1-2019

January 2019 news items

Office of Vice President for Research

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Research Development Administrator Named

Contact: Diana Berkshire-Hearit
Jan. 7, 2019

Vice President Terri Goss Kinzy is pleased to announce that effective January 7, 2019 **Kay Mortellaro** will assume the newly created position of Research Development Administrator in the Office of the Vice President for Research (OVPR). In this role, Kay will focus on developing programing and opportunities to grow our research awards and expenditures. She will expand our ability to target and disseminate research funding opportunities, oversee limited competitions, develop a library of proposal resources, oversee programing to prepare WMU faculty and staff for the many different funding sources available, work collaboratively with the colleges and the Office of Development and Alumni Relations and assist in the development of major and interdisciplinary proposals for external funding.

Kay has extensive experience working on grant submission as a research program officer in OVPR. Prior to that, she spent six years as the budget analyst for the College of Engineering and Applied Sciences and served as the center coordinator for both the Transportation Research Center for Livable Communities and The Georgeau Institute.

Changes to NIH Academic Research Enhancement—AREA/R15 Program

On December 3, 2018, the National Institute of Health released a guide notice announcing changes to the NIH Academic Research Enhancement—AREA Program. This document is intended to summarize those changes to assist WMU Principal Investigators in preparing R15 applications. There remain some questions that OVPR is continuing to research. This posting will be updated as more information becomes available from NIH.

The current Parent Announcement, PA-18-504 expired January 7, 2019 and will not be reissued.

- Going forward, the R15 activity code will include two programs:

1. Academic Research Enhancement Award—AREA for Undergraduate-Focused Institutions
2. Research Enhancement Award Program—REAP for Health Professional Schools and Graduate Schools

- Currently, there are 4 Funding Opportunity Announcements—FOAs active for the R15 mechanism. Two for Undergraduate-focused institutions (these are the FOAs for most faculty at WMU to apply to) and two for Health Professional Schools and Graduate Schools (this would apply to faculty at WMed).

1. PAR-18-714 Academic Research Enhancement Award for Undergraduate-Focused Institutions (R15 – Clinical Trial Not Allowed)
2. PAR-19-133 Academic Research Enhancement Award for Undergraduate-Focused Institutions (R15 - Clinical Trial Required)
3. PAR-19-134 Research Enhancement Award Program—REAP for Health Professional Schools and Graduate Schools (R15 Clinical Trial Not Allowed)
4. PAR-19-135 Research Enhancement Award Program—REAP for Health Professional Schools and Graduate Schools (R15 Clinical Trial Required)

- Not all institutes and centers—ICs that participated in the previous AREA Parent Announcement participate in the current FOAs Please check the FOA and any future FOAs carefully as participating ICs may change.

Summary of changes under the AREA for Undergraduate-Focused Institutions (PAR-18-714 and PAF-19-133)

- New eligibility criteria. Under these two new FOAs, eligibility criteria include the following:

1. Only non-health professional schools and colleges are eligible under this FOA (note: we are currently seeking clarification from NIH as to whether this applies to individual departments/schools within an institution that issue health professional degrees such as a BSN).
2. All non-health professional components of the institution together have not received support from the NIH totaling more than $6 million per year in 4 of the last 7 years. (Note: WMU currently qualifies under this stipulation)
3. The qualifying academic component within an institution has greater undergraduate student enrollment than graduate student enrollment.

- The new AREA for Undergraduate-Focused Institutions, as the name implies, is designed to expose undergraduates to research. The language below from the FOA excerpted below helps clarify what this means:

1. The three objectives of this FOA are:
   ♦ Provide support for meritorious research at undergraduate-focused institutions or institutional components;
   ♦ Strengthen the research environment at these institutions/components; and
   ♦ Give undergraduate students an opportunity to gain significant biomedical research experience through active involvement in the research.

2. The research project must involve undergraduate students and the research team must be composed primarily of undergraduate students.

3. An AREA application submitted to this FOA may include other investigators, such as technicians, collaborators or consultants, or other individuals such as high school students, post baccalaureate participants, graduate students, or postdoctoral fellows. However, involvement of such individuals does not fulfill the goal to expose undergraduate students in eligible environments to research.

- New information is now requested in the proposal documents. The list below highlights new information that was not requested under the previous AREA Parent Announcement and is not a complete list of what must be included in any particular document under the new FOA.

1. The Facilities and Other Resources document must now include:
   ♦ Description of plans to recruit well-qualified undergraduate students from diverse backgrounds to participate in the research project.
   ♦ Description of the likely impact of the AREA grant on the ability of undergraduate students at the institution to gain experience conducting biomedical research.

2. The Research Strategy document must now include:
   ♦ Describe how the proposed plan can achieve the specific aims using a research team composed primarily of undergraduate students.
   ♦ Describe how undergraduate students will be exposed to and supervised in conducting hands-on, rigorous research.

3. Letters of Support
   ♦ A letter signed by an institutional official certifying that WMU meets eligibility requirements. Please note, OVPR will handle drafting and signing this letter.

- The review criteria have also been modified to reflect the different goals of this FOA. The excerpts below highlight some of the new language in the review criteria. Please review the FOA carefully for the complete review criteria.

1. **Significance**

   ♦ If funded, will the AREA grant have a substantial effect on the applicant institution in terms of strengthening the research environment and exposing undergraduate students to research?

2. **Approach**

   ♦ Is the project appropriate for execution primarily by undergraduates? Have the investigators described appropriate plans for how undergraduates will be included as an integral part of the research project?

   ♦ Does the application provide sufficient evidence that the project will likely stimulate the interests of students so that they can consider a career in the biomedical sciences?

   ♦ Are appropriate plans in place to recruit a diverse and inclusive team of undergraduate researchers.

3. **Environment**

   ♦ Does the application demonstrate the likely availability of well-qualified students to participate in the research project?

   ♦ Does the application demonstrate appropriate plans to recruit well-qualified undergraduate students from diverse backgrounds to participate in the research project?

As always, please reach out to your Research Officer with any questions.

Common Rule Changes effective Jan. 21, 2019

Regulations governing human subjects research are changing. The federal Office for Human Research Protections (OHRP) has announced changes to federal regulations that protect the rights and welfare of human research participants. These regulatory changes to 45 CFR 46, referred to as the "Revised Common Rule," have been delayed twice and are scheduled to be implemented on January 21, 2019. The Common Rule changes seek to modernize, strengthen and make more effective the federal policies for the protection of human research participants.

WHAT THIS MEANS TO WMU RESEARCHERS:

All research projects that involve human subject must be submitted to the WMU IRB for review and receive approval prior to implementation (e.g., recruitment, data collection, etc. cannot

proceed without IRB approval). The IRB will make the determination on the category of review, continuing review, and post approval changes.

The WMU IRB and Research Compliance have been updating and revising policies and procedures in preparation for the Revised Common Rule.

This guidance will take you through an overview of significant changes made to each section the Common Rule. New guidance will be posted to the website as it becomes available.

Revised Common Rule Impact on Studies with Pending Approval on January 21, 2019

The most notable changes are to the consent process and form, what qualifies for exempt review, and when continuing review is required. Due to the effective date and the implementation date of the Revised Common Rule being the same, some studies awaiting approval may need to be updated and resubmitted for review. Your study approval date or pending approval will determine whether you must comply with the Revised Common Rule changes or will continue to follow the Pre-2018 Common Rule.

Approved Before January 21, 2019
If your study was approved before January 21, 2019, the Pre-2018 Common Rule regulations will continue to apply to your study.

Approved On or After January 21, 2019
Approval Date on or after January 21, 2019, you must adhere to the New Revised Common Rule.

1. Exempt or Expedited studies which are approved with modifications (revisions required), must satisfy all conditions before January 21, 2019 or must comply with the Revised Common Rule.

2. A Full-Board Study which is approved with conditions (revisions required), will have an approval date based on the date of the Full-Board Meeting when it was originally approved.

3. Important Note:
   The Pre 2018 Common Rule will still apply to studies sponsored by federal agencies that have not yet signed on to the Revised Common Rule (e.g., The Department of Justice (DOJ)).

Revised Common Rule Impact on Existing Studies

There may be some circumstances under which studies that must comply with the Pre 2018 Common Rule may switch to comply with the Revised Common Rule. The Office of the Vice President for Research continues to work with the WMU IRB on this process. Guidance on existing studies will be posted in the future.

Studies that must comply with the Revised Common Rule

"New" protocols (e.g., exempt, expedited, etc.) that are approved after the Revised Common Rule goes into effect on January 21, 2019 must comply with the New Revised Common Rule. Some change will reduce researchers' burden and other requirements will increase research responsibilities.

Consent Form—Informational Element

New Requirement—The consent form must begin with a concise summary of essential study information that individuals would want to know in order to make an informed decision about participation.

New Requirement—Consent form must disclose any plans to conduct future research using info and/or biospecimens collected during the research.

New Requirement—If applicable, consent form must disclose whether: (a) subjects will share in commercial profit; (b) clinically relevant research results will be returned; and (c) research will or might include whole genome sequencing.

Exempt Categories Updated

New revised exempt categories and updated categories.

New Option—With safeguards in place, studies using benign behavioral interventions may qualify for Exempt Review.

New Option—With a "Limited IRB Review" of a protocol plan to safeguard subjects' privacy and confidentiality, more studies will qualify for exempt review.

Continuing Review Requirement Changes

Continuing IRB review may no longer be required for many minimal risks studies. To assist researchers approval letters will indicate what type of continuing review is required. The IRB will continue to send notification at 60 and 30 days for the continuing review or progress report.

The IRB is still required to conduct post approval monitoring and an annual Progress Report and Final Report will be required.

Post Approval Changes/Amendments/Modification

Amendments and modifications will still need to be submitted, reviewed, and approved by the IRB prior to their implementation. In addition, unanticipated problems, protocol deviations, and other Reportable Events will still need to be submitted to the IRB.

Post-approval monitoring will continue to ensure that study activities are carrying on as described in the protocol.

The following studies will still need to undergo continuing review:

- Research which requires annual review by a fully convened Board
- Research which is subject to the US Food and Drug Administration (FDA) oversight or by another sponsor that requires continuing review (e.g., Department of Justice, Department of Veterans Affairs, etc.)
- Research that was approved prior to the implementation date of January 21, 2019 and has not transitioned to the revised Common Rule
- Research subject to the discretion of the Human Subject Protection Program or WMU IRB that may involve the following:
    - Student-led research;
    - Research involving non-WMU investigators;
    - Research conducted internationally;
    - Research including particularly vulnerable populations;
    - Research involving additional regulatory oversight, such as a conflict of interest (COI) management plan;
    - Research amendment or incident report revealing new findings that require additional oversight;
    - Investigator that has had previous protocol deviations.

o Investigator that has had previous serious non-compliance or a pattern of non-serious non-compliance;

Revised Common Rule Weblink

Spring Convocation 2019

Contact: Diana Hearit
Jan. 24, 2019

KALAMAZOO, Mich.—Western Michigan University Spring Convocation on March 26, 2019

This event is organized by The Office of Vice President for Research to recognize the work of WMU faculty.

FETZER CENTER

9 to 11:30 a.m.
Discovery Symposia

Discovery Symposium on Education, Room 2016/2018
Session Chairs: Selena Protacio and Charles Henderson

Discovery Symposium on Sustainability, Room 2020
Session Chairs: Xiaoyun Shao and Maarten Vanhof

Fulbright Workshop, Room 1040/1050

11:30 to 12:30 p.m.
Faculty Research and Creative Activity Awards Poster Presentations, Lobby

12:30 to 2 p.m.
Discovery Excellence Recognition Luncheon, Invited guests of the Vice President for Research

Keynote speaker: Susan Pozo, 2018 Distinguished Faculty Scholar

Downloadable copy