Laboratory Flexible Funding Model: PAR-20-105

Technical Session – Questions & Answers
February 24, 2020, 10:30 AM Eastern Time

Q1. May we have some clarification regarding the collection of environmental samples, please? Per the RFA under Analytical Track 2: Human Food Product Testing, it says "The purpose of this analytical track is to improve food testing surveillance programs through the microbiological analysis of food products and environmental samples." We were under the impression that environmental samples would be an option. Is this not correct?

A1. Environmental samples, such as agricultural water, soil and soil amendments and production facility swabs, are only acceptable during outbreak investigations or FDA assignment. Environmental samples should not be a proposed commodity type under the annual sample plans.

Q2. Clarification on the goal for the WGS Development One Year award would be helpful. Specifically, is the intent to bring in a new partner not already participating in sequencing for GenomeTrakr or is this open to current partners/awardees that might want to expand their testing?

A2. Discipline A: Analytical Track 5: Microbiology Capability/Capacity Development in WGS is specifically for laboratories that do not have this capability and would need to purchase a sequencer, train analysts, and pass a competency exam. If your laboratory is currently performing WGS, even if not for GenomeTrakr, you should apply for Discipline A: Analytical Track 4: WGS in one of the three tiers.

Q3. For the start and end date, do you want the 5-year project period or just the 1-year budget period?

A3. The start and end date should reflect all of the years for which you are requesting funding. This will depend on each application but typically it will be for a 5-year project period.

Q4. Is a line item budget needed for the "Maintenance funds" that are awarded based on the application points system?

A4. No, maintenance funds are to be added in with base funding for each analytical track. Any funds requested for Maintenance should be outlined in the detailed R&R budget for the project and explained in the accompanying narrative Budget Justification. For additional information, please reference question A7.

Q5. Are projects with low sample loads (100 samples) less likely to be funded than projects with higher sample loads given that there is a preference for projects with 200 samples of a single commodity/hazard pair?

A5. No, there is no preference given based on the sample load tier chosen.

Q6. Is each discipline or track considered a project?

A6. Each analytical track is considered a single project.

Examples:

- Discipline A: Microbiology, Analytical Track 1: Food Defense = 1 project.
- Discipline A: Microbiology, Analytical Track 2: Human Food Product Testing = 1 project.
- Discipline B: Chemistry, Analytical Track 1: Food Defense = 1 project.

Q7. How would you advise constructing the budget for a project when a salary is split between the project budget and maintenance budget?

A7. Our suggestion is that if you are going to propose maintenance as part of a project, the line item cost for the salary (or any other cost category) on the R&R Budget form should be cumulative and be the total salary for that person for both the base project and maintenance. The narrative budget justification (that is required) should outline how those salary costs will be broken down between the base project and maintenance.

Example: Dr. Joe's base project salary cost will be $50k and their maintenance salary cost is $20k. The applicant should list $70k on the R&R Budget form for Dr. Joe's salary and then in the budget justification state, $50k is for the base project and Dr. Joe will work on XYZ and $20k is for maintenance and they will work on XYZ.

Q8. Can you explain the option to "outsource" sample collection (i.e. to ensure sample integrity and document chain of custody)? What is the mechanism and timing of communicating positive and negative sample results? If positive findings, who is lead for enforcement action? Is final disposition of affected product that tests positive captured in a structured way?

A8. Although the preference is that the State Manufactured Food Regulatory and the Animal Food Regulatory Programs collect the samples on behalf of the laboratory, they do have the option to collaborate with other regulatory agencies with regulatory authority over human and animal food to collect samples, if needed.

A detailed quarterly summary of all samples collected and analyzed must be submitted through the FERN website, or other FDA approved system.

In addition, the laborites must notify the FDA project manager and the technical lead within one (1) business day of any presumptive positive or "cannot rule out" (CRO) samples. Notification via email must be sent to ORA-LFFM-CAP@fda.hhs.gov. The State regulatory program with jurisdiction over the presumptive positive or CRO sample must also be notified.

Full laboratory packages for any confirmed positive or violative sample must be submitted within three (3) business days of final determination. This would include any supplemental information, as requested. The State regulatory program and the FDA will work collaboratively to determine if regulatory action is warranted, and which organization will be the lead.

Sample disposition of affected product found under this program may be handled in a variety of ways depending on the policy of the agency that led enforcement action.

Q9. What type of animal food types could be tested for Food Defense?

A9. Samples could include, but is not limited to, various domestic and exotic pet foods and treats, and animal feed.

Q10. Do CVs need to be submitted for everyone or just those with ERA commons accounts, are ERA accounts needed for every participant?

A10. Anyone that is identified as key personnel requires a CV or biosketch. PD/PIs are always considered key personnel and require a CV or biosketch.

It is up to the applicant organization to determine if someone will be designated as key personnel on the project. Key personnel is an individual who contributes to the scientific development or execution of a project in a substantive, measurable way, regardless of whether they receive salaries or compensation under the Grant.

Key personnel do not need eRA Commons accounts; however, they do need a CV or biosketch.

PD/PIs do require eRA Commons accounts and CV or biosketch.

Q11. Is ORAPP replacing eLEXNET? What is the drop dead date for eLEXNET?

A11. FDA is consolidating the mechanisms by which food safety agencies and partners share information so that FDA can more easily perform risk assessments analysis and locate problem products. FDA is transitioning to a more streamlined data exchange solution via the Office of Regulatory Affairs (ORA) Partners Portal (ORAPP).

Sample analysis outcomes data will be collected using Excel uploads submitted via the ORAPP website, as well as related FDA system-to-system integrations such as the National Food Safety Data Exchange (NFSDX). For additional information about options for submitting regulatory data, contact the ORA Data Exchange team.

FDA will stop collecting all surveillance, voluntary, or required data via eLEXNET on May 31, 2020 and eLEXNET will be completely retired on September 30, 2020.

NOTE: At this time, data generated from the LFFM program will be uploaded via the FERN portal.

Q12. If a lab does not have regulatory authority, can they collect samples or do all samples need to come in from an agency with regulatory authority?

A12. While it is the preference that samples are collected by the State Manufactured Food Regulatory or Animal Food Regulatory programs, laboratories that fall under a State Department of Health or Department of Agriculture could conduct their own sample collections. The laboratory would have to prove that the analyst conducting the sample collections is trained and competent in this activity.

Laboratories of Institutions of Higher Education that have regulatory authority over human and/or animal food could also conduct their own sample collections.

Laboratories of Institutions of Higher Education that do not have regulatory authority over human and/or animal food cannot conduct sample collections and would need to collaborate with the agency with regulatory authority within their state.

Q13. In the past we have tested a variety of food samples, are you now looking for single commodity?

A13. The laboratories have the option of proposing a plan with single hazard/commodity pair or one that includes a variety of commodities and hazards.

Q14. Who is allowed to collect food defense samples?

A14. Laboratories selected for the Food Defense samples would be allowed to collect their own samples. They could also be provided to the laboratories from a variety of other sources including directly from FDA.

Q15. The cost of sample collection can be added to the sample analysis track, correct?

A15. Yes. Any costs that are necessary (and allowable) to achieve the objectives of the project may be proposed in the budget.

Q16. Are milk and milk-related products allowed to be tested in this CAP as long as the testing does not fall under the PMO?

A16. Milk related products such as ice cream and cheese would be acceptable under this program. However, Grade-A dairy products would not be.

Q17. Regarding the Assessment, is one completed for each project? The announcement and assessment seems to group Discipline B Track 1-3 together. Or, are Discipline B Tracks 1-3 one project or three separate projects?

A17. The Assessment, when applicable, must be completed for each project. Discipline B: Chemistry, Analytical Tracks 1-3 are three separate projects and will each require its own separate assessment. In order to allow applicants the full maximum 12 pages for the Research Strategy, the assessment, when applicable, must be uploaded to line item 4, Progress Report Publication List, on the PHS398 Research Plan form

Q18. Regarding HF and AF, can we also include retail samples or just manufacturing samples?

A18. FDA regulated pre-packaged products collected from a retail location are acceptable. Samples produced and sold at retail are unacceptable, with the exception of outbreak situations. Samples collected from the manufacturer, warehouse, or distribution center are acceptable, however these types of samples should only be collected by State or FDA investigators.

Q19. A project is defined by discipline and track, not by the 5 checklists. Where are the checklists included in the proposal?

A19. The assessments, when applicable, must be completed and included for each respective project/analytical track. In order to allow applicants the full maximum 12 pages for the Research Strategy, the assessment, when applicable, must be uploaded to line item 4, Progress Report Publication List, on the PHS398 Research Plan form. The assessment, when applicable and depending on the analytical track, can range between 1-3 pages.

Q20. What are the incentives in the way grant applications will be scored for multiple organizations to submit a single application as opposed to separate applications if their sampling and analysis plans will remain similar in either case?

A20. Although we encourage potential participants, especially those within the same organization or State, to work collaboratively, there are not any incentives for collaborative vs. single applications. It is completely at the organization's discretion to determine which option best suits them.

Q21. Is an existing ISO certification a prerequisite for the application or will university laboratories that actively seek ISO certification be considered?

A21. ISO 17025 accreditation is not a prerequisite for this program. However, laboratories are required to either have ISO 17025 accreditation OR a quality system that ensures quality assurance and quality control of laboratory testing.

Q22. I would like to confirm that the funds available for funding and maintenance are for the full 5-year cooperative agreement and not annually.

A22. The maximum total funding available for each year is $1.5M, contingent upon annual appropriations, availability of funding and satisfactory awardee performance. The $1.5M is inclusive of all projects and any maintenance costs.

Applicants have the option to apply for multiple Projects (multiple tracks under multiple disciplines) but must follow the outlined schematic to determine their maximum budget per Project.

Application budgets need to reflect the actual needs of the proposed project and should not exceed the following in total costs (direct and indirect):

YR 01: $1,500,000
YR 02: $1,500,000
YR 03: $1,500,000
YR 04: $1,500,000
YR 05: $1,500,000

Q23. How does one parse out the IDC, maintenance, administration?

A23. All costs proposed on the application is either a direct cost or indirect cost. Indirect costs are

based on the negotiated Indirect cost rate agreement. The negotiated Indirect cost rate agreement should outline the rate that you should charge against a direct cost category.

If your organization has never established an indirect cost rate and/or does not have a negotiated Federal indirect cost rate agreement, a de minimis indirect cost rate of 10 percent (10%) of modified total direct costs (MTDC) will be allowed. MTDC means all direct salaries and wages, applicable fringe benefits, materials and supplies, services, travel, and subaward and subcontracts up to the first $25,000 of each subaward or subcontract. MTDC excludes equipment, capital expenditures, charges for patient care, rental costs, tuition remission, scholarships and fellowships, participant support costs and the portion of each subaward and subcontract in excess of $25,000.

Q24. There is a preference of 200 samples for the hazard commodity pair. Is this in addition to the medium sample load of 250?

A24. No. If a laboratory selects the medium sample load of 250, 200 could be of a single hazard/commodity pair and the remaining 50 could be something different.

Q25. Is there a list of commodities that FDA is interested?

A25. Please refer to the hazard/commodity pair tables provided in the funding opportunity announcement. It is anticipated that these tables will be updated annually, as needed.

Q26. Based on a question answer regarding project, is it correct to assume that food defense is a single project that includes radiochemistry, chemistry and microbiology. How does that work with checklists and funding, is it $125,000 total or $125,000 per discipline and the single project is $375,000?

A26. These would be three separate projects.
Discipline C: Radiochemistry, Analytica Track 1: Food Defense would be 1 project with potential funding of up to $125k for base project and 3 points towards Maintenance to potentially receive up to additional $125k for Maintenance.

Discipline B: Chemistry, Analytical Track 1: Food Defense would be another separate project with potential funding of up to $125k for base project and 3 points towards Maintenance to potentially receive additional Maintenance funding.

Discipline A: Microbiology, Analytical Track 1: Food Defense would be another separate project with potential funding of up to $125k for base project and 3 points towards Maintenance to potentially receive additional Maintenance funding).

Q27. The FOA states that a facility diagram, including the location of equipment that will be utilized to support the proposed work should be included in the Research Strategy. Does that have to be listed within the document, or can we reference the documents uploaded under "Equipment" and "Facility" under R&R Other projects?

A27. In order to allow applicants the full maximum 12 pages for the Research Strategy, facility diagrams including the location of equipment should be uploaded to line item 10. Facilities & Other

Resources on the Research & Related Other Project Information form. Details about the major items of equipment already available for this project and pertinent capabilities should be uploaded to line item 11. Equipment on the Research & Related Other Project Information form.

Q28. I initiated the project in ASSIST as the Chemistry PI. How do I add another PI for Microbiology under the same project? There is no place on the initiation page to add more PIs.

A28. A project is an Analytical Track under a Discipline. Chemistry and Microbiology are at the discipline level. In ASSIST, you will need to add a new project for each Analytical Track under a Discipline. Example: Discipline B: Chemistry, Analytical Track 1: Food Defense would be considered one project and Discipline A: Microbiology, Analytical Track 1: Food Defense would be considered another project. Each Project should have a PD/PI and the PD/PI may differ from project to project. For example, Chemistry/Food Defense project has PD/PI Dr. John Smith and the Microbiology/Food Defense project has PD/PI Dr. Sarah Jones.

Q29. How do we submit data in interim when eLEXNET shuts down, but lab has still not implemented ORAPP?

A29. Laboratory data for the LFFM should be submitted through the FERN portal. eLEXNET will not be utilized for this program, and ORAPP usage is not a requirement at this time.

Q30. For the Capability/Capacity Development, we should enter zero budgets, but what do we need to do regarding the research strategy, specific aims, etc? The same question for Method Validation and Development.

A30. For the Capability/Capacity Development tracks (Microbiology, Chemistry, Radiochemistry) and Method Validation and Development track (Special Projects) ONLY, if an applicant wants to participate for future years but not in the first year, they must include the proposed project and all required forms (Specific Aims, Research Strategy, Budget, etc.) with the initial application submission. The items to be addressed in the Research Strategy for these analytical tracks are not capability specific and are written to assess the laboratory's overall ability to expand to additional areas. The applicant should propose a project start date in 2021 or later for these projects if wanting to participate after year 1.

Applicants must submit the R&R Budget form and provide the costs for each proposed budget year for each project. For the Capability/Capacity Development tracks (Microbiology, Chemistry, Radiochemistry) and Method Validation and Development track (Special Projects) ONLY, we understand that the annual opportunities and associated budgets may change year-to-year. For initial application submission purposes, please use the following maximum total costs in the proposed budget on the R&R Budget Form for any proposed budget year. Since detailed line item costs will most likely be unknown at the time of initial application submission, direct costs may be lumped together and listed all under "Other" direct costs on the R&R Budget Form.

Project	Maximum budget for each budget year on R&R Budget Form
Discipline A: Microbiology, Analytical Track 5.	$135,000 total costs (direct + indirect)

Capability/Capacity Development	
Discipline B: Chemistry, Analytical Track 4. Capability/Capacity Development	$55,000 total costs (direct + indirect)
Discipline C: Radiochemistry, Analytical Track 2. Capability/Capacity Development	$150,000 total costs (direct + indirect)
Discipline D: Special Projects, Analytical Track 3. Method Development/Validation	$35,000 total costs (direct + indirect)

After award, on an annual basis, the budgets for the above listed projects will be evaluated to determine if funding should be increased/decreased depending on the annual opportunities. Post award, FDA will communicate and work with the grantee to determine the appropriate annual budgets for these projects.

Q31. We would like to propose testing of dog and cat foods, but the agency in our state that regulates these has no sampling program. Could we have trained sampling personnel from a different agency collect these or do we have to have them collected by the agency with specific regulatory authority over these products?

A31. Please refer to **A12.** The laboratory should also be proactive in notifying the responsible regulatory agency of the intent to apply for this funding opportunity. The laboratories and regulatory agencies will have to work collaboratively in the event of a finding.

Q32. For analytical track 3 under the microbiology discipline, the assessment identifies animal virus testing. Is it correct that this testing would be in food matrices?

A32. Yes.

Q33. Do the assessments needed for each project count toward the page limit for each project?

A33. In order to allow applicants the full maximum 12 pages for the Research Strategy, the assessment, when applicable, should be uploaded to line item 4. Progress Report Publication List on the PHS398 Research Plan form. Each assessment, depending on the Analytical Track, is between 1-3 pages. The page limit for the Research Strategy for each project is 12 pages.

Q34. Is there an upper limit for the indirect rate?

A34. There is no maximum or cap on the indirect cost rate for this program. Indirect cost rates should be based on a negotiated Federal indirect cost rate agreement. A copy of the most recent Federal indirect cost rate or F&A agreement must be provided as part of the application submission. This agreement should be attached to the RESEARCH & RELATED Other Project Information Component as line #12 'Other Attachments'.

If the applicant organization has never established an indirect cost rate and/or does not have a negotiated Federal indirect cost rate agreement, a de minimis indirect cost rate of 10 percent (10%) of modified total direct costs (MTDC) will be allowed. MTDC means all direct salaries and wages, applicable fringe benefits, materials and supplies, services, travel, and subaward and subcontracts up to the first $25,000 of each subaward or subcontract. MTDC excludes equipment,

capital expenditures, charges for patient care, rental costs, tuition remission, scholarships and fellowships, participant support costs and the portion of each subaward and subcontract in excess of $25,000.

Q35. D.3: Method validation. If applying, does the lab take PART in a multi-lab validation in the list, or does the lab have to actively RUN this multi-lab validation?

A35. In general, the laboratory would take part in an FDA-led multi-lab validation study. However, a laboratory could also propose an MLV in which they run the study.

Q36. In regards to the WGS totals, which samples are acceptable for sequencing? Are we able to use historical food/environmental samples that haven't currently been sequenced?

A36. Foodborne pathogen isolates (Salmonella enterica, Listeria monocytogenes, STECs, Campylobacters, and Vibrio para.) collected from the following sources:

- FDA-regulated food
- FDA-regulated food production/packing facility or farm
- Environmental areas/watershed surrounding agriculture activity (water, sediment, air, etc.)
- Animal clinical samples (from veterinary activates)
- Meat or animal samples from USDA-regulated products (these are generally outside the GenomeTrakr scope, but a small percentage can be included in an overall sampling effort)

Yes, historical food and environmental isolates that have not been sequenced are acceptable.

Q37. How do we access the assessment?

A37. The assessments can be accessed at https://www.fda.gov/federal-state-local-tribal-and-territorial-officials/laboratory-flexible-funding-model-cooperative-agreement/.

Q38. Does the indirect cost go in each project budget or does it go only in the admin component?

A38. Any proposed Indirect costs should be listed at the project level. The indirect cost rate of the organization that will be listed on the project should be utilized. Example, if Project #1 is going to be University XYZ, then University XYZ's indirect cost rate should be applied to Project #1's budget. On Project #2, if the organization is State XYZ Dept. of Agriculture, then State XYZ Dept. of Agriculture's indirect cost rate should be applied to Project #2's budget.

If indirect costs are being proposed for the admin component, then those indirect costs should be listed in the R&R budget for the admin component.

Q39. About the ISO certification question from earlier; just to confirm, the RFA says ISO (or similar) is not needed for WGS, Development, and/or Special Project tracks, correct?

A39. This is correct. However, keep in mind that, for example, although it would not be required for

Discipline C: Radiochemistry, Analytical Track 2 once that first year was complete and if the laboratory rolled into Analytical Track 1, this requirement would apply.

Q40. Could you upload facility pictures in lieu of diagram/sketch?

A40. Pictures would be acceptable as long as they are labeled to describe the layout in the way that a diagram/sketch would. Please be mindful that any attachments must be in a PDF file format. In order to allow applicants the full maximum 12 pages for the Research Strategy, facility diagrams including the location of equipment should be uploaded to line item 10. Facilities & Other Resources on the Research & Related Other Project Information form. Details about the major items of equipment already available for this project and pertinent capabilities should be uploaded to line item 11. Equipment on the Research & Related Other Project Information form.

Q41. I see that a project narrative is not necessary for each project, but does there need to be a project summary for each project required?

A41. A project summary is required for Overall, Admin and each Project. Each project summary attachment is limited to 30 lines of text.

Q42. If we do not want to propose any human food testing for this coming year, should we still apply for it and list zero samples so that we can participate in this in future years?

A42. For all projects except for those outlined in question A30, if an applicant wants to participate in a project but start after the first year, they should include the proposed project and all required forms (Specific Aims, Research Strategy, Budget, etc.) in the initial application submission. The applicant should state the proposed project start date (2021 or later) for the project and include a detailed Research Strategy with all the required information outlined in the FOA. A R&R Budget form and Budget Justification are required and must outline the costs associated for each proposed budget year of the project.

FDA anticipates posting a companion FOA (after September 2020) in order for awarded grantees to submit applications to add on new projects to existing awards. Applicants have the option to wait to apply to the companion FOA at a later date, or submit for projects to be worked on for future years with their initial application submission using the guidelines provided above.

Funding for any given budget year are contingent upon annual appropriations, availability of funding, Program priorities, and satisfactory awardee performance.

Q43. It seems the MPI (multiple PI/PD) is available on this application, so can we have MPIs at the project level?

A43. Yes, you may propose multiple PD/PIs at the project level. Please follow all instructions regarding MPIs in the SF424 application instructions found at: https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/multi-project-forms-e.pdf.

Q44. Clarification for the Facilities/equipment question above: Do we need to include the facilities diagram and list of equipment per location as part of the Research Strategy (12

page limit) if we are already uploading the documents?

A44. In order to allow applicants the full maximum 12 pages for the Research Strategy, facility diagrams including the location of equipment should be uploaded to line item 10. Facilities & Other Resources on the Research & Related Other Project Information form. Details about the major items of equipment already available for this project and pertinent capabilities should be uploaded to line item 11. Equipment on the Research & Related Other Project Information form.

Revision History

Revision	Date	Description
1.0	03/06/2020	Creation
1.1	03/10/2020	Edited responses to A8, A10, and A36