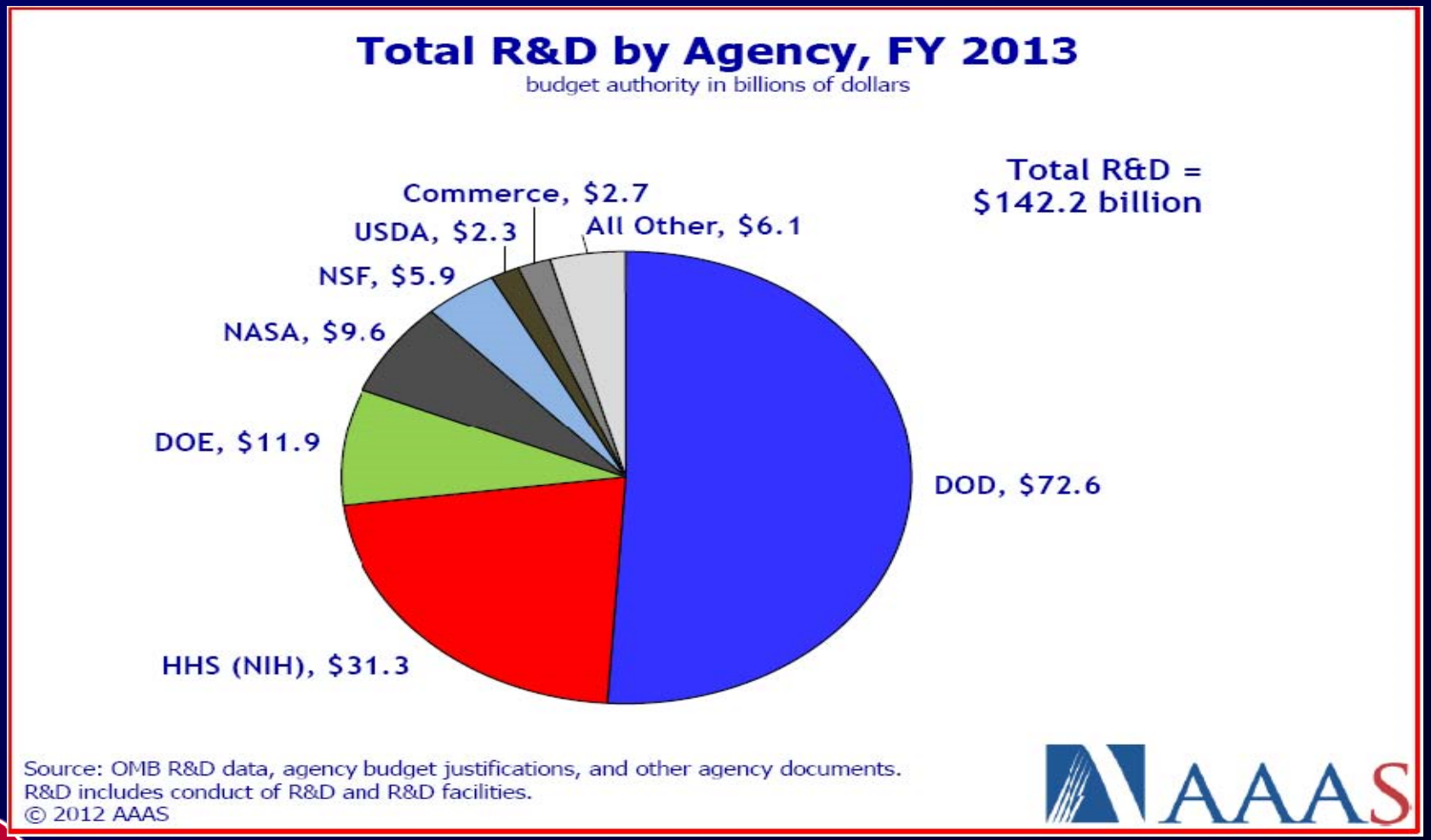
Overview of the National Institutes of Health

- Mickey McLaurin
  - Research Administration Advisor—Pre-Award
  - The University of Mississippi

Federal Funding Landscape



NIH MISSION

- **NIH's mission is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability.**

NIH Funding

- The NIH invests nearly $32.3* billion annually in medical research for the American people.
- More than 80% of the NIH's funding is awarded through almost 50,000 competitive grants to more than 300,000 researchers at more than 2,500 universities, medical schools, and other research institutions in every state and around the world.

NIH Funding Rates

- For FY15 on Research Project Grants
  - 18.3% success rate
  - 9540 awarded applications out of 52,190 applications
  - $4.3 Billion awarded
- Source https://report.nih.gov/success_rates/Success_ByIC.cfm

NIH Structure

- 27 Institutes and Centers (ICs)
- Each has its own specific research agenda, often focusing on particular diseases or body systems.
- For UM Researchers, the ICs are the entities that PROVIDE FUNDING

Mechanism/Activity Code

- An Activity Code is a 3-character code used to identify a specific category of extramural research activity, applied to financial assistance mechanisms.
- NIH uses three funding mechanisms for extramural research awards: grants, cooperative agreements and contracts.
- Within each funding mechanism, NIH uses 3-character activity codes (e.g., F32, K08, P01, R01, T32, etc.) to differentiate the wide variety of research-related programs NIH supports.
- A comprehensive list of activity codes is on the NIH Web site at http://grants.nih.gov/grants/funding/ac_search_results.htm.

Mechanism/Activity Code

- So each Activity Code has a meaning; it provides info on the amount of funding, the nature of the research proposed, and possibly the duration of the standard award

Mechanism/Activity Code

- Some of the major Activity Codes include
  - F Series—Fellowship programs
  - K Series—Research Career Enhancement and Development programs
  - P Series—Research Program Projects and Centers
  - R Series—Research Projects

R-Series Activity Codes

- Examples, not a complete list
- R01—Research Project
  - To support a discrete, specified, circumscribed project to be performed by the named investigator(s) in an area representing his or her specific interest and competencies.
- R03—Small Research Grants
  - To provide research support specifically limited in time and amount for studies in categorical program areas. Small grants provide flexibility for initiating studies which are generally for preliminary short-term projects and are non-renewable.

R-Series Activity Codes

- **R15—Academic Research Enhancement Awards (AREA)**
  - **Supports small-scale research projects at educational institutions that provide baccalaureate or advanced degrees for a significant number of the Nation's research scientists but that have not been major recipients of NIH support.**
- **R21—Exploratory/Developmental Grants**
  - **To encourage the development of new research activities in categorical program areas. (Support generally is restricted in level of support and in time.)**

Application Submission

- Registration in eRA Commons
- Submission via Grants.gov or NIH ASSIST
  - We can offer separate workshops on these processes
  - Work with your ORSP Program Development Specialist

Peer Review

- Applications go to Center for Scientific Review (CSR) for "First Level" review.
- Scientific Review Officer (SRO) reviews and assigns application to a Scientific Review Group (SRG)
  - ("Study Sections" are a type of standing SRG)
- SRG conducts peer review based on NIH Review Criteria (more later) and either does not score an application (bad), or issues an Overall Impact Score; aka a Priority Score (good)

Peer Review

- Advisory Council or Board then conducts “Second Level” review
- NIH program staff members examine applications and consider the overall impact scores given during the peer review process, percentile rankings (if applicable) and the summary statements in light of the Institute/Center's priorities.
- The Institute/Center director makes final funding decisions based on staff and Advisory Council/Board advice.

Peer Review

- Details on Peer Review process
- http://grants.nih.gov/grants/peer_review_process.htm#Overview
- Volunteer to become a Peer Reviewer
- http://grants.nih.gov/grants/peer/becoming_peer_reviewer.htm

The IDEA

- What is your hypothesis?
  - Is it testable?
  - Are the results quantifiable?
- NIH Specific Aims (handout)
  - A TESTABLE hypothesis
  - In an area of HIGH INTEREST

The APPLICATION

- NIH uses the term “application” as opposed to “proposal”
- What do you need to know first?
  - THE REVIEW CRITERIA
  - http://grants.nih.gov/grants/writing_application.htm
  - What follows is edited for space considerations, so please go to the source

NIH REVIEW CRITERIA

- **SIGNIFICANCE**
  - Does the project address an important problem or a critical barrier to progress in the field?
  - If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved?
  - How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

NIH REVIEW CRITERIA

- **INVESTIGATOR(S)**
  - Are the PD/PIs, collaborators, and other researchers well suited to the project?
  - If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)?
  - If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

NIH REVIEW CRITERIA

- **INNOVATION**
  - Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions?
  - Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense?
  - Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

NIH REVIEW CRITERIA

- **APPROACH**
  - Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project?
  - Are potential problems, alternative strategies, and benchmarks for success presented?
  - If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed?
  - If the project involves clinical research, …<are compliance questions and diversity addressed?>

NIH REVIEW CRITERIA

- **ENVIRONMENT**
  - Will the scientific environment in which the work will be done contribute to the probability of success?
  - Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed?
  - Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

NIH REVIEW CRITERIA

- **Additional Review Criteria**
- **As applicable for the project proposed, reviewers will consider the following additional items in the determination of scientific and technical merit, but will not give separate scores for these items.**
  - **Protections for Human Subjects**
  - **Inclusion of Women, Minorities, and Children**
  - **Vertebrate Animals**
  - **Biohazards**
  - **Resubmission/Renewal/Revision**

NIH REVIEW CRITERIA

- **Additional Review Considerations**
- **As applicable for the project proposed, reviewers will address each of the following items, but will not give scores for these items and should not consider them in providing an overall impact/priority score.**
  - **Applications from Foreign Organizations**
  - **Select Agent**
  - **Resource Sharing Plans**
  - **Budget and Period Support**

NIH REVIEW CRITERIA

- PLUS—look to the Program Announcement for other, specific **REVIEW CRITERIA**
- Remember, the reviewers will have a **CHECKLIST**
  - http://enhancing-peer-review.nih.gov/guidance_reviewers.html
- All of these questions must be addressed for a proposal to successful
- How do we address them? In the **APPLICATION**

The APPLICATION

- What is an "application" (or "proposal")?
  - EVERYTHING! ALL the parts
  - The Research Strategy/ Narrative/ Project Description/ Text is the *main* part of your argument
  - But all of the application components serve a purpose, and cannot be skipped over

The APPLICATION

- The SF424(R&R) Application Guide
- http://grants.nih.gov/grants/funding/424/index.htm#inst
- The GUIDEBOOK for assembling your application
- Defines WHAT information goes WHERE
- Every section has a part to play in NIH's review process

The APPLICATION

- For NIH, what are the PARTS/COMPONENTS?
  - SF 424(R&R) Form (the "cover page")
  - The Cover Letter (optional)
  - Project/Performance Site Locations
  - Other Project Info Form
    - Human Subjects?
    - Animal Subjects?
    - Proprietary Privileged Info?
    - International Collaboration?

The APPLICATION

- **NIH Application Parts/Components (continued)**
  - ***Project Summary/Abstract***
  - ***Project Narrative (two to three sentences describing the relevance to the* public health*)***
  - **Bibliography/References Cited**
  - **Facilities & Other Resources**
  - **Equipment**
  - **Senior/Key Persons Profile(s)**
    - **Biographical Sketches**

The APPLICATION

- NIH Application Parts/Components (continued)
  - Budget—Modular or Detailed?
    - Budget Justification(s)
    - *Justify* the costs, don't just explain them
    - Justification requirements are different for Modular vs. Detailed budget requests
      - Make sure the info required by the budget type is included
  - Cover Page Supplement Form

The APPLICATION

- **PHS 398 Research Plan FORM**
  - **The majority of the actual "writing"**
  - **Introduction (only for Resubmissions)**
  - ***Specific Aims***
  - ***Research Strategy***
  - **Human Subjects Sections**
  - **Vertebrate Animals**
  - **Select Agent Research (if applicable)**

The APPLICATION

- **PHS 398 Research Plan FORM (continued)**
  - **Multiple PI/PD Leadership Plan (if applicable)**
  - **Consortium/Contractual Arrangements (if applicable)**
  - **Letters of Support**
  - **Resource Sharing Plans (if applicable)**
  - **Appendices (used only rarely)**

The APPLICATION

- Once we know the PARTS/ COMPONENTS of the Application, we must MESH them with the REVIEW CRITERIA
- How to do this is covered in both the SF424 (R&R) Application Guide and on the NIH Peer Review Web Site
  - http://grants.nih.gov/grants/peer/peer.htm

The APPLICATION

- **SIGNIFICANCE, INNOVATION, APPROACH**
  - **The Research Strategy**
  - **The Project Summary/Abstract**
  - **The Project Narrative**

The APPLICATION

- **ENVIRONMENT**
  - The Biographical Sketches
  - Facilities and Other Resources
  - Equipment

The APPLICATION

- **INVESTIGATORS**
  - The Biographical Sketches
  - The Research Strategy
  - The Multiple PI Management Plan (if applicable)

The APPLICATION

- NIH gives you the map, including:
- IMPORTANT WRITING TIPS http://grants.nih.gov/grants/writing_application.htm#tips
- Remember:
  - Don't bury your hypothesis
  - Check grammar and spelling
  - Make it EASY for the reviewers

The APPLICATION

- **COMPLIANCE with Application Guidelines is CRITICAL**
  - **FONTS!!!**
  - **MARGINS!!!**
  - **PAGE LIMITATIONS!!! (Specific Aims, Research Strategy)**
  - **LINE LIMITATIONS!!! (Project Summary/Abstract)**
- **DO NOT give the sponsor an excuse to throw out a proposal before it even gets to the reviewers**

Other ways to PREPARE

- Seek out collaborators and mentors
- Serve on review panels
  - http://grants.nih.gov/grants/peer/becoming_peer_reviewer.htm
- Engage with Program Officers

Takeaways

- Consult with your peers, especially those with NIH funding histories
- Consult with ORSP
- Reach out and engage with Program Officers
  - ORSP can facilitate
- Prepare early!!!