

Questions and Answers Updated 21 July:

The most recent Question and Answers are listed at the top of each section. Similar Questions and Answers are grouped together.

BUDGET & COST PROPOSAL

If we have specific budget questions about how to substantiate costs for our proposal, can you answer and provide directions? For example, see the questions below.

ARPA-H will not provide directions on how to substantiate costs other than what is listed in the BAA. Please see the example questions below.

- a. **Is the "detailed cost breakdown" listed in the RFP considered adequately covered by the provided Cost spreadsheet, or is an additional written budget justification required?**
- b. **In the budget for each year, how can we provide the efforts for the Program Manager and Equity officer etc., as each year has different tasks? Should we split the 100% effort for each year as per the task or shall we give them 100% in any task for that year?**
- c. **How should we detail the budget for manufacturing in Phase 2 if the partners and final manufacturing process/FDA testing requirements will not be identified until the end of Phase 1?**
- d. **Do we need to include prices for cGLP and cGMP manufacturing?**
- e. **We have collaborators for the clinical trials, but since we have not developed the product yet, it is hard to get a price for manufacturing. Also, it is my understanding that each patient may run about 100,000 if they get injected in a hospital with all the testing needed. Do we need to include this in our budget right now or will this come later?**

Specifically, for a, b, c, d, and e, it is the responsibility of the Proposer to submit a cost proposal that is affordable, reasonable, and realistic. Proposers are encouraged to comply with the BAA, including a detailed cost breakdown, and cost spreadsheets. In addition to the spreadsheets, proposers are expected to provide whatever cost and pricing information required to substantiate costs with rationale and justification.

In tab "Instructions and Summary", cell B3, a Control Number is requested. Where can this information be located? In tab "SF-424A", cell F1, an Award Number is requested. Should this information be the same as the Control Number provided on tab "Instructions and Summary"?

Please disregard these for the original Cooperative Agreement application submission. If revised submissions are required at any time, these numbers will be applicable.

The SF 424A budget template discusses TT&O activities on the Other costs tab, and references Section IV.G.8 of the FOA, however, we do not find a corresponding section in the BAA. Is there a relevant section in the BAA to refer to these allowable activities, and that defines the 5% requirement, or please provide guidance. Is it acceptable to include fee/profit in TT&O on the SF424 for a Cooperative Agreement.

Please see the revised SF-424A where much of this language has been removed. While TT&O are allowable costs overall, there is no 5% requirement. Additionally, for Cooperative Agreements, fee/profit is only allowable when it is paid as part of commercial practice for routine goods or services to the recipient. It is the responsibility of the proposer to clearly articulate any such case for the Government's consideration, to determine whether the proposed fee/profit is allowable.

Uniform Guidance describes the de minimis rate of 10% in sections 200.332(a)(4) and 200.414(f). Both sections state that subrecipient can use a negotiated rate or the de minimis rate. It doesn't specifically state that the prime and sub can negotiate an indirect cost rate. In the NIH Grants Policy Statement, it does infer that the prime and the sub could establish an F&A rate. Will ARPA-H allow us to establish/negotiate a rate with our subs that do not have a federally negotiated rate?

Yes. For Cooperative Agreements specifically, ARPA-H will allow prime recipients to negotiate F&A rates with subrecipients who do not have established rates. The subrecipients can also use the de minimis rate of 10%.

For proposers requesting cooperative agreements and submitting in grants.gov, into which field should we upload the Volume 2 Cost Proposal?

Proposers may load the Cost Proposal as an attachment to the Other Project Information form.

Do the NIH Salary Caps apply to proposals submitted to ARPA-H?

Yes. The statutory salary limitation does apply to award instruments issued by ARPA-H. The SF-424A has been revised to reflect the current limitation amount of \$212,100.

Will the program fund small businesses to pay for patent costs, sales & marketing, business development, or other related costs? If allowable, do we budget these costs as Other Costs?

ARPA-H will not negotiate Cooperative Agreements or Other Transaction Agreements under the Small Business Innovation Research program authority in support of NITRO. ARPA-H may pay for reasonable costs associated with patents (excluding foreign patents, which are unallowable costs). It is the responsibility of the proposer to demonstrate why sales and marketing, business development or other related costs are necessary elements of the proposed project. In general, these costs will be considered unallowable. Proposers are advised that while not required, ARPA-H may perform a cost realism analysis in addition to the price reasonableness analysis.

Is there a list of unallowable and allowable budget costs? For instance, is tuition an allowable cost?

Please see 45 CFR Part 75 Subpart E *Cost Principles*.

The revisions to the BAA on 6/22/2023 include an upload of “the cost proposal spreadsheet (which serves the purpose of the SF-424A Budget Information form)”, we would like to confirm that this cost proposal spreadsheet is to be used for a Cooperative Agreement?

Please see Amendment 3, which provides for both the OT Cost Proposal Spreadsheet and the modified SF-424A Spreadsheet for Cooperative Agreements. Proposers requesting an OT should note the revised OT Spreadsheet provides for a higher threshold for providing supporting documentation for Other Direct Costs (as described in the amended BAA).

Cost proposal instructions in the BAA vs. cost proposal instructions on Materials-Supplies tab in the NITRO cost proposal spreadsheet. We would like confirmation that backup is only required on an entry with a unit cost over \$5,000, but not required for every entry as inferred in the BAA.

Please see Amendment 3 and also note both spreadsheets provide cells to address a justification and/or basis of estimate for all costs, not just ODCs. The requirement related to support for ODCs with an aggregate value of more than \$10,000 is in addition to the basic requirement to provide a basis for the price/cost. While ARPA-H may request additional information/documentation to substantiate a proposed cost/price, the burden falls on the proposer to sufficiently support its proposed cost/price.

Is there a limit on the level of funding and are there mandatory requirements for the cost proposal?

The BAA does not include a funding limit for individual awards. Abstracts will be evaluated based on the criteria laid out in the solicitation, to develop novel techniques for the regeneration and reconstruction of intra-articular (IA) cartilage and subchondral (SC) bone, the two key tissue types in a joint, in osteoarthritis (OA) patients, and the cost realism of such development.

There is no statutory requirement for cost sharing under any OTs negotiated by ARPA-H. ARPA-H will consider proposals for cost sharing from Proposers. Ultimately award terms and conditions will be determined for each project considering all elements of the projects (e.g., Fixed support, Expenditure with cost share or Expenditure based with no cost share). Please refer to the solicitation for all the details:

<https://sam.gov/opp/0d6d0844c8c949f39819badf44197a98/view>

What's the budget range?

Please provide realistic, justifiable, comprehensive, and reasonable budgets that demonstrate how you will accomplish the metrics of your selected program structure (e.g., Option A, Option B, Option C).

SCIENCE

If we have specific science questions about how to meet the metrics in the BAA, can you answer and provide directions? For example, see the questions below.

ARPA-H will not provide direction on scientific strategies of how to meet the metrics of the BAA other than providing clarity (e.g., describe what is allowable) and/or re-iterating the defined portions of the BAA. Please see the example questions below.

a) Can an off-the-shelf cell product be used for TA1 and or TA2?

Yes, if it meets 100% of the metrics in the BAA.

b) Can the goal of the IV therapeutic be to focus on pain relief? Or could it be a targeted anti-inflammatory?

Yes, if it meets 100% of the metrics in the BAA.

c) Can you repurpose an FDA-approved drug?

Yes, if it meets 100% of the metrics in the BAA.

d) Do we need to identify the clinical trial sites at this time, or can this be done during Phase I?

Specifically, for d) as well as a), b), and c), the proposals must meet and accommodate for all metrics listed in the BAA, and the NITRO team will not provide specific information related to the technical design or proposed solutions for individual concepts. We will be evaluating the proposals based on the four review criteria and metrics listed in the BAA. It is the responsibility and at the discretion of the Proposer to submit a technical approach, plan, and rationales that meet these criteria and metrics.

For TA3, does allogenic mean an allogenic cell source is required or is a cell free (e.g., cell homing) approach considered responsive?

All approaches will be considered; however, the chosen allogenic approach must meet all the metrics for TA3 listed in the BAA.

For TA3, what constitutes patient specific? (e.g., specific geometry)

The BAA leaves it up to the proposers to define patient-specific while meeting all metrics in TA3.

Can you please clarify how many patients are required in the phase 1 clinical trial? The BAA is a little confusing because the scalability requirements (20-100 in some parts, 1000+ in other parts of the BAA) may be interpreted as subject numbers for the phase 1 clinical trial. How many patients do we need for clinical trial phase I?

Determination of the number of patients for the Phase 1 Clinical Trial in NITRO Phase 2.2 is the responsibility of the proposers. Additionally, and different from the Phase 1 Clinical Trial, the metrics for manufacturing standards are defined in the BAA for NITRO Phase 2.1 and NITRO Phase 2.2.

Is systemic treatment for cartilage regeneration required or optional?

A systemic therapeutic for cartilage regeneration is required.

Can blood be collected from patients to for TA1 or TA2?

Please read BAA pages 7, 9, 15, 20-22. If the procurement of autologous sources is considered surgical, these approaches are not allowed for TA1 or TA2 therapeutics.

Does TA2 require development of both an intra-articular (IA) and a systemic (e.g., IV) therapeutic?

Yes. However, the two (2) therapeutics may be different; therapeutic(s) for IA and systemic delivery may be different.

a) **What does systemic delivery in the context of TA2 mean?**

Therapeutic(s) are delivered to the whole body via oral, intravenous, or another systemic route of administration.

b) **Can systemic mean simultaneous delivery into multiple joints?**

For TA2, multi-joint delivery must be via systemic administration. This does not mean repeated intra-articular injections.

c) **Does the IV therapy need to be the same as the IA delivered therapy?**

No.

d) **Following IA delivery of a bone therapeutic (TA1) and IA delivery of a cartilage therapeutic (TA2), can that be followed with something delivered systemically for cartilage?**

Yes. Proposers can use any combination of the IA bone therapeutic (TA1) with both developed IA and systemic cartilage therapeutics (TA2).

e) **Can a bone therapeutic for TA1 be delivered systemically?**

No, as NITRO seeks targeted, subchondral bone therapeutics. The off-target effects of systemic bone formation, such as heterotopic ossification, are not solicited in this BAA.

Can a product for TA3 be both allogeneic and autogenous? Can a synthetic product be utilized?

Proposals for TA3 should develop both an allogeneic and autogenous implant. The allogeneic and autogenous implants must meet the specifications in the BAA (Page 23). If the product has any allogeneic components, it will need to accomplish the allogeneic specifications in the BAA. Synthetic products may be utilized in the development of the complete constructs for implantation, noting that no permanent fixation is listed as a metric in the BAA for TA3 proposals.

Do therapeutics need to be FDA approved before the end of the project?

No. However, Phase I clinical trials will be completed.

For large animal model can a focal (> critical size defect) be used or must OA be induced and treated?

The defect must be beyond a critical size defect and regenerate all stages of OA back to Grade 0. Please refer to the BAA for the specific language. Notably, the NITRO team will host the NITRO OA Model Symposium to help performers establish the ideal OA model to use in the Preclinical Phase.

Given the therapeutic is to be defined in NITRO Phase 1, what level of detail is needed to describe the large animal model work and the FDA Phase I Clinical Trial in NITRO Phase 2?

Proposals should lay out a comprehensive response to the entirety of the program outlined in the BAA.

Does an arthroscope delivery satisfy TA3 requirements?

No, unless you can perform an allogeneic and autogenous joint replacement that meets all the metrics in the BAA for TA3 using the arthroscopic approach. An arthroscopic approach alone is not sufficient to meet all these requirements. An arthroscopic approach is, however, a valid approach for TA1 and TA2. Please reference the metrics for the program in the BAA for further information on potential approaches.

For TA3 for the patient-specific implant, would NITRO be open to a semi-custom system in which a catalog of multiple shapes and sizes are readily available for use; or must it be fully designed for each patient?

Yes, if it meets 100% of the metrics in the BAA. In general, the NITRO team does not have a preference related to specific technologies under development. If the product fits the metrics of the BAA, it will be considered.

a) For the Total Knee Arthroplasty (TKA) allograft with the technical requirements still be met if the product is off the shelf available within 24 hours?

The custom TKA allograft must be manufactured in less than 24 hours, this includes any planning to get the allograft fully manufactured and ready for implantation. Please refer to the BAA for each of the specific metrics related to TA3.

b) For TKA autograft with the program allow the graft to be designed before the 30-day manufacturing timeline?

The custom TKA autograft must be manufactured in less than 30 days, this includes any planning to get the autograft fully manufactured and ready for implantation. Please refer to the BAA for each of the specific metrics related to TA3.

c) I can make a strong scientific argument that an allogeneic cell source taking >24 hours < 30 days could provide a more robust osteochondral construct for the patient. For example, custom implant manufacturer and allogenic cell culture- is this allowed for TA3?

The allograft must be manufactured within less than 24 hours for TA3.

Single vs. multi-joint approach; what happens if one therapeutic does better than the others during the program?

At this stage, the performer team will have conversations with the NITRO team about the best path forward.

TA2 requires development of both an intra-articular (IA) and a systemic (e.g., IV) therapeutic and since the target is completion of a Phase 1 human trial, does that mean proposers are expected to develop 2 separate late pre-clinical GLP data sets and 2 separate INDs/clinical safety trials?

Yes.

a) If a therapeutic has hit clinical stage, do we still need to start at the beginning of Phase 1 of the NITRO program?

Yes. To the best of our knowledge, we are not aware of a current potential therapeutic that meets the metrics of the Phase I clinical testing that are required by the BAA. Unless the proposed therapeutic meets these metrics, performers must begin the program at the appropriate stage in which all metrics are to be met.

- b) **What happens if our novel solution is discovered in the first year of NITRO? Do we start the pre-clinical trials as stated in the program timeline?**

If **ALL** the metrics for NITRO Phase 1 are achieved earlier than the 24-month window, ARPA-H may negotiate an accelerated timeline on a case-by-case basis. However, this is contingent upon achieving all metrics listed in the BAA for NITRO Phase 1. Deviations from the prescribed NITRO timeline should not be part of the proposal.

- c) **Do proposers only need 1 of the therapeutics to progress to Phase 1 human trial? In this case what is the minimal acceptable readiness for the second candidate?**

To progress through the NITRO program, all performers must succeed within their chosen Option (e.g., Option A, Option B, Option C) for all required therapeutics. It is the proposer's responsibility to determine the minimal acceptable readiness for all candidates and should not assume that only 1 therapeutic will progress to Phase 1 Clinical Trial.

Phase 1 Clinical Trial- does a sport injury patient make the cut?

Phase 1 Clinical Trials will follow FDA rules and regulations. The patient population will be a diverse cohort described in the BAA metrics. The BAA does not exclude patients with different pathologies of OA.

STRUCTURE

Is the Project Start Date the start of the federal FY24, 10/1/23? Please confirm the Project Period is 5 years.
The NITRO Program is 5 years long and aims to start in Q1 of FY24.

The prime institution is submitting a proposal with our institution as a subaward. Would it be possible to change the prime awardee institution to the subaward institution (i.e., reverse roles) for Phase 2 (years 3-5) of the project? If so, would this be something to discuss at the proposal stage, the award negotiation stage, once awarded to the prime (applicant) institution and Phase 1 has started (years 1-2)?

If a proposal is selected to move forward for negotiation of an award instrument, this would be discussed during negotiations.

Is ARPA-H looking for proposals with technical solutions that are well-developed, likely already in NITRO Phase 2?

ARPA-H cautions proposers from making assumptions outside of the information provided in the BAA. For instance, while the program timeline indicates a 24-month discovery phase, aggressive timelines like this are standard for ARPA-H. ARPA-H is not looking for any specific technology or proposals and encourages performers to feel free to submit all technical solutions they believe can accomplish the program metrics even if they aren't "well-developed" at this time. ARPA-H welcomes compliant abstracts/proposals with technical solutions that meet the metrics outlined in the BAA. Proposals will be evaluated against the evaluation criteria provided in the BAA and will not be evaluated against each other. All potential performers will start the program at NITRO Phase 1 regardless of current technical progress in clinical trials; all performers must meet all metrics in the BAA.

Will abstracts receive feedback in addition to or beyond "encourage" or "discourage" submission?

No. Please see the BAA for further details on abstract review criteria.

The BAA and on the Proposers' Day deck states that 20% of participants in clinical trials should be Native American / Alaskan Native however I believe only about 1% of the US population is NA/AN. Given that, are these numbers for Clinical Trial Equity going to be followed and enforced?

Yes. The ARPA-H NITRO team is in consultation with experts and a revision may occur in the future, however, we are committed to equity and believe the NITRO Clinical Trials should be no exception.

Must the Equity Officer be part of the proposer's institution?

No, a subcontractor billed to the award is acceptable.

Will the program staff be suggesting groups team up based on the abstracts?

No. Teaming is at the discretion of proposers.

Will PATIO or the XIR resources be available to help match proposers to potential EOs?

While the PATIO resources – which includes the XIR resources – will be available to performers in the program at the discretion of the NITRO team, proposers must find and provide their own EO(s) for their performer teams. These EOs need to be indicated in the proposals for ARPA-H review and approval.

Timelines for clinical trials are aggressive- Will ARPA-H collaborate with clinical sites to facilitate and accelerate trials?

The ARPA-H model is inherently fast-paced and fuels innovation at an accelerated rate. While ARPA-H may collaborate with clinical sites, we expect performers to move at the pace of the program in order to succeed. More information will be provided to performers once the program begins.

Can a team change after phase 1 based on results? What would the process be?

Teaming changes may be allowed at ARPA-H's discretion and in response to new or different needs arising from the program's progress. However, requests would be dealt with on a case-by-case basis.

Will we be penalized for not partnering if we believe our group can do it all?

No. If you believe you and/or your team can accomplish all program metrics, there is no requirement to team with other entities. While we believe teaming will be important to succeed, teaming is at your discretion.

Clinical follow-up period: FDA generally mandates 2-year follow up; 5-year data for CMS; we're looking at 12-month reliability which is longer than most 5-year data requirement for CMS any chance to relax it/encourage acceptance prior to that to encourage funding?

The NITRO timelines will remain as written in the BAA to revolutionize the field.

Regulatory involvement/guidance: the type of therapeutic/species of therapeutic can determine what's 'regulatory possible'- will ARPA-H help brainstorm finding the right FDA venue?

Yes. At the discretion of the NITRO team, ARPA-H and PATIO will help performer teams find the appropriate regulatory routes with the FDA or EMA.

With an aggressive timeline, are you evaluating the feasibility and timeline?

No. The timeline is aggressive and set at the same benchmark for all proposers. The full proposals will be evaluated based on the criteria stated in the BAA.

Is attendance at Proposers' Day required for submission of an Abstract or Full Proposal?

Participation in the NITRO Proposers' Day is not a requirement for submission of an abstract, full proposal, or selection for funding.

Are Lightning Talks and Sidebars limited to in-person participants for Proposers' Day?

Lightning Talks and Sidebar conversations are not limited to in-person participants; virtual participants were also selected.

Is there a limit for in-person registrants and virtual registrants for Proposers' Day?

The in-person registration is limited to 2 individuals per institutional department, and 130 maximum in-person attendees. The virtual registration is not limited based on institutional department, and the maximum number of attendees is 3000.

I am confirmed for the in-person and virtual Proposers' Day, what should I expect throughout the day regarding travel plans and watching the event virtually?

Proposers' Day will be a full day of events with opening presentations from ARPA-H Directors to presentations on the specifics about the NITRO BAA from the Program Manager and Acquisitions.

The Proposers' Day complete Schedule will be released no later than 6/14/23 to all confirmed registrants. At this time, please note the event will take place on Thursday, June 15, 2023, from 8:30AM to 6:00PM CDT.

If selected for a timeslot to present at Proposers' Day, registrants will be notified no later than 6/14/23. Registrants notified with selected timeslots will not need to upload slides at the time of Proposers' Day (the ARPA-H team will handle all slides during the event to maintain schedule given time constraints). Registrants selected for a timeslot for a Sidebar conversation on Proposers' Day were notified on 6/9/23.

Due to the enormous interest in sidebars, ARPA-H will be scheduling additional sidebars on 6/20/23. ARPA-H will provide additional scheduling information to those who previously requested the sidebars in their registration for Proposers' Day; information will be sent no later than 6/19/20. No additional requests for sidebars will be accepted.

Can you meet with me to discuss the NITRO program?

The NITRO project team is unable to accommodate individual requests for calls or meetings to discuss concepts that a potential applicant is considering submitting to the BAA. We will evaluate and provide feedback on technical concepts once they have been officially submitted. Sidebar conversations serve as the opportunity to meet with the NITRO team to discuss your concepts and to answer any BAA specific questions.

ELIGIBILITY

Are there any limitations on collaborating with international entities?

Please see paragraph 3.1.2. *Other Applicants* of the BAA regarding international entities.

Will you fund or allow work outside the US such as clinical trials?

NITRO strongly prefers that clinical trials be performed in the US, however, trials in other countries will be considered on a case-by-case basis at ARPA-H's discretion. Additionally, foreign sub-awardees will be considered on a case-by-case basis at ARPA-H's discretion. Please see Section 3.1.2. *"Other Applicants"* of the BAA for requirements for foreign entity participation on ARPA-H awards.

How do we collaborate without NDAs?

NDAs may be used at the proposer's/performer's discretion.

Regarding qualifying for NITRO- are there restrictions to the funding we receive, who owns the company?

Receiving funding from someone else does not necessarily disqualify you. Majority ownership through a private enterprise is acceptable, but all situations will be assessed by ARPA-H at the proposal review stage with a determination made on a case-by-case basis.

I'm an OA patient, how can I get involved with the NITRO program?

ARPA-H does not conduct its own research. Instead, the agency funds research organizations such as universities and medical centers to conduct such work. If you have an interest in volunteering for studies, you could look for volunteer opportunities at hospitals, universities, or research institutions near you. For example, the National Institutes of Health maintains a webpage with information on volunteering: <https://clinicaltrials.gov/>. Thank you again for your interest, and we encourage you to stay up to date on the current state of the program at <https://arpa-h.gov/engage/programs/nitro/>.

Who is allowed to submit for Abstracts and Full proposals? Young Investigators? Industry? Academia?

We welcome investigators at all stages in both academia and industry. The NITRO program anticipates teaming will be necessary to accomplish our program goals and metrics. You can find more information about teaming on the NITRO teaming page, here: <https://arpa-h.gov/engage/programs/nitro/teaming/>.

APPLICATION AND SUBMISSION

Please clarify what is needed in the 'other documents' section of Volume II for Human Subjects Research documentation. Will a letter documenting our current Assurance of Compliance with federal regulations for human subjects' protection, including at least a Department of Health and Human Services (HHS), Office of Human Research Protection Federal Wide Assurance suffice?

Proposers are encouraged to use the Other Project Information form to document compliance with all required elements of HSR and ASR. Documents that may be included as attachments to this form are the following: IRB Approvals or Exemptions, IACUC Approvals, and the Vertebrate Animal Section (VAS).

Is there a template to use for the C&P and biographical sketches, or is any format acceptable as long as it contains the information requested by the BAA? Is there a page limit to the biographical sketches?

There is no required template for the biographical sketches and there is no page limit.

What is the difference between the Statement of Work and the Schedule and Milestones?

Please see BAA 4.2.2. Section III *Detailed Proposal Information* Paragraphs F and G for a detailed description of what is required for each.

Please clarify if we may submit the same information for the "project abstract" and "project abstract summary" on grants.gov? The BAA doesn't mention the Project Abstract, and the Project Abstract Summary is only mentioned as a requirement for the coop agreement.

Proposers requesting a Cooperative Agreement should complete both forms. The BAA directs proposers requesting a Cooperative Agreement to Grants.gov and indicates that all forms listed as "Mandatory" are required.

2 CFR 200.400 includes the following statement: The Non-Federal entity may not earn or keep any profit resulting from Federal financial assistance, unless explicitly authorized by the terms and conditions of the Federal award. See also § 200.307. Could you confirm that a fee/profit is allowable or not for ARPA-H cooperative agreement mechanisms?

Fee/profit will only be allowed under Cooperative Agreements if, in accordance with normal commercial practice, a contractor is providing routine goods and services to the Cooperative Agreement recipient (or subrecipient). For fee/profit to be allowable in these very limited cases, the proposer must clearly disclose the fee/profit and provide an explanation for ARPA-H to consider and determine whether the fee/profit is allowable.

I am unable to add information about more than 4 co-PIs into the Research and Related Personal Data form. Please advise.

Please use multiple forms if a single form is insufficient to address the proposed technical approach.

Are letters of support (and other supporting materials) discouraged and do they count against the page count?

Letters of support will count against the page count. It is at the proposer's discretion to include them or not.

When will abstract feedback be provided to proposers?

ARPA-H estimates abstract feedback, limited to encouraging or discouraging submission of a full proposal, will be provided by 6 July.

Can an entity propose through multiple proposals?

An entity may only submit a single proposal as the prime awardee. An entity may propose in multiple proposers' teams as a sub-awardee/subcontractor. If an entity, proposed as a sub-awardee, is part of multiple successful teams (i.e., award recipients), the Government may establish Associate Contractor Agreements (ACAs) with the applicable prime awardees. The requirement for an ACA will be dependent on the types of services/supplies provided by the sub-awardee; and the specific terms and conditions will be negotiated for each award.

Can a Principal Investigator (PIs) propose under multiple abstracts/proposals?

While PIs can only be on one prime award, PIs are not limited to the number of subawards given that the level of effort meets the needs of each subaward. PIs should consider their level of effort across numerous assets and expect the NITRO program to take a significant level of effort.

Can we submit with a couple of different teams using our platform technology?

You may be the Sub-Awardee on multiple proposals. You may only be the Prime Awardee on one proposal.

I've run into an issue with Abstract or Proposal submission. Can the NITRO team help?

Please email NITRO@arpa-h.gov with more specific information about the issue and a team member will get back to you to resolve the issue before July 28th at 5:00 PM EST. However, we will be unable to respond to any questions after July 28th at 5:00 PM EST until NITRO Performers have been selected and announced.

What is the difference between an Abstract and a Full Proposal?

Please refer to the information on the solicitation for the NITRO BAA here:

<https://sam.gov/opp/0d6d0844c8c949f39819badf44197a98/view>. Abstracts are limited to 6-pages to pitch the idea to the NITRO team. While not required, abstracts are intended to be an option for potential performers to receive a recommendation from ARPA-H (i.e., recommendation to submit or not submit a full proposal) prior to investing the effort required to submit a full proposal. Full Proposals are limited to 40 pages.

How do we choose which funding pathway to request? What is the reason that a proposer should select co-op agreement versus OTA?

We recommend you work within your institution/entity to establish the best funding pathway for proposer-agnostic necessities. ARPA-H will not provide guidance on which funding pathway to select; it is up to the proposer to select and make that decision. However, award type will be negotiable and will ultimately be at ARPA-H's decision.

Who owns the IP?

IP rights will be part of award negotiations between the proposer and ARPA-H. Note, there are more flexibilities regarding IP under other transactions than under financial assistance regulations.

Are multiple PIs allowed?

Yes, but only one PI may be the Prime Awardee. Similarly, an individual can only be a Prime Awardee once but can be Sub-awardee on multiple proposals.

When will my teaming information be posted on the teaming page, and can I change the teaming information after the initial submission?

The teaming information is reviewed and posted on a rolling basis. Submission of teaming information does not guarantee that the information will be posted on the NITRO Teaming Page. The NITRO team reviews the team profiles based on the completeness, relevance, and acceptability of the submitted information. Incomplete, non-relevant, and non-acceptable submissions will not be posted on the teaming page. If you wish to change your teaming information, please email NITRO@arpa-h.gov with the requested changes.

What is the timeline from abstract submission to invitation for full proposal?

There will be no invitation for full proposal. Abstracts are welcomed but not required. Regardless of abstract feedback, any potential proposer who believes he/she/they are able to accomplish the program metrics may submit a full proposal by July 28th at 5:00pm ET. Please refer to the information on the solicitation for the NITRO BAA here: <https://sam.gov/opp/0d6d0844c8c949f39819badf44197a98/view>.

Is a university, as an institution, limited to submitting one (1) proposal as a prime awardee?

A university, as an institution, is not limited to submitting one (1) proposal as a prime awardee. A department within an institution (e.g., a university) is limited to submitting one (1) proposal as a prime awardee.

a) **If so, would the limitation apply to submission of abstracts or invited full proposals?**

The limitation will only apply to full proposals, not abstracts.

b) **Or for universities, should the term proposer be understood in reference to individual PIs, and thus multiple PIs at the same university could submit in parallel on behalf of independent teams?**

Multiple PIs from different departments at the same institution may submit separate Abstracts or Full Proposals given that there is no overlap between the applications. Multiple PIs from the same department can submit an Abstract to the NITRO BAA; however, only one (1) Full Proposal will be considered from each department. It is possible that multiple Full Proposals could be accepted from different departments in the same institution, yet the teams must not overlap.

Are cover letters limited to one page? Are there margin formatting restrictions?

Please see the BAA for specific guidance related to these and other formatting questions.