? **Yes,** the individuals are human participants.
- **Are the participants prospectively assigned to an intervention?** Yes, the participants are prospectively assigned to receive a behavioral intervention.
- Is the study designed to evaluate the effect of the intervention on the participants? **Yes,** the study is designed to evaluate the effect of the intervention on mediators of behavior change.
- Is the effect being evaluated a health-related biomedical or behavioral outcome? **Yes,** the effect being evaluated, mediators of behavior change, are behavioral outcomes relevant to health.

**This study is a clinical trial.**

2) **Intervention:** “...a manipulation of the subject or subject’s environment for the purpose of modifying one or more health-related biomedical or behavioral processes and/or endpoints. Examples include: drugs/small molecules/compounds; biologics, devices, procedures (e.g., surgical techniques); delivery systems (e.g., telemedicine, face-to-face interviews); strategies to change health-related behavior (e.g., diet, cognitive therapy, exercise, development of new habits); treatment strategies; prevention strategies; and, diagnostic strategies.”

Case #17A: The study involves the recruitment of patients with disease X to be evaluated with a new executive function task. It is designed to evaluate the ability of the new task to measure executive function.

- Does the study involve human participants? **Yes.**
- **Are the participants prospectively assigned to an intervention?** Yes, the participants are
prospectively assigned to an intervention, the executive function task.

- Is the study designed to evaluate the effect of the intervention on the participants? No, the study is designed to evaluate the ability of the executive function task to measure executive function (as measured by the current standard instrument), but not to modify it.

This study is not a clinical trial.

When you first read this, did you think that the participants were prospectively assigned to an intervention? This example highlights that an intervention is not necessarily what you might think it is. The Executive Function Task in this study is being conceived of as an assessment instrument, but according to NIH, it is considered an intervention.

3) Health-related biomedical or behavioral outcome: “As related to the definition of a clinical trial, the pre-specified goal(s) or condition(s) that reflect the effect of one or more interventions on human subjects’ biomedical or behavioral status or quality of life.”

Case #29: The study involves the recruitment of healthy volunteers to test a new behavioral intervention. It is designed to evaluate the acceptability of the intervention. The outcome is acceptability, not efficacy, of the intervention to the target providers and their patients.

- Does the study involve human participants? Yes.
- Are the participants prospectively assigned to an intervention? Yes.
- Is the study designed to evaluate the effect of the intervention on the participants? No, the study is not designed to evaluate the effect of the behavioral intervention on the participants. It is designed to assess user acceptability.

In this case, acceptability is not a health-related biomedical or behavioral outcome.

Therefore this study is not a clinical trial.

Case #31b: A study involves the recruitment of school children to evaluate two different tools for monitoring food intake. Food consumption behavior will be measured by asking children to activate a pocket camera during meals and to use a diary to record consumed food. Changes to eating behavior will be assessed.

- Does the study involve human participants? Yes, children are human participants.
- Are the participants prospectively assigned to an intervention? Yes, the participants are prospectively assigned to two food monitoring methods.
- Is the study designed to evaluate the effect of the intervention on the participants? Yes, the study is designed to determine whether using the monitoring methods changes eating behavior.
- Is the effect being evaluated a health-related biomedical or behavioral outcome? Yes, eating behavior is a health-related outcome.

This study is a clinical trial.

Case #32: A study involves the recruitment of children at two schools to monitor eating behavior. Children’s food choices will be monitored using a remote food photography method. Food consumption and the accuracy of food monitoring methods will be assessed.

- Does the study involve human participants? Yes, the children participating in this study are human participants.
- Are the participants prospectively assigned to an intervention? No, not in this context. The study involves observing and measuring eating behavior but not modifying it. This is an observational study.

This study is not a clinical trial.

Do you need more help deciding if your study is a clinical trial? The NIH has more info here.