



UMSN Research Newsletter

November 2019

Message from the ADR:

The 2020 academic year is in full swing and I am aware that everyone is having a very busy year. In this issue of the newsletter, I am highlighting a couple very important things about “undue foreign influence” and critical definitions of primary and study completion dates in clinicaltrials.gov.

This first item needs a little background in terms of being clear about the philosophy of collaboration held by the UMSN Office of Research and the University of Michigan. As you may have heard, there is increased attention by the Federal Government including the Department of Justice around assessing for and following up on situations where they feel undue foreign influence may be at play. The University of Michigan Office of Research has been very clear that the philosophy of UM has not changed and they are extremely supportive of worldwide collaborations in science. In fact, it could be said that innovation and progress in science, by definition, should include worldwide perspectives and collaboration. The UMSN office of research would very much agree with that. That being said, there are certain procedures that must be observed in full when collaborating internationally and those are described in the newsletter article this month.

The second item that I would like to draw your attention to is the article on critical definitions of primary completion and study completion dates. To remain in compliance with federal regulations, it is important to understand the difference between these two dates as they determine what you report and when you report. This article gives an example of the difference between these two dates and the potential consequences of non-compliance with this aspect of reporting study results.

Finally, I want to leave with you a story.

I had the opportunity to go to Florence this past fall, the birthplace of The Renaissance. Renaissance as you know means “rebirth” and the Renaissance arguably marked a break from the past and a transition into the modern era of culture. During museum visits, I learned about many artists who were doing incredibly innovative things, but who were not recognized or credited with their influence on the Renaissance until much later than their contributions would have warranted. This was often because their ideas were too novel for the time. Several experiences inspired me to think about my career....not so much about what I had accomplished, but more about how I had been approaching science. Quotations from a very famous and brilliant scientist were brought up on more than one occasion. “Imagination is more important than knowledge” and “Logic will get you from A to B. Imagination will take you everywhere”. Do you know who said these things? It was none other than Albert Einstein, the theoretical physicist who developed the theory of relativity. As you have some “down time” over the holidays this year, I encourage you to think imaginatively about the work that you are doing. Try to free your mind from resource constraints both in terms of time and money and let your mind think freely about what you may want to do and who you may want to do it with to improve the health of our world.



Wishing you love of family and friends and joy at the upcoming holiday season,

Deb



GRO Corner



RESUBMITTING A GRANT?

Please be aware that all grant resubmissions need to have a Notice of Intent (NOI) submitted as early as possible. The GRO team has to go through the same steps and processes as with any grant application so it is imperative that they be aware of resubmissions in the same way you let them know about any grant submission.

A HEADS UP

Some recent experiences have been important reminders of “best practices” with regard to grant application submissions. It is imperative that everyone on the submission team (PI and pre-award and any project coordinators/managers) read the RFA or PA thoroughly when planning to submit a grant. There may be ADDITIONAL things required in the research strategy; there may be ADDITIONAL components that are required; or the budget requirements may have changed. Your pre-award team member, GRO manager, and ORSP will do their best to review key elements and try to catch things, but the PI should also be aware of all of the contents of the call for applications.

GRO GRANT RESOURCES

Looking for current funding opportunities? Need a template for data and safety monitoring? Not sure which guidelines to follow when creating the budget for your grant? [GRO Grant Resources](#) is available on **M | box**. Philip Furspan continues to add tags to the major folders and to their contents. Clicking on a tag allows you to pull that tag from any folder in the GRO Grant Resources box on to one search page – *amazing!* Philip also updates information regularly though you should check for the latest info from the document source as updates are frequent.

M | box is available 24/7 for your GRO Resource needs.



Research Day 2020

**Monday, April 6
8:00 am – 1:00 pm
Michigan League**

Dr. Rob Ploutz-Snyder (Chair) and Dr. Olga Yakusheva (Vice Chair) are heading up a dynamic Research Day Committee. They have been busy planning and renovating Research Day 2020. After careful consideration, the committee changed the format of the day to start in the morning versus the afternoon.

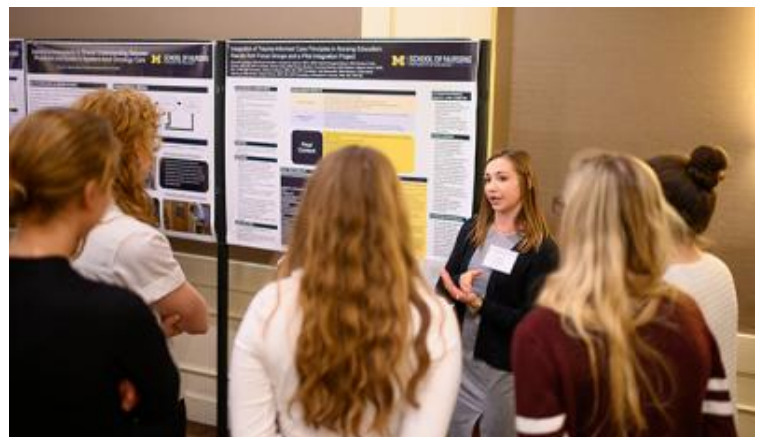
There may be some minor changes but here is the draft of the day so far:

8:00 am – 8:30 am	Registration and Continental Breakfast
8:30 am – 9 :15 am	Poster Viewing Session #1*
9:15 am – 11:15 am	Keynote and Panel Presentations and Discussion
11:15 am – 12:00 pm	Poster Viewing Session #2
12:00 pm – 1:00 pm	Luncheon and Poster Award Announcements

*(Posters removed after to make room for Poster Session #2)

Do you have questions or feedback?

Contact Deb Barton: debbartn@umich.edu



*Elizabeth Coolidge, winner of the BSN poster category
Research Day 2019*

Critical Definitions in ClinicalTrials.gov



The accuracy of your primary and study completion dates is **very important**, especially for trials that are required by law or NIH policy to report results, because it determines when results will be due.

Completion dates are based on data **collection, not** analysis, database lock, publication, or IRB closure. If you use those milestones as your completion dates, you may end up out of compliance with federal regulations! If results are required by law or policy, then results for primary outcome measure(s) are due within one year of the primary completion date, whereas secondary outcome measure results are due one year after the completion date for those outcomes if they are later than the primary outcome.

ClinicalTrials.gov defines the Primary Completion Date as the final data collection date for the primary outcome measure(s) and the Study Completion Date is the final data collection date for all outcomes of a study. If you complete data collection for all measures at once or prior to the last collected primary outcome measure, these dates will be the same.

Once your final participant has been examined or received an intervention for the purposes of data collection for the Primary Outcome Measure, please update the Primary Completion Date within 30 days. Likewise, when you have completed data collection for all the secondary outcomes, update the Study Completion Date within 30 days. Note: exploratory outcomes do not provide an extension to the Study Completion Date.

As an example: If a study completes all data collection on June 17, 2019, then the primary and study completion date should be listed as June 17, 2019. If a study completes data collection for a primary outcome measure on June 17, 2019, but continues to collect secondary outcome measure data for another 12 weeks, then the study completion date would be listed as September 17, 2019 but the Primary Completion Date would still be June 17, 2019. Even if exploratory outcome measures continue to be collected for another 3 months, the study completion date in ClinicalTrials.gov would be September 17, 2019.

As your study progresses, it's okay to indicate an anticipated completion date as long as it's a good faith estimate. However, once data collection completes, it's important to update your ClinicalTrials.gov record **within 30 days** to reflect the change in status to remain in compliance. Remember also to enter the day, month, and year of the date when you completed data collection, and enter the number of participants who enrolled in the study.

Remember that the Common Rule now requires that for federally funded trials, one IRB-approved consent form used to enroll subjects must be posted on a publically available Federal Web site (ClinicalTrials.gov is suggested) after the trial is closed to recruitment and no later than 60 days after the last study visit by any subject (for any purpose), as required by the protocol. To endure compliance with the Common Rule, upload the informed consent document at the same time when you update the study completion date.

The new Office of Research and Sponsored Projects deadline policy goes into effect JANUARY 6, 2020. If you have submitted a grant recently, you would have received a reminder email about this. The GRO office has recently received several notices of intent with less than 10 days notice before sponsor submission deadline. This does not allow for appropriate planning on the pre-award side to meet all faculty needs.

Please remember that all grants, no matter to what external sponsor or how large or small, require a core amount of work. ***GRO needs to receive your NOI the moment you know you are planning to submit a grant.*** If you are responding to a last minute request for proposal and the submission date is within 10 days, please notify the GRO Manager, Karen, to make sure your application can be accommodated in the time frame.



Last month, a new site was launched by the University of Michigan Office of Research (UMOR):
researchcommons.umich.edu.

Jill Jividen Goff from UMOR is "collecting" information on ALL internal funding throughout the University. Take a look at what is there. Also, if you know of anything that is available but missing on this site, please let [Jill](#) know.

Undue Foreign Influence

Why does this seem like an issue that has heightened attention and/or are there new regulations?

According to the University of Michigan Office of Research (UMOR), the Federal government asserts that the regulations about foreign influence are not new; they have always been there. Nonetheless, there appears to be more “watch dog” activity on the part of the Department of Justice around looking for and prosecuting unsanctioned international collaborations. The following information is taken from slides developed by UMOR’s Department of Research, Regulatory and Compliance Oversight and shared with the Research Associate Deans.

Why is this a concern at all?

It is believed and there are some data to support that foreign governments are trying to obtain economic advantage by: 1) Capitalizing on U.S.-funded research; 2) Recruiting away skilled U.S. scientists and 3) Gaining unauthorized access to research and intellectual property.

What have Federal agencies been finding?

A small number of scientists have committed serious policy violations:

- Failing to disclose foreign financial conflicts of interest
- Failing to fully and accurately disclose foreign sources of financial support
- Failing to disclose conflicts of commitment, affiliations, and positions with foreign entities that may come with resources and extra pay
- Breaching the confidentiality of peer review by sharing information and/or applications
- Manipulation of proposal review scores in an attempt to influence review results

The National Science Foundation (NSF), Department of Energy (DOE), and the NIH are all taking steps to change reporting requirements based on new interpretations of existing policies. For example, the NSF is moving to electronic reporting in January of 2020 that will better ensure that current and pending support information is fully reported, including that which involves foreign collaborations. Both the NSF and DOE are restricting involvement in Foreign Government Talent Recruitment Programs. The NIH is increasing scrutiny of foreign collaborations, regardless of whether NIH funds are spent by the foreign collaborator (all foreign collaborations require NIH’s prior approval).

What is the newest issue faculty need to be aware of?

INFORMAL international collaborations need to be reported REGARDLESS of the exchange of funding if the collaboration is related to a federally funded project.

What does that mean?

Let’s look at an example.

Suppose you have an R01 funded by NIH and when the grant is nearing completion, you meet someone from Hong Kong that would make a great collaborator and would provide a great perspective on one of the papers that will result from the R01. In addition to that, you believe you and this new collaborator should write a grant together so you want to establish your collaboration in a paper or two. YOU WOULD NEED TO GET APPROVAL FROM YOUR PROGRAM OFFICER TO HAVE THIS COLLEAGUE PARTICIPATE IN THE WRITING OF ANY MANUSCRIPTS OR ANY WORK THAT WOULD EMANATE FROM THE FEDERALLY FUNDED R01.

In short, informal foreign collaborations must be approved by NIH in advance, if NIH funds support any part of the collaboration, i.e., even if NIH funds **only** support U-M faculty.

What is the University of Michigan doing to help UM investigators meet all required reporting?

- Revised questions in M-Form, and added examples of foreign support and affiliations
- Distributed email guidance to faculty and leadership across 3 campuses about evolving requirement for disclosure of foreign support and affiliations
- Enhanced messaging in annual notice of requirement to disclose COI’s to also disclose foreign support and affiliations
- Established an International Research Security Working Group
- Created an International Research & Scholarship
- [Guidance website](#) and [guidance document](#)

If you have any relationships you are concerned about or have any questions about this area, please do not hesitate to [make an appointment to talk to Deb Barton](#). She will make sure all questions are answered and concerns are addressed.