Everything but the Science: Grantsmanship Beyond Your Aims and Strategy

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Overview

- Most important advice
- Human subjects
- Citations
- Budgets
- Abstract and project narrative
- Facilities and resources
- The **new** biosketch (starting 25 May 2025)
- MPI plan
- Tricks of the trade

Most important pieces of advice

- Understand the funding mechanisms
  - Read the Funding Opportunity Announcement (FOAs) closely
  - Call the project officer
- Follow directions
  - Follow the format directions and read the instructions
  - Looks for special instructions in the FOAs

Most important pieces of advice

- Strategize
  - Incorporate the review criteria into your DNA
  - Look at the study section composition
  - Do an NIH RePORTER search to see who is working and NIH-funded in your area
- Talk to your institution's research office as soon as you know you want to submit a grant

New Simplified Framework for NIH Peer Review Criteria

- Grant reviewers will now use these factors to determine the scientific merit of the proposed project and to assign an overall impact score, as follows:
  - Factor 1: The importance of the research (Significance, Innovation), scored 1-9
  - Factor 2: Rigor and feasibility (Approach), scored 1-9
  - Factor 3: Expertise and resources (Investigator, Environment), to be evaluated as either sufficient for the proposed research or not
- https://grants.nih.gov/policy-and-compliance/policy-topics/peer-review/simplifying-review/applicant-guidance#how-to-tell-if-your-application-will-be-impacted

There are new forms for R grants!

SF424 (R&R) - Version I

(Due dates ON/AFTER Jan. 25, 2025)

https://grants.nih.gov/grants/how-to-apply-application-guide/forms-i/research-forms-i.pdf

Format directions

- Use paper size no larger than *standard letter paper size (8 ½" x 11")*
- Provide at least ½-inch margins (top, bottom, left, and right) for all pages
  - No applicant-supplied information can appear in the margins
- No headers or footers
- Hyperlinks and URLs are only allowed when specifically noted in funding opportunities and/or form field instructions
  - It is highly unusual for a funding opportunity to allow links in Specific Aims, Research Strategy, and other page-limited attachments
  - Hyperlinks and URLs may not be used to provide information necessary to application review

https://grants.nih.gov/grants-process/write-application/how-to-apply-application-guide/format-attachments

Format directions: Font

- **Size**: Must be 11 points or larger
  - Smaller text in figures, graphs, diagrams and charts is acceptable, as long as it is legible when the page is viewed at 100%
- **Recommended fonts:** Arial, Georgia, Helvetica, Palatino Linotype
- **Type density**: Must be no more than 15 characters per linear inch (including characters and spaces)
- **Line spacing**: Must be no more than six lines per vertical inch
- **Text color**: No restriction
  - Though not required, black or other high-contrast text colors are recommended since they print well and are legible to the largest audience
  - If you are going to add color, keep in mind reviewers who may be color blind

https://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/format-attachments.htm

Human subjects forms

NIH human subjects section

- PHS Human Subjects and Clinical Trials Information form
  - Consolidates human subjects, inclusion enrollment, and clinical trial information previously collected across multiple agency forms
  - Collects information on human subjects and clinical trials at the study level
    - Leads applicants through the human subject and clinical trial information collection requirements
    - Aligns with ClinicalTrials.gov (where possible) and positions the NIH for future data exchange with ClinicalTrials.gov

https://grants.nih.gov/policy/clinical-trials/new-human-subject-clinical-trial-info-form.htm

Form sections

1. Basic information
2. Study population characteristics
3. Protection and monitoring plans
4. Protocol synopsis
5. Other clinical trial-related attachments

https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general/g.500-phs-human-subjects-and-clinical-trials-information.htm

Human subjects attachments

- Section 2
  - Inclusion of Women and Minorities
  - Inclusion of Children
  - Inclusion Across the Lifespan
  - Recruitment and retention plan
  - Study timeline
- Section 3
  - Protection of Human Subjects *
  - Multi-site study that will use the same protocol to conduct non-exempt human subjects research at more than one domestic site *
  - Data and Safety Monitoring Plan *
  - Overall Structure of the Study Team *

A note on the consent process description

- Simply saying that there will be a consent form will likely not be enough
- Describe the complete consent process, including how to deal with those who refuse to participate
- Note proposed reading level of consent form and solutions for those who cannot read
- Note that you will obtain a certificate of confidentiality (as appropriate)
- Special considerations for focus groups and in-depth interviews

Certificates of confidentiality (CoCs)

- CoCs protect the privacy of research subjects by prohibiting disclosure of identifiable, sensitive research information to anyone not connected to the research except when the subject consents or in a few other specific situations
- NIH funded researchers are automatically issued a CoC through their award
  - Other Department of Health and Human Services (HHS) agencies issue CoCs to researchers they fund
  - Researchers not funded by HHS can continue to apply to NIH or the FDA as appropriate to request a CoC for HHS-mission relevant research

https://humansubjects.nih.gov/coc/index

Vulnerable subjects

- Pregnant Women, Fetuses, and Neonates or Children
- Institutionalized individuals
- Prisoners
  - OHRP certification for the involvement of prisoners in research
- Others who may be considered vulnerable populations
  - Educationally disadvantaged
  - Economically disadvantaged

Special topics for human subjects

- Secondary data analysis
- Technology
  - GIS
  - Social media
  - Online surveys
- Educational and economic disadvantage

Exempt categories

- Exempt studies are of such limited risk that they don't need detailed IRB review
- Categories:
  - 1 – Educational Research
  - 2 – Surveys/Interview/Educational Tests
  - 3 – Benign Behavioral Interventions
  - 4 – Secondary Research
  - 5 – Research and Demonstration Projects
  - 6 – Taste and Food Quality
  - 7 – Storage/Maintenance for Secondary Research (Broad Consent)
  - 8 – Secondary Research (Broad Consent)

Exempt categories: Definitions

- Benign Behavioral Interventions (Cat. 3)
  - Research takes less than a day, is harmless/painless, and no risk of harm, emotional discomfort, offense, or embarrassment
- "Broad Consent" is optional and most institutions consider it currently unworkable
  - An alternative consent process for the storage and secondary use of identifiable private information or identifiable biospecimens for unspecified future research
  - An institution must track those who have agreed or refused consent

The rest of the application

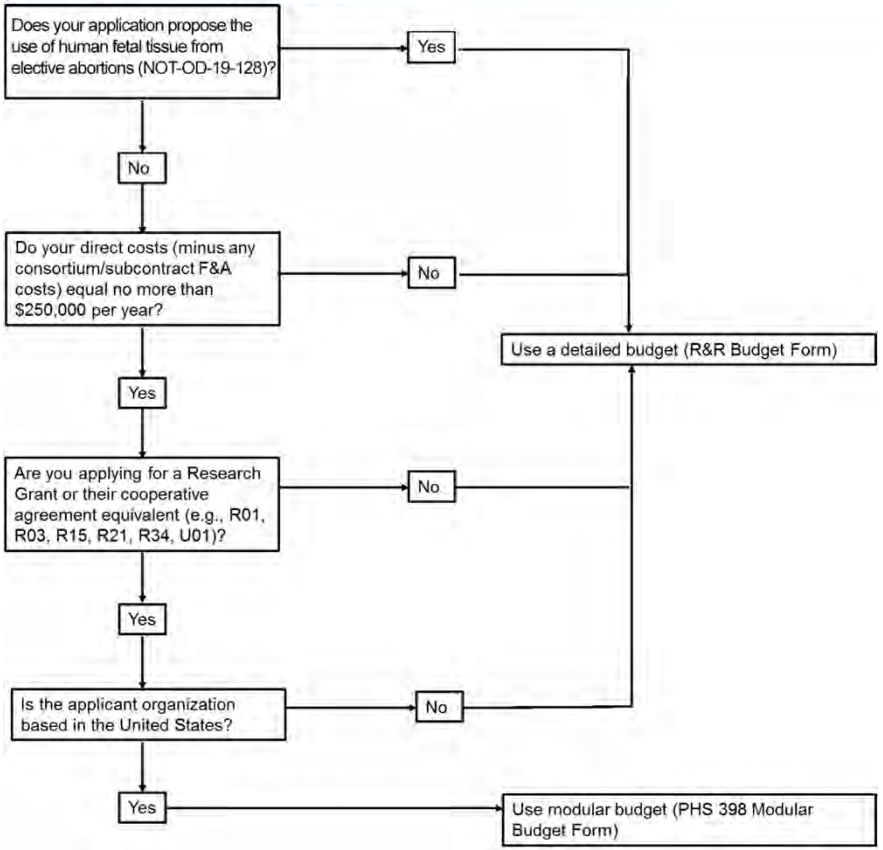
Literature Cited

- Style depends on preference/discipline
  - Pro tip: AMA (numeric superscripts) give more room to write than APA
- Use consistent format for citations
- Literature cited page does not count in page limitations
- Be strategic about citations
  - Do not leave out “heavy hitters” and competitors
  - Look at the study section roster
    - Does anyone on that roster have something relevant to your work?

Budgets

- Personnel
  - PIs & co-Is
  - Research assistants
  - Interviewers
  - Analysts
- Consultants
- Equipment
  - ≥$5000
- Trainee costs
  - Tuition
- Supplies
  - Software, printing, computers
- Travel (local, domestic, international)
- Patient care costs
- Alterations/ Renovations
- Other costs
  - Participant incentives
  - Laboratory testing
  - Phones/ Postage
  - Animals
  - Publications
- Consortium/Contractual costs
  - Subcontracts to vendors or investigators at other institutions

Modular vs. Detailed budgets



- Modular budget
  - Request funds in lump sums of $25,000 intervals
  - Reduced detail for budget and justification
  - You may need a detailed budget for your internal system
  - For annual budgets <$250,000
  - Used for R03s and R21s, sometimes R01s

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Budgeting

- Need to think carefully about effort of each team member
  - If they are named on the budget, it is a good idea to make sure they are named in the “science”
  - Make sure you have all the expertise needed to pull off the research
- Incentives can be cash, gift cards, objects, etc.
  - Depending on your population, you might want to budget for snacks
- Budget is not a part of the review criteria, but reviewers do see it
- It is typical for budgets to be cut (5-15%) if grant is awarded

Budget Justification

- Helps answer the question: “Is the bang worth the buck?”
- This section provides the rationale for all budget requests in terms of on and off-campus personnel, equipment, supplies travel, rent, etc.
- No Page Limit
- Must be credible in the experience of the reviewers
- Required for both detailed and modular budgets

Project summary/abstract

- Format
  - 30 lines of text (a longer abstract generates an error message)
- Content
  - State the application's broad, long-term objectives and specific aims, making reference to the health relatedness of the project (i.e., relevance to the mission of the agency)
  - Describe the research design and methods for achieving the stated goals
  - Be sure that the project summary reflects the key focus of the proposed project so that the application can be appropriately categorized
  - Do not include proprietary, confidential information or trade secrets in the project summary
  - **If the application is funded, the project summary will be entered into an NIH database and made available on the NIH Research Portfolio Online Reporting Tool (RePORT) and will become public information**

Project narrative

- Describe the relevance of this research to public health in, at most, **three sentences**
- For example, NIH applicants can describe how, in the short or long term, the research would contribute to fundamental knowledge about the nature and behavior of living systems and/or the application of that knowledge to enhance health, lengthen life, and reduce illness and disability
- If the application is funded, this public health relevance statement will be combined with the project summary and will become public information

Facilities and resources

- Your institution may already have boiler plate for this!
- Describe how the scientific environment in which the research will be done contributes to the probability of success (e.g., institutional support, physical resources, and intellectual rapport)
  - Discuss ways in which the proposed studies will benefit from unique features of the scientific environment or from unique subject populations or how studies will employ useful collaborative arrangements
- If there are multiple performance sites, describe the resources available at each site

Facilities and resources

- Describe any special facilities used for working with biohazards and any other potentially dangerous substances
- For early stage investigators (ESIs), describe institutional investment in the success of the investigator
  - See NIH's New and Early Stage Investigator Policies
  - Your description may include the following elements:
    - Resources for classes, travel, or training
    - Collegial support, such as career enrichment programs, assistance and guidance in the supervision of trainees involved with the ESI's project, and availability of organized peer groups
    - Logistical support, such as administrative management and oversight and best practices training
    - Financial support, such as protected time for research with salary support

The New Biosketch (for submissions on or after May 25, 2025)

- NIH will:
  - Require the use of Science Experts Network Curriculum Vitae (SciENcv) to complete Common Forms
  - Require all Senior/Key Personnel to enter their ORCID ID into SciENcv in the Persistent Identifier (PID) section of the Common Forms
  - No longer accept the NIH Biographical Sketch format page
  - Require the use of the Common Form for Biographical Sketch
  - Require the use of a new NIH Biographical Sketch Supplement to collect the "Personal Statement," "Contributions to Science," and "Honors" statements
- Additional details are coming
- https://grants.nih.gov/grants/guide/notice-files/NOT-OD-24-163.html

The Biosketch

Contribution to Science

- Briefly describe up to five of your most significant contributions to science
  - Historical background that frames the scientific problem
  - Central finding(s)
  - Influence of the finding(s) on the progress of science or the application of those finding(s) to health or technology
  - Your specific role in the described work
  - For each contribution, reference up to four relevant peer-reviewed publications or other non-publication research products
  - Description of each contribution should be no longer than one half page including figures and citations
  - Provide a URL to a full list of your published work as found in a publicly available digital database such as SciENcv or My Bibliography for PubMed

MY NCBI > SCIENCV

SciENcv

My Profile Edit

Name: Danielle Ompad, PhD

Title/Department: Professor of Epidemiology
Deputy Director, Center for Drug Use and HIV Research
New York University School of Global Public Health

ORCID ID: https://orcid.org/0000-0003-0240-0393

eRA Commons ID: 7611285

Helpful Links

About SciENcv
How to Use SciENcv

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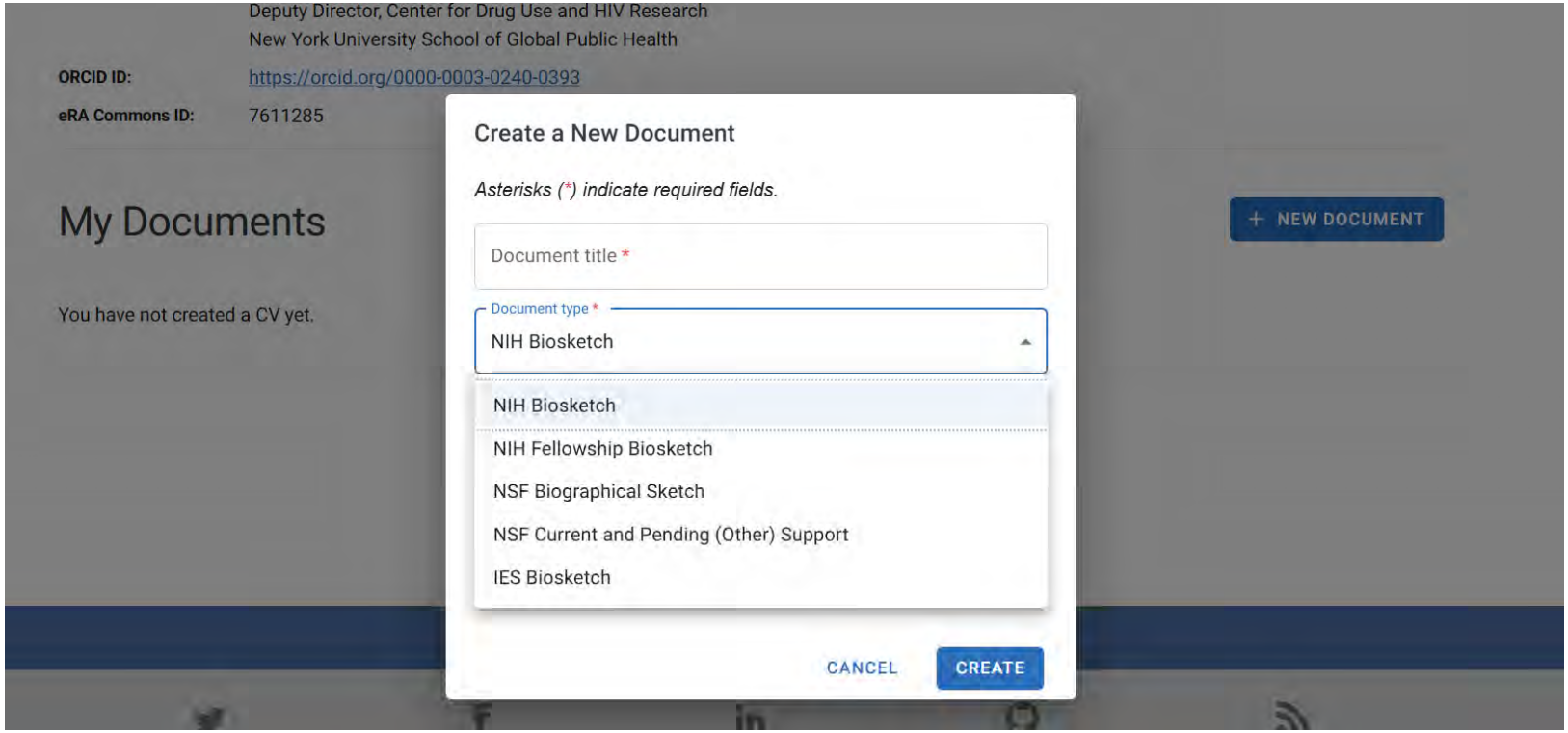
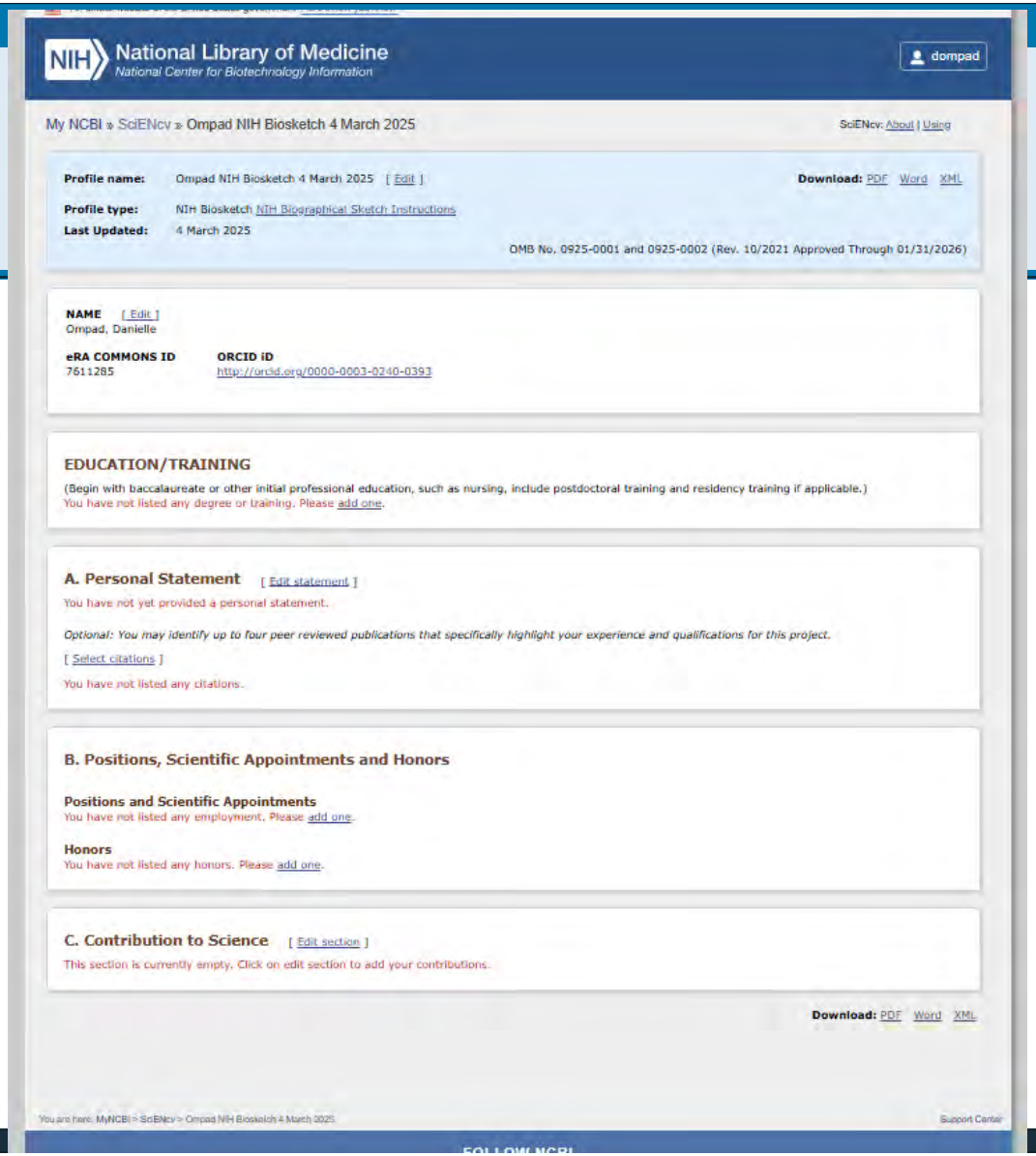

Deputy Director, Center for Drug Use and HIV Research
New York University School of Global Public Health
ORCID ID:
https://orcid.org/0000-0003-0240-0393
eRA Commons ID:
7611285
My Documents
You have not created a CV yet.
+ NEW DOCUMENT
Create a New Document
Asterisks (*) indicate required fields.
Document title *
Document type *
NIH Biosketch
NIH Biosketch
NIH Fellowship Biosketch
NSF Biographical Sketch
NSF Current and Pending (Other) Support
IES Biosketch
CANCEL
CREATE



NIH National Library of Medicine
National Center for Biotechnology Information

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SciENcv: About | Using

Profile name: Ompad NIH Biosketch 4 March 2025 [Edit]

Profile type: NIH Biosketch NIH Biographical Sketch Instructions

Last Updated: 4 March 2025

Download: PDF Word XML

OMB No. 0925-0001 and 0925-0002 (Rev. 10/2021 Approved Through 01/31/2026)

NAME [Edit]
Ompad, Danielle

eRA COMMONS ID
7611285

ORCID iD
http://orcid.org/0000-0003-0240-0393

EDUCATION/TRAINING

(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)
You have not listed any degree or training. Please add one.

A. Personal Statement [Edit statement]

You have not yet provided a personal statement.

Optional: You may identify up to four peer reviewed publications that specifically highlight your experience and qualifications for this project.

[Select citations]

You have not listed any citations.

B. Positions, Scientific Appointments and Honors

Positions and Scientific Appointments
You have not listed any employment. Please add one.

Honors
You have not listed any honors. Please add one.

C. Contribution to Science [Edit section]

This section is currently empty. Click on edit section to add your contributions.

Download: PDF Word XML

You are here: MyNCBI > SciENcv > Ompad NIH Biosketch 4 March 2025

Support Center

FOLLOW NCBI

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Linking to your work

- You may provide a hyperlinked URL to a full list of your published work
- This hyperlinked URL must be to a Federal Government website (a .gov suffix)
  - NIH recommends using My Bibliography
- Providing a URL to a list of published work is not required

If your biosketch looks sparse…

- If you are new to research, that is to be expected!
- You do not have to have five contributions to science
- Research products can include:
  - Audio or video products
  - Conference proceedings such as meeting abstracts, posters, or other presentations
  - Patents
  - Data and research materials
  - Databases
  - Educational aids or curricula
  - Instruments or equipment
  - Models
  - Protocols
  - Software or webapps

MPI Plan

MPI Plan Overview

- Describe the MPIs
- Describe roles and responsibilities
- Describe conflict resolution plan

MPI Plan: An Example

14. Multiple Principal Investigator (PI) Leadership Plan

Overview: In line with the multidisciplinary nature of the proposed project, leadership will be shared by two researchers with complementary backgrounds and areas of expertise: Dustin T. Duncan, ScD and Justin Knox, PhD. Dr. Duncan is an Associate Professor of Epidemiology at the Columbia University Mailman School of Public Health and directs Columbia's Spatial Epidemiology Lab and co-directs the department's Social and Spatial Epidemiology Unit. Dr. Knox is an Assistant Professor of Clinical Implementation Science and Intervention in the Department of Psychiatry at Columbia University Irving Medical Center. He is a New and Early Stage Investigator and is building his own research program on the intersection of substance use and HIV epidemiology among racial and sexual minorities. He has an appointment with the New York State Psychiatric Institute and is affiliated faculty at the HIV Center for Clinical and Behavioral Studies and in Columbia University's T32 Substance Abuse Epidemiology Training Program. Their combined expertise and leadership will ensure the success of this project. Dr. Duncan will serve as the contact principal investigator (PI) and overall administrator of the project, with support from Dr. Knox.

Graphical Representation of Multiple PI Leadership Plan (Personnel and Responsibilities)
The schematic below outlines how specific and shared tasks/responsibilities and personnel oversight will be divided between the multiple-PIs in the proposed research. More detail of this approach is described below.

PI
Dustin T. Duncan, ScD
Columbia University

PI
Justin Knox, PhD
Columbia University

Co-I
John Schneider, MD, MPH
University of Chicago

Consultants
Jonathan Rendina, PhD
Hunter College

Steven Safren, PhD
University of Miami

Shared Tasks/Responsibilities
- Scientific direction and study design
- Coordination of study implementation
  - Study protocols, including survey design
  - Participant recruitment procedures
- Research team communication
- Dissemination of research findings
  - Conference presentations
  - Manuscript publication
- Oversee recruitment and retention protocol
- Oversee data collection
- Oversee data entry and management

Co-Is
Silvia Martins, MD, PhD
Columbia University

Jennifer Manuz, PhD
Tulane University

Consultant
Adam Carrico, PhD
University of Miami

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Tricks of the Trade

A brief guide to NIH grantsmanship

Writing Style

- Clear
- Succinct
- Easy to follow
  - “Tell a story”
- Organized
  - Parallel construction

Signposting

- Tell your reader what you are going to tell them
  - Abstract, aims
- Tell them what you want to tell them
  - Research strategy
- Summarize what you told them
  - Abstract, aims, last paragraph of research strategy if you have room

Integrate theory or conceptual framework

- Do not just talk about your guiding theory or framework generally
- We should see it in the:
  - Study design
  - Measures
  - Analysis

Incorporate the players

- Incorporate the research team throughout the grant
  - PI
  - Co-investigators
  - Consultants
  - Institutions and organizations

Remember grammar and spelling

- USE SPELL CHECK
- Use the grammar check
- Read over the grant before you send it out
- Ask someone to read it before you submit
- Read it out loud

Things to avoid

- Narrative that jumps around
- The grant doesn’t have a logical flow
- Not defining acronyms the first time you use them
- Not incorporating figures and tables into the narrative

Don’t try to be slick

- The reviewers will focus on your science
- Do not try to put things that should be in the science into the human subjects section

Things to consider

- Figures and tables, when appropriate, are useful tools and they can break up the page for the reader
- Too much white space or not using all the pages allowed often results in the knee-jerk critique “not enough detail”
  - On the other hand… a colleague who does rat studies submits R01s with fewer than 12 pages
- Highlight “economies of scale”

Some “fatal” mistakes

- Waiting until the last minute
- Funding mechanism does not match the project
- Weak statistical plan or low power
- No back-up plans
- Lack of expertise in a key area
- Poor organization
- Weak or missing hypotheses and/or conceptual framework
- Lack of significance
- No innovation
- Too ambitious

Courtesy of Steffanie Strathdee and Tom Patterson at UCSD

Final thoughts

- Getting funded is hard and there is a lot of rejection
  - But it is NOT impossible

Institute	Proposals reviewed	Proposals funded	2023 success rate
NIAAA	717	219	30.5%
NIAID	6750	1405	20.8%
NIDA	1808	399	22.1%
NIMH	2671	579	21.7%
NIMHD	637	120	18.8%

https://report.nih.gov/funding/nih-budget-and-spending-data-past-fiscal-years/success-rates

And some hope…

- Early Stage Investigator (ESI)
  - Completed their terminal research degree or end of post-graduate clinical training, whichever date is later, within the past 10 years

    AND
  - Has not previously competed successfully as PD/PI for a substantial NIH independent research award
- ESI applications with meritorious scores will be prioritized for funding

Final thoughts

- Writing grants in a vacuum (e.g., alone) is not always productive. Even if you are the main writer…
  - Conversations about the science with colleagues will help shape your thinking
  - A second pair of eyes is invaluable
    - If someone can't read the whole document, ask them to focus on a specific section
- Talk to the project officer, they are there for clarification about the funding announcement and may be able to give some info on what's "hot" and what's "not"

Key Resources

Key resources

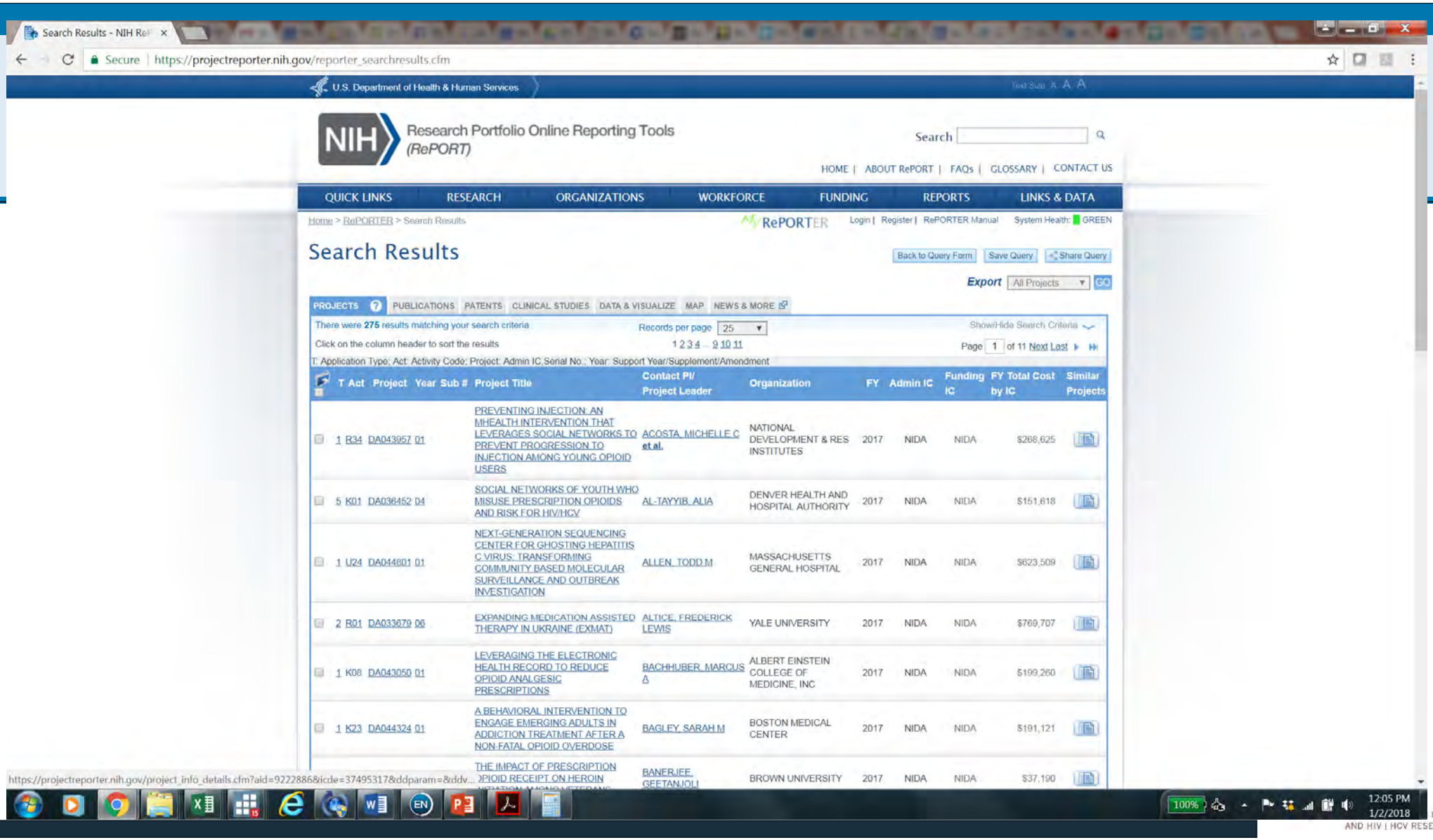
- NIH Funding Opportunities and Notices
- NIH RePORTER
- SF424 (R&R) Application Guide
- NIH Project Officers
- Other researchers

NIH Funding Opportunities and Notices

- The NIH Guide TOC
- Weekly email with new FOAs
  - To Subscribe to the NIH Guide LISTSERV, send an e-mail to listserv@list.nih.gov with the following text in the message body (not the "Subject" line):
    - subscribe NIHTOC-L your name
      - (Example: subscribe NIHTOC-L Bill Jones)
    - Your e-mail address will be automatically obtained from the e-mail message and add you to the LISTSERV

NIH RePORTer

- Research Portfolio Online Reporting Tools
- Provides access to reports, data, and analyses of NIH research activities, including information on NIH expenditures and the results of NIH supported research
  - You can get some details on funded projects
- https://reporter.nih.gov/



SF424 (R&R) Application Guide

- SF424 (R&R) Application Guide for NIH and Other PHS Agencies
  - Your bible
  - https://grants.nih.gov/grants/how-to-apply-application-guide/forms-i/research-forms-i.pdf

Thank you

Danielle Ompad: dco2@nyu.edu

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