DARPA-PS-25-34
Medics Autonomously Stopping Hemorrhage (MASH)
Frequently Asked Questions

Version 2
9 October 2025 – Updates highlighted/underlined below

Please note: Amendment 1 to DARPA-PS-25-34 was published to SAM.gov on 8 October 2025, providing an updated version of the proposal abstract template (Attachment A).

General Information

1. **Question (Q): Has the Program Solicitation (PS) been published? Where is it posted?**
   Answer (A): Yes, it was published on 16 September 2025 and can be found on SAM.gov.

2. **Q: Will the slides from the Proposers' Day be made available to the registered attendees or posted online?**
   A: Yes. Information relayed during the Proposers' Day will be made available on the MASH program page at DARPA's website: https://www.darpa.mil/research/programs/medics-autonomously-stopping-hemorrhage.

3. **Q: Is teaming required?**
   A: While teaming is not required, it is strongly encouraged to provide the expertise and capabilities needed to achieve the MASH program goals. Proposing teams should have a plan in place for managing team interactions and future technology transitions.

4. **Q: Do you prefer that Proposers bring a consortium, bringing together all the necessary pieces or a specific technology?**
   A: There is no requirement to engage or form a consortium to propose to this solicitation. DARPA strongly encourages teaming to provide the necessary expertise and capabilities, but this can take many forms.

5. **Q: Can we make a "super team", or does the government prefer individual teams?**
   A: Proposers should consider what they believe will be best to get the work done and provide justification.

6. **Q: Non-traditional contractors appear to have limitations regarding recent/active contracts with DoD, does this also apply to nonprofit academic institutions?**
   A: The definition of non-traditional contractor applies to the organization's CAS status in accordance to Section 1502 of Title 41. Non-profit academic institutions are in a different category, and these institutions are allowed to have an OT with no cost sharing.

7. **Q: Could you confirm if the contract will use Cost Plus Fixed Fee or Fixed Price with payment for milestones?**
   A: Award(s) for MASH program will be an Other Transaction (OT) for Prototype with fixed payable milestones, which is more similar to fixed price with payment for milestones. We have published the key payable milestones for the program, both in the MASH PS and see Schedule of Milestones and Payment embedded within the draft OPP Guidance (MASH PS Attachment D). Proposers may add to this list and justify the proposed costs for all the payable milestones.

8. **Q: Could you confirm the expected award size range? How many awards are expected?**
   A: DARPA has not predetermined award amounts – awards will be based on the quality and innovation of the proposals received. DARPA has a budget of $32.4M for MASH and intends to fund multiple efforts, but the number of awards is based on the quality of the proposals that will be received. The Government reserves the right to select a proposal for full funding or partial funding.

9. **Q: Is there an applicable salary cap that should be applied when creating the budget?**
   A: No. However, please note that "Cost Rough Order of Magnitude (ROM)" is one of the proposal abstract evaluation criteria, as listed and defined in Section 4.3 of DARPA-PS-25-34.

10. **Q: Should we incorporate the commercial strategies officer during the application process or is this part of the post-contract process?**
    A: Engagement with the DARPA/CSO team is typically reserved for active and historical performers; proposers should not engage with the CSO team during the proposal process.

11. **Q: Relevant prior work is held with an FFRDC / UARC / other government-affiliated organization, previously funded by the U.S. Department of Defense. Are we permitted to transfer data from this previously-funded project to our performer team if all parties (including DoD sponsor) are amenable?**
    A: DARPA does not intend to get in between the prior sponsor and individual proposer teams. It is recommended that the rights to this information be confirmed, and if the information can be shared and the FFRDC or UARC is not a member of the proposing team, this seems viable.

12. **Q: How much detail is desired in the ROM cost? Is the performer bound to this estimate between abstract and OPP phase?**
    A: The ROM should provide sufficient cost information for the program team to assess direct and indirect costs for reasonableness of the proposed effort. Although proposer is not bounded by the ROM, it should be carefully crafted, and the total cost would be very closed to the proposed cost within OPP.

13. **Q: For the submission of abstract, should we address both phases, or just for the Phase I?**
    A: As stated in DARPA-PS-25-34 (page 10), "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."

14. **Q: Is an organization allowed to submit more than one abstract in collaboration with different teams particularly if each submission proposes a distinct solution?**
    A: Yes. Teams can be primes or subcontractors on multiple proposals. If chosen for multiple awards, a clear path will need to be established to ensure no conflicts are present between the efforts. Proposers who are on multiple teams should be cognizant of the distribution of the level of effort across multiple awards and will be required to ensure that DARPA is only charged once for any potential duplicate efforts.

15. **Q: In the first paragraph of Page 15 of the program solicitation: DARPA-PS-25-34, it states: "DARPA will not fund the manufacture of the prototype system under the MASH program." Does the word "manufacture" mean commercial production?**
    A: DARPA will fund the manufacture of the Demonstrator System. In the context of the program, the word "prototype" as printed in the MASH PS refers to the Objective System, also referred to as the portable prototype, and is speaking to the system that would ultimately need to be put

through rigorous safety and efficacy testing as part of a regulatory submission package in order to pursue approval for use as a medical device. This regulatory submission is beyond the scope of the MASH program, and as such the Objective System will not need to be built during the life of the program; rather, work on this portable prototype ends with a preliminary design. The Other Transaction for Prototype award vehicle is being leveraged, which implies that a prototype is being built, but in the contractual sense, the prototype unit being built under a MASH award is referred to in the MASH PS as the "Demonstrator System". This occurs in name only for the contracting vehicle, and all required deliverables and milestones refer back to the assembly and use of the Demonstrator System, not the Objective System (portable prototype).

16. **Q: I'd like to better understand the IP terms of the contract with DARPA. I assume background (pre-existing) IP remains in a performer's ownership (e.g. current arm designs) but need to know what the terms around foreground (generated as part of the program) IP. Also – what is the position on derivative IP?**
A: The IP terms of the contract is customizable and negotiable. DARPA does not intend to obtain commercial rights for performer IP but would require an IP arrangement that enable the Government and offer the flexibility to use, modify, and disclose for government functions and support future vision. It is critical during the proposal, and subsequently during the development of the award language, to spell out the IP assertions being made at the start of the project, and the desired rights at the end of the project.

17. **Q: What is required in the abstract package and does the page count include both Attachments B and C?**
A: The abstract package must include Attachments A, B and C, and proposers must complete these attachments in accordance with the direction and guidance provided within the attachments and section 4.1 of the Program Solicitation DARPA-PS-25-34. The abstract shall not exceed a maximum of 6 pages, and the page count exclude Attachments B and C. Refer to Attachment A, version 2, for additional details.

Regulatory Questions

18. **Q: Can you clarify how DARPA defines an acceptable clinical indication for this program? Specifically, is demonstrating Level 5 autonomy in large animal trauma models sufficient, or does DARPA expect teams to show a direct pathway to a deployable clinical device within this effort?**
A: For the purposes of this solicitation, clinical indication refers to the robotic platform being proposed for use. This platform needs to have either regulatory approval or be well on the way to a regulatory approval (in any country). Demonstrating autonomy at the onset is certainly of value, but this does not ensure that the robotic platform has a solid regulatory foundation from which to begin the process of adding MASH-related indications.

19. **Q: Does an adjunct injectable contrast material have to already have an Investigational New Drug (IND) approval prior to submission, or is this something that can be obtained during the course of the project?**
A: As mentioned in the MASH PS, page 6, "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".

20. **Q: It was mentioned that all are encouraged to work with the Office of Regulated Activities (ORA). How will that work? Will ORA be involved in 100+ proposals? Can you explain this in more depth?**

A: ORA will engage with performers once they (the performers) are selected and under an agreement with DARPA. ORA will not be available for assistance during the development of proposals.

21. **Q. Do I need to bring my own regulatory team?**
    A: Ideally, yes, but this is not a requirement to propose. Performers are expected to have expertise in the regulatory process, at least insofar as would be necessary to develop the market determination and sizing elements of the techno-economic assessment (TEA) per the MASH PS, pg. 12. Performers will have the ability to work with the ORA team at no additional cost, but it should be noted that ORA will act purely in a consultative fashion and will not develop any regulatory submission packages on behalf of the performers, should they be pursued during the course of the program.

22. **Q: Is the ORA a mandatory element of the contract? Are there varying levels of engagement of the DOD ORA?**
    A: Taking advantage of the ORA collaboration opportunity is strongly encouraged. Engagement with the ORA team can range from nothing, to a one-time or ad-hoc engagement, to a sustained relationship of consultative support. The ORA offer of support is intended to be a resource available to all selected performer teams aimed at promoting strategy development for regulatory plans.

23. **Q: DARPA is requesting a robotic platform with prior FDA approval, however these items will require adaptation to the MASH program. How do we present this in a proposal?**
    A: Proposer teams should identify the robotic platform they believe is a fit for the program, and present as well as justify the modifications needed. As per MASH PS pg. 6, 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. Note that only the robotics platform, and/or pharmaceuticals if included, require a prior FDA approval – the AI software does not require prior approval.

24. **Q: In terms of FDA approval, do existing robotic platforms need to be approved for a specific indication (e.g., hemorrhage control)?**
    A: See MASH PS pgs. 6 and 22 for more detail. Existing robotic platforms don't need to have a previous approval for hemorrhage control, but rather for any surgical indication.

25. **Q: Can performers use human data?**
    A: Use of new human data would be considered human subject research, which is not allowed for MASH. Therefore, use of human data would depend on what kind of data was collected, under which circumstances, and if appropriate approvals and permissions are in place.

Battlefield Environment

26. **Q**: **Many large-scale combat operations (LSCO) scenarios have some limitations on what can be transported or have added requirements on being mobile. Are there any added characteristics in terms of device deployment that need to be considered?**
    A: The MASH project will provide ample opportunity to learn from field medics on the limitations associated with technologies that would exist in a forward-deployed environment. Such opportunities will occur well before the portable ("Objective System") prototype design will be presented at the Preliminary Design Review as one of the later program milestones.

27. **Q: Does the program foresee a need for multi-terrain capable anthropomorphic robots?**
A: The intended use case of MASH technology would be in a Role 1 military treatment facility, which has obstacles but would not be considered rough terrain. There is no requirement for a mobile robot, or an anthropomorphic robot. There is also nothing precluding either of these options, so long as the robotic platform has a related current, in-process, or anticipated near-term clinical indication by a recognized medical device regulatory authority (per MASH PS pg. 22).

28. **Q: Will there be access to fluoroscopy or will sensor availability be restricted to ultrasound use? Are there any other sensor type restrictions?**
A: There are no explicit restrictions to sensor types or contrast agents other than those listed in the PS (dyes / tracers must have an approved FDA indication or IND approval, per MASH PS pg. 6). However, sensors such as X-rays and CT scanners, as well as fluoroscopy systems, must have a viable path to a portable form factor for the Objective Design. Proposals must outline sensor type(s) selected or under consideration and should outline how this would be suitable at a Role 1 MTF for the objective system.

29. **Q: How much do performers need to consider high levels of care and evacuation to higher roles?**
A: This is an important consideration for the ultimate utilization of a MASH system but will not be a focus of the MASH program.

30. **Q: Will performers be required to document the procedure that their developed MASH system performs, in order to output medical records that can be passed along to higher echelons of care?**
A: This is not explicitly necessary under the MASH program, but there is nothing prohibiting this from being an output of a MASH system.

31. **Q: What is the expected level of triage that will be performed on the casualty prior to when our system encounters them to begin our workflow?**
A: MASH assumes that a casualty has already been identified as a possible candidate for the MASH system due to concern for noncompressible torso hemorrhage. As stated on MASH PS pg. 6, MASH assumes that injuries leading to death from hemorrhage in less than 30 minutes are considered not salvageable due to the time required for patients to receive care from the MASH system. Proposals should lay out which injury cases their system can address.

Medic Availability and Insertion Point

32. **Q: Can we assume that there will be a medic that can insert the introducer sheath for vascular access and then be able to deploy the endovascular robot?**
A: Yes, as mentioned in the MASH PS pg. 5-6, "Teams can assume that intravascular access and access to the intra-abdominal space (i.e., trocar placement) is available for the MASH system."

33. **Q: Can our system upskill the medic with AI-guided procedures?**
A: The medic cannot be relied upon to make surgical decisions but having a MASH system's autonomy guide the medic to perform tasks is viewed as in-scope. Proposals should clearly outline what tasks are being proposed to add to the medic's responsibility when enabled by such a paradigm. As stated on MASH PS pg. 13, the medic can be leveraged for manual tasks such as robotic platform placement, end effector changes, or manual scans.

34. **Q: Does the system need to be fully autonomous to reach the target location of the bleed and stop it, or can the system work in conjunction with the medic guiding the robot (intravascular or extravascular) to the bleed location and stopping it?**

A: The medic should be considered as part of the system. As mentioned in the MASH PS, pg. 5, "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." Consider that the medic represents skilled personnel who can follow instructions, move or reconfigure system components, and provide actuation force and displacement if properly guided by the remainder of the system.

35. **Q: The solicitation stipulates that the medic can function as an enabler to position effectors. Can basic physical exam info from the medic such as mechanism of injury and wound location be used to inform decision algorithms that drive navigation and hemorrhage localization?**
A: This is up to the proposer but is viewed as in-scope. MASH systems should assume that basic field triage has been performed, that the medic is able to perform routine assessments to include mechanism of injury and wound location, and that these pieces of information might guide initial guesses for where the system needs to look for non-compressible torso hemorrhage.

36. **Q: For work in endovascular platforms, is it safe to assume there will be a medic who would be able to guide the endovascular robot within the vessel and deploy the hemostatic procedure?**
A: Assume vascular access is provided, and do not include this in a proposal. As mentioned in the MASH PS pg. 5, "MASH also assumes a medic is present and can provide actuation and support to the system (robotic platform and sensors). The medic should not be making decisions about how to navigate / guide the endovascular robot. The medic should not be making decisions about the hemostatic procedure.

37. **Q: How important is the collaboration between medic and robotic element? What is the level of support for the autonomy system?**
A: As noted on MASH PS pg. 13, teams are expected to leverage full autonomy for the robotic system with the exception of working with the medic for manual tasks (robotic platform placement, end effector changes or installation, manual external sensor scans. As noted on page 12 of the MASH PS, a description of the medic-system interaction is an expected component of the Phase II Preliminary Design Review.

38. **Q: Considering a new trocar system is not needed; does that disqualify a new system for entry, zone of injury, intraabdominal monitoring of hemostasis? Or adding systems to existing trocars?**
A: Proposers should assume there's abdominal access and medic can provide basic trocar access. If their proposal requires more than a basic approach, explain why it's necessary to include it. If the proposed trocar would add components to the overall system, specific to their approach, explain why it is necessary beyond basic systems.

39. **Q: In terms of automated trocar placement, is there something for central line placement?**
A: As mentioned in the MASH PS, pg. 5-6, proposers should assume access will be present, whether for intravascular or intra-abdominal approaches. This would include a central line, if desired.

40. **Q: It is stated that we can assume that intravascular access and access to the intra-abdominal space (i.e., trocar placement) is available for the MASH system, and that the MASH USG team will identify further gaps in technologies and training related to obtaining anatomic access to the casualty. Will the results of this research be made available**

to the performers? Will there be an opportunity to talk with the team performing this study?
A: Yes, results of this research will be made available to the performers. Yes, there will be an opportunity to talk with the MASH USG team as this study is being performed.

41. **Q: Do we define the resources at Role 1 that will be available?**
A: These will be defined no later than the start of Phase II, when performers will meet with Role 1 medics at a Role 1 training site for a requirements capture session. MASH does not prescribe specific size, weight and power requirements or limitations. The demonstrator must be able to be transported twice (once per phase) to the IV&V testing site for end of phase evaluation testing. The Objective System must have a viable pathway to portable field use.

42. **Q: Is there consideration to the environment in how teams come up with the solution?**
A: MASH does not prescribe specific size, weight and power requirements or limitations. The demonstrator must be able to be transported twice (once per phase) to the IV&V testing site for end of phase evaluation testing. The objective system must have a viable pathway to portable field use.

43. **Q: What are the resources currently required for surgical teams to identify intraabdominal bleeding in forward military operating environments?**
A: In current forward operating environments (specifically, Role 1 military treatment facilities), diagnostic options focus heavily on physical examinations and occasionally handheld ultrasound.

Robotics and Software

44. **Q. What is meant when you say "no new end effectors" are needed? Does that include the addition of sensors and algorithms to existing devices?**
A: In this context, end effectors refer specifically to the surgical tool(s). DARPA does not intend to fund the development of new surgical tools that can be placed at the end of the robotic platform. Incidentally, DARPA also does not intend to fund the development of novel sensors either. Proposals should detail the system elements planned for use.

45. **Q: The PS states that autonomy must be capable of understanding the underlying physics (pg. 21), and at Proposers' Day, DARPA mentioned the importance of physics in modeling. How much physics modeling is required in our concept? Can this focus on just the forward model for robotic control, or do we need to have inverse models as well?**
A: Proposer teams can choose whichever of these solutions can be proven to be safe and reliable and achieve the program metrics, which would include sufficient awareness of tissue anatomy and/or techniques that will avoid damage due to naïve robotic platform movement.

46. **Q: What is the expectation for the level of prototype after the first and second focus areas?**
A: The MASH program is focused on developing a demonstrator system, not a prototype, that demonstrates the ability to find and stop the hemorrhage. It is expected that the IV&V partners will verify the capability of the demonstrator system.

47. **Will performers be provided with databases with trauma data for the training set? Instead, do you anticipate that the performer team would create or bring the necessary data?**
A: DARPA does not have, and therefore cannot share, such data. Teams are allowed to bring their own data sets as part of their proposed approach.

48. **Q: Which technology readiness level (TRL) should proposers work towards?**
A: TRL levels are not defined or required to be met within the MASH program; projects must meet the stated program milestones and metrics with a system of indeterminate TRL. However, given that the robotic platform, sensors, and surgical end effectors should be either off-the-shelf or slightly modified off-the-shelf system elements, DARPA anticipates that some components will have a high TRL (7-9).

49. **Q: Does the proposed MASH system have to be a robot? Can it be a family of devices that allow more autonomy?**
A: A MASH system doesn't need to use a single monolithic device and can be a system-of-systems with multiple components, actuators, and sensors.

IV&V and Testing

50. **Q. How will the government animal testing be incorporated?**
A: Please review Sections 1.7 and 1.8 of DARPA-PS-25-34.

51. **Q: Can the performer visit the IV&V locations prior to capability test time?**
A: DARPA will provide options for performers to interact with the IV&V partners. Travel to the IV&V site ahead of schedule will be considered in a proposal and should be included in costing.

52. **Can the performer receive feedback from the IV&V partner on the developed prototype?**
A: First, take note that the MASH program is not requesting a prototype, but a demonstrator system, and a design of an eventual prototype as the "Objective System" that will not be built during the life of the program. That being said, performers will have numerous opportunities over the life of the program to gather feedback from the IV&V partner on the developing prototype design, in addition to the engagement with field medics during the field use requirements capture at the start of Phase II.

53. **Q: Are performers expected to set up their own testbeds? How does DARPA anticipate the data being shared with the IV&V and Government?**
A: Yes, DARPA anticipates that performers will need to set up their own testbeds to meet program metrics. DARPA will work with the IV&V team to determine how data sharing will take place. Data sharing will be contingent on approach.

54. **Q: Are teams required to perform animal work on their project?**
A: Yes, all performer teams will be required to perform animal work.

55. **Q: The Objective (prototype) system will need to take into consideration the space, weight, or power (SWAP) constraints associated with a Role 1 facility. However, no such considerations are true for the Demonstrator system that will be used during the life of the program. Does this imply that there are no constraints on the space, weight, and power of the proposed hardware?**
A: While it is true that no explicit requirements for low SWAP for the Demonstrator system, performers should note that this hardware must be transported twice to IV&V sites during the life of the program, and that there must be an eventual path to realizing the prototype system suitable for use in a Role 1 facility. Solutions with no viable path to a portable system will be viewed less favorably than those that can be made portable without substantial investment.

56. **Q: For the detection metric, the MASH PS lists 95% PPV on a bleed in a listed anatomical structure. Should the detection component give a negative classification if a bleed is present in an anatomical structure that is not on the organ/vessel list?**

A: DARPA does not intend to evaluate bleeding cases that aren't in the MASH Vessel and Organ list, and IV&V testing will not include these injury models. Therefore, neither a positive nor negative classification will be needed for these injuries during tests at the performer site that the government team will incorporate into their combined evaluation strategy.

Clinical Questions

57. **Q: In the MASH workflow, will detection of bleeding lead to determination of the need for robot deployment, or is the supposition that bleeding is present and bleeding detection is performed intracorporeally?**
A: There is no supposition that bleeding is present, in fact for some of the final trials there will be negative controls to validate the negative predictive value metric. Bleed detection does not need to be performed intracorporeally, though this would be a viable approach.

58. **Q: Can you clarify the desired information for the timeframe column in Attachment C? Does this refer to development timeframe or anticipated time to localization/hemorrhage control?**
A: Per the instructions within Attachment C, the timeframe column is requesting information "in Column D for when within MASH program this target will be addressed, including any grouping if planning to address targets in batches throughout the program. For either column, if answer is unknown, list as "TBD".

59. **Q: The solicitation states that the government is specifically not interested in cell salvage, but what if the proposer believes that this is a necessary element to save lives?**
A: DARPA assumes that resuscitation is already ongoing and that some strategies may make better use of resuscitative fluids than others. DARPA is not going to invest in more effective resuscitation elements under MASH. The MASH USG team will protocolize damage control resuscitation for each system with an overall survival assessment per MASH PS pg. 14, but even this will still focus on inputs needed, whether autologous blood or transfusions.

60. **Q: What resuscitation modalities (such as CRRT, portable lab sensing, etc.) do you think will be required to stabilize a trauma patient from a critical care standpoint out to 48hrs to manage complications such as ischemia-reperfusion, hyperkalemia, and sepsis prior to definitive surgery?**
A: DARPA assumes that resuscitation is already ongoing and that some strategies may make better use of resuscitative fluids than others. DARPA is not going to invest in more effective resuscitation elements under MASH. The MASH USG team will protocolize damage control resuscitation for each system with an overall survival assessment per MASH PS pg. 14, but even this will still focus on inputs needed, whether autologous blood or transfusions.

61. **Q: How far downstream should performers worry about fluid resuscitation?**
A: The IV&V team will initiate resuscitation soon after injury as described in MASH PS page 14. As noted on PS page 7, performer solutions that require excessive amounts of resuscitative fluids may be viewed less favorably. As noted on MASH PS page 20, resource utilization will be tracked for the 48-hour period after injury.

62. **Q: Table 5 performance metrics lists "Distance to nearest upstream branch point accurate to +0/-1 cm (location can't be downstream from true site)". This metric seems applicable only to intravascular interventions. Extravascular/intraabdominal interventions that use hemostatic materials or focal pressure application will be downstream from bleeding site in most instances. Please clarify.**

A: This metric applies to both intravascular and extravascular approaches and focuses on the accuracy of localizing the hemorrhage only, which is envisioned to be necessary for hemostasis procedure (intervention) planning purposes. The appropriate positioning of end effectors is rolled into the hemostasis metric.

63. **Q: Is it acceptable to incorporate semiautonomous vascular access into workflow if device is available and also being used for other hemorrhage control purposes in project?**
A: Teams can assume that intravascular access will be provided. As noted on MASH PS page 22, approaches to initial access to the vasculature are not of interest to the MASH program. Teams leveraging semiautonomous vascular access for hemorrhage control should explain why that approach is necessary to meet program metrics.

64. **Q: What about partial use of REBOA, or not making the hemorrhagic region completely ischemic, autonomous system to control so body doesn't go into total shock?**
A: Partial aortic occlusion is an acceptable adjunct but consider that distal methods of hemostasis or methods that allow for perfusion through an injured blood vessel will be favored over proximal, full occlusion methods as noted on MASH PS page 7.

65. **Q: If the goal is to maintain hemodynamic stability for 48 hours, does this mean that REBOA could be a solution, as it gets deployed for 48 hours?**
A: As noted in MASH PS page 7, a solution occluding blood flow in the aorta for the required 48 hours will not be a viable approach.

66. **Q: Bleed detection and localization are evaluated separately. Are they different techniques or is this separation a result of how the program is set up?**
A: There is no explicit requirement that detection and localization testing use separate techniques, and this assessment is correct – the separate evaluations reflect how the program is set up. Each function has its own metric(s), and each one is subject to a separate Capability Demonstration. Final MASH systems must demonstrate performance for both functions to step through the envisioned workflow. Performers are welcome to perform both functions from the onset, though DARPA views localization as a harder problem to solve than detection, which is why more time is allocated to achieve this function reliably.

67. **Q: What is the expectation for how long it takes to find bleed?**
A: Per MASH PS metrics (pg. 19), systems must perform a full inspection to find any active bleeding within 1 hour, in Phase I. By the end of Phase II, the combined action of finding active bleeding AND stopping the bleeding must be accomplished within 1 hour.

68. **Q: Can performers propose new interventional approaches?**
A: Performers should focus on approaches that have predicate devices or are already being used in the minimally invasive surgery realm. If new approaches are suggested, they would need justification.

69. **Q: How do we handle hollow viscus injury?**
A: Per MASH PS pg. 7, the handling of hollow viscus injury is not within the scope of the MASH program.

70. **Q: Do proposers need to consider treating ongoing contamination?**
A: Per MASH PS pg. 7, treatment of ongoing contamination is not within the scope of the MASH program.

71. **Q: Does the solution need to be interoperable between chest, retroperitoneum, and abdominal cavity?**
A: The MASH program will focus on peritoneum and retroperitoneum.

72. **Q: Should proposers consider a single bleed or multiple bleeds?**
A: The MASH program asks performers to consider multiple bleeds.

73. **What are the challenges of providing localized, directed treatments for intra-abdominal hemorrhage control which limit damage to nearby or downstream structures?**
A: This is a great question. It is suggested that all approaches, be they intra-abdominal or intravascular, consider this and provide their assessment of the foreseen challenges, to include ischemia, physical accidental damage to neighboring structures, and other considerations. Different approaches will introduce different challenges, and these challenges (along with the proposers' understanding of them) will be considered in the evaluation of the proposed concept.

74. **Q: Are autonomous, non-invasive detection and treatment approaches that do not require laparoscopic or intravascular access in scope? If so, to what extent would robotic positioning be required (vs. e.g., being handheld by medic)?**
A: Non-invasive detection is in scope. There is no requirement for robotic positioning of the detection sensor(s) – it is open to proposing teams as to the optimal means of the interactions between casualty, medic, robotic platform(s), and sensor(s). Non-invasive detection sensors are therefore allowed, but not required, to be handheld by the medic. Non-invasive treatment could be in scope if proposers can demonstrate how this will address targets in the MASH Vessel and Organ List. Such an approach must still comply with DARPA-PS-25-34, namely that the robotic platform and surgical end effector has either received regulatory approval for a surgical indication or that it is currently under a regulatory pathway for future approval (See "Program Considerations" – DARPA-PS-25-34, page 6).

75. **Q: Will the standard resuscitation protocol developed by the government team be provided early in the process since the extent of ongoing resuscitation directly influences the success of hemorrhage control interventions and shock tolerance of the injured patient? Can automated resuscitation capability be incorporated into Phase 2 proposal or will all performers use the same protocol?**
A: The IV&V team will document any necessary supplemental resuscitative fluids provided under DCR, specific to each performer's approach – this will not be a program-wide standard protocol. Proposals should not include language for automated resuscitation capabilities in either phase.

76. **Q: Please explain the Phase 2 hemostasis metric regarding <30% total blood volume. How is this measured since free intra-abdominal blood will be mixed with hemostatic agents in some cases. Additionally, the significance of this volume is variable depending upon the extent of resuscitation received during that time period. Accumulation of 30% blood volume within the abdominal cavity would be expected and tolerable if sufficient adjunct resuscitation is provided and bleeding temporized.**
A: Loss of 30% total blood volume was chosen as a cut-off value to optimize survival in future environments with anticipated shortages of adjunct resuscitation resources. This will be measured either with metered suction or CT scans, and knowledge of provided resuscitation resources.

77. **Q: Can angioembolization be used as an adjunct to surgery?**
A: Yes. Angioembolization is an acceptable adjunct, but proposals including this should describe how this will not lead to life-threatening ischemia or reperfusion injury while meeting the 48 hour program metrics.

78. **Q: REBOA is not in scope for the program, but what if we can improve on REBOA by using sensing and AI to address current limitations of REBOA? For example, can we automate REBOA and make it safe and temporize. Can it be in scope?**
A: Yes, if you can justify and meet metric of 48h along with all other program metrics. Proposals pursuing this approach should describe how this will not lead to life-threatening ischemia or reperfusion injury while meeting the 48 hour program metrics.

79. **Q: Most existing platforms are Minimally Invasive Surgery (MIS), how does this impact platforms for MASH?**
A: DARPA anticipates that MIS methods will be the only mechanism for intravascular or extravascular procedures, and that medics will not have the ability to perform open procedures.

80. **Q: What would be the limitations of ultrasound? For example, image quality, access to trained staff, use of contrast enhanced ultrasound?**
A: Contrast agents will be considered, but as a reminder, any contrast agents utilized to enhance imaging quality must have an approved FDA indication or IND approval as per MASH PS pg. 6. As mentioned in the MASH PS, pg. 5, MASH assumes a medic is present and can provide actuation and support to the system, but medical decision-making must be managed by the system's autonomy." Consider that the medic represents skilled personnel who can follow instructions, move or reconfigure system components, and provide actuation force and displacement if properly guided by the remainder of the system.

81. **Q: Should the platform developed for MASH be able to address all types of interventions, including shunts?**
A: As noted on page 7 of the PS, MASH will not address all aspects of damage control surgery (DCS), but rather will focus on stopping torso bleeding for long enough to buy time to reach definitive care and remaining DCS procedures. Interventions outside of hemorrhage control are beyond scope of the MASH program. Shunts may be considered if deemed necessary.