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NIH Grantsmanship Workshop

Preparing an R01 Research Application

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1

What is an R01 Grant?

The Research Project (R01) grant is an award made to support a discrete, specified, circumscribed project to be performed by the named investigator(s) in an area representing the investigator's specific interest and competencies, based on the **mission of the NIH**

https://grants.nih.gov/grants/funding/r01.htm

2

What is an R01 Grant?

- The Research Project Grant (R01) is the original and historically oldest grant mechanism used by NIH.
- R01s provide support for health-related research and development based on the mission of the NIH.
- R01s can be investigator-initiated or can be solicited via a Request for Applications.
- The R01 research plan proposed by the applicant must be related to the stated program interests of one or more of the NIH Institutes and Centers based on their missions

https://grants.nih.gov/grants/funding/r01.htm

3

View funded R01 Grants

- The Research Portfolio Online Reporting Tools (RePORT) website provides information about research grants including the number of funded new and competing R01s, average award dollars and characteristics of research project grants.
- Also allows users to access publications and patents resulting from NIH funding.
- Enter just about anything in the RePORTER Quick Search box (text, PI names, project numbers, fiscal year, agency) or launch “Advanced Search” to precisely configure searches using separate search fields.

https://report.nih.gov

4

Components of an R01 Grant

- Project summary / abstract
- Specific aims
- Significance
- Innovation
- Approach / r
- Budget and J
- Human Subje
- Resources ar
- Research sha
- Leadership p

- Focus & parts may vary depending on the NIH program announcement
- PA = program announcement whose applications will be reviewed
- PAR = program announcement with special receipt, referral and/or review considerations.

- Identify and work with your grant administrator at your institution

5

Project Summary /Abstract

(usually around 30 lines)

- Describe succinctly every major aspect of the proposed project
  - Brief background of the proposed project
  - Specific aims; objectives; hypotheses
  - Significance and relevance to public health
  - Unique features and innovation
  - Methodology
  - Expected results
  - Impact on the research field

Write Last

- Write the abstract last
  - Used in review
  - In annual reports
  - Dissemination to the public

6

Specific Aims

Three key aspects about your proposal

- **why** you want to do the work?
- **what** you want to do?
- **how** you want to do it?

7

Specific Aims (one page)

- Long-term goals (short narrative)
- Specific objectives/aims and hypotheses to be tested
  - Usually 2-4 aims (each with a sentence with short paragraph)
  - Make sure your aims are testable
  - Make sure they are related
  - Make sure they are not too ambit
  - Make sure they have supporting data
  - Make sure you give succinct approach
- Note the innovation
- Summarize expected outcomes
- Describe impact on the research field

- Draft First
- Organize Thoughts
- Discuss with others

8

Significance

- Explain the importance of the problem or describe the critical barrier to progress in the field that is being addressed
- Give state of existing knowledge
  - Literature Review
- Rationale of the proposed research
- Gaps that the project is intended to fill
- Potential contribution of this research to the scientific fields and public health
- Clarify the scientific premise

9

Scientific Premise

- Scientific premise is NOT scientific significance
- The research that is used to form the basis for the proposed research question(s)
- Retrospective consideration of the foundation for the application rather than a prospective analysis should the aims be achieved.
- Describe the general strengths and weaknesses of prior research (published or preliminary data) critical to the support of the application
  - Information gaps
  - Rigor (or lack of) in the previous experimental designs
  - Incorporation of relevant biological variables
  - Authentication of key resources

10

Innovation

- Explain how the application challenges and seeks to shift current paradigms
  - Support with literature review
- Why are concepts and methods are novel to the field
- Note innovation in study design and outcomes
- Summarize novel findings that is included in the preliminary data in the approach

11

Approach

- Can present the plan, aim by aim, and have within each aim preliminary studies and methods (research design)

Or

- Can present the plan by initially noting all the preliminary studies, and then going through the methods (research design) aim by aim

12

Approach: Research Design and Methods

- Overview of preliminary studies
  - Relevant to research plan
  - Concise
- Overview of research design
  - Research team and collaborations
  - Presence of crucial resources
  - Methods of "how" and "why"
- Discussion of potential difficulties and limitations, and how these will be overcome or mitigated
  - Expected results and alternative approaches if unexpected results are obtained
- Timeline
- Include scientific rigor in methods of data collection and statistical evaluations & comparisons
- Include biological variables in methods

13

Scientific Rigor

- Relates to the strict application of the scientific method to ensure robust and unbiased experimental design, methodology, analysis, interpretation, and reporting systems
- Robust results are obtained with solid, well-controlled experiments capable of being reproduced under well-controlled conditions using reported experimental details.
- Consider methods to reduce bias. Examples:
  - Define terminology in advance
  - Use independent blinded assessors
  - Bootstrapping

14

Biological Variables

- Critical factors that affect health or disease, such as sex, age, weight, and underlying health condition.
  - For example, sex is a biological variable that is frequently ignored in animal study designs and analysis, leading to an incomplete understanding of potential sex-based differences in basic biological function, disease processes, and treatment response.
  - NIH expects that sex as a biological variable will be factored into research designs, analyses, and reporting in vertebrate animal and human studies
  - Strong justification from the scientific literature, preliminary data, or other relevant considerations must be provided for applications proposing to study only one sex.
- This aspect is now included into your review score.

15

Human Subjects

https://humansubjects.nih.gov

- **For applications that propose the use of human specimens or data but are not considered human subjects research**: Check "No" to Human Subjects. You should upload a Protection of Human Subjects section that clearly discusses the source of all human specimens and data and state whether or not anyone on the research team has the ability to link the specimens or data to subjects' identifiable information.
- **For applications that propose research involving human subjects that meets one of the six exemptions**: Check "Yes" to Human Subjects. Check "Yes" to Exempt from Federal regulations. Check the appropriate exemption number(s). You will need to provide a detailed justification in the Protection of Human Subjects section that explains why your study is considered to be exempt from Federal regulations.
- **For applications that propose non-exempt research involving human subjects**: Check "Yes" to Human Subjects. Check "No" to Exempt from Federal regulations. You must submit a complete Protection of Human Subjects section.
- https://humansubjects.nih.gov/sites/hs/public_files/preparing_the_human_subjects_section.pdf

16

Vertebrate Animals

- https://grants.nih.gov/grants/olaw/VASfactsheet.pdf
- Description of Procedures
- Justifications
- Minimization of Pain and Distress
- Euthanasia

17

Investigative Team

- Single PI vs. Multiple PIs
  - Need to justify having multiple PIs
  - Leadership Plan part of grant
  - New investigator?
- Do you have all the needed expertise via the grant PIs, co-investigators, collaborators, statistician, and consultants
- Have biosketches and consultant letters

18

Environment; Resources & Facilities

- Demonstrate that you have all the necessary resources and facilities
  - Including institutional support
  - Equipment & Cores
  - Statistical resources
  - Are their unique aspects of your environment?
    - Databases?
    - Subject populations?
    - Existing collaborations?

19

Budget & Budget Justification

- Present and justify all expenses required to achieve project aims and objectives
- For multi-institutional collaborations, each must have a budget & justification

20

Budget & Budget Justification

Allowable Costs

- Salary and fringe benefits for Principal Investigator, key personnel, and other essential personnel
- Equipment and supplies
- Consultant costs
- Alterations and renovations
- Publications and miscellaneous costs
- Contract services
- Consortium costs
- Facilities and Administrative costs (indirect costs)
- Travel expenses

- As a general rule, R01 application budgets are not limited but need to reflect the actual needs of the proposed project. However, R01s can be limited in a specific FOA, so it is important that applicants note any budgetary limits

21

NIH New Data Management and Sharing (DMS) Policy

- NIH has a longstanding commitment to making the results of NIH-funded funded research available.
- Responsible data management and sharing has many benefits, including accelerating the pace of biomedical research, enabling validation of research results, and providing accessibility to high-value datasets.
- PIs and funding recipient institutions are expected to make the results and accomplishments of their activities available to the research community and to the public at large.

https://sharing.nih.gov

22

Sharing Scientific Data

- Sharing scientific data accelerates biomedical research discovery, enhances research rigor and reproducibility, provides accessibility to high-value datasets, and promotes data reuse for future research studies.
- Under the NIH Data Management & Sharing Policy, investigators are empowered to choose the most appropriate methods for sharing scientific data.
- Selecting data repositories.
- https://sharing.nih.gov

23

Repositories for Sharing Scientific Data

- In general, NIH does not endorse or require sharing data in any particular repository, although some initiatives and funding opportunities will have individual requirements.
- Overall, NIH encourages researchers to select the repository that is most appropriate for their data type and discipline.

- https://sharing.nih.gov/data-management-and-sharing-policy/sharing-scientific-data/repositories-for-sharing-scientific-data
- Imaging examples on the list include
  - TCIA http://www.cancerimagingarchive.net
  - IDC https://portal.imaging.datacommons.cancer.gov
  - MIDRC https://www.midrc.org

24

Components of an R01 Grant

- Project summary / abstract
- Specific aims
- Significance
- Innovation
- Approach / research design
- Budget and Justification
- Human Subjects and/or Vertebrate animals
- Resources and environment
- Research sharing plan
- Leadership plan if multiple PIs

- Discuss with others
- Avoid typos

- Identify and work with your grant administrator at your institution

25

Preparing an R01 Research Application
Closing Comments

- Write your grant for the main reviewers so that they will advocate for it at the study section
- Remember that study section includes many intelligent scientists from different fields
  - not all members are experts in your area, but they all score your grant. Also, there could be a biostatistician.
- Make your proposed plan clear to the reviewers
  - Don't make them do the work, e.g., clearly state what a figure or table is "saying"
- Make the reviewer understand that your proposed research is important, and that you and your team can do the research.

26

Thank you

- Questions?

27