Making the K to R Transition

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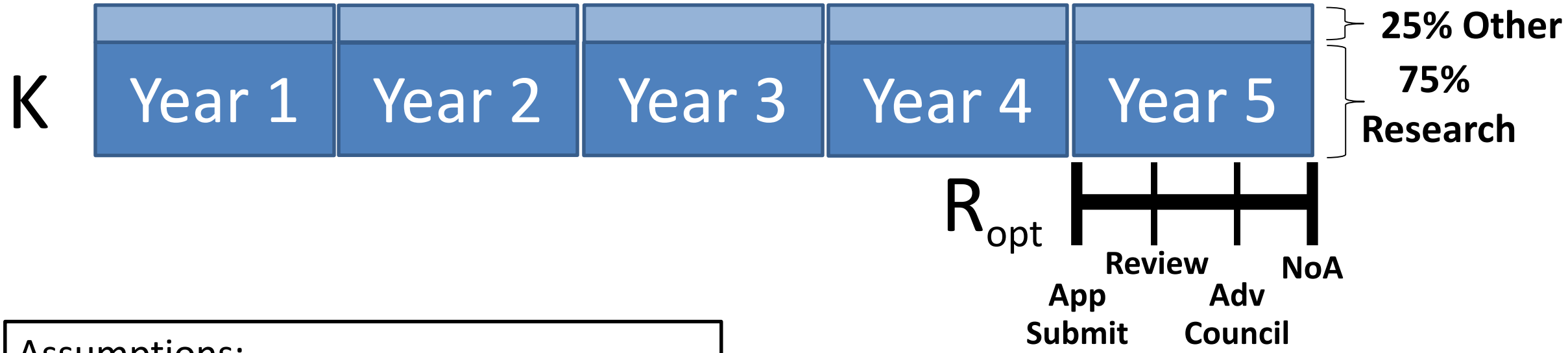
FHS ESI Retreat

October 27, 2021

National Heart, Lung, and Blood Institute

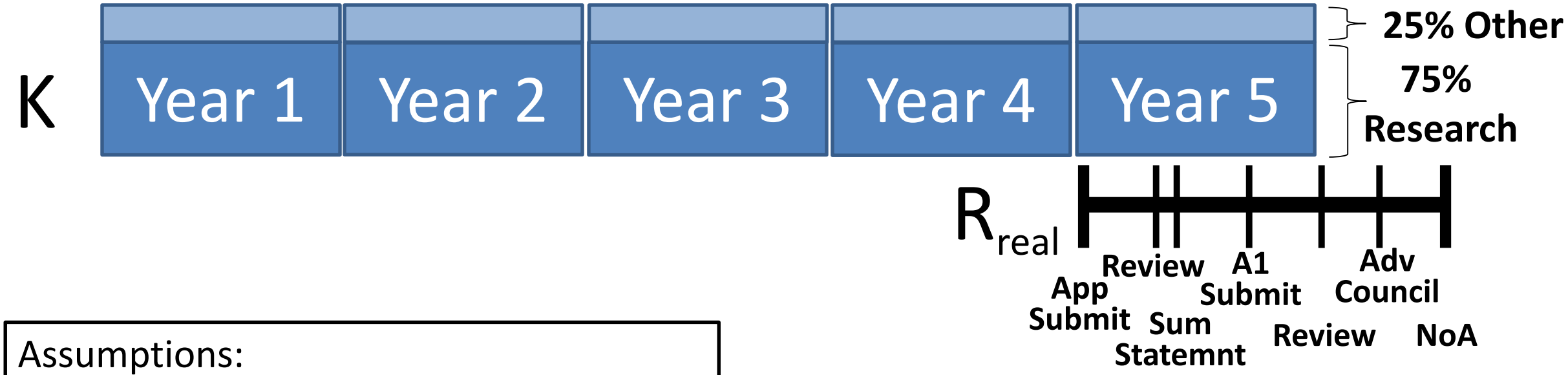
Timelines



Assumptions:

1) No funding gap
2) Ignoring dates and removing variation due to specific council cycle (NHLBI Oct. Council for cycle I)
3) Error term +/- 2 months

Timelines



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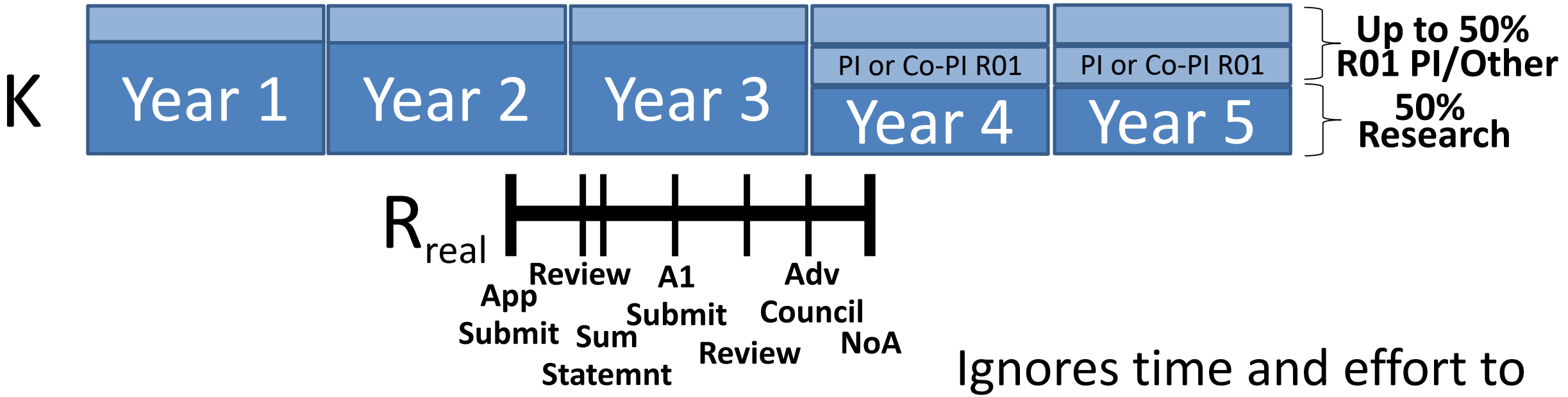


Ignores time and effort to develop application!

Conclusion: Never too early to begin R01 planning, but waiting until after the end of third year is likely too late to avoid a funding gap

Timeline Penalties (Factors prolonging time to an R01 Submission)

- Inadequate attention to the complexity of an R01 submission
  - Insufficient statistical power, need to add sites, covering all expertise needs, etc.
- Lack of attention on the budget until finalizing application
  - Budget determines what is actually feasible
- Pandemics and other unexpected or unanticipated events
  - Life events, change in institutions, department/institutional leadership changes

What can you do?

- “A goal without a plan is just a wish” - Antoine de Saint-Exupéry
  - Addition of a detailed R01 plan across the K award
    - Integrate into career development and training timeline
    - What activities are ***required*** in order to compete for an R01
      - Critical publications, prelim/pilot data
  - Review plan frequently, update timeline regularly

Consider diversifying your funding portfolio

- Major advantage of the K is the protected time for research; however, research support is limited
- Institutional awards, foundations/societies, Industry awards can provide source of funds to bolster research dollars from the K award.
- Can hold an AHA Career Development Award in addition to an NHLBI K

Take advantage of your people resources

- Mentors and advisors, local grants administrative support

- Networking opportunities with other K awardees and established investigators

Your NIH PO

Critical Life Event Supplement

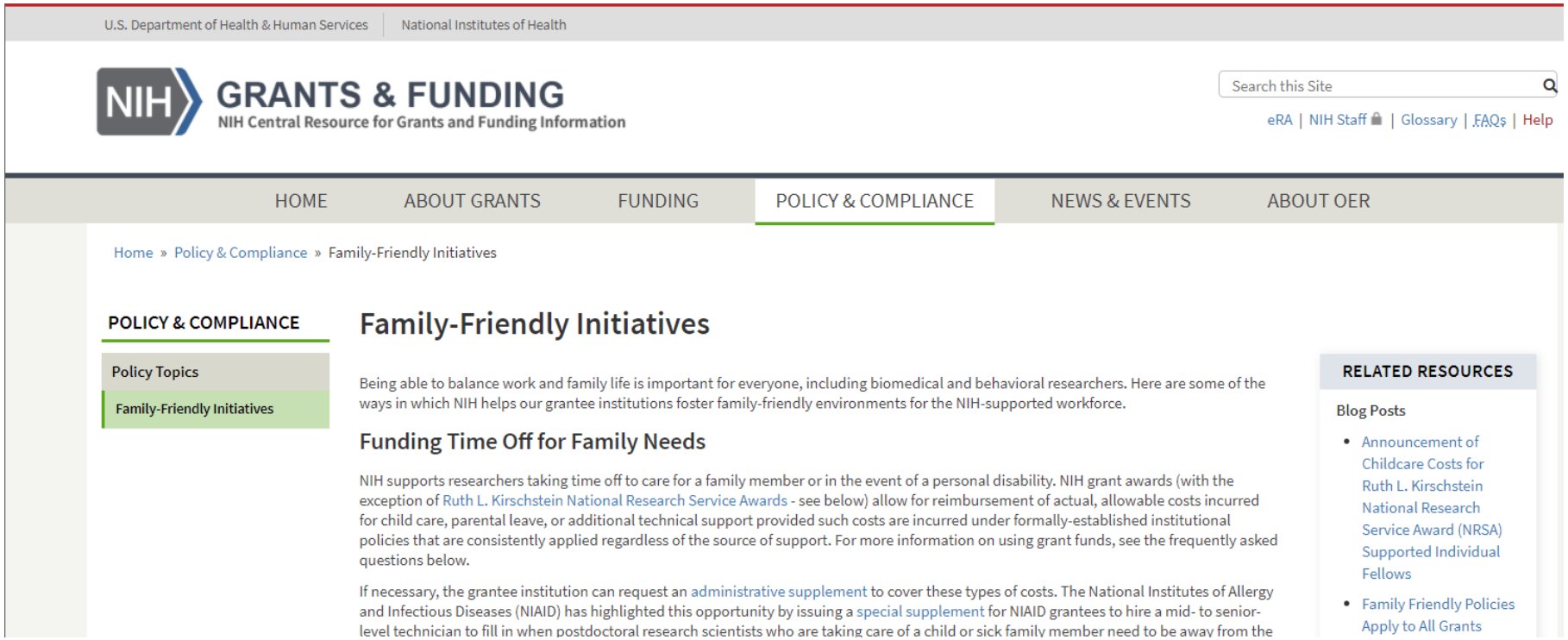
- **Critical life event (CLE)**: childbirth, adoption, or primary caregiving responsibility for an ailing immediate family member

- CLE that occurs (or expected to occur) during your project period, to provide administrative supplement funding to sustain research, help investigator remain competitive, and maintain progress toward research independence.
  - **NOT-OD-20-054 for supplements to career development awards**: K01, K08, K22, K23, K38, and K99/R00 (on the mentored K99 portion of the K99/R00)
  - **NOT-OD-20-055 for supplements to *first-time* RPGs**: R01, R00, R15, R21, R35, and U01

- Application Details:
  - NHLBI has three supplement application due dates/fiscal year: Feb 1, June 1, Oct 1
  - Describe how the life event is curtailing or is expected to curtail their research and career development and justification for how supplemental support will help them to maintain productivity. Supplement requests should be within the scope of the parent grant.
  - Any additional forms of support including carryover funds and institutional matching funds should be clearly described
  - Projects should have a minimum of one year remaining on their award on the submission due date and those in a no-cost extension period are not eligible to apply.
  - Scientific Program Contact: Jane Scott, ScD, MSN, FAHA scottj2@nhlbi.nih.gov

Family Friendly Policies

- NOT-OD-19-125 Notice of System Change and Procedure for Requesting an Extension to Early Stage Investigator (ESI) Status
- NOT-OD-18-156 Career Award (K) Policy Update: Temporary Adjustments to Percent Effort or Part-Time Institutional Appointment: Temporary reduction in % effort for up to 12 months



https://grants.nih.gov/grants/policy/nih-family-friendly-initiative.htm
https://grants.nih.gov/faqs#/nih-family-friendly-initiatives.htm

Limited Competition Small Grant Program

- RFA-HL-20-039: Limited Competition – Small Grant Program for NHLBI K01/K08/K23 Recipients (R03 – CT Optional)
  - K awardees in final two years of award, or
  - Recently completed K awardees if the earliest start date of the R03 is within 2 years of K project period end date.
  - Expand current research objectives or branch out into research that resulted from the K
  - Budgets limited to direct costs of $50K/year for up to 2 years
  - Can be helpful if need to make a pivot for R, proof of concept for methods, feasibility studies. Small budget can limit publication opportunities and draw time away for developing R

Limited Competition Small Grant Program

- RFA-HL-20-039: Limited C… …g… for M… …ecipients (R03 – CT Optional)

Currently Expired

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  - Can be helpful if need to make a pivot for R, proof of concept for methods, feasibility studies. Small budget can limit publication opportunities and draw time away for developing R

NIH 101 – The Players

- Program staff (Health Scientist Administrators, Program Directors, or Medical Officers): Institute scientists who manage all programmatic aspects of your grant
  - Pre-application: scientific and technical assistance (i.e., Institute-specific information and advice about funding opportunities, mechanisms, policies and procedures)
  - Post-application: review of summary statement and ongoing administrative oversight of funded projects

- Review staff (Scientific Review Officers or SRO's): Scientists at either the Center for Scientific Review (CSR) or within each Institute who manage the grant review process

- Grants management staff: Institute financial management specialists who oversee the budgetary/monetary aspects of your grant

NIH 101 - Funding Opportunity Announcements

- Parent announcements - “unsolicited”
  - Majority of NIH-funded research, scored and percentiled, CSR review through established IRGs/SRGs, ESI “bump”
    - NIH Research Project Grant – CT Not allowed (PA-20-185)
    - NIH Research Project Grant – CT Required (PA-20-183) ***NHLBI Mechanistic Only**
    - NIH Research Project Grant – CT Basic Experimental Studies with Humans required (PA-20-184) ***NHLBI Does not participate in this PA**

- RFAs, PARs, PASs - Institute-initiated Research (“solicited” grant)
  - Typically, an area of research and/or type of scientist not well represented in current funding portfolio, scored but not percentiled, often uses a Special Emphasis panel (SEP) for review, no specific ESI bump
    - Secondary analysis of Existing Datasets in HLBS -R21 CT Not Allowed (PAR-20-078)
    - Investigation of Co-occurring conditions across the Lifespan to Understand Down Syndrome (INCLUDE) – R21 CT Not allowed (RFA-OD-21-007)
    - NHLBI Clinical Trial Pilot Studies -R34 CT Optional (PAR-21-079)

NIH 101 - Notice of Special Interest (NOSIs)

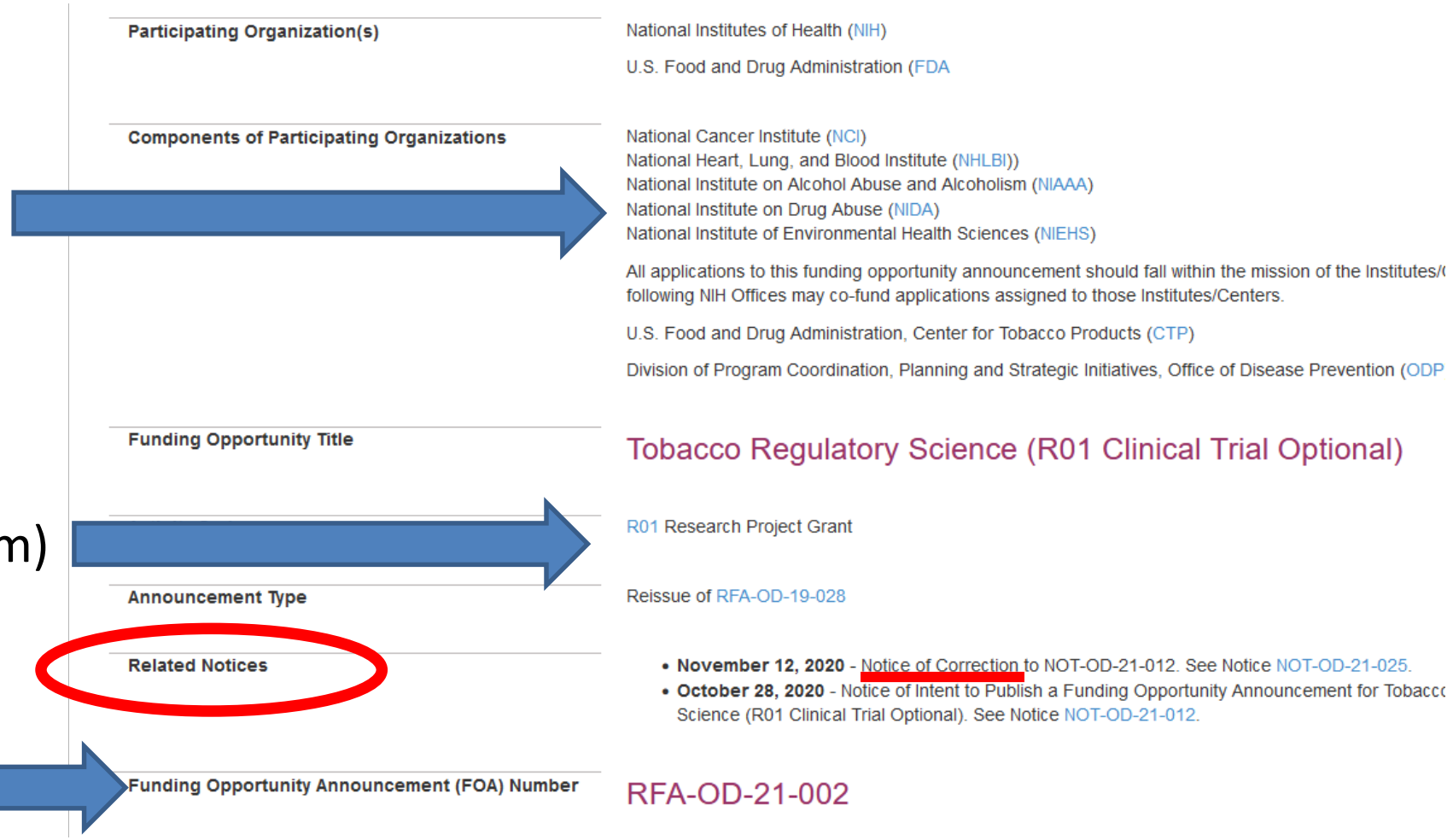
- Essentially an announcement of Institute interest in a research area. Idea is to stimulate a specific area of need.
- Does not have set-aside funds or special review criteria or review considerations
- Will include list of FOAs (typically parent PA for mechanism(s) eligible for submission) and Institutes
- Examples:
  - Promoting Cardiovascular and Cardiometabolic Health in Early Stages of the Lifecourse: Pre-adolescence Through Adolescence to Young Adulthood – parent R01s NOT-HL-21-015
  - Stimulate Research on the Diagnosis, Treatment, and Mechanistic Understanding of Postural Orthostatic Tachycardia Syndrome (POTS) – parent R01s NOT-HL-21-008
  - Electronic Nicotine Delivery Systems (ENDS) and Alternative Nicotine and Tobacco Delivery Systems: Population, Clinical and Applied Prevention Mechanisms of Health Effects – Multiple mechanisms, multi-IC, NOT-OD-21-137

Know Your FOA!

Participating Institutes

Activity Code (mechanism)

FOA Number



Know Your FOA! Part 2

Key Dates

Posted Date	February 17, 2021
Open Date (Earliest Submission Date)	June 14, 2021
Letter of Intent Due Date(s)	60 days prior to the application due date. Please note, although LOIs are typically due 30 days before the due date, for this FOA LOIs are due 60 days prior to the application date.
Application Due Date(s)	July 14, 2021, February 15, 2022, July 14, 2022, February 14, 2023 All applications are due by 5:00 PM local time of applicant organization. All types of non-AIDS applications allowed for this funding opportunity announcement are due on the listed date(s) No late applications will be accepted for this Funding Opportunity Announcement. Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date.
AIDS Application Due Date(s)	Not Applicable.
Scientific Merit Review	November 2021, June 2022, November 2022, June 2023
Advisory Council Review	January 2022, October 2022, January 2023, October 2023
Earliest Start Date	April 2022, September 2022, April 2023, September 2023
Expiration Date	February 15, 2023

Know Your FOA! Part 3

Part 2 : Section I. Describes what you need to know to decide whether or not to apply

Part 2. Full Text of Announcement

Section I. Funding Opportunity Description

Part 2 : Section IV. Describes what you need to include in your application

Section IV. Application and Submission Information

1. Requesting an Application Package

The application forms package specific to this opportunity must be accessed through ASSIST, Grants.gov Workspace or an institutional system-to-system solution. Links to apply using ASSIST or Grants.gov Workspace are available in Part 1 of this FOA. See your administrative office for instructions if you plan to use an institutional system-to-system solution.

2. Content and Form of Application Submission

It is critical that applicants follow the Research (R) Instructions in the SF424 (R&R) Application Guide, except where instructed in this funding opportunity announcement to do otherwise. Conformance to the requirements in the Application Guide is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review.

Letter of Intent

Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows IC staff to

Know Your FOA! Part 4

Part 2 : Section IV, cont'd. Review carefully, RFAs, PARs, PASs can include additional material that must be included in application in order to be considered complete.

Instructions for Application Submission
The following section supplements the instructions found in the SF424 (R&R) Application Guide and should be used for preparing an application to this FOA.

SF424(R&R) Cover
All instructions in the SF424 (R&R) Application Guide must be followed.

SF424(R&R) Project/Performance Site Locations
All instructions in the SF424 (R&R) Application Guide must be followed.

SF424(R&R) Other Project Information
All instructions in the SF424 (R&R) Application Guide must be followed.

SF424(R&R)
All instructions in the SF424 (R&R) Application Guide must be followed.

R&R or Modular Budget
All instructions in the SF424 (R&R) Application Guide must be followed.

R&R Subaward Budget
All instructions in the SF424 (R&R) Application Guide must be followed.

PHS 398 Cover Page Supplement
All instructions in the SF424 (R&R) Application Guide must be followed.

PHS 398 Research Plan
All instructions in the SF424 (R&R) Application Guide must be followed, with the following additional instructions:

Resource Sharing Plan: Individuals are required to comply with the instructions for the Resource Sharing Plans as provided in the SF424 (R&R) Application Guide. The research findings generated from this FOA may be used to provide scientific evidence informing the regulation of the manufacture, distribution, and marketing of tobacco products to protect public health. If the research data are cited publicly in support of regulation, institutions of higher education, hospitals, and other non-profit organizations are subject to the Freedom of Information Act (FOIA) as outlined in 2 CFR 200 (http://gpo.gov/fdsys/pkg/CFR-2015-title2-vol1/pdf/CFR-2015-title2-vol1-part200.pdf) and the NIH Grants Policy Statement (http://grants.nih.gov/grants/policy/nihgps_2011/nihgps_ch2.htm#info_confidentiality).

- All applications, regardless of the amount of direct costs requested for any one year, should address a Data Sharing Plan.

Appendix:

Only limited Appendix materials are allowed. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide.

Know Your FOA! Part 5

Part 2 : Section V. Describes what reviewers should consider as score driving components of an application.

Section V. Application Review Information

1. Criteria

Only the review criteria described below will be considered in the review process.

Applications submitted to the NIH in support of the NIH mission are evaluated for scientific and technical merit through the NIH peer review system.

In addition, for applications proposing clinical trials:

A proposed Clinical Trial application may include study design, methods, and intervention that are not by themselves innovative but address important questions or unmet needs. Additionally, the results of the clinical trial may indicate that further clinical development of the intervention is unwarranted or lead to new avenues of scientific investigation.

Overall Impact

Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following review criteria and additional review criteria (as applicable for the project proposed).

Scored Review Criteria

Reviewers will consider each of the review criteria below in the determination of scientific merit, and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

Significance

Does the project address an important issue or a critical barrier in the field? Is the prior research that serves as the key support for the proposed project rigorous? If the aims of the project are achieved, how will scientific knowledge and/or technical capability be improved? How will successful completion of the aims affect the concepts, methods, and technologies related to the manufacture, distribution, and marketing of tobacco products?

In addition, for applications involving clinical trials:

Are the scientific rationale and need for a clinical trial to test the proposed hypothesis or intervention well supported by preliminary data, clinical and/or preclinical studies, or information in the literature or knowledge of biological mechanisms? For trials focusing on clinical or public health endpoints, is this clinical trial necessary for the concepts, methods, and technologies that could inform the manufacture, distribution, and marketing of tobacco products in order to protect public health? For trials focusing on behavioral, physiological, biochemical, or other biomedical endpoints, is this trial needed to advance scientific understanding that could help inform the manufacture, distribution, and marketing of tobacco products in order to protect public health?

Investigator(s)

Are the PD(s)/PI(s), collaborators, and other researchers well suited to the project? If Early Stage Investigators or those in the early stages of independent careers, do they have appropriate experience and training? 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?

In addition, for applications involving clinical trials:

With regard to the proposed leadership for the project, do the PD/PI(s) and key personnel have the expertise, experience, and ability to organize, manage and implement the proposed clinical trial and meet milestones and timelines? Do they have appropriate expertise in study coordination, data management and statistics? For a multicenter

R01 Tips

- Avoid chasing “Shiny objects”
  - What can you do uniquely and do well?
- A good R01 application …
  - Is timely and relevant to stakeholders, advances the field in a meaningful way
  - Has aims that are independent of each other and obtainable
  - Has an investigator team that can demonstrably work together and covers all important elements
  - Has preliminary data strongly suggestive of feasibility
  - Well written, free of grammatical errors, creates excitement, walks the reviewer through all the elements of the grant proposal

Questions?

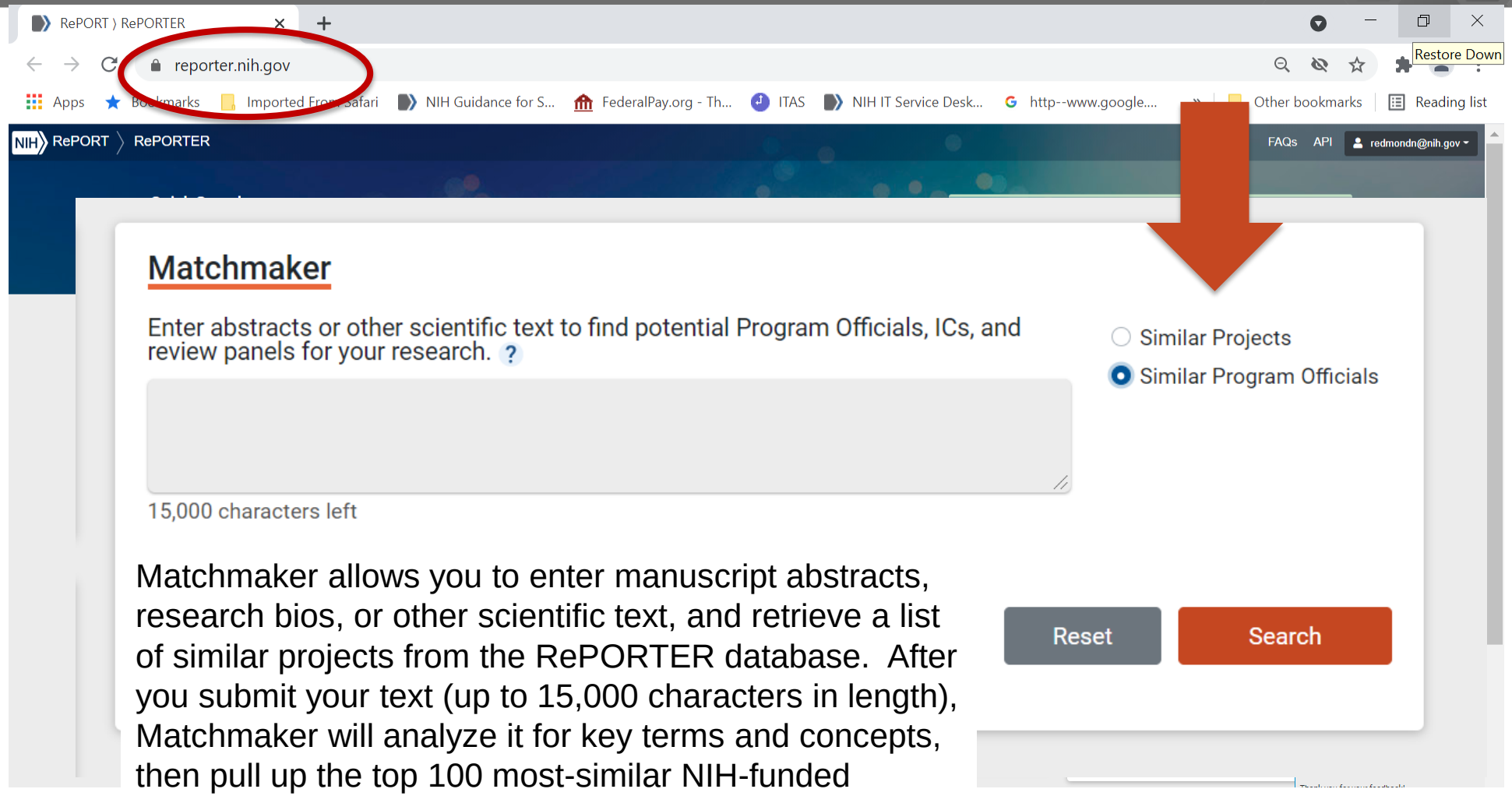
Contact me at : coadys@nhlbi.nih.gov

For details on NHLBI funding guidelines (length of awards, ESI "bump", select pay, etc.) for FY2022 see the NHLBI FOG

Introductory info on BioData Catalyst

Bonus Slides 22 and 23: NIH Matchmaker. Can suggest appropriate ICs, study sections, etc. via a copy and paste of specific aims

NIH's Research Portfolio Online Reporting Tools (RePORT) Matchmaker



Matchmaker allows you to enter manuscript abstracts, research bios, or other scientific text, and retrieve a list of similar projects from the RePORTER database. After you submit your text (up to 15,000 characters in length), Matchmaker will analyze it for key terms and concepts, then pull up the top 100 most-similar NIH-funded projects, ranked by match score.

http://reporter.nih.gov

NIH's Research Portfolio Online Reporting Tools (RePORT) Matchmaker