Checklist for REAP (R15) submissions:

If your project doesn't include a clinical trial, you will submit to Program Announcement PAR-19-134.

The NIH clinical trial definition is:
A research study in which one or more human participants 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.

The simplified case studies provided below are designed to illustrate the differences between clinical trials and clinical studies using the following four questions:
- Does the study involve human participants?
- Are the participants prospectively assigned to an intervention?
- Is the study designed to evaluate the effect of the intervention on the participants?
- Is the effect being evaluated a health-related biomedical or behavioral outcome?

If the answer to all four questions is "yes," then the clinical study would be considered a clinical trial according to the NIH definition.

If your project includes a clinical trial, you will submit to Program Announcement PAR-19-135.

Submit your budget and justification to the ORSP at least two weeks in advance of the grant deadline. The completed Proposal Approval Form and Conflict of Interest Form must be completed, signed and submitted to our office before the application can be submitted. Conflict of Interest statements must be completed by all MWU personnel (students included) devoting effort to the project even if the individual doesn't receive any salary support. Check with your Chair/Program Director and Dean to be sure they are available to sign off on the Proposal Approval Form before grant due date. When requested and if applicable, IT's approval can be provided via email. If the project involves international travel, e-mail approval must be obtained from your Dean, as well as Dr. Goeppinger. Our office requests that all forms and applicable approvals be submitted to our office at least one week in advance of the grant deadline. If you are submitting on the AZ campus, please send your documents to Michelle Hanke, and if you are submitting on the IL campus, please send your documents to Michelle Bos.

The Office of Research and Sponsored Programs will be submitting your application using ASSIST (Application Submission System & Interface for Submission Tracking), which is a web-based system used to prepare and submit applications. Use of this NIH system will streamline the application preparation and submission process, giving you continual, real-time access to your application as we prepare it for submission. If you would like editing support for your proposal, please contact Michelle Hanke (AZ campus) or Michelle Bos (IL campus) at least three weeks in advance of the deadline.
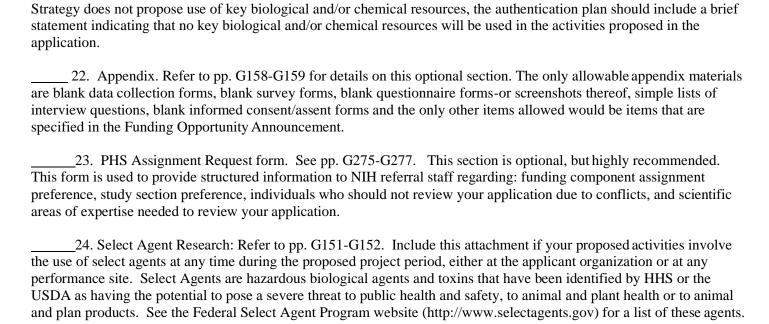
Below is a checklist of items to complete during the application process based on the general instructions for NIH and other PHS agencies dated October 16, 2020:

_____**1. Make sure you and all collaborators have an active eRA Commons account. You can't** submit to NIH without one.
- If you do not have a Commons account, please contact the ORSP and one will be set up for you.
- If you already have a Commons account, please log in and make sure your account is active and your personal information is up to date.
- IF YOUR LOGIN IS NOT WORKING THEN THE NIH WILL REJECT YOUR APPLICATION.
- To access your application via ASSIST visit https://public.era.nih.gov/assist and log in using your eRA Commons userid and password.

_____2. Subawards (Consortiums). If your project will involve collaborations with other institutions who will receive funding from the proposed grant if awarded, please notify our office with the name of the institution/s and the respective grants office contact information as soon as possible.

_____3. Develop your budget. Use the spreadsheet and checklist on our webpage and call our office if you require assistance. Budgets should be detailed as possible and in a near-final state and submitted to the ORSP two weeks prior to your deadline.

_____4. Budget justification will be one of two types: (the justification is due two weeks prior to submission along with the budget):
- If your direct costs are 250K or under, follow the justification instructions for **modular budgets**, pp. G118-G121 of the SF424 Guide. In most cases, only a Personnel Justification is required. Please note that if you opt for the modular budget, we expect that all effort provided by MWU employees will be charged to the grant.
- If your direct costs are between 250K and 300K, follow the justification instructions for the **R&R budget**, also called a detailed budget, pp. G92-G93.
- Since a primary objective of the REAP program is to expose students to meritorious research, you should describe in your Budget Justification any students who will participate in your project. If your project will involve student participation you should provide the number, the academic level, the number of calendar months of those students who will devote effort to your project, and indicate aspects of the proposed research in which students will participate. If there are any collaborators or consultants for the project, provide their names, organizational affiliations, and the services they will perform.

_____5. Vertebrate Animals Section. See pp. G149-G150 of SF424 Guide. If you checked "No" to AVMA guidelines, then you need to describe the method of euthanasia and provide a scientific justification for its use. If you checked "Yes", leave this section blank.

_____6. Project Summary/Abstract: limit is 30 lines. Instructions are on p. G65 of SF424 Guide.

_____7. Project narrative (aka public health relevance statement): 2 or 3 sentences, succinct, understandable to lay audience. Instructions on p. G66 of SF424 Guide.

_____8. Bibliography and References Cited: Important to note - When citing articles that fall under the Public Access Policy, were authored or co-authored by the applicant and arose from NIH support, provide the NIH Manuscript Submission reference number (e.g., NIHMS97531) or the PubMed Central reference number (e.g., PMCID 234567). Instructions are on pp. G66-G68 of SF424 Guide.

_____9. Facilities and Other Resources Section: There are two sets of instructions that you need to take into consideration as you draft: (1) See pp. G68-G69 of SF424 Guide for basic instructions. (2) Also, you will need to address the items in the current R15 Funding Announcement. (3) Use the "Template of Resources Section REAP R15 Proposals" document and modify to your specifications (document is found on our website).

_____10. Equipment statement, if applicable: instructions on pp. G69-G70. Note: this section refers to equipment you already have available, not to any equipment you request in your budget. This section should describe major equipment, location and pertinent capabilities. MWU defines capital assets as tangible property, plant, and equipment used in operations with an estimated useful life greater than one year. Non-computer items that have a value of $2,500 or greater; or computer/information technology related capital items that are greater than $500.

_____11. Biographical sketch(es) for PI & any other senior/key personnel (5 pages). The Personal Statement should include a summary of previous and/or current experience in supervising students in research. If you are an "Early Stage Investigator" or a "New Investigator" this should also be denoted in the Personal Statement. You are allowed to cite up to four publications or research products in the Personal Statement. The PI should also indicate which publications involved students under his or her supervision. If the publications you list arose from NIH support, make sure you provide the NIH Manuscript Submission reference number or the PubMed Central (PMC) reference number (e.g., PMCID234567) for each article. In the Contribution to Science section, briefly describe up to five of your most significant contributions to science. Each contribution should be no longer than one half page, including citations. You may also cite up to four papers accepted for publication or research products that are relevant to each contribution. Also in the Contribution to Science section, indicating a URL for a publication list is optional and, if provided, must be to a government website (.gov) such as "My Bibliography." The NIH allows publications (peer-reviewed and non-peer-reviewed) and research products to be cited in both the personal statement and the contributions to science sections. Research products can include conference proceedings such as meeting abstracts, posters, or other presentations. Research products that are under development,

such as manuscripts that have not yet been accepted for publication, can be mentioned in the narrative sections; however, they cannot be cited as one of their citations. Start-up and/or intramural support from MWU should be included in the Research Support section. Please note that graphics, figures and tables are not allowed in the Biographical Sketch. Instructions are on pp. G82-G86.

_____ 12. Introduction to Application, if applicable: This is ONLY for PIs who are revising and resubmitting a previously unfunded proposal. Address previous reviewers' comments in one page or less. See p. G141 for instructions.

_____ 13. Specific Aims (1 page). See pp. G143-G144 of SF424 Guide.

_____ 14. Research Strategy (12 pages). See pp. G144-148 of the SF 424 Guide. NIH wants PIs to address rigor and reproducibility in their grant application. Under the section "Significance", describe the rigor of the prior research for the proposed project, including consideration of the strengths and weaknesses of published research or preliminary data crucial to the support of your application. Also, the PI should address how the REAP award will have a substantial effect on the school/academic component in terms of strengthening the research environment and exposing students to research. The PI should describe how students will participate in research activities such as planning, execution and/or analysis of research. Also, a sound rationale should be offered as to why the approach and the research team, including graduate students, are appropriate to accomplish the specific aims and to make an important scientific contribution. Under the section "Approach", describe the experimental design and methods proposed and how they will achieve robust and unbiased results. Also in "Approach" explain how relevant biological variables, such as sex, are factored into research designs and analyses for studies in vertebrate animals and humans. For example, strong justification from the scientific literature, preliminary data, or other relevant considerations, must be provided for applications proposing to study only one sex. Another element you should describe in "Approach" is how your project will stimulate the interests of students so that they consider a career in the biomedical or behavior sciences.

_____ 15. Progress Report Publication List, if applicable: This is for renewals only. See pp. G148-G149 of SF424 Guide.

_____ 16. Human Subjects and Clinical Trials Information, if applicable: see pp. G239-G273 of SF424 Guide. If you answered "Yes" to the question "Are Human Subjects Involved?" on the R&R Other Project Information form, you must include at least one human subjects study record using the "Study Record: PHS Human Subjects and Clinical Trials Information" form or a "Delayed Onset Study" record.

_____ 17. Vertebrate Animals, if applicable: see pp. G149-G150. Each of the following criteria must be addressed: (1) Description of Procedures. Provide a concise description of the proposed procedures to be used that involve vertebrate animals in the work outlined in the "Research Strategy" section. Identify the species, strains, ages, sex, and total number of animals by species, to be used in the proposed work. (2) Justifications. Provide justification that the species are appropriate for the proposed research. Explain why the research goals cannot be accomplished using an alternative model. (3) Minimization of Pain and Distress. Describe the interventions including analgesia, anesthesia, sedation, palliative care and humane endpoints to minimize discomfort, distress, pain, and injury.

_____ 18. Multiple PD/PI Leadership Plan, if applicable. Instructions on pp. G152. If you are designating Multiple PIs, please also refer to this page for information and samples: http://grants.nih.gov/grants/multi_pi/index.htm.

_____19. Letters of support, if applicable. Instructions are on pp. G155-G156.

_____20. Resource Sharing Plan: See pp. G156-G157. A Resource Sharing Plan is required for R15 applications. If you need examples, please contact our office.

_____21. Authentication of Key Biological and/or Chemical Resources (1 page). See pp. G157 of SF424 Guide. If applicable to the proposed science, briefly describe methods to ensure the identity and validity of key biological and/or chemical resources used in the proposed studies. These include, but are not limited to, cell lines, specialty chemicals, antibodies and other biologics. Standard laboratory reagents (buffers and other common biologicals or chemicals) that are not expected to vary do not need to be included in the plan. Information in this section must focus only on authentication and/or validation of key resources to be used in the study; all other methods and preliminary data must be included within the page limits of the research strategy. For example, PIs proposing to use cell lines should describe the method they plan to use to verify the identity and purity of the lines. PIs proposing to use chemicals that are key to the research should

describe the method used to validate the chemical, which might include liquid or gas chromatography. If the Research Strategy does not propose use of key biological and/or chemical resources, the authentication plan should include a brief statement indicating that no key biological and/or chemical resources will be used in the activities proposed in the application.

     22. Appendix. Refer to pp. G158-G159 for details on this optional section. The only allowable appendix materials are blank data collection forms, blank survey forms, blank questionnaire forms-or screenshots thereof, simple lists of interview questions, blank informed consent/assent forms and the only other items allowed would be items that are specified in the Funding Opportunity Announcement.

     23. PHS Assignment Request form. See pp. G275-G277. This section is optional, but highly recommended. This form is used to provide structured information to NIH referral staff regarding: funding component assignment preference, study section preference, individuals who should not review your application due to conflicts, and scientific areas of expertise needed to review your application.

     24. Select Agent Research: Refer to pp. G151-G152. Include this attachment if your proposed activities involve the use of select agents at any time during the proposed project period, either at the applicant organization or at any performance site. Select Agents are hazardous biological agents and toxins that have been identified by HHS or the USDA as having the potential to pose a severe threat to public health and safety, to animal and plant health or to animal and plan products. See the Federal Select Agent Program website (http://www.selectagents.gov) for a list of these agents.

(Taken from the SF424 Application Guide dated October 16, 2020).