UMSN Research Newsletter
February 2021

Message from the ADR:

The end of February, beginning of March is always a welcome time for me. As the old saying goes, "March comes in like a lion and out like a lamb", and I start to get more impatient with winter weather the closer spring gets. I find that I am getting that way now with the pandemic as well. With the vaccine approved and being distributed, it is possible to start envisioning life post-pandemic. Yet, many of us continue to wait patiently while the risk prioritization of the vaccination order rolls out. This time of waiting seems the hardest for me.

I want to update you about the status of research during this phase of the pandemic and share some news about support related to the impact of the pandemic from NIH and our School.

Lab density increase: I hope you all saw the email from the Vice President for Research, Dr. Rebecca Cunningham, that was sent on February 15. Specifically, lab density is increasing to 75% and observational human subjects tier 2 studies are now able to be implemented. Tier 3 studies are still on pause. Please be aware that as of right now, even if you are vaccinated, in person activities still require personal protective equipment. Furthermore, be reminded that students, undergraduate, graduate and professional, who are coming onto campus or who live on campus must get weekly COVID testing, regardless of vaccine status.

Faculty Survey: Thank you to all who completed the survey that I distributed at the end of January about whether faculty anticipated no cost extensions or the need for additional resources to complete their active research. Thirty-five faculty answered the survey. Twenty-four of you (69%) are doing human subjects research remotely. For those of you with externally funded grants, 12 (60%) answered that you expect to need a "no cost extension" and 5 (25%) thought they may need additional resources to complete their study. For those with internal funding, 10 (53%) thought they may need additional time and 4 (22%) thought they might need additional resources. I will be reviewing the donated funds for research in the next months and developing some calls for proposals to help address some of the shortfalls that the pandemic has caused for those who are not able to get federal administrative supplements (see below).

On the NIH front: *Early Stage Investigators:* NIH has declared the pandemic as a justification to request extensions for early stage investigators (ESI). An ESI is defined as someone within 10 years of their terminal degree. If you just completed that 10 year landmark, you could request a year extension due to career disruptions during the pandemic. *Resource needs:* If you have an NIH grant and think you will need additional resources to complete your aims due to the impact of COVID, there is a parent program announcement [PA 20-272 "Administrative Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional)"](). The best thing to do would be to reach out to your program officer to inquire whether your funding institute has funds that you can request under that parent program announcement. You will likely need to describe how the pandemic impacted your budget and be very specific about what funds you will need to complete the aims.

Support from UMSN: The School has initiated some things in response to the negative impact of the pandemic as well. These include:

- In concert with University guidance, restrictions on research funding have been lifted.
- Procedures to request clock extensions have been developed.
- Procedures for PhD student extensions have been developed.
- Language has been drafted to promotion and tenure reviewers to address COVID impact during the review of the packet.

(continued on page 2)

Support from UMSN (continued):

- Language has been added to the faculty handbook to note the need to consider the impact of COVID on annual, end-of-term, and promotion and/or tenure reviews.
- Finally, if you still have aspects of your research that have not been able to be implemented or you have any concerns or questions, please contact me via email and we can set up a phone or zoom meeting.

Moving on from pandemic news, **in this newsletter:**

- We highlight the exciting virtual Research Day 2021 "Avenues of Impact" that is being finalized. ***Please block your calendars on April 5 and 6 from 9 am to 2 pm.*** The full agenda and registration link is on the website under UMSN research and then there is a clickable "research day" link. ***Please register NOW.*** We received 72 abstracts.
- We also introduce you to our **new post award administrator in GRO, Lisa Parker**. Please join me in welcoming her to our School.
- There are numerous news items and reminders that are important as well, so please look through this communication tool to stay in the know.

Here is to a productive and satisfying finish to winter term 2021.

Deb

University of Michigan School of Nursing's Research Day Virtual Conference

Monday and Tuesday, April 5 and 6, 2021   9am to 2pm on both days

Avenues of Impact celebrates the many ways faculty and staff contribute to advancing health. It truly does take a team with different areas of expertise, different ways of understanding a problem, and a variety of philosophical and theoretical approaches.

The Avenues of Impact	- Patient-centered Care - Policy and Public Engagement - Practice Implementation and Dissemination - Innovative Digital and Technical Solutions
WHAT'S DIFFERENT ABOUT RESEARCH DAY 2021?	- This year's event will be 100% virtual. The event will feature live presentations from two plenary speakers and a live panel of experts as well as virtual poster sessions. - To beat "online fatigue," the event will occur over <u>two half-days</u> starting at 9 a.m. on both days and ending in the early afternoon. The preliminary agenda can be found here and you can register here.
CONTINUING EDUCATION	*Up to 7.8 nursing contact hours will be provided based on attendance. Michigan Medicine Nursing Professional Development & Education is approved as a provider of nursing continuing professional development by the Ohio Nurses Association, an accredited approver by the American Nurses Credentialing Center's Commission on Accreditation.* **(OBN-001-91)**

Who's New at GRO? Lisa Parker

Lisa recently joined the Grants and Research Office (GRO) staff! Working at the University of Michigan since 1993, Lisa has over 20 years pre award experience and 24 years of post award experience at the University, most recently with the Institute for Research on Women and Gender, IRWG for the past 20 plus years.

The NEW UMICH Single IRB (sIRB) Review Core

If you are part of or applying for a multi-site or cooperative human research project, you probably already know that a single IRB-of-Record (sIRB) must be designated for most of these projects if they are federally-sponsored.

If you want the U-M IRB to serve as the sIRB for a proposed project, the Principal Investigator (or designated study team member) must submit a request to their U-M IRB *during the Develop Proposal stage and prior to proposal submission* to confirm whether IRBMED or IRB-HSBS will agree to be the sIRB.

It is VERY IMPORTANT to understand that this is a PRE eRESEARCH task!
The sIRB Core does not replace the eResearch systems used to submit a sponsored funding proposal or to submit the IRB application for the human research study.

As of February 8, 2021, this request is made using the new UMICH Single IRB (sIRB) Review Core. The "sIRB Core" is part of the Michigan Research Cores (MiCORES) platform, a third-party software system from Agilent/iLabs.com.

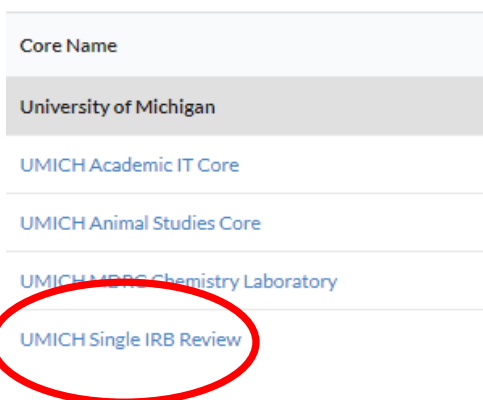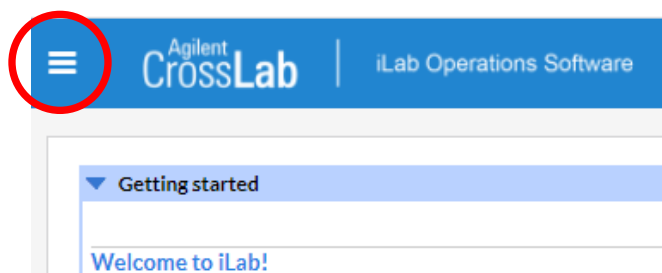Select green log-in using level 1 password

Select menu and in menu, select Core Facilities, then select UMICH Single IRB Review

Core Name
University of Michigan
UMICH Academic IT Core
UMICH Animal Studies Core
UMICH MPRC Chemistry Laboratory
UMICH Single IRB Review

The NEW UMICH Single IRB (sIRB) Review Core *(continued from pg. 3)*

What Form Should I Request?

Request Form	Why this form?	Helpful links
Form 1:	U-M IRB as the sIRB for multi-site studies ➢ NIH-funded clinical trials and other studies ➢ Same human research protocol will be conducted at U-M and at external domestic research sites ➢ These studies are typically under IRBMED jurisdiction.	(see NIH sIRB definition/regulation here)
Form 2:	**U-M IRB as the sIRB on collaborative studies** Supports the establishment of IRB Authorization Agreements (here) with: ➢ External collaborators from other institutions ➢ Individual investigators who are not affiliated with an IRB-holding institution ➢ Utilized most by units/studies under IRB-HSBS jurisdiction ➢ **sIRB Coordinators will direct you when it is appropriate to use this form**	(Common Rule definition/regulation here)
Form 3:	**Consultation with IRB staff member** ➢ Email form used while within sIRB Core to ask questions of sIRB coordinator ➢ Examples: sIRB options, assistance with form questions, general requests for sIRB budget information ➢ Can also send email to IRB staff from outside sIRB Core	IRB-HSBS: irbhsbs@umich.edu IRBMED: irbmedreliance@umich.edu

Who Should Use the sIRB Core?

PIs and/or a designated Study Coordinator/Study Team member – they are the best source of the study details required in the sIRB Request Forms.

When to Use sIRB Core?

AT LEAST 8 weeks prior to sponsored proposal submission. This request:

- Provides key study details to the U-M IRB
- Gives IRB the necessary time to validate U-M's capacity for initial IRB review and ongoing oversite of the project as well as IRB resource allocation needed to serve the sIRB
- Enables the IRB to provide sIRB budget information for proposal or pending award (IRBMED only)
- Allows IRB to confirm who will be sIRB for the project (i.e., U-M, other institution, or commercial IRB) *before* the PI or Research Administrator answers the sIRB questions in the PAF

Need to know more?

Guidance Documentation:
UMICH Single IRB Review Core Features and Guidance
MiCORES Learning Site (UMICH, Level 1 login required)

U-M sIRB Webpages:
 Single IRB-of-Record Process (HRPP)
Collaborative Research: IRB-HSBS sIRB Process
IRBMED sIRB and Multi-Site Research (MSR) Guidance

NEWS from the NIH National Institutes of Health
*Turning Discovery Into Health*

Are you an ESI?
NIH Extension for Early Stage Investigators (ESI) for COVID Disruptions

What is an ESI?

An Early Stage Investigator is a Program Director (PD) or Principal Investigator (PI) who is within 10 years of completion of a terminal research degree or post-graduate clinical training, and who has not yet competed successfully for a substantial (R01-equivalent) NIH research grant as a PD/PI. The benefit of the ESI status is that ESI grant proposals are reviewed in a separate pool from established investigators, and ESI proposals with meritorious scores are prioritized for funding. Reasons that researchers request to extent their ESI beyond 10 years include: family care, medical concerns, disability, active duty military service and natural disaster.

And now – research delays due to COVID – 19 will be considered valid justification for ESI extension requests.

NIH considers ESI status extension requests on a case-by-case basis. This link has details. See how to request an ESI extension here.
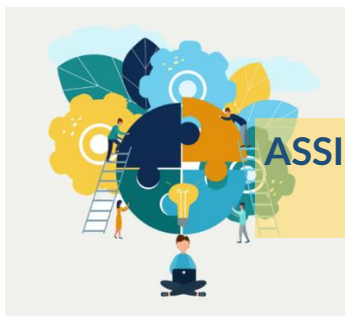
ASSISTED REFERRAL TOOL (ART)

Do you have a hard time knowing what study section to request for your grant? This resource can help!

The Center for Scientific Review (CSR) at the NIH rolled out a new tool last year – the Assisted Referral Tool (ART) with the aim of recommending potentially appropriate study sections for your grant. The information you provide to ART is only used to recommend study sections and is not stored. The recommendations made by ART are solely for the benefit of the user.

How does it work?

ART uses natural language processing and large-scale machine learning technology to make recommendations (cool!). As of August 2020, 175 study sections are represented in ART. More about how it works in the ART User Guide.

How do I use it?

Entering the title of your grant is optional but strongly recommended. Scientific concepts found in the title are given full weight by the indexer.

Entering both Abstract and Specific Aims is recommended. In general, an abundance of text improves performance.

ART ignores stop words such as "abstract" and "specific aim" so it is in your best interest to include both the Abstract and Specific Aims from your application. You can just copy and paste the text, section headers and all. It is not recommended including other sections as they will not be filtered out by section header.

ART requires at least 10 scientific concepts – it needs a strong enough "signal" to overcome potential "noise".

Researchers can also use the tool to "tailor" their project before submitting to make sure it is a "strong" fit with their preferred study section.Researchers can also use the tool to find the most recent rosters for each study section to make sure the reviewers who are on each study section are from the disciplines best suited to review their science.

Is it updated?

Yes! 3 or 4 new releases of ART are issued per year to keep up with changes in study sections.

Using ART along with doing some background research using tools offered by NIH Reporter to see what study sections are funding projects most similar to your project are two great tools UMSN researchers can use now and with future grant submissions.

Dr. Sean McCabe and the ART website provided this information.

If you have been trying to access the **NCI's Team Science Toolkit** you probably know it is "under construction". It is undergoing an update to be sure it is compliant with policies and regulations in place for websites hosted by government agencies.

Questions or thoughts regarding the Toolkit? Feel free to email Kara L. Hall, PhD, Director of Science of Team Science (SciTS) at halka@mail.nih.gov

GRO NOTES

GRANT RE-SUBMISSIONS...

...are not less work for your GRO colleagues! Grant re-submissions still need the <u>same amount of time</u> for review by the office of research and sponsored projects for review. PLEASE SUBMIT NOI'S AS SOON AS POSSIBLE. Questions? Contact your gro pre-award colleague!

Is it Human Subjects Research?

When submitting a grant, how do I know if my study involves human subjects, particularly when I have a subcontract and I am not recruiting participants at my location?

It is important to understand when you are and are not engaging in human subjects research for purposes of the single IRB and also for any IRB applications. Sometimes this can be confusing, particularly if you are a "multiple PI" or co-investigator on a grant where the grant work is being conducted at a site where YOU are not. NIH has developed an interactive decision tool that can be very helpful. It is found at the following link: https://grants.nih.gov/policy/humansubjects/hs-decision.htm and is called: **Decision Tool: Am I Doing Human Subjects Research?** The tool incorporates the 2018 revised common rule definitions.

In short, if you are engaged in a grant application and you are recruiting participants and collecting identifiable data of any kind, you are doing human subjects research. If you are recruiting participants and collecting de-identifiable data, you are still doing human subjects research which may be IRB exempt but an application to IRB is needed to determine that.

If you are engaged in a grant application where all of the recruitment is going to be done by your collaborators and none will be done by you, BUT you will have access to all of the identifiable data, then you are still doing human subjects work.

If you are engaged in a grant application where all of the recruitment is going to be done by your collaborators and none will be done by you, AND you will have access to data which is NOT identifiable in any way, and in performing your role on the project would never require you nor allow you to access any identifiable data, then you are likely not doing human subjects research.

It is a good idea to use the tool to help guide your decision making. The tool includes several different scenarios for consideration and is easy to use.