

# Laboratory Flexible Funding Model (LFFM) / PAR-20-15

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# Agenda

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**01**

FOA Overview

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**02**

Things to Consider/Remember

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**03**

Application Process

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Question & Answer Session

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# Housekeeping

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- This call is being recorded
- Please make sure that your phone is muted at all times, unless you are speaking
- Type questions into the chat box at any time during the presentation

# Eligibility Information

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## Government

- State
- County
- City or Township
- Special District
- Indian/Native American Tribal
- U.S. Territory or Possession



## Non-domestic (non-U.S.) Entities

- Foreign Institutions
- Components of U.S. Organizations



## Higher Education Institutions

- Public/State Controlled
- Private

# Laboratory Flexible Funding Model

Discipline	Analytical Tracks
Microbiology	<ul style="list-style-type: none"><li>• Food Defense</li><li>• Human Food Product testing</li><li>• Animal Food Product Testing</li><li>• Whole Genome Sequencing</li><li>• Microbiology Capability/ Capacity Development</li></ul>
Chemistry	<ul style="list-style-type: none"><li>• Food Defense</li><li>• Human Food Product testing</li><li>• Animal Food Product Testing</li><li>• Chemistry Capability/ Capacity Development</li></ul>
Radiochemistry	<ul style="list-style-type: none"><li>• Food Defense</li><li>• Radiochemistry Capability/ Capacity Development</li></ul>
Special Projects	<ul style="list-style-type: none"><li>• Sample Collection</li><li>• NFSDX Integration or ORAPP Adoption</li><li>• Method Development and Method Validation</li></ul>

# Program Structure and Aims

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- 15 overarching specific aims that apply to all analytical tracks under microbiology, chemistry, and radiochemistry (except WGS and development)
- Additional specific aims per analytical track
- Some aims require enrollment in specific initiatives – e.g. FERN, signed 20.88 agreement

# Disciplines A - C

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- All Food Defense, Human Food and Animal Food Product Testing tracks have minimum testing capabilities
- Expectation is that applicants have these minimum testing capabilities at start of the cooperative agreement
- These are considered “maintenance” tracks and are not for development of the minimum capabilities

# Disciplines A – B: Analytical Tracks 2 & 3 (HF & AF Product Testing)

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- An annual sample plan is required
  - Proposed plan for Year 1 should be included in the application
- Hazard/Commodity Pair table of areas of interest to be provided annually for consideration
- Complete study of 200 samples of a single hazard/commodity pair is preferred



# Selecting a Sampling Organization

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- If lab is the primary servicing lab for MFRPS or AFRPS, they must collect at least 15% of your samples
- Regulatory programs for human and animal food are our preferred sampling organizations
- May outsource sample collection to another government organization with regulatory authority over human/animal food that meets the requirements

# Sample Plan for HF & AF Product Testing Tracks

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- Required annually (does not include Food Defense)
- Should be risk-based, if proposing hazard/commodity pairs other than pairs listed in the tables
- Include number of samples per commodity type, analyte(s), method, and frequency
- Has to be reviewed/approved prior to work being initiated

# Sample Plan for HF & AF Product Testing Tracks

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- The same sample cannot be utilized for 2 separate tracks
  - 1 package of spices cannot be split and  $\frac{1}{2}$  sent for micro and  $\frac{1}{2}$  sent to chem)
  - 2 packages can be collected and 1 sent to micro and 1 sent to chem
  - There must be clear separation of sample collection and analysis activities (chain of custody, etc.)

# Sample Plan for HF & AF Product Testing Tracks

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- Plans should not include
  - Environmental swabs
  - Municipal water
  - Irrigation water
  - Products produced and packaged at a retail location
  - Products regulated by EPA or USDA
- Some of these types may be allowed under special circumstances (e.g. outbreak investigation or special assignment)

# Disciplines A – C, Capability and Capacity Development Tracks

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- One (1) year in length
- Development opportunities are fixed – other projects cannot be proposed
  - May change annually based on need
- Even if opportunities for 2020-2021 are not of interest, apply for this track to have the ability to participate in subsequent years

# Disciplines A – C, Capability and Capacity Development Tracks

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- After 1<sup>st</sup> year the competencies developed should be added to the work being done the respective track
- EXAMPLE:

	<b>Year 1</b>	<b>Year 2</b>	<b>Year 3</b>	<b>Year 4</b>	<b>Year 5</b>
<b>A.5 WGS Development</b>	X				
<b>A.4 WGS</b>		Low (100)	Low (100)	Low (100)	Low (100)

# Discipline D.1 – Sample Collection

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- Need-based
- Tier of qualification is based on the total number of samples you are selected to analyze from the HF & AF product testing tracks
- Food defense numbers cannot be factored into the sample loads

# Discipline D.2 – NFSDX & ORAPP

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- Only for one (1) year
- Can be applied to any year of the CAP
- Note that additional agreements must be signed by the agency to participate
  - Memorandum of Understanding (MOU)
  - Interconnection Security Agreement (ISA)



# Discipline D.3 – Method Development and Method Validation

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- Only for one (1) year, but can be continued based upon need and demonstration of progress
- Additional projects can be proposed outside of what is listed as potential opportunities for 2020-2021
- Even if opportunities for 2020-2021 are not of interest, apply for this track to have the ability to participate in subsequent years

# Available Funding & Award Expectation

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- 5 year cooperative agreement
  - 1 yr of support + 4 yrs of future support contingent upon annual appropriations, availability of funds, and satisfactory performance
- \$23 million for fiscal year 2020
- Up to 100 individual awards
- Each award cannot exceed \$1.5 million in total costs (direct + indirect)
- Federal indirect cost rate applies (no cap)

# Things to Consider/Remember

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- Include a table on the first page of the “overall” research plan that explicitly explains which tracks for which you are applying
- For analytical tracks under Disciplines A – C (with the exception of development tracks), complete the assessment and upload it as the 1<sup>st</sup> page of the research strategy of respective project

# Things to Consider/Remember

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- Although we anticipate the opportunity for labs to participate in FDA assignments, the labs must be prepared to obtain all samples proposed in their application
  - This includes product samples and isolates
- Labs concerned about a shortage of isolates to sequence should reach out to other agencies, institutions, and other neighboring partners in advance

# Things to Consider/Remember

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- The assessment is 50% of the score for FD, H&AF product testing, and WGS
- Failure to include the assessment could cost you an award
- Assessment declarations should be verifiable through research strategy
- Can the questions in the scoring criteria be answered by the information in the research strategy?

# Things to Consider/Remember

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- Are you prepared to begin the work when the project begins?
  - Analyst trained? Sample collectors trained and identified?
- Can you still participate if you aren't awarded the additional funds for sample collection?
- FDA will not be providing loaner equipment under the Food Defense track
  - If new equipment is needed is must be purchased from the cooperative agreement funds

# Things to Consider/Remember

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- Funds can be divided among the entire discipline at the labs discretion, to meet the goals of the projects
- EXAMPLE: Microbiology

Analytical Track	Funding (6pts)	Project Budget
Food Defense	$\$125,000 + \$55,000 +$ $\$20,000 + \$110,000 (M)$  <b>Total = \$310,000</b>	\$180,000
Human Food (medium)		\$100,000
Animal Food (low)		\$30,000
		<b>Total = \$310,000</b>

# Prior to Submission

- **You must:**
  - Obtain a DUNS number;
  - Complete/maintain active SAM( System for Award Management) registration;
  - Register with eRA Commons;
  - Download the application package;
  - Download the instructions.

**Applications due dates is April 6, 2020 11:59 PM Eastern Time**



# Multi component Submission Process


- Registration is the same process as prior FDA applications
- Use the NIH ASSIST system to prepare, submit and track your application online.  
(RECOMMENDED)
- Use an institutional system-to-system (S2S) solution to prepare and submit your application.

# Page Limitations/ Submission of Multi-Component


- Page limitations on available component types
  - Overall: 12 research strategy/ program plan page limits
  - Admin Core: 6 research strategy/ program plan page limits
  - Project: 12 (each Project) research strategy/ program plan page limits
- The application should consist of the following components:
  - Overall: required; maximum 1
  - Admin Core: required; maximum 1
  - Projects: required; minimum 1

# Overall Component

Overall Component



**PD/PIs:** Cher D. Money, Ben A. Round  
**Organization:** A  
**Project Title:** Research Center to Cure the Diseases of the World



### Required Forms

- SF424 (R&R)
- Project/Performance Sites
- R&R Other Project Info
- R&R Senior/Key Persons
- PHS 398 Cover Page Supplement
- PHS 398 Research Plan
- PHS Human Subjects and Clinical Trials Information

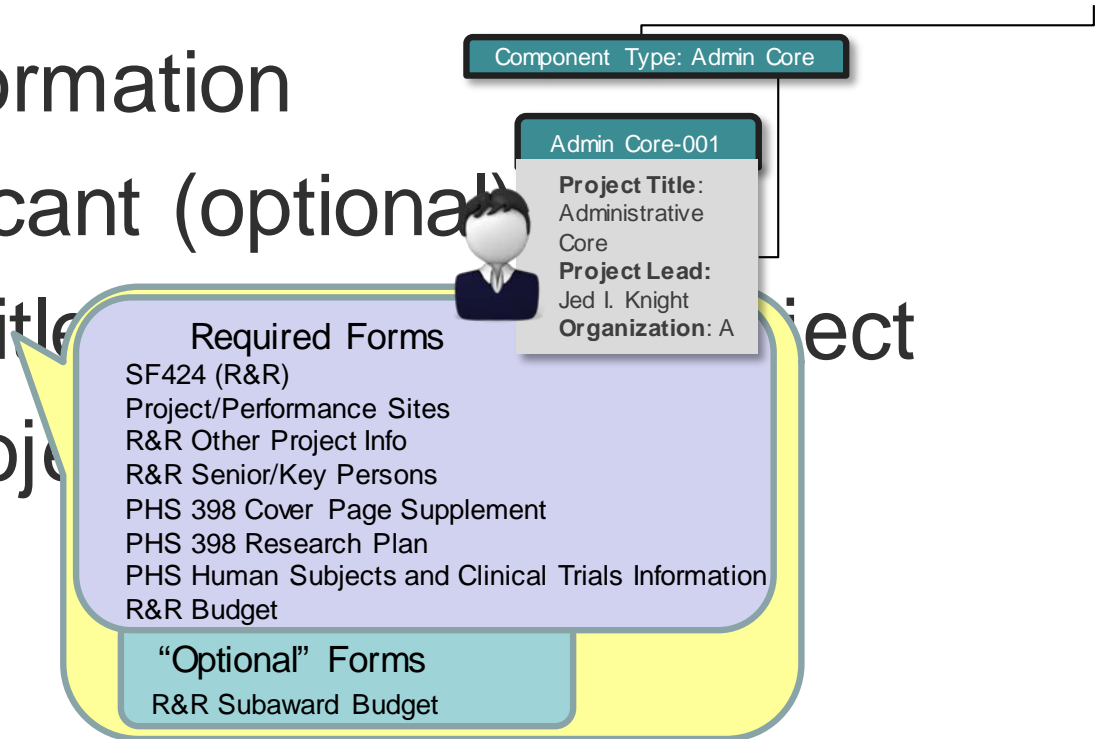
### “Optional” Forms

- PHS Additional Indirect Costs
- PHS Assignment Request Form

# Administration (Admin) Component

Component Type:

- Applicant Information
- Type of Applicant (optional)
- Descriptive Title
- Proposed Project
- Starting/Ending Dates



# Project Component

- Applicant Information
- Type of Applicant (optional)
- Descriptive Title of Applicant's Project - Title must include the following
- Discipline Name
- Analytical Track Name
- Proposed Project Start/Ending Dates

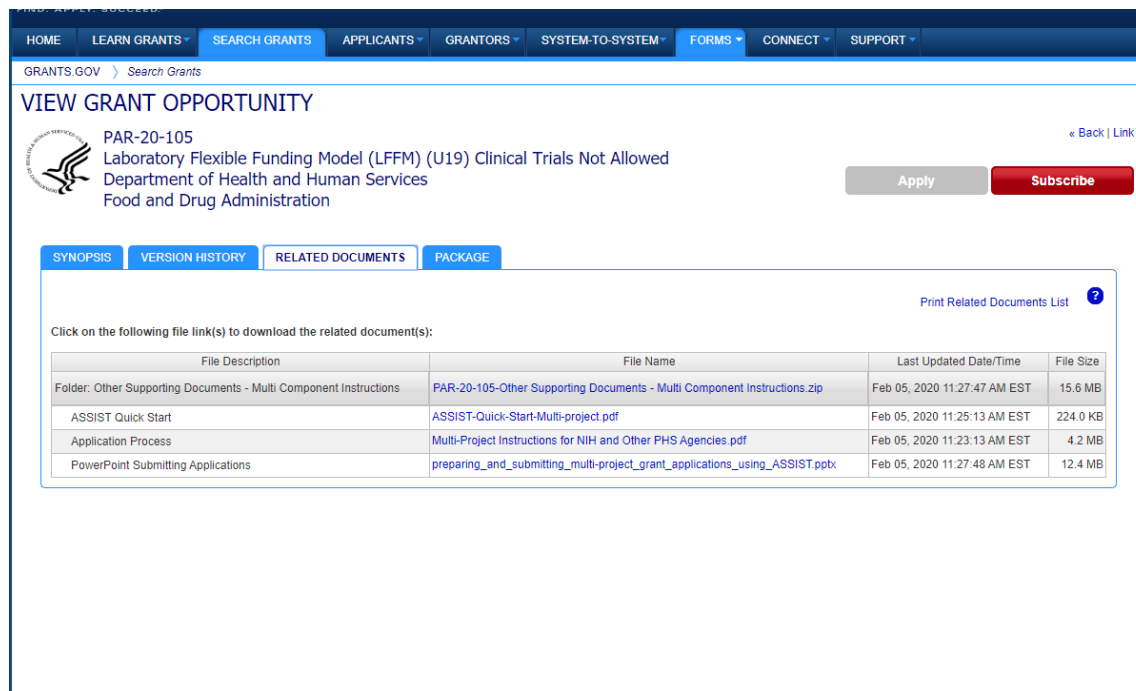
## Required Forms

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 R&R Senior/Key Persons  
 PHS 398 Cover Page Supplement  
 PHS 398 Research Plan  
 PHS Human Subjects and Clinical Trials Information  
 R&R Budget

## "Optional" Forms


R&R Subaward Budget

# Helpful forms available in Grants.gov



GRANTS.GOV > Search Grants

**VIEW GRANT OPPORTUNITY** « Back | Link


**PAR-20-105**  
 Laboratory Flexible Funding Model (LFFM) (U19) Clinical Trials Not Allowed  
 Department of Health and Human Services  
 Food and Drug Administration

Print Related Documents List ?

Click on the following file link(s) to download the related document(s):

File Description	File Name	Last Updated Date/Time	File Size
Folder: Other Supporting Documents - Multi Component Instructions	<a href="#">PAR-20-105-Other Supporting Documents - Multi Component Instructions.zip</a>	Feb 05, 2020 11:27:47 AM EST	15.6 MB
ASSIST Quick Start	<a href="#">ASSIST-Quick-Start-Multi-project.pdf</a>	Feb 05, 2020 11:25:13 AM EST	224.0 KB
Application Process	<a href="#">Multi-Project Instructions for NIH and Other PHS Agencies.pdf</a>	Feb 05, 2020 11:23:13 AM EST	4.2 MB
PowerPoint Submitting Applications	<a href="#">preparing_and_submitting_multi-project_grant_applications_using_ASSIST.pptx</a>	Feb 05, 2020 11:27:48 AM EST	12.4 MB

# Application Tips

- **Confirm your registrations – today!**
  - DUNS – must have for other registrations
  - SAM (formerly CCR)– requires annual renewal
  - eRA Commons (Signing Official and PI)
- **Submit your application early – Late applications will not be accepted for this FOA**

# Important Dates

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Letter of Intent Due Date	February 19, 2020
Technical Session	February 24, 2020 10:30am-12pm ET
Application Due Date	May 6, 2020 by 11:59pm ET <b>*Late applications will <u>NOT</u> be accepted</b>
Objective Review	May 2020
Earliest Start Date	July 2020





# Contact Information

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