

# ARPA-H Proposal Submissions @ Emory

Presenters:

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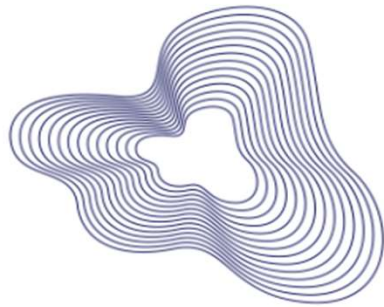


## Who We Are

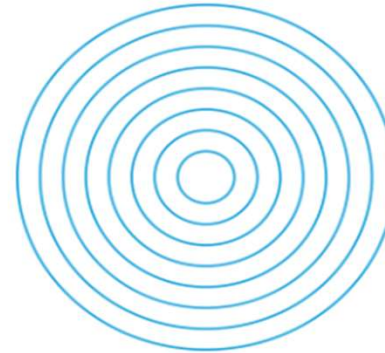
ARPA-H advances high-potential, high-impact biomedical and health research that cannot be readily accomplished through traditional research or commercial activity. ARPA-H awardees are developing entirely new ways to tackle the hardest challenges in health.



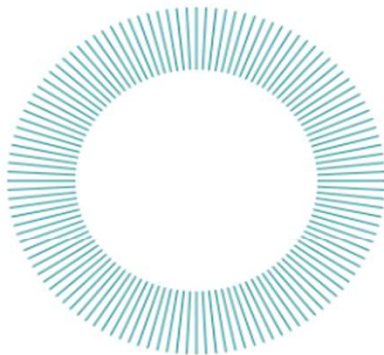
## Focus Areas



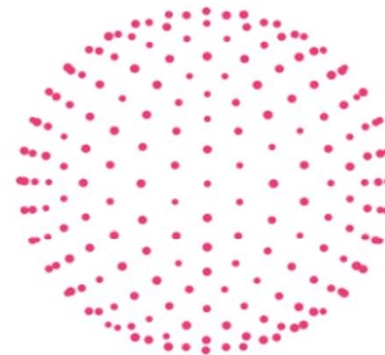
**Health Science Futures**  
*Expanding what's technically possible*  
[Learn More](#)



**Scalable Solutions**  
*Reaching everyone quickly*  
[Learn More](#)

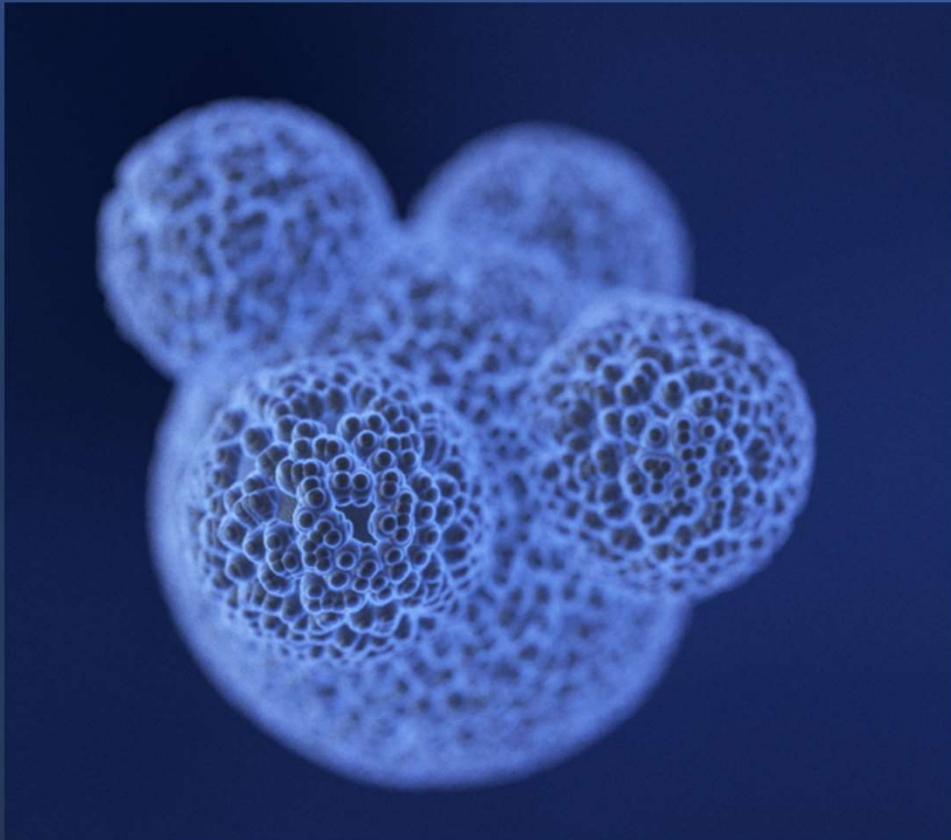


**Proactive Health**  
*Keeping people from being patients*  
[Learn More](#)



**Resilient Systems**  
*Building integrated healthcare systems*  
[Learn More](#)



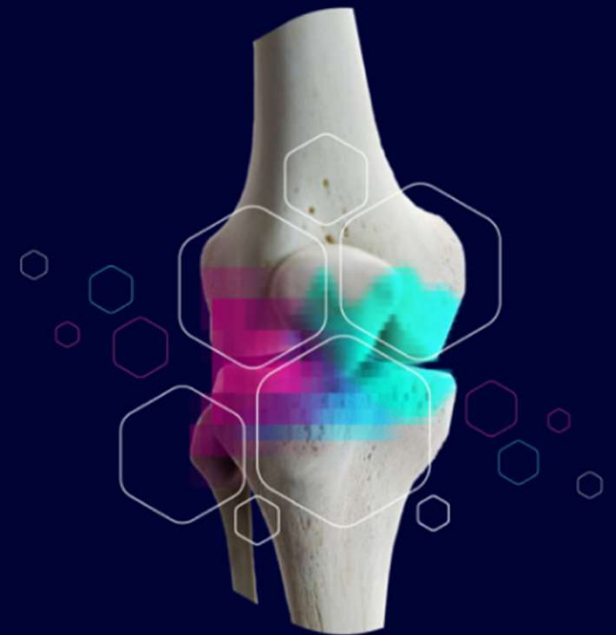


## **What We Do**

With a scope spanning the molecular to the societal, ARPA-H programs have the potential to radically improve everyone's health. Our streamlined awards process enables us to act quickly and catalyze cutting-edge biomedical and health research.



**ARPA-H  
launches  
program to help  
joints heal  
themselves**



## How we're different

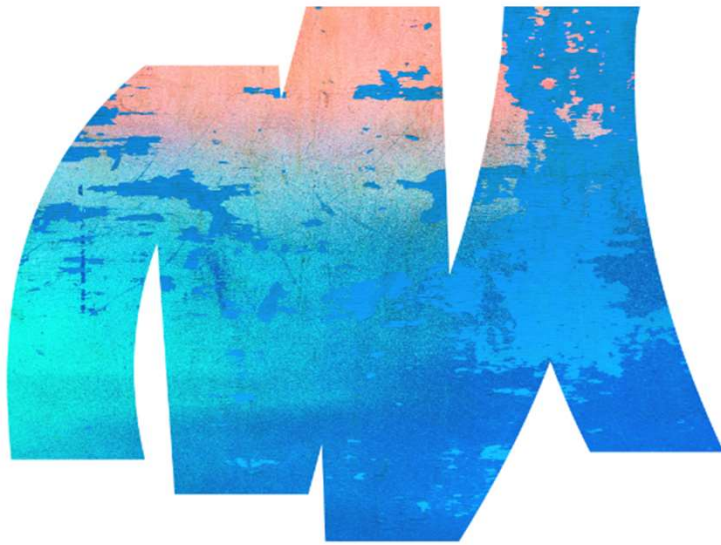
### Hard problems, high-impact answers

ARPA-H makes pivotal investments in breakthrough technologies and broadly applicable platforms, capabilities, resources, and solutions with the potential to transform important areas of medicine and health that cannot readily be accomplished through traditional research or commercial activity. ARPA-H solutions aim to benefit everyone.



**RFI open to  
solicit ideas for  
ARPA-H, FDA  
collaboration**





## Our Values

### **INNOVATIVE**

Seek novel ideas, collaborations, and approaches

### **NIMBLE**

Be flexible and urgent, time-bound

### **RESPONSIBLE**

Maintain highest levels of scientific integrity and fiscal accountability

### **TRANSPARENT**

Remain open and honest; engage stakeholders

### **BOLD**

Be courageous in goals and approach; be undaunted by the potential for failure

### **DIVERSE**

Represent a myriad of demographics, geographies, expertise and experiences





# Training Mission & Objectives

To introduce Research Administration staff to the newest federal R&D funding agency: the Advanced Research Projects Agency for Health (ARPA-H).

## Objectives:

- Provide insight into the type and structure of ARPA-H awards
- Emphasize the timeline for submission and the need for communication with OSP
- Highlight key considerations when developing and submitting proposals

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# ARPA-H Overview

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# ARPA-H General Information

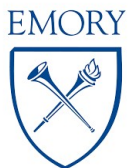
- Mission: Accelerate better health outcomes for everyone by supporting the development of high-impact solutions to society's most challenging health problems
- Established under the Biden Administration in 2022, ARPA-H is a new federal R&D funding agency
  - Congress has funded \$2.5B to start operations & research
- Organized under the U.S. Department of Health and Human Services (DHHS); exempt from NIH policies & requirements

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# ARPA-H: R&D Focus Areas

- The Advanced Research Projects Agency for Health (ARPA-H) supports transformative research to drive biomedical and health breakthroughs... to provide transformative health solutions for all.
- Focus Areas
  - Health Science Futures
  - Proactive Health
  - Scalable Solutions
  - Resilient Systems



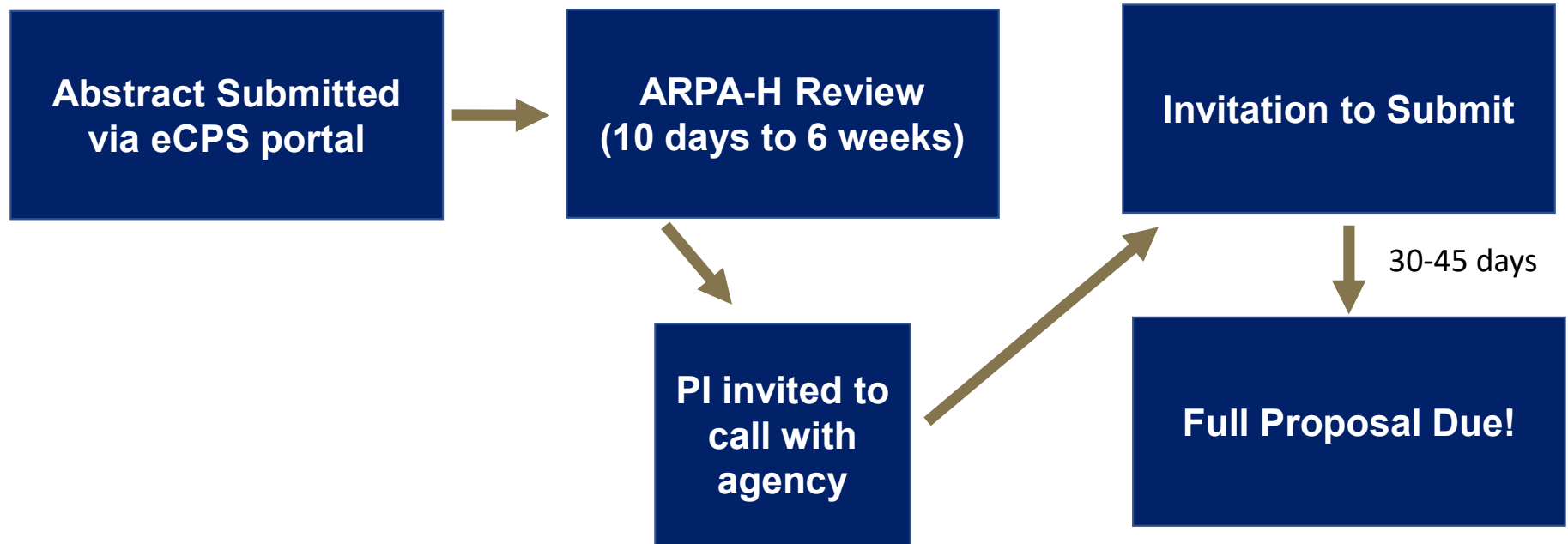
# ARPAs vs. Others

- Broad Agency Announcements (BAAs)
- Empower program managers to initiate and run programs of their own creation
- Incorporate business practices that reflect commercial industry standards and best practices
- Quick execution
- High-risk / high-benefit projects

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# Open Office BAA Timeline\*



# ARPA-H Open Office BAA 75N99223S0001 Review

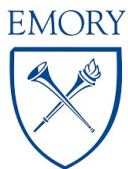
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**Let's find it!**





# ARPA-H Open Office BAA Find



By what date are abstracts due?



What types of award instruments may be awarded?



What types of entities are eligible to apply?



Is there a limit on the # of ARPA-H awards for an investigator or institution?



# ARPA-H Open Office BAA Review

- Part I: Overview Information
  - Details pertinent sponsor and solicitation
    - Federal agency name, announcement type, submittal due dates, types of award instruments, agency contacts, etc.
  - Abstracts Due Date: 3p ET, March 14, 2024
    - Abstracts can be submitted, and will be evaluated on a rolling basis
  - Award Instruments:
    - Cooperative Agreement, Other Transaction Agreement (OTA or OT) and Procurement [FAR BASED] Contract

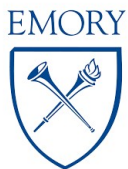


# Award Instrument Types



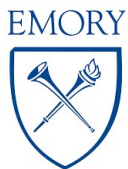
\*Grants are not an authorized award instrument for this BAA

\*\*ARPA-H reserves the right to decide which award instrument will be used, if awarded.



# Proposal Preparation & Submittal Award Instrument & Agreement Types

Award Instrument	Agreement Type	Governing Regulation ARPA-H BAA	Reference
Grant & Cooperative Agreement	<ul style="list-style-type: none"> <li>• Cost reimbursement</li> <li>• Fixed price</li> </ul>	<ul style="list-style-type: none"> <li>• Uniform Guidance</li> <li>• HHS Grants Policy Statement</li> <li>• Uniform Administrative Requirements...for HHS Awards</li> </ul>	<ul style="list-style-type: none"> <li>• 2 CFR 200.201</li> <li>• 2 CFR 200.333</li> <li>• 45 CFR 75</li> </ul>
Procurement Contract	<ul style="list-style-type: none"> <li>• Cost reimbursement</li> <li>• Fixed price</li> </ul>	<ul style="list-style-type: none"> <li>• Federal Acquisition Regulation (FAR)</li> <li>• Health and Human Services Acquisition Regulations (HHSAR)</li> </ul>	<ul style="list-style-type: none"> <li>• FAR Subpart 16.2</li> <li>• FAR Subpart 16.3</li> <li>• HHSAR Subpart 316</li> </ul>
Other Transaction Agreement	<ul style="list-style-type: none"> <li>• Fixed price, milestones</li> <li>• Expenditures (cost reimbursement)</li> </ul>	<ul style="list-style-type: none"> <li>• United States Code</li> <li>• US Law</li> </ul>	<ul style="list-style-type: none"> <li>• If selected for a full proposal, request copy of the draft OTA terms for review.</li> </ul>



# ARPA-H Open Office BAA Review

- Part II: Full Text of Announcement
  - III. Eligibility Information
    - A. Eligible Applicants
      - All responsible sources capable of satisfying the Government's needs
        - FAR Subpart 9.1 Responsible Prospective Contractors
      - FFRDCs, Government Entities, and Other Applicants
        - Other applicants include businesses, non-profits, universities, individuals and non-US entities (subject to BAA requirements)
      - Limitation on Number of Awards
        - Active awards limited to 3 per entity.



# Eligible Applicants

## Prime Awardee

- Prime Awardee
  - Institution that is directly receiving funds from the sponsor and will be in direct line communication with the agency
  - Performs a substantive role in the conduct of the planned research
  - Provides appropriate oversight of all scientific, programmatic, financial, and administrative matters related to the award instrument



# Eligible Applicants

## Subawardees

- Subawardee/Consultant (Team Member)
  - Receives funding from the prime awardee to complete a portion of the scope of work
  - *May* be expected to provide the same level of detail in the budget as the prime
  - Subawardees are encouraged to request the applicable prime agreement flow-downs early
  - May have little contract experience and need guidance from the prime



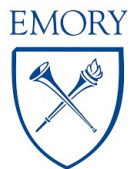
# ARPA-H Open Office BAA Review

- Part II: Full Text of Announcement
  - III. Eligibility Information
    - B. Organizational Conflicts of Interest (OCI) –
      - FAR Subpart 9.5 Organizational and Consultant Conflicts of Interest
      - Disclosure required with each proposal submittal, regardless of award type requested
      - FAR does not apply to OTs, however, OCI must be addressed as prescribed in FAR 9.5
    - Agency Supplemental OCI Policy
      - Restrictions: Advisory & Assistance Services (A&AS) & Science Engineering and Technical Assistance (SETA) support to any ARPA-H office(s)
      - See BAA for specific details regarding disclosure requirements





# Proposal Preparation & Submission



# ARPA-H Open Office BAA Find



What is the font size for abstract and proposal text?



Are abstracts required?



What are the two volumes that make up a full proposal?



# Proposal Preparation & Submittal

- Part II: Full Text of Announcement
  - III. Eligibility Information
    - D. Content and Form of Application Submission
      - Abstract Format
        - Cover page, concept summary, innovation & impact, proposed work, team organization and capabilities, and rough order of magnitude.
    - Full Proposal Format – consists of 2 volumes
      - **Volume I Technical and Management Proposal**
        - Cover page required – 1 pg. max
        - See Statement of Work requirements detailed on pages 15-16
        - OT requests require a list of milestones & payment schedule
        - See Attachment 5 for packaging & delivery instructions



# Proposal Preparation & Submittal

## SOW MILESTONES FOR OTs

- Each milestone must include the elements detailed in BAA (pg15)
- Milestones are not required to match actual expenditures but should realistically align to the effort expended or products delivered
- Milestones should relate directly to accomplishments of program technical metrics as defined in the BAA and/or proposal

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# Proposal Preparation & Submittal

## REFERENCE TOOL – SAMPLE MILESTONE PAYMENT PLAN FOR OTs

Milestone #	Milestone Description	Exit Criteria Or Deliverable	Due Date	Payment Amount
1	Outline to the formal modeling approach	Milestone Report	Month 1	\$100,000
2	A plan of case studies consistent with formal approach...	Milestone Report	Month 3	\$500,000
Total				\$600,000

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# Proposal Preparation & Submittal

- Part II: Full Text of Announcement
  - III. Eligibility Information
    - D. Content and Form of Application Submission
      - Full Proposal Format – consists of 2 volumes
        - **Volume II Cost Proposal**
          - Cover page required – 1 pg. max
          - Cost proposal does not have page limit
          - See Attachment 5 for packaging & delivery instructions
    - Include supporting cost or pricing data in sufficient detail to substantiate the summary of cost estimates
    - Subcontractor/Subawardee proposals should be prepared to the same level of detail as the prime



# ARPA-H Open Office BAA Find



Through what system are abstracts and proposals submitted?



Are there any funding restrictions?



What are the four actions that ARPA-H may take after reviewing an abstract?

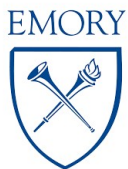


What are two actions that ARPA-H may take after reviewing a full proposal?



# Proposal Preparation & Submittal

- Content and Form of Application Submission
  - Other Documents, as applicable
    - Proprietary Markings
    - Representations & Certifications
    - Human Subject Research
    - Animal Subjects Research
    - OCI Disclosures & Mitigation Plan
    - Small Business Subcontracting Plan (for contracts meeting a \$ threshold)
    - Section 508 of Rehabilitation Act (FAR Subpart 39.2)
    - Cooperative Agreement Summary
    - Intellectual Property Representations & Assertions (i.e., Data Rights Assertions)





# Proposal Preparation & Submittal

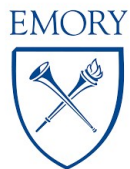
## REFERENCE TOOL - DATA RIGHTS ASSERTION CERTIFICATE - COMMERCIAL

Data Rights Assertions for BAA \_\_\_\_\_

Applicant Name: \_\_\_\_\_

Proposal Reference No. \_\_\_\_\_

COMMERCIAL				
Technical Data or Computer Software to be Furnished With Restrictions	Summary of Intended Use in the Conduct of the Research	Basis for Assertion	Asserted Rights Category (e.g. Unlimited, Limited, Restricted, as defined in FAR 27.401)	Name of Person Asserting Restrictions
(LIST)	(NARRATIVE)	(LIST)	(LIST)	(LIST)



Date

Printed Name and Title

Signature



# Proposal Preparation & Submittal

## REFERENCE TOOL - DATA RIGHTS ASSERTION CERTIFICATE - NON-COMMERCIAL

Data Rights Assertions for BAA \_\_\_\_\_

Applicant Name: \_\_\_\_\_

Proposal Reference No. \_\_\_\_\_

NONCOMMERCIAL				
Technical Data or Computer Software to be Furnished With Restrictions	Summary of Intended Use in the Conduct of the Research	Basis for Assertion	Asserted Rights Category (e.g. Unlimited, Limited, Restricted, as defined in FAR 27.401)	Name of Person Asserting Restrictions
(LIST)	(NARRATIVE)	(LIST)	(LIST)	(LIST)

Date

Printed Name and Title

Signature



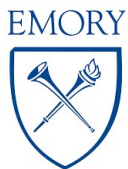
# Proposal Preparation & Submittal

- Content and Form of Application Submission
  - Submission Information – Abstract & Full Proposal
    - Abstract Submission
    - Electronic Contract Proposal Submission (eCPS)
    - BAA Attachment 5 – Packaging and Delivery of Proposals via eCPS Website
  - Forms 1-3 are required when requesting a cooperative agreement
    - See BAA and FAQs for additional guidance
  - Funding Restriction – Pre-Award Cost Agreement
    - Pre-award costs will not be reimbursed unless a pre-award cost agreement is negotiated prior to award.



# Budget Questions

- How is personnel time quantified in the budget?
- Is cost share required or expected?
- Are the materials/supplies, equipment, and other direct costs itemized?
- Are indirect costs allowable?
- Is equipment allowable?



# Budget Considerations

- If the project will include any subawardees or consultants:
  - Follow your institution's policies and 2 CFR 200
  - Provide subawardee/consultant documentation including proposed scope of work and other documentation to verify costs
- If the project will include travel:
  - Detailed travel information (destinations, # of days, # of people, etc.) and cost estimates are required
  - Utilize federal per diem rates - <https://www.gsa.gov/travel/plan-book/per-diem-rates>



# Lessons Learned

- Project management is key
- Provide a heads-up to your Manager / Supervisor due to time commitment
- OCI due at the time of full-proposal submission
- There is little time to go through multiple budget revisions with subrecipients
- Forms may be non-standard (i.e., Other support form)
- Budget templates are mailed out to invited applicants

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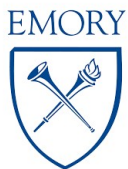
# References & Tools

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# Proposal Preparation & Submittal ARPA-H Proposal Checklist

Item	Description
Proposal Transmittal Letter (Optional)	An official transmittal letter endorsed by authorized representative (e.g. Sponsored Programs).
Volume 1 Technical and Management Proposal	Follow BAA guidelines for Volume I requirements.
Volume 1 Cover Sheet	Volume I cover sheet does not require signature and can be completed by anyone preparing the proposal.
Milestone Payment Plan	See reference tool example
Data Rights Assertions Certificate	Requires applicant to identify whether any restrictions apply to intellectual property (i.e., technical data or computer software) that the Prime Awardee (and Subrecipient) will include in its deliverable. See reference tool example.

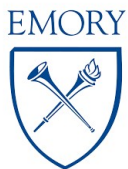




# Proposal Preparation & Submittal

## ARPA-H Proposal Checklist

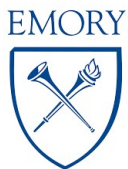
Item	Description
Volume 2 Cost Proposal	Follow BAA guidelines for Volume II requirements.
Volume 2 Cover Sheet	Volume II cover sheet does not require signature and can be completed by anyone preparing the proposal.
Cost or Pricing Data	Required for procurement contracts only; Cost or pricing data may include vendor quotes, nonrecurring costs, F&A rate agreement, etc. Refer to FAR for guidance.
Certificate of Current Cost or Pricing Data	The certificate should be submitted after negotiations, at the time of price agreement.
Small Business Subcontracting Plan	Required for FAR-based contracts requesting \$750K or more in total costs. Refer to institutional policies and procedures to request a small business subcontracting plan specific to support the proposal.
Organizational Conflict of Interest or Financial Conflicts Of Interest	Disclosure that describes the actions the institution has taken or intends to take to prevent the existence of conflicting roles. An OCI mitigation plan is required if a disclosure is made.



# Proposal Preparation & Submittal

## ARPA-H Proposal Checklist

Item	Description
Agency Supplemental OCI Policy	As a part of the OCI disclosure, proposer must affirm whether the proposer or any proposed team member is providing SETA, A&AS or similar support to any ARPA-H office
Signed Cooperative Agreement Summary	1 page max; Submit PDF and word versions. The summary must explain the program or project. ARPA-H publish the statement for awardees.
Attachment 2 Cooperative Agreement Form 1	SF424 R&R Application For Federal Assistance required in addition to other documents referenced in BAA.
Attachment 3 Cooperative Agreement Form 2	SF424 R&R Senior Person Profile required in addition to other documents referenced in BAA. Consists of current and pending support and biosketch
Attachment 4 Cooperative Agreement Form 3	SF424 R&R Personal Data Form required in addition to other documents referenced in BAA.



# Proposal Preparation & Submittal

## ARPA-H Proposal Checklist

Item	Description
Pre-Award Cost Agreement	Pre-award costs will not be reimbursed unless a pre-award cost agreement is negotiated prior to award.
Exceptions to BAA Terms and Conditions	The proposal must include a list of exceptions and supporting rationale for any terms the institute cannot accept.
IRB – Human Subject Research	Must provide documentation of one or more current Assurance of Compliance with federal regulations for human subjects protection
IACUC – Animal Subject Research	Must provide brief description of plans for Institutional Animal Care and Use Committee (IACUC) review and approval.
Representations and Certifications	Verify <a href="http://www.sam.gov">www.sam.gov</a> reps and certs are current. Include any supplemental reps and certs identified in the BAA and/or provided by the sponsor in the full proposal invitation.



# References & Tools

- ARPA H Website
  - <https://arpa-h.gov/>
- For Cooperative Agreements/Subaward proposals – SF424 R&R Forms
  - <https://www.grants.gov/forms/r-r-family.html>
- HHS Subcontracting Plan Template (for contracts over \$750,000)
  - <https://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/HHS%20SubK%20Plan%20Template%20-%20updated%20March%202022.pdf>

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# References & Tools

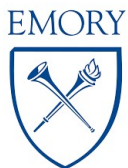
- For Cooperative Agreements – 2 CFR 200
  - <https://www.ecfr.gov/current/title-2/subtitle-A/chapter-II/part-200?toc=1>
- For Procurement Contracts – Federal Acquisition Regulation
  - <https://www.acquisition.gov/browse/index/far>
- For Other Transaction Agreements
  - <https://aaf.dau.edu/aaf/ot-guide/>

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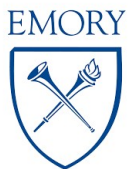
# References & Tools

- Data Rights Assertion Table (DRAT) – DOD reference template
  - <https://www.acquisition.gov/dfars/252.227-7017-identification-and-assertion-use-release-or-disclosure-restrictions>.
- Contract Proposal Submission (eCPS) website and references
  - <https://ecps.nih.gov>
  - <https://ecps.nih.gov/howtosubmit>
  - <https://ecps.nih.gov/faq>



# References & Tools

- ARPA H Virtual Proposer's Day Slides, FAQs, and Video
  - <https://sam.gov/opp/64140dd96ee04f0d91b70cca21d6d2fc/view>
  - <https://www.youtube.com/watch?v=Mt5UbRaBhtU>
- Emory University ARPA-H Resources
  - <https://research.emory.edu/research-development/arpa-h.html>
  - Thursdays @ 3 (T@3) 9/15/2022 - <https://research.emory.edu/webinars-podcasts/index.html>
- University of Illinois Urbana – Champaign ARPA-H Virtual Information Session
  - <https://www.youtube.com/watch?v=H278bAQNLAY>



# References & Tools

- Georgia Tech and Emory ARPA-H Training Day Recordings
  - Introduction and Q&A
    - [Advanced Research Projects Agency for Health \(ARPA-H\) Introduction and Q&A - Recording.mp4](#)
  - Budget Workshop
    - [ARPA-H Budget Workshop Recording.mp4](#)
  - Terms & Conditions Workshop
    - [ARPA-H Terms & Conditions Workshop Recording.mp4](#)

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# Questions?

