



MEDICAL SCHOOL
UNIVERSITY OF MICHIGAN

GRANT SERVICES & ANALYSIS

Medical School GPAC Meeting

November 14, 2018

New Name

- Research Development
- Grant Review
- Post-award Services
- Departmental Support
- Data Analysis

Today's Agenda

- NIH announcements: Parent PAs, Participants, Training Grants
- PRE vs. PAF Standard Operating Procedure changes – what does it mean for Med School?
- Big Bang Theory Session
- Umbrella IRBs

New NIH Parent Announcements

- New FOA #s
 - ❑ [PA-19-056](#): Parent R01 Clinical Trial Not Allowed
 - ❑ [PA-19-055](#): Parent R01 Clinical Trial Required
 - Some ICs only accept [mechanistic studies](#) that meet NIH's definition of a [clinical trial](#).
 - ✓ *NHLBI, NIAMS, NINDS, NCCIH*
 - PIs are encouraged to contact ICs for questions
 - Useful link: <https://grants.nih.gov/grants/guide/contacts/Clinical-Trial-Parent-R01.html>
- Updated additional review criterion
 - ❑ Inclusion of Women, Minorities, and *Individuals Across the Lifespan*
- Earliest submission date: 1/5/2019

Inclusion of Participants Across the Lifespan

- [NOT-OD-18-116](#)
- Policy: Individuals of all ages, including children and older adults, must be included in all human subjects research, conducted or supported by the NIH, unless there are scientific or ethical reasons not to include them.
- Effective 1/25/2019

New Requirement for NIH Training Grant Applications

- [NOT-OD-19-029](#)
- Major change: Only one institutional letter; 10 pages maximum
- Effective: 1/25/2019
- Requirements
 - To be signed by a key institutional leader
 - Institutional commitment to ensuring proper policies/procedures/oversight in place to prevent discriminatory harassment and other discriminatory practices
- U-M contact: Lisa Gubaci (gubaci@umich.edu), OGP

PAF vs. PRE - A Change of ORSP SOP

- ORSP Standard Operating Policy: ([PRE vs PAF SoP](#))
- Route a PRE: For a two-step submission process, *only* if:
 - institutional signature is required OR
 - ORSP must submit the pre-proposal (e.g. AHA, DoD)
- Route a PAF:
 - for *any* single-step application process OR
 - (Uncommon) If the pre-proposal information being sent to the sponsor may end up in award, even with minimal information.

PAF vs. PRE - A Change of ORSP SOP

- Medical School Business Process under the ORSP SOP:
- Same basic guidelines as ORSP. It is an “Honor System” through the school.
- If the unit would like the Medical School to review pre-proposals that do not require routing under the ORSP SOP, a request may be made to msgnants@umich.edu 2 weeks prior to deadline.
- Caveats:
 - Limited Submission – must work with UMOR
 - If you representing categorical budgets, any resource or effort commitments, the information must follow standard Med School/UM policy of representation. Full proposal will be required to include the appropriate information and no exceptions will be made on the final / official proposal based on pre-proposal information.
- If the “honor system” does not work over time, the Medical School may need to revamp the approach at a future time.

PAF vs. PRE - A Change of ORSP SOP

- Dept Business Process under the ORSP SOP and Medical School Expectations:
- For two-step proposals that require no university review, each Dept should decide if they internally require a PRE completed in the eRPM System.
- Options:
 - Depts may choose to create a PRE without routing to see the information
 - Depts may choose to route the PRE if you would like it to be recorded in Medical School data sets. This may result in the pre-proposal being reviewed and commented.
- Notes should be added to the PAF in the ORSP Instructions indicating:
“This is being routed under Unit requirements and requires no action by ORSP.”

Big Bang Theory Session

- Topics – video clips
 - Discussions
- Watch for email and share!
 - Dec 19, Med Sci I
 - Time: TBD

Medical School Grant Proposal Sampler

- <https://wiki.med.umich.edu/plugins/servlet/samlSso?redirectTo=%2Fspaces%2Fviewspace.action%3Fkey%3DUMRPG>
- Accessible for Medical School faculty and staff