Program Solicitation

Medics Autonomously Stopping Hemorrhage (MASH)

BIOLOGICAL TECHNOLOGIES OFFICE

DARPA-PS-25-34

September 16, 2025

PROGRAM SOLICITATION OVERVIEW

- **Federal Agency Name** – Defense Advanced Research Projects Agency (DARPA), Biological Technologies Office (BTO)
- **Funding Opportunity Title** – Medics Autonomously Stopping Hemorrhage (MASH)
- **Announcement Type** – Initial Announcement
- **Funding Opportunity Number** – DARPA-PS-25-34
- **Dates -**
    - Posting Date: **September 16, 2025**
    - Proposers' Day: **September 18, 2025**
    - Questions Due Date: **October 8, 2025**, 1200 EST
    - Abstracts Due Date and Time: **October 15, 2025**, 1200 EST
    - Full Proposal/Oral Proposal Package (OPP) Due Date and Time: **November 25, 2025**
- **Description of the funding Opportunity:** The Defense Advanced Research Projects Agency (DARPA) is soliciting proposals to develop demonstrator autonomous systems to stabilize torso hemorrhage without need of a surgeon in forward medical sites, providing 48+ hours to reach definitive care. The Medics Autonomously Stopping Hemorrhage (MASH) program is seeking approaches that merge multi-modal automated bleed detection and localization with automated, minimally invasive robotic end effectors and sensors. MASH's vision is to push the standard of pre-hospital hemorrhage control to 48 hours; stop lethal forms of torso hemorrhage without a surgeon; and provide minimally invasive surgery (MIS) a path to enter the trauma market and utilize full autonomy.
- **Types of instruments that may be awarded** – Other Transaction for Prototype
- **Total Funding** – approximately $32.4M, multiple awards are anticipated
- **Technical Point of Contact** – Lt Col Adam Willis
- **Agency Contact**

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- **Attachments**
    A. Abstract Template and Instructions
    B. Concept Technical Overview Template
    C. MASH Vessel and Organ List
    D. OPP Guidance (Planning Purposes Only)

PROGRAM SOLICITATION
Defense Advanced Research Projects Agency (DARPA)

1. PROGRAM INFORMATION

1.1. Background

An estimated 24% of battlefield deaths in recent conflicts were potentially survivable, and non-compressible torso hemorrhage (NCTH) contributed to 60% of these deaths. The Medics Autonomously Stopping Hemorrhage (MASH) program aims to find and stop the source of life-threatening bleeding in the torso following combat trauma. More specifically, the program aims to demonstrate that it is possible to localize a targetable source of life-threatening bleed and then precisely stop that bleed, without surgical expertise and outside of a hospital. The program will initially focus on obtaining the signals associated with bleeding to localize hemorrhage anatomically, as performed using an autonomous system guided by a field medic for eventual use at forward military treatment facilities (MTFs, specifically Role 1). After localization, the program then will focus on placing robots inside the vasculature (intravascular) or within the body cavity (extravascular) to autonomously stop the bleed for at least 48 hours, buying time to evacuate the casualty to definitive care.

Hemorrhage is the leading cause of death among combat injuries which could be survivable with immediate access to advanced medical and surgical capabilities. Therefore, stopping hemorrhage is requisite to survival. Survival from hemorrhage in the limbs has improved with rapid application of tourniquets[1], which block all blood flow in and out of entire limb but only temporize a casualty until surgical options exist. However, if tourniquets are not removed quickly (usually in under 2 hours), there is a significant risk the injured limb will need to be amputated. If the hemorrhage is from sites that cannot be manually compressed (e.g., NCTH), the risk of mortality is doubled[2]. Current ultrasound techniques on the battlefield can detect torso hemorrhage but are unable to localize the source. Instead, localizing the source of hemorrhage requires either direct observation from a surgeon during surgery, or advanced medical imaging[3]. Temporizing measures for NCTH are limited to manually blocking the flow of blood (from within the major artery of the torso) or giving blood products to replace volume loss from hemorrhage until surgical repair is achieved. Manual blockage of blood flow requires advanced training and can only be employed for < 90 minutes before potentially unrecoverable ischemia to vital organs.

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[1] Kotwal RS, Montgomery HR, Kotwal BM, Champion HR, Butler FK Jr, Mabry RL, Cain JS, Blackbourne LH, Mechler KK, Holcomb JB. Eliminating preventable death on the battlefield. Arch Surg. 2011 Dec;146(12):1350-8. doi: 10.1001/archsurg.2011.213. Epub 2011 Aug 15. PMID: 21844425.

[2] Stannard A, Morrison JJ, Scott DJ, Ivatury RA, Ross JD, Rasmussen TE. The epidemiology of noncompressible torso hemorrhage in the wars in Iraq and Afghanistan. J Trauma Acute Care Surg. 2013 Mar;74(3):830-4. doi: 10.1097/TA.0b013e31827a3704. PMID: 23425743.

[3] Martin MJ, Brown CVR, Shatz DV, Alam H, Brasel K, Hauser CJ, de Moya M, Moore EE, Vercruysse G, Inaba K. Evaluation and management of abdominal gunshot wounds: A Western Trauma Association critical decisions algorithm. J Trauma Acute Care Surg. 2019 Nov;87(5):1220-1227. doi: 10.1097/TA.0000000000002410. PMID: 31233440.

Before casualties reach a surgical team, combat medics have limited options to stop torso hemorrhage and buy more time to accomplish medical evacuation. Optimally, casualties would be rapidly transported to surgical teams which open the casualty (usually the torso which includes the thorax, pelvis, or abdomen), localize the source of the bleed, plan how to stop the bleed while minimizing risks, and then definitively stop the bleed. However, even with robust medical and evacuation infrastructure, this process takes too long for many wounded soldiers (Figure 1). In the Global War on Terror (GWOT), where the Golden Hour was achieved > 70% of the time, over 90% of potentially survivable fatalities were from secondary uncontrolled blood loss, two thirds of which were from NCTH[4]. Furthermore, reaching care still isn't enough - NCTH was the most common cause of potentially survivable death (38.4%) for combat wounded who reached medical treatment facilities[5]. By pushing new capabilities to stop NCTH forward and at scale via a medic, MASH aims to provide more time for wounded casualties to reach definitive care, increasing survival odds by mitigating the primary risk factor for death in the first 48 hours of injury (Figure 1) below.

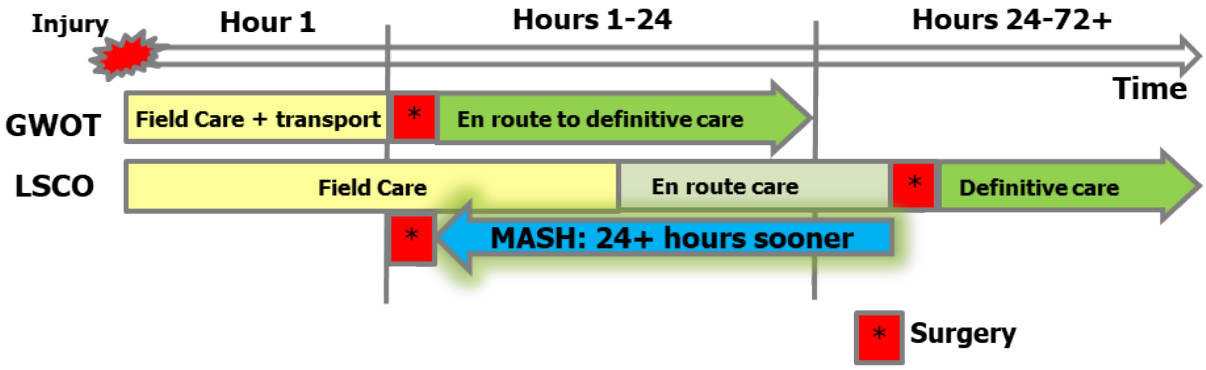

Figure 1. The top row displays time expected for wounded warfighters to receive care in the Global War on Terror (GWOT) and the bottom row shows future projects for Large Scale Conflict Operations (LSCO). MASH (blue arrow) will enable earlier hemorrhage control in these future environments, better stabilizing casualties prior to reaching definitive care.

Success in MASH can also lead to safer and swifter return to duty for non-life-threatening injuries. Algorithms to detect hemorrhage developed in the MASH program could also confirm if an internal bleed is absent, allowing for faster return to duty for warfighters no longer requiring surgical resources and improve allocation of scarce surgical resources. During GWOT, over 10% of evacuations for suspected NCTH were determined not to have a NCTH; getting these

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[4] Eastridge BJ, Mabry RL, Seguin P, Cantrell J, Tops T, Uribe P, et al. Death on the battlefield (2001–2011): Implications for the future of combat casualty care. Journal of Trauma and Acute Care Surgery. 2012 Dec;73(6):S431–7.

[5] Eastridge BJ, Hardin M, Cantrell J, Oetjen-Gerdes L, Zubko T, Mallak C, Wade CE, Simmons J, Mace J, Mabry R, Bolenbaucher R, Blackbourne LH. Died of wounds on the battlefield: causation and implications for improving combat casualty care. J Trauma. 2011 Jul;71(1 Suppl):S4-8. doi: 10.1097/TA.0b013e318221147b. PMID: 21795876.

casualties back to service would greatly increase force lethality and preserve precious medical resources for other urgent cases.

The key insight for MASH is that bleeding provides a rich signal across multiple domains that can be measured indirectly to detect and localize the bleeding source that doesn't require an open procedure performed by a surgeon, or even line of sight of the bleed during a laparoscopic procedure. The program's hypothesis is that if the bleed can be physically localized, then it can be stopped.

1.2. Acquisition Strategy

This Program Solicitation (PS) solicits independent abstract submissions for a 36-month effort across two phases. Phase I (base period) will be 24 months, and Phase II (option period) will be 12 months. Proposers with successful abstracts will be invited to provide an Oral Proposal Package (OPP) to describe their approach to the DARPA MASH program team. The Government will review all OPPs, and selected proposers may be awarded an Other Transaction (OT) for Prototype Agreement.

This PS encourages solutions from all responsible sources capable of satisfying the Government's needs, including large and small businesses, nontraditional defense contractors as defined in 10 U.S.C. § 3014, universities, and research institutions.

1.3. Program Description/Scope

MASH will mature the capability to autonomously perform hemorrhage control surgery for torso hemorrhage without an attending surgeon, but rather with a medic present to provide limited oversight and support.

The program will produce demonstrator systems incorporating off-the-shelf sensors, robotic platforms, and surgical end effectors to autonomously detect, localize, and stop bleeding for at least 48 hours in large animal models. For the purposes of the MASH program, a "robot" is defined as a device that has actuation capabilities sufficient to move the surgical end effectors within the body, and to then perform those procedures automatically. Also, for the purposes of the MASH program, torso areas of concern are limited to the abdominal and pelvic space, and do not include the intra-thoracic space. A list of key blood vessels and solid organ regions of interest is provided as Attachment C. MASH also assumes a medic is present and can provide actuation and support to the system (robotic platform and sensors), as well as damage control resuscitation. However, medical decision-making (e.g. localizing bleed, choice of treatment, and whether to treat) must be managed by the system's autonomy. The demonstrator is not expected to be field-ready during the life of the program; instead, a design for an eventual portable system ("Objective System") will be developed under the life of the program (see Section 1.5.1.2 for more detail); systems only need to be portable enough to transport to the government independent verification and validation (IV&V) test site twice during the program.

The program will consider two approaches to access and stop the bleed: intravascular (through the blood vessels) or extravascular (directly into the injured cavity such as abdomen, using minimally invasive techniques). Teams can assume that intravascular access and access to the

intra-abdominal space (i.e., trocar placement) is available for the MASH system. Teams will be responsible for providing an existing robotic platform integrated with existing surgical end effectors, as well as autonomy and sensors. The robotic platform is expected to either have received regulatory approval for a surgical indication or currently be under a regulatory pathway for future approval. Teams are required to include the robotics platform, end effectors, sensors, autonomy, and the ability to integrate these elements together into a functional demonstrator system. The bottom line is that MASH aims to advance robotic surgical capabilities that can both find and stop life-threatening torso hemorrhage autonomously, to bring innovation (that can be accomplished by existing platforms and end effectors) to the minimally invasive surgery community, while also bringing minimally invasive techniques to the trauma care sector.

Program Considerations:

- Teams are expected to pick robotic platform(s) at the time of proposal that will be used throughout the duration of the program, as opposed to evaluating multiple platform options within the program. Teams can utilize intravascular approaches, extravascular approaches, or both, and should propose plans that utilize their chosen platforms for the duration of the program.
- Systems can use multiple steps in the management of NCTH. For example, a more rapid but coarse procedure can be employed to buy additional time and prevent further blood loss while the exact bleeding source is localized, and a second, more site-specific procedure can better stop the bleeding and minimize tissue damage. Additionally, the system workflow doesn't have to be strictly linear (detect / localize / navigate to / stop bleeding) and could instead allow for a revisit to any step in the process, for example a secondary bleeding detection step to check for rebleeding following the procedure(s), or a loop to check for and address multiple bleeding sites.
- Sensors are allowed to be integral to, proximal to, or separate from the robotic platform. Sensors can be external or internal to the body cavity. Multiple sensors may be used, and do not need to be utilized simultaneously or for the entirety of the procedure. For example, external sensors can be used for bleeding detection and/or localization, and internal sensors can be added or used instead during robotic platform navigation and surgical procedure steps. Radiological dyes or other tracers and contrast agents are allowed in concert with the sensor(s) if such agents have an approved FDA indication (even if off-label) or Investigational New Drug (IND) approval.
- Systems are allowed to perform procedures that require periodic monitoring (though this can only be done by a medic) throughout the 48-hour window. For example, an occluding device can be adjusted or pulsed. Solutions requiring observation and action on the part of the medic will be less favored than solutions which perform a "one-and-done" procedure that requires minimal monitoring and oversight.
- MASH technologies are not expected to manage <u>all</u> non-compressible hemorrhages. MASH assumes that injuries leading to death from hemorrhage in less than 30 minutes are not salvageable. Instead, MASH is focused on injuries that can be stabilized with current trauma surgical interventions, and that are viewed as potentially survivable if arriving at a surgical site within the Golden Hour. Additionally, some approaches to hemostasis may not be able to address the spectrum of bleeding managed during damage

control surgery. To address this, MASH will focus on addressing hemorrhage targets from a specific Vessel and Organ list (Attachment C) that will allow for systematic evaluation of capabilities to stop bleeding with varying levels of severity, and with different combinations of damage to multiple targets.

- Proposed solutions must be able to control hemorrhage while minimizing life-threatening ischemia and reperfusion injury. A solution occluding blood flow in the aorta for the required 48 hours will not be a viable approach, and for a given injury, the most distal methods of hemostasis (furthest down the vascular branching tree) or methods that allow for perfusion through an injured blood vessel will be favored over proximal, full occlusion methods.
- MASH will not address all aspects of damage control surgery (DCS) (for example, managing contamination due to hollow viscus injury), but rather will focus on stopping torso bleeding for long enough to buy time to reach definitive care and remaining DCS procedures. It is recognized that additional investments for components such as managing contamination and resuscitation may be required beyond the scope of this program.
- Pharmacological solutions are not allowed as the sole means of performing hemostasis, however adjunct pharmaceuticals are allowed as part of the total solution. Planned use of pharmaceutical agents should be clearly outlined in the proposal.
- It is recognized that damage control resuscitation (DCR) using resuscitative fluids (blood, plasma, etc.) will be a critical element in the survival of the patient under treatment. For the purpose of this solicitation, solutions that rely solely on the addition or re-integration of resuscitative fluids are discouraged. Provision of fluids may be an element of an overall survival strategy and are understood to be an essential task of the field medic, but should not be proposed as part of a MASH solution. Instead, teams will be judged upon how quickly bleeding is stopped and how much blood loss occurs before hemostasis. Additional details can be found in Section 1.7. Solutions that require more resuscitation resources will be viewed less favorably than those that require less, which here is meant to indicate solutions that more rapidly stop the bleeding.
- While the MASH program will only require the use of a demonstrator system suited for in-lab use, the goal use case for a MASH system is a far-forward field environment. Therefore, demonstrator system implementations with high weight and power requirements will be viewed less favorably than solutions with clear pathways to portable use in the Objective System design.

1.4. Government Furnished Resources

The MASH government team will provide the following elements of government furnished information to each performer team over the life of the MASH program. Key delivery dates when these products will be provided to performers are indicated for each element and highlighted in Figure 2.

- Government-furnished information (GFI):
    - **Support from the Defense Health Agency Office of Regulated Activities**. The Office of Regulated Activities (ORA) is a multidisciplinary team of regulatory affairs, compliance, and clinical support professionals dedicated to supporting the Department of Defense's mission of developing Food and Drug

Administration regulated medical products for the Warfighter. As part of the strategy for regulatory engagement, the ORA will offer consultative support to each selected MASH performer team. This support will consist of a pre-determined number of hours from the ORA team to assist in the development of a regulatory strategy, as well as assistance with engaging with the FDA team as needed. Expected availability window: full duration of performer award.

- ***In vivo* / *ex vivo* test methods document**. The MASH IV&V team will provide a list of planned testing protocols specific to each performer approach that will be used for IV&V testing at the government test site for both Phase I and Phase II testing. Each performer team will need to consider this in the development of their own testing plans. Expected availability window: NLT program month 6 (Phase I test methods), NLT program month 28 (Phase II test methods).
- **Field use requirements capture report**. The MASH government team will arrange one or more engagements with DoD field medics at military treatment facility training sites, to gather insights on design considerations for the portable form factor. The government team will assist in the documentation of key outcomes and provide a report to the performer team summarizing the engagement(s). Additional details are provided in Section 1.5.1.2. Expected availability window: NLT program month 26 (Phase II).
- **Field medic utility testing report**. The MASH government team will arrange at least one opportunity to put the as-built MASH demonstrator system (or a mockup of the field-ready prototype design, if available) in the hands of field medics to perform studies on usability, learnability, and compatibility with current and projected future workflows, with the goal of gathering feedback that will improve the portable prototype design. The government team will assist in the documentation of key outcomes and provide a report to the performer team summarizing the engagement(s). Additional details are provided in Section 1.5.1.2. Expected availability window: NLT program month 31 (Phase II).
- **Survival assessment report**. MASH development is focused on hemostasis, not overall survival. That said, the MASH USG team will perform a study on animal survival during the 48 hours necessary for the hemostasis procedure to be in force. This will include any necessary supplemental resuscitative fluids provided under DCR, specific to each performer's approach, as well as medications and procedures to manage contamination, through a process of critical care management and protocolized DCR. Results of this assessment will be compiled and provided to the performer and the DARPA team, for future consideration. Expected availability window: NLT program month 35 (Phase II).

- Government-furnished equipment:
  - None

1.5. Program Structure

The MASH program is a 36-month effort, suited to inter-disciplinary teams with capabilities in a range of topics, such as trauma/vascular surgery; large animal models; robotics; robotic surgery; autonomous systems; AI/ML; physics and physiology modeling systems; and/or anatomy segmentation. Teams are expected to make use of a combination of an existing robotic platform and surgical end effectors (forceps, needle holders, cautery, etc.). Such medical devices should be already available or currently under active development and should not require MASH funding. The robotic platform proposed for MASH must have either already have an approved clinical indication (does not have to be hemostasis) or be on a regulatory and developmental pathway to seek regulatory approval for any indication. Limited engineering may be necessary to integrate end effectors or sensors not previously integrated onto the selected robotic platform, or to adapt the use of the device for the MASH application. It is expected that the robotic platform developer is a member of the performer team, to allow for integration and business model development.

Performers will be expected to rapidly establish their testbeds for finalizing demonstrator system elements, to include sensor suite, surgical end effectors, sensor fusion approaches, and control strategies for actuated system elements. This will also allow for collection of training data across simulated and physical hemorrhage cases, suitable to enable reliable autonomy performance across the range of injury types and severity levels. Core milestones are set in Section 1.6.1 to promote the rapid stand-up of these testbeds and to characterize training data needs.

As the testbeds are being established and a series of progressively more involved Capability Demonstrations (CDs) is executed at the performer sites, teams will mature the software needed to interpret sensor data, perform AI/ML calculations, plan robotic motion, and plan and execute the surgical procedures required by the selected end effectors. Performers should account for the software interplay and/or integration between autonomy, robotic platform actuator control, and sensor data perception and fusion. DARPA anticipates that the key challenge for intravascular approaches will be rapid signal processing to detect and localize bleeding anatomically, and for extravascular approaches will be safe autonomous maneuvering and manipulation within the abdomen and pelvis. DARPA anticipates that teams will need to utilize advances in mathematical and physics-based modeling to aid in signal processing as well as novel robotic learning strategies which leverage the latest in AI/ML learning, robust synthetic training platforms, and judicious use of animal models.

Within the framework of the MASH Vessel and Organ List (Attachment C), performers will work throughout the life of the program to identify and expand the range of injury severity (number of concurrent bleeds, tissue damage, deranged anatomy, overall hemorrhage rates, etc.) they are capable of stabilizing, and quantify the impact of proposed interventions when considering the incidence of different types of NCTH expected in modern conflict. Performers will also need to develop a strategy to detect and manage aberrant vascular anatomy and demonstrate reliable performance across these variants. Performers will determine their multi-step workflow as informed by in silico, physical phantom, and *in vivo* / *ex vivo* testing, which may include multiple procedures as described in Section 1.3. These steps will ultimately be captured in a software pipeline living document, as mentioned in the list of core milestones of Section 1.6.1.

1.5.1. Program Phases

The program is a 36-month total effort structured with a 24-month Phase I and a 12-month Phase II (Figure 2). Proposers must present a plan for both Phases, to include a comprehensive approach to meeting all Phase I and Phase II program metrics, milestones, and objectives. Progression from Phase I to Phase II is dependent on demonstrated success in meeting program metrics and objectives, as described in Section 1.6. Metrics and objectives will be assessed and scored by the United States Government (USG) team, with test plans developed by the MASH USG team per Sections 1.4 and 1.7. The USG team will consist of DARPA, USG stakeholders, and government IV&V partners.

Figure 2 below presents the timeline for both Phase I and II, highlighting select key milestones and MASH USG activities related to performer activities. Performer activities and MASH USG activities (as they relate to performer work) are outlined in the below sections. Of particular note is the need for multiple efforts to be executed in parallel by varying members with a performer team: detection, localization, navigation, and hemorrhage control development need to be matured alongside hardware development, a rigorous series of demonstrations and evaluations, and product market fit efforts related to the techno-economic assessment and ultimate business model of the finished MASH system. Performer teams are expected to have the bandwidth and management expertise to execute these tasks concurrently.

1.5.1.1. Phase I – Base Period (24 months)

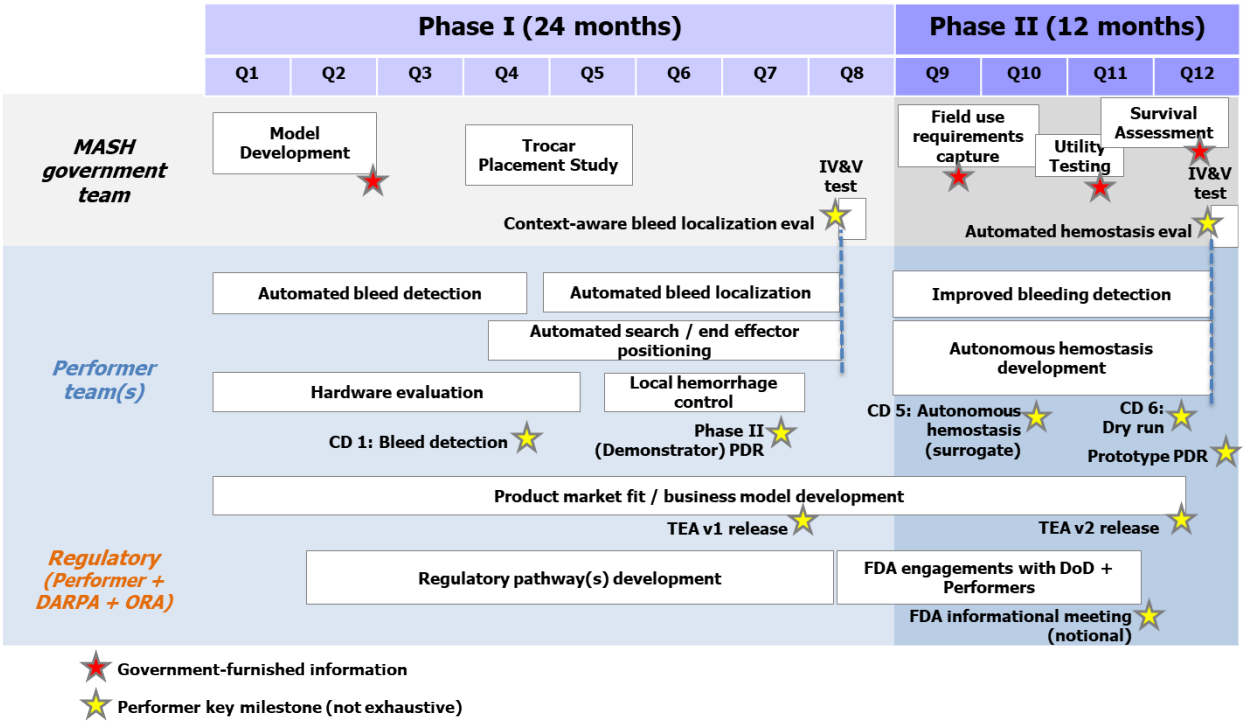

Figure 2. Timeline showing concurrent activities (non-exhaustive) across performer and MASH USG teams during Phases I and II, and illustrating milestones and capability demonstrations. Abbreviations: IV&V: independent verification and validation; CD: capability demonstration; PDR: preliminary design review; TEA: techno-economic assessment; ORA: Office of Regulatory Affairs.

Year 1: Bleed detection focus
During the first 12 months of Phase I, performer teams will focus on data augmentation and model development, with the goal of de-risking and demonstrating autonomous bleed detection. This will also include work towards finalizing the appropriate sensing devices and strategy to be implemented for bleed detection and tracking. At the end of the 12th month, performers will be required to host and execute capability demonstration 1 (CD 1) for an automated bleed detection proof of principle, to assess the ability to integrate sensor data with predictive algorithms. Further details on all capability demonstrations are listed in Section 1.8.

It is also expected that development towards the remaining system elements will begin during this period. Performers should develop a data collection strategy that will support autonomy training for contextual bleed localization, navigation within the body for the robotic platform, and execution of the hemostasis procedure(s) using planned end effectors. Performers should consider testing motion planning of the robotic platform via integration of hardware and autonomy software in an appropriate environment. During this time, performers are expected to set up necessary simulation, physical phantom, and other benchtop testing environments, to begin gathering data and developing software algorithms and movement strategies. These software algorithms will be captured in a software pipeline document, a draft of which will be developed during this period. Program milestones relating to these tasks are provided in Attachment D and Table 3.

It is desired that performers establish, as quickly as possible, the strategies for performing hemorrhage control for the maximum number of relevant targets within the MASH Vessel and Organ List (Attachment C). To this end, this first year should also be leveraged to determine prioritization of this list, and to provide detail back to the MASH USG team regarding a roadmap for how successful hemorrhage control will be demonstrated for each of the targets.

Performers will also begin development of their business model in support of the techno-economic assessment (see below for additional detail) and begin regulatory discussions via engagement with either the FDA directly through information sessions, or with the ORA team organic to the MASH USG team.

Towards the end of the first program year, DARPA will hold a Principal Investigators (PI) Meeting for performers to showcase their models and test results.

Year 2: Bleed localization and end effector positioning focus
In the second year of Phase I, performer teams will expand focus to three concurrent technical tasks: bleed localization, search / positioning, and hemorrhage control. Each of these tasks will have capability demonstrations (CDs 2-4, see Section 1.8) during this period, showing progress towards respective metrics. This period will culminate in a final IV&V test led by the MASH IV&V team and at the IV&V site. Milestones, deliverables, metrics and product transitions are listed in Table 5. Teams will be scored based on compliance with the metrics listed in Section 1.6. Details on the Phase I IV&V testing can be found in Section 1.7.

During this period, there will be a study performed by the MASH USG team to identify any gaps in technologies and training that, once addressed, would allow a medic to obtain anatomic access to the casualty (trocar placement, automated vascular access, etc.)

Also, during this period performers will develop a comprehensive review of their Demonstrator System design (as used during the MASH program effort) that is planned for use in Phase II. Specifically, the review should focus on the final design to be evaluated at the Phase II IV&V test in Month 35, able to both find and stop hemorrhage. This will be briefed at a Phase II Preliminary Design Review (PDR). The PDR will serve as an opportunity to convey system evolution over the course of Phase I, planned revisions and enhancements for Phase II, and strategies to minimize execution risk for the remainder of the program. The PDR will also enable detailed planning for the next phase, and ensure mutual understanding of performance requirements. Expectations for the PDR include a review of performance requirements and validation against these requirements, subsystem definitions and specifications, risk mitigation plans, detailed schematics or other visuals to convey software and hardware architecture, discussion of medic-system interaction, and design data supporting the selected final design. This design review is in addition to the prototype (Objective System) design review mentioned in Section 1.5.1.2. The Phase II (Demonstrator System) PDR is NOT focused on the portable form factor for the eventual prototype ("Objective System"), which will be developed over the course of Phase II following engagement and requirements capture with DoD stakeholder communities, and briefed towards the end of the program. More details on expected content for the Phase II Demonstrator PDR will be made available to selected performers once the program is underway.

Techno-Economic Assessment

Throughout Phase I and in support of the Product Market Fit metrics from Table 5, performers shall conduct a comprehensive Techno-Economic Assessment (TEA) for the proposed medical technology. Any selected MASH performer team will be responsible for the development of a TEA for their overall system. This document will be updated in the second phase as additional capabilities are added to the system, and as additional clarity is gained regarding optimal regulatory pathways.

This assessment must 1) evaluate technical feasibility, including technology readiness level (TRL), integration risks, and projected development milestones and 2) analyze economic viability, including cost structure, anticipated return on investment (ROI), pricing strategy, and long-term scalability. This must include costs associated with realizing the prototype design to be finalized during Phase II as discussed in Section 1.5.1.2; costs associated with building the prototype from the reference design are expected to become more refined in the Phase II updated TEA and ultimately should outlook ongoing full-scale production while noting relevant cost/revenue assumptions and including a sensitivity analysis.

As part of the revenue factor above, the TEA should include market determination and sizing, as well as clearly outlining assumptions, methodologies and data sources. It should also include relevant regulatory and reimbursement pathways, timelines, cost implications and demonstrate:

- Alignment with clinical and market needs,
- Economic justification for product adoption and deployment, and
- Strategic insight into regulatory and commercialization pathways.

In addition to the TEA, it is the expectation that the performer specifically notes the system elements viewed as suitable for regulatory submission as unique medical devices and propose a roadmap of regulatory submission plans based on market need and profitability. Satisfaction of the Product Market Fit metric will require a detailed report that includes realistic projections for profitability in civilian, and U.S. DoD markets, and will consider the following categories**:**

- Technical Feasibility (TRL, Supply Chain, Integration)
- Economic Viability (Cost (Cost of Goods Sold, CapEx/OpEx), Profitability (Internal Rate of Return, Net Present Value, Payback Period))
- Regulatory & Compliance (Approval path, insurance reimbursement)
- Strategic/Venture investments (Alignment with venture portfolio strategy, IP position, HW/SW licensing)

Phase I Meetings

A list of anticipated meetings and their locations is provided in Table 1 below.

Table 1**. List of anticipated meetings during Phase I.**

Meeting Type	Anticipated Location	Frequency
Phase I Kickoff	Arlington, VA	Once
Phase I IV&V test	Bethesda, MD	Once
Demonstrator PDR	TBD	Once
Site visit	Performer site	3x
PI meeting	Arlington, VA	At least once a year
Technical & Programmatic update	Teleconference/videoconference	At least monthly

1.5.1.2. Phase II - Option Period (12 months)

During Phase II, performer teams will pivot their development to incorporating the elements proven during Phase I – the independent abilities to detect, localize, and treat a bleed, as well as the ability to navigate and search within the body using the robotic platform – to perform the end-to-end workflow of performing hemostasis. Teams will be required to conduct two additional CDs (see Section 1.8) to identify and reduce risks associated with demonstrating program metrics. One of these CDs is a preliminary demonstration of autonomous hemostasis without navigation to the bleed site; the other is a full practice run of hemostasis on large animal model. Teams are expected to integrate all workflow steps developed under Phase I into a consolidated process, leveraging full autonomy for the system with the exception of working with the medic for manual tasks (robotic platform placement, end effector changes or installation, manual external sensor scans, etc.). Teams will also be responsible for enhancing their positive and negative predictive values for bleeding detection, to ensure that their MASH system can most accurately determine whether or not a bleed is present when assessing a

casualty. As with Phase I, this phase will culminate in an IV&V test managed at the IV&V government team site.

During this period performers will update the comprehensive review of their Demonstrator System design (as used during the MASH program effort) from the PDR-level design presented during Phase I, and provide a Critical Design Review (CDR) of the Demonstrator System to be utilized at the Phase II IV&V test. The CDR should ensure that the system under review can proceed into system demonstration and test, and that it can meet the stated performance requirements within project cost, schedule, risk, and other system constraints. No changes to the Demonstrator System design, in particular the software architecture and hardware, are anticipated after this point. More details on expected content for the Demonstrator System CDR will be made available to selected performers once the program is underway.

This phase will also see a new work stream relating to the evolution of the Demonstrator System to a field-ready portable variant by way of a paper study (not to be physically realized under the MASH program, but rather to be captured as an Objective System design). For the purposes of this topic call, “portable” is yet to be defined in terms of specific size, weight and power. This will be characterized by DoD stakeholder interests over a period of requirements capture at military treatment facility training sites, as explained below. Details on this are outlined below.

Performers will continue to expand on their TEA from Phase I with an updated product, incorporating lessons learned over the course of this phase, and through engagement with the stakeholder community. This should include a more refined regulatory submission roadmap, informed by all conversations with ORA, FDA, or any other international regulatory bodies over the course of the program.

Survival Assessment. As mentioned in Section 1.4, the MASH USG team will establish and validate an optimized damage control resuscitation (DCR) and critical care protocol to integrate with MASH performer hemostasis. This assessment will determine how DCR fluids and critical care measures should be applied to maximize casualty survival when MASH hemostasis is maintained for 48 hours or longer. During this period, the MASH USG team will provide protocolized DCR and critical care management, directly supporting and enhancing the hemostasis treatment delivered by the proposed MASH solution. Results of this assessment will define the optimized resuscitation and critical care approach and will be provided to the performer and DARPA as GFI, to inform future development and transition.

Objective System Design. While systems developed during the MASH program will only be required to function in a laboratory environment (comparable to a TRL of 4-5), performers will be responsible for maturing a design study for the Objective System - the portable form factor suitable for use in a field-forward MTF. The design of this portable prototype system will be presented at a Prototype PDR to the MASH USG team, along with key stakeholders, during program Month 36. The PDR, and the associated objective design of the portable MASH prototype system presented therein, is intended to allow for a smooth takeover from the DARPA team back to the MASH performer team (nominally the robotic platform manufacturer) in moving to the next step in maturing MASH systems towards an effective regulatory and

transition pathway; having a well-informed design of this prototype is viewed as essential for efficiently producing prototype units that would undergo safety and efficacy testing, and that will ultimately be presented to the DoD and civilian acquisition communities. Expectations for the content of the Objective System PDR are similar to those of the Demonstrator System PDR developed in Phase I, though the system requirements will be derived through engagement with stakeholders, as opposed to the demonstrator design aimed at satisfying the MASH program metrics. DARPA will not fund the manufacture of the prototype system under the MASH program.

During Phase II, two MASH USG team activities will be performed in concert with performer teams, to assist the performer in maturing their Objective System design, with outcomes provided as GFI per Section 1.4. These activities will both require travel by the performer, and are as follows:

1. A field use requirements capture effort will occur at a military medicine training site with surrogate Role 1 MTFs and active-duty military medics. The MASH USG team will provide an opportunity to meet with medics and representatives of the military medicine requirements development community, to understand and close the gap between the benchtop demonstrator systems built during MASH, and a field-capable design needed for eventual transition. This will include understanding details on space, weight, and power (SWAP), integration with other existing DoD medical devices anticipated at a Role 1 MTF, logistics / packaging, detail on MILSPEC field durability testing in accordance with MIL-STD-810, and other factors necessary for successful future integration within a Role 1 site. This requirements capture effort will begin very early in Phase II, nominally during the Phase II kick-off, in support of maturation of the objective system design to be presented at the PDR. There will be multiple opportunities for engagement throughout the phase, to allow continued dialog aimed at maturing the design. The MASH USG team will arrange these efforts and assist in the documentation of key outcomes, providing a report to the performer team summarizing the engagement(s) as GFI.
2. A field medic utility assessment will be performed partway through Phase II, with exact timeframe to be determined once the program is underway. This utility assessment will put the MASH demonstrator system (or a mockup of the field-ready prototype design, if available) in the hands of field medics to perform studies on usability, learnability, workflow (in concert with other existing medic functions operating under varying capacity but skewing towards treating mass casualty situations), fit/feel, cognitive loading, and other dimensions intended to strengthen the overall system design. Medics will provide feedback directly to the performer team and will offer suggestions based on lessons learned with other medical devices in use or considered for use at the Role 1 MTF. The MASH USG team will arrange these efforts and assist in the documentation of key outcomes, providing a report to the performer team summarizing the engagement(s) as GFI.

Phase II Meetings

A list of meetings with anticipated locations is provided in Table 2 below.

Table 2. List of anticipated meetings during Phase II

Meeting Type	Anticipated Location	Frequency
Phase II kickoff / field use requirements capture	San Antonio, TX	Once
Field medic utility assessment	Ft. Detrick, MD	Once
Phase II IV&V test	Bethesda, MD	Once
Demonstrator CDR	TBD	Once
Portable Prototype PDR	TBD	Once
Site visit	Performer site	Once
PI meeting	Arlington, VA	Once
Technical & Programmatic update	Teleconference/videoconference	At least monthly

1.6. Milestones, Deliverables, and Metrics

Phased work is decomposed into milestones for the purpose of program management. This includes work towards meeting program metrics as validated by the MASH USG team, as well as successfully completing additional program milestones. **The timelines for the program milestones, including key IV&V testing events, are non-negotiable**. **However,** proposers may take liberties to schedule performer-defined Performer Milestones that are structured to work towards remaining program tasks. For each Performer Milestone, proposers should include technical and experimental plans, risk assessments and mitigation, anticipated problems, and tangible outcomes. Experimental plans must include intermediate metrics, set by the proposer, for performer-led test activities. As outlined in Section 1.4, the MASH USG team will provide a consolidated test plan for each performer team, but the purpose of this consolidated plan is to develop a shared understanding of how performance against program metrics will be evaluated, and should not supplant efforts from the performer to develop experimental plans for performer-led testing.

1.6.1. Milestones

A list of core Performer Milestones structured towards achieving the program vision is listed in Table 3 for Phase I (base period) and Table 4 for Phase II (option period). Proposers may recommend additional milestones that demonstrate technical and/or techno-economic assessment achievements to accomplish the program's goals. Final specifics of milestones and supplemental metrics beyond the program metrics are to be negotiated at the time of contracting and are subject to DARPA approval. Proposers should note that evaluation against the program metrics may serve as the basis for determining whether satisfactory progress is being made to warrant continued funding of the program.

Table 3. Phase I Core Milestones Schedule

Month #	Description of Milestone
Month 1	Performer attends kick-off meeting

Month 2	All relevant hardware (robotic platform, sensors, actuated end effectors) has application programming interface (API) or similar made available to autonomy development team
Month 3	• **Deliverable:** TEA outline • **Deliverable:** Animal subjects research protocols submitted to local Institutional Animal Care and Use Committee (IACUC)
Month 4	Performer demonstrates modeling framework across simulation and physical phantom
Month 8	Performer demonstrates quantification of training data gap and demonstrates developed strategy to close gap to find and stop bleeding
Month 9	**Deliverable:** First draft of software pipeline documentation
Month 12	**Capability Demonstration (CD) 1**: Performer-hosted demonstration to detect bleeding
Month 15	Performer finalizes sensor suite
Month 18	**CD 2**: Performer-hosted demonstration to localize bleeding
Month 20	• **CD 3:** Performer demonstration of end effector efficacy to stop bleeding • **CD 4**: Performer conducts demonstration of automated search / end effector positioning
Month 21	**Deliverable:** Preliminary Design Review of Phase II Demonstrator system
Month 22	Performer supports government-managed Phase I IV&V evaluation
Month 23	**Deliverable:** End of Phase I report, to include: Phase I TEA satisfying relevant Phase I metrics, response to IV&V team evaluation report, analysis on performance against all Phase I metrics, plan to address Phase II metrics, hemorrhage control strategy for list of possible injuries

Table 4. Phase II Core Milestones Schedule

Month #	Description of Milestone
Month 25	Performer attends Phase II kick-off meeting and participates in requirements capture session
Month 28	**Deliverable:** Critical Design Review (CDR) for Demonstrator System
NLT Month 30	**CD 5**: Performer demonstration of autonomous hemorrhage control in surrogate model
Month 30	Performer brings prototype mockup or demonstrator to MASH USG-directed site for field medic utility study
Month 34	• **Deliverable:** Phase II TEA • **CD 6:** Performer-hosted final demonstration ("dry run") of autonomous hemorrhage control, including training of MASH IV&V team in system use
Month 35	Performer supports government-managed Phase II IV&V evaluation
Month 36	• **Deliverable:** Preliminary Design Review for Portable Prototype System ("Objective System") • **Deliverable:** Phase II final report, including rebuttal to IV&V results, training materials for system use, market plan, regulatory strategy, final software pipeline

1.6.2. Deliverables

Proposers must provide deliverables that include quantitative results, which are expected to achieve specific performance metrics. Key deliverables are outlined in the milestone tables of Section 1.6.1, and include:

- Phase I
    - TEA outline (Month 3)
    - Animal subjects research protocols submitted to local IACUC (Month 3)
    - First draft of software pipeline documentation (Month 9)
    - Preliminary Design Review of Phase II Demonstrator system (Month 21)
    - End of Phase I report, to include: Phase I TEA satisfying relevant Phase I metrics, response to IV&V team evaluation report, analysis on performance against all Phase I metrics, plan to address Phase II metrics, hemorrhage control strategy for list of possible injuries (Month 23)
- Phase II
    - Critical Design Review briefing package for Demonstrator System (Month 28)
    - Phase II TEA (Month 34)
    - Preliminary Design Review briefing package for Portable Prototype System ("Objective System") (Month 36)
    - Phase II final report, including rebuttal to IV&V results, training materials for system use, market plan, regulatory strategy, final software pipeline (Month 36)

Additional deliverables may be proposed as appropriate per the milestone plan. All products, material, and outcomes related to the research that will be provided to DARPA during and at the close out of the program should be defined as part of the proposal.

1.6.2.1. Program Data

Curated datasets on trauma surgery, in particular minimally invasive surgery, are both rare and valuable. Testing performed under the MASH program is expected to produce a high volume of such data, to include physiological data, robotic platform telemetry, sensor data, and outcomes data. It is desired that curated datasets from trials run by the performer be collected and archived by the MASH USG team. Proposals should outline their approach to data archive and philosophy on sharing curated data with the community as a final or interim deliverable. More detail on data rights is provided in Section 6.4.

1.6.3. Metrics

MASH performers are required to meet the specific and quantitative performance metrics in support of the selected technical approach. Quantitative performance metrics apply equally to each performer. As mentioned in Section 1.8, to achieve statistical power a combination of government-led and performer-led testing will be considered in the satisfaction of program metrics.

Performers will focus Phase I efforts on searching for, detecting, and localizing bleeding, along with demonstrating that the robotic end effector planned for use in Phase II can successfully navigate to all necessary regions within the body (but not perform hemostasis). Additionally at the end of Phase I, teams will demonstrate the effectiveness of end effectors at stopping bleeding – assuming it has been properly positioned. Bleed localization will be

measured by accuracy of anatomical ID from a list of potential blood vessels or solid organ regions and will be sufficient to plan treatment based on the nature of the bleed location. Phase II will focus on autonomously stopping bleeding within 1 hour from start of search, as measured by not exceeding total blood loss (internal and external) of 30% of total blood volume at 48 hours after initial injury.

Performers' systems will be evaluated based on compliance with metrics. Final metrics may be negotiated at the time of contracting and are subject to DARPA approval. Proposers should note that program metrics may serve as the basis for determining whether satisfactory progress is being made to warrant continued funding of the program.

Table 5. Performance metrics by phase

	Phase I	Phase II
Detect bleeding	• Positive predictive value > 90% (correctly identifying that an active bleed is in any listed target (artery, organ, vein) from the MASH Vessel and Organ list) • Negative predictive value > 90%	• PPV > 95% • NPV > 95%
Localize bleeding	• Correct target > 90% accurate (from possible MASH Vessel and Organ list, see attachment) • Distance to nearest upstream branch point accurate to +0/-1 cm (location can't be downstream from true site)	N/A
Time to complete inspection*,ǂ	< 1 hour	N/A
Position end effector	End-effector moved to all key abdominal regions in < 1 hour (to within region of effect of Phase II end effector at correct target from MASH Vessel and Organ list)	N/A
Hemostasis	With manual positioning of end-effector, demonstrate ability to stop bleeding (arterial, solid organ, venous)	Stop bleeding* within 1 hour (hematoma<30% total blood volume for 48 hours$^{\Psi}$)
Product Market Fit	Profitability and time to profitability of MASH Phase I capabilities across civilian, DoD markets and in different geographies	• Profitability and time to profitability of MASH Phase II capabilities across civilian, DoD markets and in different geographies • FDA regulatory submission roadmap

** With animal baseline survival of 50% and approximately 20% blood volume loss at 1 hour*

ǂ From insertion to anatomic localization of all bleeds and positioning of end effector

$^{\Psi}$ Independent of any fluid resuscitation protocolized during IV&V testing and studied under government survival assessment

At a minimum, performers need to find sites that are actively bleeding. Ideally, performers will also be able to determine sites of previous hemorrhage that have stopped bleeding, but this is not a tracked program metric.

Success against program metrics will be measured by the IV&V team through a combination of performer-led and IV&V team-led testing, as described below.

1.7. Independent Verification and Validation (IV&V)

IV&V testing will be conducted by the MASH USG team during Phases I and II. To accomplish this, performers will need to provide their Demonstrator System to the IV&V team – a subset of the MASH USG team, nominally located in Bethesda, MD – to execute testing against program metrics on a limited number of large animal models. Performers will have the option of shipping their equipment to the IV&V site or hand-carrying as appropriate. Performers can be present for testing. Exact specifics regarding IV&V test execution will be developed as part of the test methods document (per Section 1.4) to be developed by the IV&V team for each performer.

Because the IV&V testing will not be exhaustive against the MASH Vessel and Organ list, final performer evaluation will be prepared using a combination of IV&V-managed test results as well as the outcomes of performer-managed testing, notably the outcomes of CDs 1-6. Following the completion of IV&V testing, the IV&V team will aggregate all results and provide a summary of testing methods and an assessment of performer progress against program metrics to the DARPA team and the performer within 30 days of test completion. The results of this test report need to be reviewed by the performer, and a response addressing deficiencies needs to be presented in the end of phase reports.

Similar to the Phase II survival assessment, the use of resuscitative resources and supplemental damage control procedures to address contamination will not be a focus of this program, but they will be tracked. During IV&V testing, the MASH USG team will provide protocolized DCR and critical care management during the 48 hour period, supplementing the hemostasis treatment provided by the proposed MASH solution.

For each phase, IV&V partners will collect several CT images per test, including pre-injury, during performer test, and post-test. Of note, these images will not be available to the performers during the IV&V testing. IV&V partners will consider key performance metrics such as accuracy of positioning, accuracy of hemorrhage localization (required accuracy depends on planned intervention), effectiveness of intervention to stop bleeding (Phase II) and time to positioning or intervention. This will occur via a combination of manual evaluation by SMEs, automated analysis using medical imaging, or a hybrid of both approaches. Exact evaluation methods for positioning will need to be tailored for each specific robotic platform (i.e. intravascular methods will be different than rigid extravascular robots, which will be different from flexible extravascular robots) and each specific proposed method of hemostasis.

1.8. Test and Evaluation (T&E)

Performers will undergo two rounds of formal IV&V testing, one near the end of each phase, per Section 1.7 and the Table 5. In addition, performers are responsible for developing a test and evaluation strategy for their own managed testing, to be refined with support from the MASH USG team. This testing is anticipated to include a combination of virtual (in silico), physical phantom, *ex vivo*, and *in vivo* testing, and must be sufficient to demonstrate progress against program metrics. A number of key program milestones rely on effective execution of this testing strategy over the life of the program, notably the six Capability Demonstrations (CDs) mentioned in Sections 1.5.1.1, 1.5.1.2, 1.6.1, and in Attachment D. The six CDs will be attended by the MASH USG team, and results from these tests will feed into the overall metric evaluation process. Performers are expected to develop a test plan factoring in details from the MASH

IV&V test methods document (see Section 1.4), which will outline the mapping of metrics against government-led and performer-led testing that aims to achieve proper statistical power across the range of test runs and environments without relying exclusively on large animal testing.

1.8.1. Capability Demonstrations (CDs)

This section provides a mapping between each CD, associated program metric, and the anticipated test month. Note that two CDs occur in the same month, as they are anticipated to be developed in parallel.

Table 6. Capability demonstrations (CD) by month, with associated metric

CD	Timeframe	Relevant metric(s)
1. Bleeding detection	Month 12	Detect bleeding
2. Bleeding localization	Month 18	Localize bleeding
3. End effector efficacy to stop bleeding	Month 20	Hemostasis
4. Automated search and end effector position	Month 20	Time to complete inspection, Position end effector
5. Autonomous hemorrhage control	NLT Month 30	Hemostasis
6. Dry run	Month 34	Hemostasis

1.9. Areas Specifically Not of Interest

DARPA is not interested in proposals that focus on or include the following:

- Human subjects research (efforts should leverage large animal models).
- Cell salvage technologies.
- Approaches that require manual surgical techniques for hemostasis as performed by the medic, or require medics to perform medical decision making.
- Approaches not pursuing full (Level 5) surgical autonomy[6].
- Approaches proposing novel end effectors, sensors, or robotic platforms
- Autonomy not capable of understanding underlying physics (of movement, obstacles, blood flow patterns, etc.).
- Approaches proposing the use of pharmacological solutions as the sole means of performing hemostasis. No pharmacologic dosing experiments will be supported, however pharmacologic agents with an approved FDA indication (even if off-label) or with Investigational New Drug (IND) approval can be proposed if in support of hemostasis.
- Approaches requiring continuous monitoring by the medic following the hemostasis procedure.

[6] Lee, A., Baker, T.S., Bederson, J.B. *et al.* Levels of autonomy in FDA-cleared surgical robots: a systematic review. *npj Digit. Med.* **7**, 103 (2024). https://doi.org/10.1038/s41746-024-01102-y

- Approaches with no viable path to a prototype design suitable for use in a field-forward, Role 1 military treatment facility.
- Approaches for obtaining initial access to the vasculature or abdomen (e.g. trocar placement) for the robotic platform, or studies to train medics to obtain such access
- A proposed robotic platform with no current, in-process, or anticipated near-term clinical indication for a related use by a recognized (though not explicitly domestic) medical device regulatory authority. Note: the clinical indication does not have to be for the exact use proposed to support the MASH program.

1.10. Public Release of Information and Security Guidance

At this time, DARPA expects much of the work performed under MASH to be unclassified, fundamental research but still subject to pre-publication review. Information generated that does not clearly identify as "CUI" (controlled unclassified) may still need to undergo review prior to public release. All publications, articles, and scientific presentations will be submitted to DARPA for review and approval 45 days in advance of required submission date, to give time to remove any sensitive information. It is anticipated that workshops and milestone reviews will be used to work towards mutually agreeable plans for review of publication, methods, data, and code prior to release, involving Government partners, DARPA, and performers.

2. PROGRAM SOLICITATION (PS) AUTHORITY

This PS may result in the award of an OT for Prototype Agreement, which can include not only commercially available technologies fueled by commercial or strategic investment but also concept demonstrations, and development activities that can significantly improve commercial technologies, existing Government-owned capabilities, and/or concepts for broad defense and/or public application(s). The Government reserves the right to award an OT for Prototype Agreement under 10 U.S.C. § 4022 or make no award at all. In all cases, the Government agreements officer shall have sole discretion to select the award agreement type, regardless of agreement type proposed, and to negotiate all agreement terms and conditions with selected proposers. The OT Agreement will not require cost sharing unless the proposer is a traditional defense contractor who is not working with a non-traditional defense contractor or nonprofit research institution to a significant extent.

2.1. PS Procedures

In response to this solicitation, and after verifying eligibility, proposers are required to submit an abstract as described in Section 4. Additional instructions for abstract submission are contained within Attachment A. This process allows DARPA to ascertain (1) whether the proposers understand the key challenges of the MASH program and (2) whether they are capable of executing their proposed concept. Specific evaluation criteria used by DARPA to make the assessment can be found in Section 4.3. If DARPA finds that both conditions are met, it may invite the proposer to submit an Oral Proposal Package (OPP), and participate in an oral presentation to DARPA, where the proposed technical solution will be evaluated. Further details regarding the oral presentations will be sent with the request for submission of an OPP. After the oral presentations, DARPA will decide which proposers will be selected for award. The

Government will not pay proposers responding to this PS for the costs associated with abstract submissions, OPP preparation, and oral presentation for the MASH program proposal development.

DARPA will use the following process to facilitate the MASH source selection:

a. **Proposers' Day (Optional):** The Program Manager will hold a virtual Proposers' Day on September 18, 2025, where he will briefly describe the program and its goals and solicit questions from the audience. Where possible, the Government will provide answers in real time, and a comprehensive list of questions and answers will be provided afterward via a question and answer (Q&A) document. Participation in the Proposers' Day is optional and is not a requirement for proposers seeking to submit an abstract. Additional details about the Proposers' Day were provided in Special Notice DARPA-SN-25-103 separate from this PS.

b. **Program Solicitation Questions and Answers (Q&A) (Informational Only):** DARPA will host a Q&A session during the MASH Proposers Day and will post a consolidated Q&A document. The Q&A document will be available online at https://www.darpa.mil/research/programs/medics-autonomously-stopping-hemorrhage. Following Proposers Day, questions can be sent to MASH@darpa.mil. DARPA will respond to any relevant and/or PS clarification question(s) prior to the final abstract due date and post consolidated Q&As at the MASH program page (https://www.darpa.mil/research/programs/medics-autonomously-stopping-hemorrhage).

c. **Abstracts (Required):** Abstracts shall be submitted as specified in Section 4.1 of this PS. The Government will review all submitted abstracts for technical comprehension**,** technical ability and estimated cost (see Section 4.3). Selected proposers will be invited to provide an OPP and participate in an oral presentation to the Government. Note that proposers must submit an abstract in response to this solicitation to be considered for participation in the MASH program. Proposers will not be invited to submit an OPP, provide an oral presentation, or be included in any further progression of the program without participating in the abstract phase of the solicitation.

d. **Oral Proposal Package (OPP) / Oral Presentation (Required if invited):** Oral presentations are anticipated to take place approximately six weeks after notification of selection and are by invitation only. DARPA will send an invitation to submit an OPP to those who are invited to participate in oral presentations. OPP content and format, to include templates, submittal instructions for OPPs, evaluation criteria, and proposed presentation dates for oral presentations will be provided in the invitation. The Government will review all OPPs in accordance with the evaluation criteria provided within the invitation to submit an OPP. The content of the OPP will not be made public or provided to other proposers. DARPA will evaluate the OPPs and oral presentations to determine which proposed solutions sufficiently meet the program's needs. Upon the selectability determination, and subject to the availability of funds, the Government may award an OT for Prototype under 10 U.S.C. § 4022 with fixed, payable milestones for both Phase I and Phase II (**Note** – Milestones represent a completed event. Milestone schedule is based on key observable events on the critical path to accomplish program objectives. Payments are triggered by successful performance of observable technical events (payable milestones). Fixed payable milestones are payments based on successful

completion of the milestone accomplishments agreed to in the milestone plan (Schedule of Milestones and Payments). Additional details will be provided within the invitation to submit an OPP.

2.2. Program Length

Phase I (base period) will be 24 months, and Phase II (option period) will be 12 months. This PS is requesting a proposal for both phases. The cost proposal should include cost breakouts for both phases and with the same level of details and support documentation. It is noted that the Government is not required to exercise the option period at all, which is subject to the availability of funds and is dependent on the program goals during and after Phase I.

3. ELIGIBILITY INFORMATION

3.1. Eligible Applicants

3.1.1. Federally Funded Research and Development Centers (FFRDCs) and Government Entities

DARPA encourages technical solutions from all responsible sources capable of satisfying the government's needs. To ensure fair competition across the ecosystem, DARPA prohibits contractors/performers from concurrently providing Systems Engineering Technical Assistance (SETA), Advisory and Assistance Services (A&AS), or similar support services and being a technical performer, unless the DARPA Deputy Director grants a written waiver. DARPA extends this prohibition to University-Affiliated Research Centers (UARCs) and FFRDCs including Government partners, who because of their specialized expertise and areas of competencies, are able to accomplish integral tasks that cannot be met by Government or contractor resources. Therefore, these entities are highly discouraged from proposing against this solicitation as awards to UARCs or FFRDCs will only be made by exception. UARCs and FFRDCs interested in this solicitation, either as a prime or a subcontractor, should contact the Agency Point of Contact (POC) listed in the Overview section prior to abstract due date to discuss potential participation as part of the government team or eligibility as a technical performer.

3.1.2. Other Applicants

Non-U.S. organizations and/or individuals may participate in accordance with applicable laws, regulations, and policies, including those pertaining to export controls and security.

3.2. Organizational Conflicts of Interest (OCI)

An organization cannot simultaneously provide scientific, engineering, technical assistance (SETA), advisory and assistance services (A&AS), or similar support to DARPA, and also be a performer on a DARPA research program.

If a prospective proposer believes a conflict of interest exists or may exist (whether organizational or otherwise) or has questions on what constitutes a conflict of interest, the proposer must send their contact information and a summary of the potential conflict via the specific e-mail address identified in this PS before time and effort are expended in preparing any submission documentation.

4. Guidelines and Guidance for Abstracts

4.1. General Guidelines

The submitted abstract must follow the "Abstract Template and Instructions" as described in Attachment A. Abstracts shall contain:

- Hypothesis corroborating, extending, or challenging the foundational principles of MASH.
- Narrative supporting the proposed approach, to include description of the system elements combined with algorithmic methodologies. The text shall demonstrate a thoughtful integration of robotics and software development.
- Populated Attachment B outlining technical approach (planned robotic platform(s), sensors, role of medic, etc.)
- Preliminary evidence of the feasibility of the proposed innovations.
- Identified risks to successful execution and fulfillment of program goals and proposed strategies for mitigating these.
- Specific plans, including cost, time estimates, and teaming composition to address all topics outlined in the program description.
- Anticipated testing strategy over the life of the planned effort, with sufficient detail as to lend confidence that the planned scope will provide sufficient autonomy training data, validate system functionality, and ultimately arrive at a successful demonstration of program metrics, both through performer-led and MASH USG team-led testing. This should include, at a minimum, a discussion on how simulation, phantoms, *in vivo*, and *ex vivo* models will be used
- Strategy for addressing all targets in MASH Vessel and Organ List (Attachment C).
- Details on how the techno-economic assessment will be managed, along with transition planning. This should include initial thoughts on the pathway to medical device regulatory approval.
- Rough order of magnitude budgets for Phase I (base period) and Phase II (option period).

Abstracts will not:

- Include elaborate brochures. Abstracts shall include only information relevant to the submission requirements or evaluation criteria.
- Reiterate the justifications or background information provided in the solicitation.
- Reflect cost strategies intended to artificially enhance competitiveness—such as minimizing technical risk, limiting innovation, or relying primarily on junior personnel.

Abstracts will be deemed non-conforming and not considered for further review if they:

- Are received through other mechanisms such as through Grants.gov or directly to the MASH@darpa.mil e-mail.
- Address only one Phase.

All proposal abstracts are required to be submitted via DARPA's Broad Agency Announcement Tool (BAAT). Please visit Proposer Instructions and General Terms and Conditions for

instructions on how to submit your abstract through DARPA's BAAT. It is important to note that the terms and conditions on the remainder of the Proposer Instructions and General Terms and Conditions link above do not apply to this solicitation. The purpose of referencing the website is for you to obtain instructions for DARPA's BAAT. Questions regarding Proposal Abstracts can be sent to MASH@darpa.mil, by November 18, 2025.

4.2. Associate Performer Agreements (APA)

DARPA anticipates that a large amount of data will be generated under this program by each performer team. Data analysis and modeling will be strengthened by compiling and integrating information across performers as well as shared with other government partners. Data sharing plans to facilitate exchange will then be formalized in an Associate Performer Agreement (APA), to be included as an attachment to the agreement award. Performers will be encouraged to share data externally with the broader research community, after any sensitive information or capabilities are controlled per security regulations and guidance, and performers may include plans for external data sharing in the milestones, metrics, and deliverables.

4.3. Abstract Evaluation

Abstracts will be evaluated by DARPA using the evaluation criteria listed below in descending order of importance, and not against other abstracts submitted in response to this PS. As stated above, proposers are required to submit an abstract for evaluation by DARPA to be considered for any subsequent award. DARPA will respond to proposed abstracts with a statement as to whether or not DARPA invites the submission of an Oral Proposal Package. Upon review of abstracts, the Government may elect to invite all, some, or none of the proposers to submit an OPP and participate in oral presentations. *Only abstract proposers invited by DARPA to submit an OPP and participate in oral presentations are eligible to provide one.*

- ***Technical Comprehension:*** The proposed technical understanding is accurate, proposed approach is clearly described, and key technical challenges and risks are identified. Technical approaches to challenges are supported by brief calculations or physical estimates where possible.
- ***Technical Ability:*** The proposer's team and organization demonstrate the ability to achieve the goals of the program.
- ***Cost Rough Order of Magnitude (ROM):*** The proposed ROM is reasonable, realistic, and affordable for the technical approach and accurately reflects the technical goals and objectives of the Program Solicitation.

DARPA's policy is to ensure impartial, equitable, and comprehensive proposal evaluations based on the evaluation criteria listed above and to select the source (or sources) whose abstract meets DARPA's technical, policy, and programmatic goals. DARPA will conduct a review of each conforming abstract, and all evaluations will be based solely on the evaluation criteria in this section.

For the purposes of this abstract evaluation process, DARPA defines a "selectable" abstract as follows:

- ***Selectable:*** *A selectable abstract is one that the Government has evaluated against the*

evaluation criteria listed in the PS, and the positive aspects outweigh the negative aspects.

For the purposes of this abstract evaluation process, DARPA defines a "non-selectable" abstract as follows:

- ***Non-Selectable:*** *An abstract is considered non-selectable when the Government has evaluated it against the evaluation criteria listed in the PS, and the positive aspects do not outweigh the negative aspects*

5. Oral Presentation Package (OPP) Instructions & Process

If DARPA requests an Oral Presentation Package (OPP), the proposers will be asked to provide further details on their proposed solution. As mentioned under Section 2 Program Solicitation (PS) Authority, OPP content and format (to include templates, submittal instructions for OPPs, evaluation criteria, and proposed presentation dates for oral presentations) will be provided in the invitation to submit an OPP to those being selected for oral presentation.

Oral presentations are expected to be held in-person (encouraged) over the course of 1-2 days in October in the Washington, DC metro area. Virtual presentations will be allowed, on a case-by-case basis, where in-person attendance is not possible. Travel costs for oral presentation will not be reimbursed by the Government. It is anticipated that each oral presentation will be scheduled for 60 minutes, allowing for a strictly limited 40-minute presentation time, and up to 20 minutes of questions and answers following. However, further details will be provided at the time of selection, and presentation times may be adjusted based on the number of participants. Additional details will be provided in the invitation to submit an OPP. Attachment D OPP Guidance highlights the process and instructions for OPP and is being provided for planning purposes only and is subject to change.

6. Awards

6.1. General Guidelines

Upon favorable review of the OPP and subject to the availability of funds, DARPA may choose to negotiate and award an OT for Prototype Agreement. The Government Agreements Officer reserves the right to negotiate directly with the proposer on the terms and conditions prior to execution of the resulting OT Agreement, including payment terms, and will execute the agreement on behalf of the Government. Be advised, only a Government Agreements Officer has the authority to enter into, or modify, a binding agreement on behalf of the United States Government. To receive an award:

- Proposers must have a Unique Entity Identifier (UEI) number and must register in the System for Award Management (SAM). Proposers are advised to commence SAM registration upon notification of entry of the competition.
- Awardees will be required to submit invoices for payment electronically via the Wide Area Work Flow (WAWF) module in the Procurement Integrated Enterprise

Environment at https://piee.eb.mil/, unless an exception applies. Registration in PIEE is required prior to any award under this PS. For assistance with PIEE, please contact 866-618-5988 or DARPAInvoices@DARPA.mil.

- Proposers must be determined to be responsible by the Agreements Officer and must not be suspended or debarred from award by the Federal Government nor be prohibited by Presidential Executive Order and/or law from receiving an award.

6.2. Competition Sensitive Information

DARPA policy is to treat all submissions as competition sensitive, and to disclose their contents only for the purpose of evaluation. Restrictive notices notwithstanding, during the evaluation process, submissions may be handled by support contractors for administrative purposes and/or to assist with technical evaluation. All DARPA support contractors performing this role are expressly prohibited from performing DARPA sponsored technical research and are bound by appropriate nondisclosure agreements.

6.3. Intellectual Property Rights

The Government expects unlimited rights for the technology and data developed and/or generated under the program but is open to flexible intellectual property (IP) proposals from proposers that are advantageous to the Government. IP proposals should, at a minimum, allow DARPA to:

- Brief U.S. Government stakeholders regarding technical progress and accomplishments.
- Allow validation of technical performance, capabilities, and accomplishments by independent technical (potentially non-Government) experts, subject to NDA restrictions.
- Facilitate discussion of technical challenges and applications with the broader technical community – for example, by starting a new DARPA program that attempts to solve a serious technical challenge that limits further progress.
- Support analysis of alternatives, and
- Support transition opportunities, including design and performance data required to support other acquisition activities. These latter activities may require the Government to conduct an independent performance analysis.

Proposers responding to this PS shall appropriately identify any potential restrictions on the Government's use of any intellectual property furnished by the proposer. This includes both Noncommercial Items and Commercial Items. Proposers are encouraged to identify these restrictions in a format like the table depicted below. If no restrictions are intended, then the proposer should state "NONE."

List of restrictions

Technical Data, Computer Software To be Furnished with Restriction	Summary of Intended Use in the Conduct of the Research	Basis for Assertion	Asserted Rights Category	Name of Person Asserting Restrictions

(LIST)	(NARRATIVE)	(LIST)	(LIST)	(LIST)

6.4. Data Rights

The Government shall have unlimited rights in data, including technical data and software, first produced/generated and delivered in the performance of this contract regardless of success or failure of work performed on the contract. However, the Government is open to flexible data rights proposals from proposers that are advantageous to the Government. Proposers are expected to explain how data will be used, stored, and disseminated, including clarifying its intended use (e.g., internal use, public database). Data includes manuals or instructional and training material for installation, operation, or routine maintenance and repair of items, components, or processes developed, delivered or furnished for use under this contract.

6.4.1. Release, publication, and use of data.

The Performer shall, with prior approval of the Agreements Officer, have the right to use, release to others, reproduce, distribute, or publish any data first produced or specifically used by the Performer in the performance of this contract.

6.4.2. Subcontracting

The Performer shall obtain from its subcontractors all data and rights therein necessary to fulfill the Performer's obligations to DARPA under the resultant award. If a subcontractor refuses to accept terms affording the DARPA those rights, the Performer shall promptly notify the Agreements Officer of the refusal and shall not proceed with the subcontract award without authorization in writing from the Agreements Officer.

6.4.3. Copyrights

Performers may, with prior approval of the Agreements Officer, assert copyright in scientific and technical articles based on or containing data first produced in the performance of this contract and published in academic, technical or professional journals, symposia proceedings, or similar works.

6.5. Procurement Integrity

All awards under this PS shall be treated as Federal Agency procurements for purpose of 41 U.S.C. Chapter 21. Accordingly, the competitive solicitation process and awards made thereof must adhere to the ethical standards required by 41 U.S.C. Chapter 21.

6.6. Human Subjects Research /Animal Subject Research Use

Proposers that anticipate involving human subjects or animals in the proposed research must comply with the approval procedures detailed at https://www.darpa.mil/work-with-us/humanresearch to include providing the information specified therein as required for proposal submission. Proposers should anticipate that IV&V testing will include animal subjects, and that government-managed events (field use requirements capture and field medic utility study) will include human subjects work as part of a collaboration with the Government team.

7. DARPA Fundamental Research Risk-Based Security Review Process

It is DoD policy that the publication of products of fundamental research will remain unrestricted to the maximum extent possible. National Security Decision Directive (NSDD) 189 defines fundamental research as follows:

'Fundamental research' means basic and applied research in science and engineering, the results of which ordinarily are published and shared broadly within the scientific community, as distinguished from proprietary research and from industrial development, design, production, and product utilization, the results of which ordinarily are restricted for proprietary or national security reasons.

Proposers should indicate in their proposal whether they believe the scope of the research included in their proposal is fundamental or not. While proposers should clearly explain the intended results of their research, the Government shall have sole discretion to determine whether the proposed research shall be considered fundamental and to select the award instrument type. Appropriate language will be included in resultant awards for non-fundamental research to prescribe publication requirements and other restrictions, as appropriate. Please see - https://www.darpa.mil/work-with-us/communities/academia/fundamental-research

For certain research projects, it may be possible that although the research to be performed by a potential awardee is non-fundamental research, its proposed sub awardee's effort may be fundamental research. It is also possible that the research performed by a potential awardee is fundamental research while its proposed sub awardee's effort may be non-fundamental research. In all cases, it is the potential awardee's responsibility to explain in its proposal which proposed efforts are fundamental research and why the proposed efforts should be considered fundamental research.

The Decision Matrix to Inform Fundamental Research Proposal Mitigation Decisions found in OUSD(R&E) Countering Unwanted Influence in Department Funded Research at Institutions of Higher Education, dated June 29, 2023, has been updated and replaced by the new Decision Matrix found in the Memo "Introduction to the 2025 DoD Component Decision Matrix to Inform Fundamental Research Proposal Mitigation Decisions" – Dated May 5, 2025.

In addition to Government support for free and open scientific exchanges and dissemination of research results in a broad and unrestricted manner, the performer or recipient, regardless of tier, acknowledges that such research may have implications that are important to U.S. national interests and must be protected against foreign influence and exploitation. As such, a performer or recipient agrees to comply with the following requirements:

1. On June 8, 2023, the Office of Undersecretary of Defense for Research and Engineering (OUSD (R&E)) released a memo entitled "Policy on Risk-Based Security Reviews on Fundamental Research" directing components to establish a risk-based security review program to identify and mitigate undue foreign influence in fundamental research consistent

the requirements mandated by NSPM-33. **On May 5, 2025, OUSD(R&E) issued an updated document titled "2025 DoD Component Decision Matrix to Inform Fundamental Research Proposal Mitigation Decisions," which serves as an update to the original matrix published in 2023. The update strengthens research security by simplifying and clarifying reviews of problematic behaviors, and includes new requirements established by Congress.** In accordance with these requirements DARPA will assess all Covered Individuals proposed to support DARPA under all fundamental research proposals, selected for award, for potential undue foreign influence risk factors relating to professional and financial activities. This will be done by evaluating information provided via the OSTP Common Disclosure Forms, and any accompanying or referenced documents, in order to identify and assess any associations or affiliations the Covered Individuals may have with foreign countries of concern (FCOC) (i.e., The Peoples Republic of China, the Russian Federation, the Islamic Republic of Iran, and the Democratic People's Republic of North Korea) or FCOC connected entities.

2. The performer or recipient must establish and maintain an internal process or procedure to address malign foreign talent programs, conflicts of commitment, conflicts of interest, and research integrity consistent with USD(R&E) direction. The performer or recipient must also utilize due diligence to identify Foreign Components or participation by Covered Individuals in Foreign Government Talent Recruitment Programs and agree to share such information with the Government upon request.

3. DoD Grant Information Notice 24-01 (GIN 24-01) published on September 25, 2024, OUSD(R&E) which requires the use of Common Disclosure Forms for the submission of biographical (biosketch) information and current and pending (other) support from key personnel on proposals for assistance awards for research and development (R&D). In alignment with federal research security policy and to promote consistency across award mechanisms, these requirements are also required for Other Transactions (OTs) for R&D. Accordingly, key personnel named in OT proposals are required to submit Common Disclosure Forms in the approved format, as well as provide a digital persistent identifier (DPI), prior to award. GIN 24-01 was issued to implement the February 14, 2024, OSTP Memorandum entitled "Policy Regarding Use of Common Disclosure Forms for the 'Biographical Sketch' and the 'Current and Pending (Other) Support' Sections of Applications by Federal Research Funding Agencies."

4. All submissions proposing fundamental research to R&D solicitations will use the Common Disclosure Forms, biosketch, and current/pending support forms. Forms can be found here:

   - Common Form for Biographical Sketch (nsf.gov)
   - Common Form for Current and Pending (Other) Support (nsf.gov)

5. **Effective 1 April 2025,** DoD must use Digital Persistent Identifiers (DPIs) required on the OSTP Common Disclosure Forms, and DARPA will require proposers to include the ORCID (https://orcid.org/) number for each covered person listed in a proposal for non-FAR

based award instruments. ORCID numbers will be used since ORCID is currently the only DPI provider that meets the requirements for DPI common or core standards in the NSTC NSPM-33 implementation guidance.

6. Any changes to covered individuals will require submission of the Common Disclosure Forms, a security-based risk assessment, and approval by the contracting officer and program manager.

   The above-described information must be provided to the Government as part of the proposal in response to the solicitation and will be reviewed and assessed utilizing a risk-based security review process prior to award. See "Proposers Requesting an Other Transaction" below for instructions.

   DARPA's risk-based security review process takes into consideration the entirety of the Covered Individual's Common Disclosure Forms. These potential risk factors, along with any publicly available validation information, are then compared to the "DoD Risk Decision Matrix" to determine the level of mitigation that may be required to proceed, if possible.

   The risk-based security review process will leverage publicly available lists, or reports, published by the U.S. federal government. Those lists and reports include, but are not limited to:

   - FY22 Lists Published in Response to Section 1286 of the John S. McCain National Defense Authorization Act for Fiscal Year 2019 (Public Law 115-232), as amended.
   - Executive Order 13959 "Addressing the Threat From Securities Investments That Finance Communist Chinese Military Companies"
   - The U.S. Department of Commerce, Bureau of Industry and Security, List of Parties of Concern
   - Director of National Intelligence (DNI) "Annual Threat Assessment (2025)"
   - Various Defense Counterintelligence and Security Agency (DCSA) products regarding targeting of US technologies, adversary targeting of academia, and the exploitation of academic experts: www.dcsa.mil

The DoD has explicitly stated in policy that there are foreign influence risks that are not able to be mitigated and thus would require denial of award. They are:

1. BEGINNING IN FISCAL YEAR (FY) 2024 (1 OCTOBER 2023), NO U.S. INSTITUTION OF HIGHER LEARNING THAT HOSTS A CONFUCIUS INSTITUTE* MAY RECEIVE DOD FUNDING UNLESS THE INSTITUTION OF HIGHER EDUCATION HAS BEEN ISSUED A WAIVER BY THE SECRETARY OF DEFENSE PURSUANT TO SECTION 1062 OF THE WILLIAM M. (MAC) THORNBERRY NATIONAL DEFENSE AUTHORIZATION ACT FOR FY 2021. INSTITUTIONS HOSTING A CONFUCIUS INSTITUTE ARE AUTOMATICALLY CLASSIFIED AS "PROHIBITED" UNDER OUSD(R&E) "POLICY ON RISK-BASED SECURITY REVIEWS ON FUNDAMENTAL RESEARCH"

2. AS OF AUGUST 9, 2024, THE DOD IS PROHIBITED FROM FUNDING OR MAKING AN AWARD OF A FUNDAMENTAL RESEARCH PROJECT PROPOSAL IN WHICH A COVERED INDIVIDUAL IS PARTICIPATING IN A MALIGN FOREIGN TALENT RECRUITMENT PROGRAM (MFTRP) OR TO A PROPOSING INSTITUTION THAT DOES NOT HAVE A POLICY ADDRESSING MFTRP PURSUANT TO SECTION 10632 OF THE CHIPS AND SCIENCE ACT OF 2022. INDIVIDUALS PARTICIPATING IN A MFTRP, AND INSTITUTIONS WITOUT A POLICY ADDRESSING MFTRP, ARE AUTOMATICALLY CLASSIFIED AS "PROHIBITED" UNDER OUSD(R&E) "POLICY ON RISK-BASED SECURITY REVIEWS ON FUNDAMENTAL RESEARCH"

* The term "Confucius Institute" means a cultural institute directly, or indirectly, funded by the Government of the People's Republic of China.

1. Security-based risk assessments will also be conducted if changes to covered individuals reporting criteria are reflected in the Research Performance Progress Reports.

2. To the greatest extent practicable, DARPA will work with the performer to ensure that if the risk is able to be mitigated, it will make every effort to do so. If the performer refuses to, or is unable to mitigate the identified risks, it may result in a denial of award.

3. Proposers may challenge DARPA's risk-based security review decision. In that instance, DARPA will refer the challenge to the OUSD(R&E) for mediation.

4. Failure of the performer or recipient to reasonably exercise due diligence to discover or ensure that neither it nor any of its Covered Individuals are involved in the subject award are participating in a Malign Foreign Government Talent Program or have a Foreign Component with FCOC or FCOC-connected entity may result in the Government exercising remedies in accordance with federal law and regulation.

   4.1. If, at any time, during performance of this research award, the performer or recipient should learn that it, its Covered Individuals, or applicable team members or subtier performers on this award are or are believed to be participants in a malign foreign government talent program or exhibiting behaviors/actions identified in the DoD Component Decision Matrix (i.e. funding from a FCOC or FCOC connected entity, patents resulting from U.S. Government funded research that were filed with a FCOC or on behalf of a FCO-connected entity, and associations or affiliations with foreign government connected entities), the performer or recipient will notify the Government Contracting Officer or Agreements Officer within 5 business days.

      4.1.1. This disclosure must include specific information as to the personnel involved and the nature of the situation and relationship. The Government will have 30 business

days to review this information and conduct any necessary fact-finding or discussion with the performer or recipient.

4.1.2. Such disclosure may lead to the Government considering termination of the award.

4.1.3. If the University receives no response from the Government to its disclosure within 30 business days, it may presume that the Government has determined the disclosure does not represent a threat.

4.2. The performer or recipient must flow down this provision to any subtier contracts or agreements involving direct participation in the performance of the research.

DARPA's analysis and assessment of affiliations and associations of Covered Individuals is compliant with Title VI of the Civil Rights Act of 1964. Information regarding race, color, or national origin is not collected and does not have bearing in DARPA's assessment. Performers with proposals selected for negotiation that have been assessed as having potential undue foreign influence risk factors, as defined by the DoD Decision Matrix, may be given an opportunity during the negotiation process to mitigate the risk. DARPA reserves the right to request any follow-up information needed to assess potential risk factors or proposed risk mitigation strategies.

Definitions can be found in the USD(R&E) "Policy for Risk Based Security Reviews of Fundamental Research", June 8, 2023 (or as it is amended). Definitions can be found at the following link: https://media.defense.gov/2023/Jun/29/2003251160/-1/-1/1/COUNTERING-UNWANTED-INFLUENCE-IN-DEPARTMENT-FUNDED-RESEARCH-AT-INSTITUTIONS-OF-HIGHER-EDUCATION.PDF

Regardless of the proposal submission method, proposers must submit the two forms listed below for all covered individuals and for all other key personnel. The biographical sketch should include information pertaining to the researchers:

- Identifying Information (ORCID Digital Persistent Identifier (DPI))
- Position Title
- Organization and Location
- Professional Preparation (education and training)
- Appointments and Positions
- Products
- Certification

Form 2, Common Form for Current and Pending (Other) Support Information form, available on the NSF.gov website, will be used to collect the following information for all covered individuals, including Project Director/Principal Investigator and Co-Project Director/Co-Principal Investigator, whether or not the individuals' efforts under the project are funded by the DoD and any individual designated as a "covered individual" by the funding agency. The form

includes 2 parts: Proposals and Active Projects; and the In-Kind Contributions. The Current and Pending Support form is mandatory for all covered individuals including the PD/PI. This attachment should include the following information:

- Proposals and Active Projects
    1. Source of Support
    2. Primary Place of Performance
    3. Active Project Start/End Date
    4. Total Anticipated Project Amount
    5. Person-Month(s) per year devoted to Active Project
    6. Overall Objectives
    7. Statement of Potential Overlap
- In-Kind Contributions
    1. Status of Support
    2. Receipt Date of In-Kind Contributions
    3. Source of Support
    4. Summary of In-Kind Contributions
    5. Person-Month(s) per year devoted to the In-Kind Contribution
    6. US Dollar Value of In-Kind Contribution
    7. Overall Objectives
    8. Statement of Potential Overlap
- Certification

Note, if DARPA receives a proposal without the required information, DARPA may determine that the proposal is non-conforming. This could result in the submission being eliminated from further review and consideration under the solicitation. DARPA reserves the right to request further details from the proposer before making a final determination on funding the effort.

8. PS Glossary

- A&AS: advisory and assistance services
- AI/ML: Artificial Intelligence/Machine Learning
- API: Application Programming Interface
- BAAT: Broad Agency Announcement Tool
- BTO: Biological Technologies Office
- CD: Capability Demonstration
- CDR: Critical Design Review
- CUI: Controlled Unclassified Information
- DARPA: Defense Advanced Research Projects Agency
- DHA: Defense Health Agency
- DOD: Department of Defense
- DCR: Damage Control Resuscitation
- DCS: Damage Control Surgery
- FDA: Food & Drug Administration
- FFRDCs: Federally Funded Research and Development Centers

- GFI: Government-furnished information
- GPR: Government Purpose Rights
- GWOT: Global War on Terror
- IACUC: Institutional Animal Care and Use Committee
- IP: Intellectual Property
- IV&V: Independent Verification and Validation
- LSCO: Large-scale combat operations
- MASH: Medics Autonomously Stopping Hemorrhage
- MTF: Military treatment facility
- NDA: Non-Disclosure Agreement
- NCTH: Non-Compressible Torso Hemorrhage
- NPV: Negative predictive value
- OCI: Organizational Conflicts of Interest
- OT: Other Transaction
- OPP: Oral Proposal Package
- ORA: Office of Regulated Activities
- PDR: Preliminary Design Review
- PPV: Positive predictive value
- PI: Principal Investigator
- PIEE: Procurement Integrated Enterprise Environment
- POC: Point of Contact
- PPE: Personal Protective Equipment
- PS: Program Solicitation
- Q&A: Question and Answer
- RAI: Responsible Artificial Intelligence
- ROM: Rough order of Magnitude
- SAM: System for Award Management
- SETA: Scientific, engineering, technical assistance
- SME: Subject Matter Expert
- TBD: To Be Determined
- TCD: Technical Clarification Document
- T&E: Test and Evaluation
- TR: Technical Representatives
- TRL: Technology readiness level
- UARC: University-Affiliated Research Centers
- UEI: Unique Entity Identifier
- USG: United States Government
- WAWF: Wide Area Workflow

9. Additional Information

Please e-mail MASH@darpa.mil if you wish to be added to our blast list for future program updates.