NIH Proposal Workshop

Time	Activity	Participants
3:00-3:05	Welcome & Introductions	VCRGS Costas Tsatsoulis
3:05-3:30	Getting to Know NIH Programs & R15s	Yue-Wern Huang
3:30-3:55	NIH R01s & Tips for Specific Aims and Proposals	Hu Yang
3:55-4:25	Panel Discussion & Questions	S&T NIH Mentoring Team*
4:25-4:30	Closing Remarks	VCRGS Costas Tsatsoulis

***NIH Research Proposal Mentoring Panelists**

Hu Yang, Professor and Chair, Chemical and Biochemical Engineering

Chang-Soo Kim, Professor, Electrical Engineering

Nuran Ercal, Professor, Chemistry

Pericles Stavropoulos, Professor, Chemistry

Yue-Wern Huang, Professor, Biological Sciences

MISSOURI S&T

Select an Institute within NIH

- List of Institutes (21), Centers (6), and Offices
  - https://www.nih.gov/institutes-nih/list-nih-institutes-centers-offices
- Talk to PO or PD before submission
- Search funded projects: https://report.nih.gov
- Subscribe to weekly announcements
  - NIH Guide Listserv at https://grants.nih.gov/grants/guide/listserv.htm
    - Weekly New Funding Opportunities
    - Notices of Special Interest
- Attend NIH Regional Seminars on Program Funding and Grants Administration
  - https://grants.nih.gov/news/contact-in-person/seminars.htm

MISSOURI S&T

Two additional Government Funding Sources

- Governmentwide point of entry (GPE): FedBizOpps
  - www.fbo.gov (*beta.SAM.gov*)
- HHS Forecast
  - https://www.hhs.gov/grants/index.html

MISSOURI S&T

Types of Funding Opportunity Announcements (FOA)

- **PA** – Program Announcement: both solicited and unsolicited (aka parent announcements); growing use of Notices of Special Interest (NOSI) rather than topic-specific PAs
- **RFA** – Request for Applications – one receipt date (typically) and funds set aside to fund (grants)
- **RFP** – Request for Proposal (contracts)
- **PAS** – Program Announcement with set aside funds
- **PAR** – Program Announcement reviewed by the Institute/Center not Center for Scientific Review (CSR)

MISSOURI S&T

Grants vs. Contracts

Grant	Contract
• Assistance mechanism to support research for the public good • Peer review of broad criteria • Limited Government oversight and control • Reports	• Legally binding agreement to acquire goods or services for the direct use or benefit of the Government. • Award based on stated evaluation factors • More Government oversight and control • Deliverables

Contracts

- https://grants.nih.gov/funding/contracts.htm

MISSOURI S&T

Small Grant Program (R03)

- Pilot or feasibility studies, collection of preliminary data, secondary analysis of existing data, small, self-contained research projects, development of new research technology
- Direct costs limited to $50,000/year
- Limited to 2 years of funding, not renewable
- Due date: 2/16, 6/16, 10/16
- Parent FOA (CT not allowed)
    - http://grants.nih.gov/grants/funding/r03.htm

MISSOURI S&T

Exploratory/ Developmental Research (R21)

- Encourages exploratory and developmental research projects for early stages of development. Sometimes used for pilot and feasibility studies.
- Combined budget for direct costs $275,000 for the two year project period, no more than $200,000 in any one year; not renewable
- Research Strategy: 6 pages
- Due Dates: 2/16, 6/16, 10/16
- https://grants.nih.gov/grants/funding/r21.htm

MISSOURI S&T

NIH Research Enhancement Awards (R15)

- In FY2019 program changed to
  - Academic Research Enhancement Award (AREA) for Undergraduate-Focused Institutions (FOA No. PAR-18-714)
  - Research Enhancement Award Program (REAP) for Health Professional Schools and Graduate Schools (FOA No. PAR-19-134)
  - https://grants.nih.gov/grants/guide/notice-files/NOT-OD-19-015.html
- Direct costs limited to $300,000 for the project period, multi-year funded for project periods of up to 3 years; renewable.
- Due dates: 2/25, 6/25, 10/25

MISSOURI S&T

Eligibility of an Individual PI for R15

- The PD(s)/PI(s) must have a primary appointment at an eligible institution.
- The PD(s)/PI(s) may not be the PD(s)/PI(s) of an active NIH research grant at the time of award of a grant to this FOA, although he or she may be one of the Key Personnel for an active NIH grant held by another PD/PI.
- The PD(s)/PI(s) may not be awarded more than one R15 grant at a time, although he or she may hold successive new or renewal grants.

Note: These eligibility criteria only apply to the PD(s)/PI(s) of the application, not to other Key Personnel such as collaborators and consultants.

MISSOURI S&T

How to Apply?

- Read the Instructions first
  - https://grants.nih.gov/grants/how-to-apply-application-guide.html
- NIH R15 Checklist
- Establish an eRA Commons account: ask S&T OSP

MISSOURI S&T

Education Components in R15s

- Final Paragraph of Specific Aims:
  - Scientific Premise and Impact
    - Your research ideas and NIH mission (institute-specific)
    - Impact:
      - describe educational values
      - point to Facilities and Other Resources file
- Main Proposal (12 pages)
  - A section about education prior to timetable
- Facilities and Other Resources
  - See next slide

MISSOURI S&T

Facilities and Other Resources

- Laboratories
- Offices and Personnel Support
- Computing Facility
- If R15, include
  - Existing academic programs and centers related to the research
  - Institutional Support for Undergraduate Research (e.g., OURE)
  - Likely impact of a R15 grant on the PI(s)/PD(s)
  - How R15 can strengthen S&T research and education programs
    - Be specific in assigning students to subprojects
  - Outreach Activities
    - Women and under-represented minority groups
    - K-12 students

MISSOURI S&T

More on How Students Will be Involved (For R15)

- Perform & troubleshoot experiments
- Present at (lab) meetings & (campus) conferences
- (Help) design experiments
- Collect & analyze data
- Draft articles
- Collaborative interactions

MISSOURI S&T

Resources and Data Sharing Plan

- Standards of Documentation
- Policies for Accessing, Sharing, and Archiving
- Policies for Data Reuse
- Sharing Model Organisms
- Genomic Data Sharing

MISSOURI S&T

Animals, Humans, Select Agents, and Recombinant Nucleic Acids

- Vertebrate Animal Plan
  - Guidelines: https://nexus.od.nih.gov/all/2020/07/24/new-vertebrate-animals-section-training-module/
  - S&T Institutional Animal Care and Use Committee (IACUC)
    - https://iacuc.mst.edu or
    - Contact me at huangy@mst.edu
- Recombinant Nucleic Acids (DNA/RNA) or Select Agents
  - S&T Institutional Biosafety Committee (IBC)
    - https://ibc.mst.edu or
    - Contact me at huangy@mst.edu
- Humans as Research Subjects
  - UM-System Institutional Review Board (IRB)
    - https://research.missouri.edu/irb/index

MISSOURI S&T

Authentication of Key Biological and/or Chemical Resources

- Why this statement?
- Exemplary:
  - Cell line misidentification, cross-contamination, and genetic drift can result in inconsistent or invalid studies. Although our cell lines from American Type Culture Collection (ATCC) were authenticated when received, each year we will reauthenticate them through Short Tandem Repeat (STR) profiling and karyotyping to ensure quality. Samples will be sent to ATCC for reauthentication. In addition to STR, we will record morphologies of cell lines on a regular basis.

MISSOURI S&T

Authentication of Key Biological and/or Chemical Resources

- Exemplary writing:
  - The highest grade and purity of chemicals, bioassay kits, and supplies will be obtained from credible vendors such as XYZ. These vendors include product specifics and material certificates in their products. Supplies will be used within their shelf life.
  - When and if necessary, key antibodies will be validated by XYZ methods.
  - Key chemicals will be validated by analytical chemistry such as XYZ instruments.

MISSOURI S&T

Multiple PI Mode

- Rationale(s) for Use of the Multiple PI Mode
- Roles and Responsibilities
- Communication Plan
- Process for Making Decisions on Scientific Direction
- Access to Study Data and Results
- Budgetary Oversight
- Process for Resolving Conflicts
- Change in PI Location

MISSOURI S&T

Project Narrative & Project Summary

- Project Narrative (for taxpayers and Congress to read)
  - 3-4 sentences
- Project Summary (for taxpayers to read)
  - Layman style
  - 30 lines

MISSOURI S&T

A Few Important Things

- 2-3 Months to develop a New Proposal
  - Office of VCR Can Help
    - > Proposal development (Maria & Summer at OVCR)
- Writing Style
  - Short and simple sentences
  - Professional (no errors in writing)
  - Act like Steve Jobs (sell your ideas)
- Reiterate important messages in different places
  - Hypothesis, goals
- Translational knowledge / medicine

MISSOURI S&T

A few Important Things

- Letter of Support from a MD
  - Be specific in role playing
- Letter of Institutional eligibility for R15 from Provost or similar official
- Be careful when using Appendix
- Budgeting & Justifications (S&T OSP)
- Resubmission: https://grants.nih.gov/grants/policy/amendedapps.htm

MISSOURI S&T

Upcoming Changes

- There will be changes after May 25th, 2021
  - Biosketch Format Page
  - Other Support Format Page
  - Refer to
    - https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-073.html

MISSOURI S&T

Research Interest at S&T

1. Eye research (disease treatment) - **funded**
2. Biomarkers for disease diagnosis - **funded**
3. Chemistry for pharmaceuticals and agrochemicals – **funded**
4. Machine learning and cardiovascular diseases – **funded**
5. Sensor related to infectious diseases, diabetes, wound healing - **funded**
6. Imaging and diseases - submitted
7. Music and neurodegenerative diseases - submitted
8. AI to enhance instrument algorithm
9. Bioinformatics / Medical Informatics

MISSOURI S&T

Newly Published Today!

- Early-Stage Development of Data Science Technologies for Infectious and Immune-mediated Diseases (U01 Clinical Trial Not Allowed)
  (RFA-AI-21-020)
  National Institute of Allergy and Infectious Diseases
  Application Receipt Date(s): Multiple dates, see announcement.
- Enhancement or Sustainment of Data Science Tools for Infectious and Immune-Mediated diseases (U24 Clinical Trial Not Allowed)
  (RFA-AI-21-021)
  National Institute of Allergy and Infectious Diseases
  Application Receipt Date(s): Multiple dates, see announcement.
- Exploratory Data Science Methods and Algorithm Development in Infectious and Immune-mediated Diseases (R21 Clinical Trial Not Allowed)
  (RFA-AI-21-035)
  National Institute of Allergy and Infectious Diseases
  Application Receipt Date(s): Multiple dates, see announcement.

MISSOURI S&T

Bio-X Constellation Shared Drive

- https://drive.google.com/drive/u/0/folders/0AO8rI_hfHukyUk9PVA
- Let me know at huangy@mst.edu

MISSOURI S&T

From NIH Reviewer's Perspective

Your proposal shall make it easy for the reviewers to fill the template in ("The Significance of this application…", "The innovativeness of this application…", etc.)

Significance

If all the specific aims are achieved, what would the project contribute to this field and how significant/important is this contribution?

- Significance assumes success of the specific aims.
- Premise pertains to the strength of the scientific foundation upon which the objectives of the study, or Clinical Trial, are built. Is the current project based on sound scientific knowledge or concepts?
- Focus on the importance of the proposed work in the field, NOT the importance of the disease or condition (e.g., child obesity, probe development) being studied.
- Direct relevance to human health is not required. Significance can be related to the basic/ fundamental, mechanistic, technological, translational, clinical and public health contributions.

MISSOURI S&T

Investigators

Does the investigative team have the collective expertise to lead the project, do the work and interpret the results?

- Assess evidence of appropriate expertise for the proposed project.
- Assess evidence of or potential for successful project management and execution.
- Investigator independence should not be considered.
- For Multi-PI applications, you should address each Principal Investigator and the leadership plan.
- For Multi-Center Clinical trials, you should address the organizational structure and investigators for the coordinating center.

MISSOURI S&T

Innovation

Does the application challenge or seek to shift current research or clinical practice paradigms? Are novel concepts/approaches/methods/instrumentation/interventions employed?

- Assess the level of "out-of-the-box" thinking. This may involve new directions and/or unique approaches, or for example, the use of existing methods in one field to advance another field.

Don't feel obligated to look for reasons why an application is innovative if you don't think it is. Innovation need not be a driver of impact. High innovation is often related to high significance, but there is important work that will impact the field that is not innovative by nature. You can assign a weak innovation criterion score and still assign a strong Overall Impact score.

MISSOURI S&T

Approach

Are the strategy, methods, and analyses well-reasoned and appropriate to accomplish the aims?

- Keep your focus on the big picture. Focus more on rationale and study design than on minor details.
- Describe why you think an aspect of the approach is a strength or a weakness. Evaluate if the strategy proposed is likely to produce unbiased and interpretable results. Does the application appropriately account for sex and relevant biological variables? If a Clinical Trial, does the study provide adequate power, use an appropriate study population, address potential ethical issues and include methods to assess effects of intervention and quality control?
- Avoid simply restating the key aims of the application.
- Taking risks in the approach is acceptable.
- Prioritize strengths/weaknesses, i.e. if the comment is major (score-driving) or minor, state this in the critique (otherwise, concerns will be assumed to be of equal weight).

MISSOURI S&T

Environment

Are the resources, facilities and equipment appropriate for the needs of the proposed project?

- This should NOT be an assessment of the quality of the institution.
- Think about what environment and resources are necessary for the project's success and evaluate the institution's ability to provide the necessary conditions and support.
- For Clinical Trials, think about capabilities of all sites/centers for data coordination, enrollment, laboratory testing and conducting the trial.

MISSOURI S&T