Considerations for NIDA/NIH Funding in HIV/AIDS Ethics Research

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So, what's the next step

- An efficacy-type trial (R01)?
- A pilot intervention trial (R34)?
- A larger exploratory study (R21)?
- A very large explanatory study (R01)?
- Something else?

Considerations for Intervention R01s

- Efficacy trials of interventions (R01) need:
  - Strong empirical and theoretical base for the intervention
  - A well integrated conceptual framework
    - Aims, hypotheses measures should align
    - Premise should be strong
    - Mediators and moderators should be addressed, and integrated into the evaluation of outcomes
  - Clear clinical or public health implications
  - Pilot data
    - The more the pilot work resembles the R01 the better
    - Substantial changes or adaptations to a new setting, population or mode of delivery often are more appropriate for R34 than an R01
  - Pilot data should provide:
    - Bases for estimating power & sample size
    - Evidence of acceptability, feasibility, & indications of behavior change
  - New clinical stewardship guidelines apply: premise, timeline, rigor/replicability, sample size justification, dissemination plan

Considerations for Non-intervention R01s

- Large explanatory studies (R01) need:
  - Strong empirical and conceptual bases for the aims & hypotheses
    - Research questions that are novel in terms of content or methods
    - Aims should be aligned with important clinical or public health questions
    - Premise should be strong
  - A well-integrated conceptual framework
    - Aims, hypotheses, and measure should align; premise (justification from past research) should be strong
    - Mediators and moderators should be addressed and integrated into the principal analyses
  - Pilot data should have similar methods and populations
  - Preliminary research should provide:
    - Bases for estimating power & sample size
    - Evidence supporting the importance of the question and the associated variables of interest

Considerations for R34s

- Pilot trials of interventions (R34) need:
  - Feasibility/acceptability as primary objectives
  - Strong empirical and theoretical base for the intervention
    - Preliminary/pilot data not required, but formative findings or a small pilot can help
    - Premise should be strong
  - A well integrated conceptual framework
    - You won't have power to test the complete model, but should be able to look at gross, univariate outcomes & changes in possible mediators/moderators
  - Any preliminary research should:
    - Provide a rationale for moving to an intervention
    - Be relevant to the population, setting, or modality of interest unless the R34 is used for adaptation/implementation
  - New clinical stewardship guidelines apply: timeline, rigor/replicability, sample size justification, dissemination plan

Considerations for R21s

- Further exploratory research (R21). Needs:
  - Strong empirical and theoretical base for aims & hypotheses
    - Address novel research questions in terms of content or methods
    - Aims aligned with important clinical or public health questions
    - Strong premise
  - Well integrated conceptual framework
    - Aims, hypotheses & measures should align
    - Potential mediators and moderators should be addressed at least at the univariate level
  - Preliminary data not required; any preliminary research should provide:
    - Evidence supporting the importance of the question and related variables of interest
    - A rationale for continuing exploratory research
      - Going from analogue to real world;
      - Going from 2ndary analysis, meta-analysis or thematic review to empirical study

R15 AREA/REAP

- Institution must meet criteria
  - Less than $6M in NIH grant support during the previous 4 years
  - Institution must document; NIH no longer keeps a roster
- AREA: Focus on undergraduate research training
  - NIGMS PAR 19-133 (Clinical Trial), PAR18-714 (Not Clinical Trial)
  - Up to 300K over up to 3 years
- REAP: Focus on health profession and graduate training
  - NIDCR PAR 19-134 (Clinical Trial), PAR19-135 (Not Clinical Trial)
  - Up to $300K over up to 3 years

NIDA Mechanisms/Opportunities for Young Investigators

- A-START (R03) PA-18-916 (Clinical Trial Optional)
  - Large R03 (up to 100K/yr), up to 2 years; new investigators including new to HIV or new to drug Use
- B-START (R03) PAR-18-082 (Clinical Trial Optional)
  - Large R03 (up to 75K) but short (1 yr) award; new investigators, not HIV-specific
- Avenir Award RFA-DA-18-004
  - Innovative projects (300K/yr for up to 5 years)

Other Recent NIDA Current Funding Announcements

- PrEP for HIV Prevention among Substance Using Populations - RFA-DA-20-013 (R01 Clinical Trial Optional)
- Development and Testing of Novel Interventions to Improve HIV Prevention, Care, and Program Implementation - PA-DA-18-780 (R34)
- HIV/AIDS High Priority Drug Abuse Research (R01) PAS-DA-18-915

- International Research Collaboration on Drug Abuse and Addiction Research - PA-DA-18-773 (R01)

Parent Funding Announcements

- R01:
  - PA 19-055 (Clinical Trial)
  - PA 19-056 (No Clinical Trial)
- R21
  - PA 19-054 (Clinical Trial)
  - PA 19-053 (No Clinical Trial)
- R03
  - PA 19-052 (No Clinical Trial)
- NOSIs (Notices of Special Interests): NIH Guide, Institute Websites, NIH Office Websites (SGM, OBSSR, Fogarty)

Funding Announcements: Decoding the Alphabet Soup

- **PA** – Standing Program Announcement (usually a 3 year cycle with an expiration date; often renewed)
- **PAR** – Standing Program Announcement with Special Review
- **PAS** – Standing Program Announcement with Set Aside Funds
- **RFA** – Typically a One Time Announcement with Set Aside Funds and Special Review (rarely renewed)
- **RFP** – For Contracts: Typically a One Time Announcement with Set Aside Funds and Special Review

New-ish Review Considerations

- NIH Clinical Trial Definition
  - Affects funding announcements you can use (some require a trial, others do not allow trials or make them optional)
  - Adds requirements for review, registration, reporting
  - Definition components:
    - Human participants
      - Can be healthy individuals
    - Prospective assignment to an intervention
      - Comparison condition not necessary
      - Can be intervention evaluation in service of a basic research question like pharmacokinetics
    - Evaluation of an intervention on an outcome
      - Can be a behavioral or biomedical intervention
    - Behavioral or biomedical outcome

New-ish Review Considerations

- Reproducibility (Rigor & Transparency)
  - Rigor
    - Past research—is there a strong premise for the proposed research
    - Proposed research—Rigorous, unbiased use of experimental design, methodology, analysis, interpretation and reporting
    - Sex as a biological variable; selection of population (age, race/ethnicity, gender) should be adequately defended
  - Transparency
    - Rigor and adequate explication of methods
    - Authentication of key biologic and biomedical measures

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NIDA AIDS Research Program:
https://www.drugabuse.gov/about-nida/organization/offices/aids-research-program-arp