Broad Agency Announcement
GOLDen hour extended EVACuation (GOLDEVAC)

BIOLOGICAL TECHNOLOGIES OFFICE

HR001124S0024

April 3, 2024

This publication constitutes a Broad Agency Announcement (BAA) as contemplated in Federal Acquisition Regulation (FAR) 6.102(d)(2) and 35.016 and 2 CFR § 200.203. Any resultant award negotiations will follow all pertinent law and regulation, and any negotiations and/or awards for procurement contracts will use procedures under FAR 15.4, Contract Pricing, as specified in the BAA.

Overview Information:

- **Federal Agency Name –** Defense Advanced Research Projects Agency (DARPA), Biological Technologies Office
- **Funding Opportunity Title** – GOLDen hour extended EVACuation (GOLDEVAC)
- **Announcement Type –** Initial Announcement
- **Funding Opportunity Number –** HR001124S0024
- **Assistance Listing Number:** 12.910 Research and Technology Development
- **Dates/Time - All Times are Eastern Time Zone (ET)**
  - Posting Date: **April 3, 2024**
  - Proposal Abstract Due Date: **April 24, 2024,** at 4:00 p.m. (Eastern Daylight Time)
  - Proposal Due Date: **June 4, 2024**, at 4:00 p.m. (Eastern Daylight Time)
  - BAA Closing Date: **June 4, 2024**
  - Industry Day: **April 4, 2024**

    https://sam.gov/opp/f9fb6f4caa6449649436fc633c035ebf/view
- **Anticipated individual awards** - Multiple awards are anticipated.
- **Types of instruments that may be awarded** – Procurement contract, cooperative agreement, or other transaction.
- **NAICS Code:** 541714
- **Agency contact**
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1. Funding Opportunity Description

The Defense Advanced Research Projects Agency (DARPA) is soliciting innovative proposals in the following technical area: intravascular gas-exchange and trauma resuscitation through a single intravascular cannula. Proposed research should investigate innovative approaches that enable revolutionary advances which would develop the necessary device(s) to enable management of a polytrauma patient through a single intravascular access without the thrombotic complications associated with extracorporeal membrane oxygenation. Specifically excluded is research that primarily results in evolutionary improvements to the existing state of practice.

1.1. PROGRAM OVERVIEW

Survival from combat trauma is predicated on a rapid sequence of events that escalate care as soon as possible[1]. Current evacuation and care practices that were able to achieve rapid evacuation within the "Golden Hour" to surgical care in conflicts such as Afghanistan are not scalable to large scale combat operations in future theaters. Rather, it is expected that the duration of time from injury to being managed at a facility with surgical capabilities will greatly extend beyond an hour – necessitating a need to provide advanced medical care as close to point of injury as possible[2] to extend the "Golden Window" and allow more time to evacuate casualties to higher levels of care.

At present, advanced intensive care medicine for injured warfighters can be provided outside of a hospital (e.g. Critical Care Advanced Transport Team, providing care on-board a moving aircraft), requiring an expert team (typically a physician, nurse, and respiratory therapist) to place a suite of interfaces (i.e., the lines and tubes that deliver medication, fluids, blood and oxygen) between essential devices (i.e., the medicine pumps and mechanical ventilator) and the patient, and then to continuously manage those support devices. With advances in autonomous fluid resuscitation[3] and blood resuscitation, innovations in closed loop gas exchange[4], and miniaturized sensor suites[5], it may be possible to provide advanced medical care – via closed-loop control of the support devices – in the field near point of injury, and manage care with less (or even no) oversight. However, the challenge of creating a physical interface between the patient and such an advanced closed-loop system that is small enough to be easily placed in the field is a significant barrier to rapidly deploying care to numerous casualties with severe

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[1] National Academies of Sciences, Engineering, and Medicine. 2016. "A National Trauma Care System: Integrating Military and Civilian Trauma Systems to Achieve Zero Preventable Deaths After Injury." *The National Academies Press*. https://doi.org/10.17226/23511.

[2] Remondelli *et al.,* 2023. Casualty care implications of large-scale combat operations. *J Trauma Acute Care Surgery: 95 (2),* S180 – S184.

[3] Libert *et al.,* 2021. "Performance of closed-loop resuscitation in a pig model of haemorrhagic shock with fluid alone or in combination with norepinephrine, a pilot study." *J Clin Monit Comput*. Aug; 35(4):835-847. doi: 10.1007/s10877-020-00542-7. Epub 2020 Jun 12. PMID: 32533529.

[4] Brendle *et al.,* 2017. "Physiological closed-loop control of mechanical ventilation and extracorporeal membrane oxygenation." *Biomed Tech* (Berl). Apr 1;62(2):199-212. doi: 10.1515/bmt-2016-0077. PMID: 28121615.

[5] Tehrani *et al.*, 2022. "An integrated wearable microneedle array for the continuous monitoring of multiple biomarkers in interstitial fluid." *Nat Biomed Eng*. Nov;6(11):1214-1224. doi: 10.1038/s41551-022-00887-1. Epub 2022 May 9. PMID: 35534575

polytrauma (while common battlefield polytraumas can involve multiple concurrent bleeding, lung, brain, etc. injuries, the GOLDEVAC program will focus explicitly on concurrent bleeding and lung injury).

GOLDEVAC aims to test whether it is possible to manage a complex polytrauma patient, starting near the point of injury and continuing throughout the evacuation process, via a single intravascular cannula that can be placed by a field medic. Specifically, GOLDEVAC will answer a critical question regarding this care: whether it is possible to resuscitate and oxygenate a patient via a single interface, for extended periods, without the thrombotic complications associated with current extracorporeal oxygenation methods/devices. This single intravascular interface must be relatively small at the insertion site (less than 15 French, equivalent to 5 mm). Additionally, medics and non-medical personnel must be able place such an interface safely and reliably, in concert with the rest of a complete device necessary to monitor and actuate the resuscitation, under operational conditions. If successful, GOLDEVAC will yield a single intravascular device and gas exchange (i.e. oxygenation) strategy designed in such a way that all medications, fluids, and gas exchange can be infused into a patient through one invasive access point, addressing a wide range of life-threatening injuries and buying more time to accomplish medical evacuation. In this way, GOLDEVAC could provide a medical force multiplier that could enhance the Department of Defense's (DOD) ability to successfully care for and then evacuate many more wounded service members, even during large-scale conflict.

1.2. PROGRAM STRUCTURE AND TECHNICAL APPROACH

GOLDEVAC will develop the foundational cannula and gas exchange technology at the heart of a system that, when combined with advances in algorithms for closed-loop critical care and miniaturization of supporting hardware (e.g., infusion pumps, blood warmers), would bring advanced medical care to near point of injury and continue throughout the entire evacuation process. GOLDEVAC projects should plan to utilize existing sensors, actuators (with exceptions for custom gas exchange systems), and available open- or closed-loop control algorithms for fluid and medication administration as well as gas exchange. While some tuning of sensors, actuators and control techniques may be necessary to effectively develop and test the GOLDEVAC cannula and gas exchange, strong proposals will not involve significant development in those areas (more detail on this is provided in the Systems Engineering section). Rather, development should focus on the cannula design and gas exchange strategy that will allow complete management of the casualty through a single invasive interface with breadboard supporting hardware. In Phase I, cannula capabilities can be demonstrated separating for bleeding management and oxygenation, whereas in Phase II cannula capabilities for a polytrauma scenario (combining both hemorrhage and lung injury) must be demonstrated, see Phase Structure below. Additionally, near the conclusion of Phase II, performers will develop preliminary designs that would illustrate how they could miniaturize the sensor suite and actuator package and migrate the breadboard system to a portable form factor that would allow the entire GOLDEVAC system to fit within a standard M-9 medic backpack. These designs will be informed by feedback and input from the stakeholder community provided throughout the program, which will aim to shape systems-level design requirements that will balance the efficacy of the technologies to extend the Golden Hour against the practical concerns of deployability and usability by medics in a field setting.

Proposals must address the development and testing of the full GOLDEVAC capability, with particular focus on the cannula design and gas exchange. It is expected that the single cannula will require overcoming significant fluid dynamics obstacles, biological hurdles, and practical user challenges of existing intravascular or extracorporeal systems while unifying all intravascular access for fluid resuscitation, medication administration, and blood sampling to a single intravascular device. Proposals must clearly describe how their approach will overcome such challenges and the rationale for both the use of any preexisting components or technologies, as well as the development of new technologies, paying particular attention to how the cannula and supporting breadboard elements of the full GOLDEVAC system will:

1) Provide sufficient flow in a small diameter at insertion site cannula design to support necessary blood/fluid and medication delivery,
2) Mitigate thrombotic complications, vascular injury, shear damage to red blood cells as well as any other adverse effects secondary to intravascular devices, blood flow and interaction within and through cannula and gas exchange circuit.
3) Provide sufficient oxygenation/gas exchange to support a patient under trauma conditions (e.g. sufficient oxygenation to support a patient during evacuation or other emergency care conditions) in parallel with resuscitation support via the single port of access,
4) Achieve a sufficiently small cannula size/insertion diameter (see Section 1.3). NOTE: This BAA is not soliciting any proposals for technologies that are intended to reduce the complexity, risk, or training required to place such cannulas by medics and or minimally trained personnel.
5) Efficiently utilize resuscitation fluids (real and artificial blood products, lactated Ringer's, saline, etc.).

Effectively achieving these goals will require careful consideration of the risks of pathological hemodynamics in and around the cannula, minimizing both damage to blood cells and risk of stagnated flow which could lead to thromboses. Designs must judiciously identify and pursue only the necessary key components of resuscitation of traumatic injuries and downstream sequalae. Potential approaches to achieve these goals could include, but are not restricted to, developing novel coatings that reduce drag and/or reduce clotting in cannula and/or gas exchange circuit, effective use of novel cannula design geometries and/or use of multiple cannula lumens, new approaches to effectively supporting gas exchange in the body, etc. Proposals should also describe the intended cannula employment, with sufficient detail to understand how (and where) the cannula would ultimately be inserted in a field environment. Additionally, while performers will not be limited on volume or type of fluids and medications needed to resuscitate and support the animal models, competitive proposals will describe a strategy to minimize the necessary logistical requirements that would be required to resuscitate and support a severe trauma patient (i.e. minimize blood products, intravenous fluids, and medications). Once underway in experimentation, performers must report consumption of fluids and medications utilized during large animal resuscitations to support conversations with end users and to take under consideration for logistics planning.

Areas specifically not of interest under GOLDEVAC are as follows:

1. Research containing clinical trials or human subjects research.

2. Investigations only employing novel pharmaceutical agents. No pharmacologic dosing experiments will be supported, however existing investigational pharmacologic agents can be proposed if in support of reducing logistical needs of supporting severe casualties (i.e. medications to reduce need for blood administration).
3. Investigations using only existing FDA approved products and or devices.
4. Study designs not informed by hemodynamics or not optimized to reduce thrombotic complications and blood cell lysis.
5. Studies which propose only management of bleeding or intravascular gas exchange – all proposals must address managing a polytrauma patient through the same single intravascular interface.
6. Novel sensor design(s) or biomarker(s) to guide resuscitation.
7. Applications that are not focused upon traumatic injuries.

While a preliminary design of a portable medical device that integrates the GOLDEVAC cannula into a complete system (which includes supporting actuators and sensors) must be presented by the end of Phase II, as outlined below, prototyping and testing of a portable form factor for the GOLDEVAC sensor(s) and actuator(s) is not within the scope of this solicitation. Rather, proposals should describe the list of technologies being employed during the breadboard process to be used during Phases I and II, with particular detail provided on the envisioned cannula to be used or developed at the core of the project.

Testing and demonstration of performance will be required via *in vivo* experiments using an established large animal trauma model of uncontrolled hemorrhage resuscitation through a single port of access, as well as oxygenation support to a lung injury model through a single port of access (see Section 1.3). During Phase I the bleeding resuscitation and oxygenation goals may be achieved in separate large animal model demonstrations, each involving its own cannula for access. However, proposals opting to split the resuscitation into two separate designs and suites of experiments in Phase I should be clear on a planned path towards integrating all functionality in Phase I into a single cannula for Phase II. Phase II efforts will culminate in *in vivo* demonstrations using a single port of access to provide resuscitation support under polytrauma conditions (see Section 1.3). Proposals must clearly describe the planned large animal models intended for both Phase I and II, the strategies planned for the injury models (blood resuscitation, oxygenation support, and the combined polytrauma case), and rationale for their effectiveness in addressing hemorrhage when combined with lung injury. Successful completion of these demonstrations will involve achieving the resuscitation goals described in Table 1 as well as sufficient follow-up evaluations (e.g. histological assessments) of the animal models to suggest that the resuscitation efforts would have been sufficient for complete recovery of the subjects, as would clearly be the goal for their use in medical applications.

1.2.1. Phase Structure

DARPA will use a phased acquisition approach for GOLDEVAC, which is a 30-month research and development effort comprising two phases: a core 18-month Phase I and a 12-month Phase II option period. Proposers must provide fully detailed technical and cost proposals for the Phase I Base effort, and Phase II Option. Phase II selection decisions are at the sole discretion of the Government and will be based on performance against the program goals and metrics (see Section 1.3); overall progress towards the GOLDEVAC program objectives such as successful

resuscitation support through a single cannula that could be operationally deployed in field conditions; each performer's individual programmatic objectives; and the availability of funds. The Government retains the right to award all, some, one, none, or portions of the proposed Phase II options. A potential Phase III may be pursued at a later date. This Phase would focus on finalizing and prototyping the notional portable design into a fully portable GOLDEVAC system, leveraging the cannula developed in Phases I and II. Proposers must not include details (technical or cost) regarding the notional Phase III in proposals submitted in response to this BAA. **This BAA will only be soliciting for Phases I and II.**

Phase I (Base): Performers will design a cannula and gas exchange strategy that can support effective hemodynamic resuscitation with compromised lung function. The primary goal of the cannula is to achieve this support via a single point of vascular access, i.e., the user only needs to place a single cannula to provide all the fluid and medication necessary to enable resuscitation and support. Additionally, the cannula must be able to provide a prescribed rate of oxygenation to the blood, per Table 1. In Phase I the performer can demonstrate bleeding and oxygenation support separately in two different animal model tests, so long as only a single cannula is necessary in either case, and with sufficient evidence provided on the pathway to consolidation into a single cannula for combined hemorrhage and oxygenation support in Phase II. Similarly, the cannula designs used in the Phase I bleeding and oxygenation evaluations can be customized to each goal, or a single design can be used for either test. Work to be performed under Phase I includes initial design and test of the cannula device, development of resuscitation and gas exchange control strategies, integration of supporting breadboard system, demonstration of resuscitation via testing in large animal models, and engagement with the government Independent Verification and Validation (IV&V) team (see Technical and Management Milestones). The Phase I injury model will be a 6-hour abdominal uncontrolled hemorrhage, as outlined in Section 1.5. Additionally, a separate gas exchange experiment (with the option of using a separate cannula) will be demonstrated with the developed system for 24 hours without systemic anticoagulation.

In Phase I, performers shall begin engagement with the FDA regarding the regulatory process supporting commercialization of their cannula device and gas exchange design. A series of notional milestones is presented in Table 2 related to regulatory agency engagement.

Finally, during Phase I performers will begin to capture design constraints and key system requirements for a future portable form factor, by way of engagement with the government team and other stakeholders. At least one formal opportunity for engagement will be provided in the form of a Technical Interchange Meeting (TIM) with a stakeholder panel. This will support Phase II activities that will culminate in the Preliminary Design Review (PDR), as outlined in the Systems Engineering section. A draft of compiled system requirements will be delivered by the end of Phase I.

Phase II (Priced Option): In Phase II, performers must integrate the oxygenation and hemorrhage support into a single cannula, if they have not done so during Phase I. They will demonstrate the combined cannula's ability to provide effective resuscitation and casualty support in a polytrauma scenario. Specifically, the polytrauma model will involve both a controlled hemorrhage and a true lung injury (vice the oxygenation rate metric from Phase I),

defined further in Section 1.5. Work to be performed under Phase II includes refinements to the cannula as-needed to address the Phase II polytrauma injury model via single access point, incorporation of lessons learned from Phase I experiments and post-experiment histological assessments, techniques to extend the resuscitation window to the full 48 hours, engagement with the government IV&V team and design work on a portable system culminating in a PDR, described further in the Systems Engineering section below. During Phase II performers will have continued opportunities to engage with the end user community and the GOLDEVAC government team to finalize requirements for the portable design. Finally, performers shall work towards submitting an Investigational Device Exemption (IDE) to the FDA for their final Phase II cannula design and gas exchange design by the end of this phase.

As a reminder, large animal models will be used for assessing the cannula capabilities in both phases; no human subjects testing is desired under this solicitation for either phase.

When demonstrating hemorrhage and/or oxygenation approaches in Phases I and II, performers will not be restricted in terms of how much fluid and/or blood products are used to achieve resuscitation. The primary goal is to show that resuscitation and/or oxygenation can be maintained through a single cannula, though competitive approaches should consider methods that can be efficient in the use of blood/fluid. During Phases I and II oxygen can be provided, but the ultimate reference design for consideration in the PDR should plan for oxygen concentration and not the use of purified oxygen tanks.

1.2.2. Systems Engineering

To demonstrate the efficacy of the GOLDEVAC cannula for automated resuscitation, performers will need to integrate appropriate sensors, actuator hardware, and control algorithms into a functional breadboard system. While a limited amount of sensor (e.g. blood pressure, oxygenation, lactate, etc.) customization may be necessary in Phases I and II, proposers should leverage existing, commercial-off-the-shelf (COTS) sensor technologies, without redesigns for portability. Likewise, in Phases I and II, performers should leverage COTS or already fabricated hardware to provide the actuation needed for the patient interface (e.g. fluid warmer, medical pumps) without redesign for portability, although limited customization may be necessary to work with the GOLDEVAC patient interface and control algorithms. Finally, it is desired that teams harness existing or developed control strategies for effective resuscitation and gas exchange, although it is understood that some degree of algorithm development may be necessary to combine existing algorithms in Phases I and II. Nominal teams would include members with experience in existing algorithms for resuscitation and gas exchange. However, teams may also propose clinical algorithms for demonstration of the GOLDEVAC system's ability to resuscitate and support large animal trauma models via the single cannula.

While the Phase I and II realizations of the GOLDEVAC system will predominantly take the form of a breadboard suite of components (sensors, actuators, control algorithms, and the novel GOLDEVAC cannula), a miniature form factor reference design is planned within the program. To realize this design, GOLDEVAC will implement a requirements capture and review process, followed by a design effort that will culminate in a PDR. As mentioned above, DARPA will provide multiple opportunities to help GOLDEVAC performers inform their system design, in the form of regular engagement with the end user community. Both through the government

IV&V team efforts as well as key meetings with other government stakeholders throughout the program evolution, requirements capture opportunities will be afforded to discuss design features such as usability, interoperability and standards, training, form factor, connectivity, and setup workflow. In Month 12, a Technical Interchange Meeting between the performer and government stakeholders (to include members of the GOLDEVAC government team as well as other DoD organizations who would ultimate use the portable GOLDEVAC system) will be facilitated by DARPA, representing at least one opportunity for engagement. From this meeting, as well as other performer-initiated conversations with stakeholders, performers will derive requirements and system constraints. Performers will then outline their project-specific design requirements in draft form by the end of Phase I, and in final form by the time of a formal System Requirements Review, to be held in Month 24 of the program. One the requirements are formalized and agreed upon jointly with the GOLDEVAC government team, the team can develop (though not physically prototype) a portable system design, to be briefed at a formal PDR at the end of Phase II. Were a program expansion to occur, the notional Phase III would then focus on finalizing and prototyping the notional portable design into the fully portable GOLDEVAC system, leveraging the cannula developed in Phases I and II. Again, Phase III is not being solicited at this time.

1.3. PROGRAM METRICS AND MILESTONES

In order for the Government to evaluate the effectiveness of a proposed solution in achieving the stated program objectives, proposers should note that the Government hereby promulgates the following program metrics that may serve as the basis for determining whether satisfactory progress is being made to warrant continued funding of the program. Although the following program metrics are specified, proposers should note that the Government has identified these goals with the intention of bounding the scope of effort, while affording the maximum flexibility, creativity, and innovation in proposing solutions to the stated problem.

1.3.1. Program Metrics

To meet program goals, performers must develop methods of using a single cannula to provide automatic resuscitation support. In Phase I, teams will have to demonstrate two key capabilities, namely *in vivo* resuscitation of a large animal uncontrolled hemorrhage for > 6 hours and the ability to provide gas exchange for a large animal. As mentioned above, in Phase I performers have the option to decouple bleeding support and demonstration of gas exchange in order to expedite cannula development and simplify demonstration of key metrics of hemorrhage management and oxygenation support (Table 1). However, in Phase II only a single cannula will be used to support an animal with both hemorrhage and a concomitant with a lung injury, as outlined in Section 1.5. At a minimum, resuscitation support must satisfy the metrics shown in Table 1 to demonstrate validity. Evaluation against metrics will be supported by large animal (e.g. porcine) model data. Metric evaluations will occur using data from performers' own large animal model tests as well as tests executed by the GOLDEVAC IV&V team – more detail to be provided in Section 1.5. No human testing is permitted in either Phase I or II of the GOLDEVAC program.

Table 1 - GOLDEVAC metrics

Phase I: 18 months	Phase II: 12 months
• Hemorrhage survival for ≥ 6 hrs during uncontrolled hemorrhage scenario, with sufficiency* • Oxygenation for ≥ 24 hrs, with oxygen transfer rate ≥ 75 mL/min • Single cannula insertion diameter ≤ 5 mm (15 French)	Survival ≥ 48 hrs with lung injury** and 6 hrs controlled hemorrhage, with sufficiency*
In addition to the above metrics, performers should propose other health assessments of the animal models to demonstrate successful resuscitation, e.g. burden of clots and end organ injury. *Sufficiency: systolic blood pressure 100 mmHg; temperature > 95.0F; oxygen saturation > 90%; mean arterial pressure > 65; heart rate < 110; lactate < 2.5mmol/L; Base Excess >-4) for > 20 minutes) **Lung injury will follow established protocols for significantly diminished lung function (see Section I.5)	

As referenced above, while not a formal metric the rate of fluid consumption and resuscitation products required should be measured during animal testing and reported to DARPA.

Note that while a maximum cannula insertion diameter of 15 French is required, smaller size cannulas are preferred.

1.3.2. Technical and Management Milestones

Significant program milestones geared to show progress are listed in Table 2 and must be integrated into proposed efforts. If one or more milestones are not applicable to a particular approach, appropriate alternative milestones at similar intervals must be proposed, and proposers should provide significant justification. In addition to the programmatic milestones listed below, proposals should include additional quantifiable objectives and milestones, as appropriate, to reflect progress towards goals with approximately 3- to 4-month intervals.

As appropriate, performers must propose specific deliverables (report, data, demonstration, etc.) that demonstrate completion of a milestone or metric (notional deliverables are enumerated in Section 1.4). The content of each deliverable will vary from task to task but must be designed such that the Government can evaluate performer progress towards the end goals of the program. In particular, performers will be interacting with a government IV&V team to support assessment of system performance against program metrics. The IV&V assessments will utilize large animal model (e.g., porcine) tests of bleeding resuscitation and oxygenation support for Phase I evaluations, and polytrauma models for Phase 2. These assessments are in addition to the performer provided end of phase assessments of program metrics. Performers shall provide devices and support to the IV&V team in advance of the end of Phase I and Phase II assessments to support effective demonstration of their cannula's capabilities. In Phase I, the IV&V assessments of bleeding and oxygenation support can be done simultaneously in a single animal model or decoupled based on the specific performer's design strategy, using either a single cannula design or a design customized to each test. In the Phase II polytrauma IV&V

assessment, hemorrhage and lung injury support must be provided simultaneously as described in Table 1 and Table 2.

Table 2 – GOLDEVAC milestones

	Month-after-award	**Milestone**
Phase I (18 mo)	3	Submission to Animal Care and Use Review Office (ACURO) of the Institutional Animal Care and Use Committee (IACUC) approved animal testing protocol(s)
	7	FDA engagement – Informational meeting to support overall FDA engagement strategy in Phases I and II
	9	Sensor and control strategy to enable a single cannula to provide closed loop support for (separately and/or simultaneously) Bleeding and Oxygenation
	11	FDA engagement – Q-submission to support IDE submission (e.g., proposed pre-clinical safety data collection)
	12	Technical Interchange Meeting with GOLDEVAC stakeholder community for requirements capture on portable design
	12	Provide technical details of animal injury model and testing strategy to IV&V team.
	15	Prototype cannula(s) and /or gas exchange circuits and breadboard actuator for supporting IV&V assessments in large animal models.
	16	Support Phase I program metric evaluation consistent with Table 1
	17	Rebuttal of IV&V assessment of bleeding and oxygenation capability
	18	Phase I completion report, including histology review and lessons learned from all large animal experiments to-date
Phase II (12 mo)	21	Provide system-level overview of sensor and control strategy to support closed-loop polytrauma support by a single cannula
	22	Provide technical details of animal injury model and testing strategy to IV&V team.
	24	System Requirements Review for portable design
	25	FDA engagement – IDE-submission: GOLDEVAC single interface cannula
	27	All necessary hardware and software provided to IV&V team for assessment.
	28	FDA engagement – Informational meeting submission: proposed design for operational form factor realization of the system with autonomous/semiautonomous functionality (e.g., cannula, sensor strategy, supporting hardware and software)
	28	Provide results of in-house testing against Phase II program metrics
	28	Preliminary Design Review of the portable design of the GOLDEVAC system: i.e., indicating how cannula, sensors, etc. would be integrated into a portable, operational form factor with full and semiautonomous modes of operation
	28	Support assessment of polytrauma (hemorrhage & lung injury) performance by IV&V team by providing a usable test system, documentation and instruction in its use, and technical support as needed during the IV&V data collection. For planning purposes, the IV&V data collection can be estimated as occurring over a one week period in a central US location.

	30	Phase II completion report, including histology review and lessons learned from all large animal experiments to-date

Successful proposals will involve animal testing and must plan for the Institutional Animal Care and Use Committee (IACUC) and the secondary Animal Care and Use Review Office (ACURO) reviews that are necessary for Government-sponsored animal research in the proposed cost and schedule. No Animal Testing data collection can begin prior to ACURO approval. Performers can submit IACUC approved protocols to ACURO for secondary review any time after contract award but will be required to submit them to ACURO for secondary review no later than 3 months after award (see Milestones). To meet this deadline, proposers should submit protocols to their organization's IACUC for initial approval with sufficient lead time for the necessary IACUC approvals to be in place to support on schedule ACURO submissions. Proposers are encouraged to include a draft IACUC protocol for initial test investigations and/or a plan for submission to and review by an IACUC with proposals as an appendix to **Attachment D: PROPOSAL TEMPLATE VOLUME 1: TECHNICAL & MANAGEMENT** to show feasibility of the regulatory approval timeline; this paperwork will not count against the page limit.

1.4. GENERAL REQUIREMENTS

Abstracts and Proposers Day

- DARPA will hold an Industry Day to provide opportunities for the formation of proposer teams and enable sharing of information among interested proposers through the DARPA Opportunities Page.
- Prior to submitting a full proposal, proposers are **strongly encouraged** to first submit an abstract (see Section III). DARPA will respond to abstracts with a statement as to where DARPA:
    - Recommends the proposer submit a full proposal or,
    - Does not recommend the proposer to submit a full proposal with a rationale for this decision.

Regardless of DARPA's response to an abstract, proposers may submit a full proposal. DARPA will review all conforming full proposals using the published evaluation criteria and without regard to any comments resulting from the review of an abstract. Proposers should note that a favorable response to an abstract is not a guarantee that a proposal based on the abstract will ultimately be selected for award negotiation. It is DARPA policy to attempt to reply to abstracts within thirty calendar days. These official notifications will be sent via email to the Technical POC and/or Administrative POC identified on the abstract cover sheet.

Abstracts must be submitted per the instructions outlined herein *and received by DARPA* no later than the due date and time listed in the Overview Information. Abstracts received after this time and date may not be reviewed.

Proposing Teams

- It is expected that proposals will involve teams that have the expertise needed to achieve all the program goals in both Phase I and Phase II. In particular, expertise in cannula

design, closed-loop controls, hemodynamics, biocompatible coatings, medical trauma and resuscitation, large animal models, physiological monitoring and modeling, systems engineering, etc. are expected. Specific content, communications, networking, and team formation are the sole responsibility of the proposer teams. Proposer teams must submit a single, integrated proposal led by a Principal Investigator (PI), under a single prime contractor that addresses all program phases, as applicable.

- Proposers should provide a technical and programmatic strategy that conforms to the entire program schedule and presents an aggressive plan to fully address all program goals, metrics, milestones, and deliverables.
- The task structure must be consistent across the proposed schedule, Statement of Work, and cost volume.
- A target start date of November 2024 may be assumed for planning purposes.
- All proposals must include the following meetings and travel in the proposed schedule and costs:
    - To foster collaboration between teams and disseminate program developments, GOLDEVAC will conduct regular Program meetings. For budget planning purposes, proposers should assume locations split between the East and West Coasts of the United States and can plan for two (2) two-day meetings over the course of Phase I and for two (2) two-day meetings over the course of Phase II.
    - Virtual or hybrid meetings may be held in place of in-person meetings.
    - In addition to the travel necessary for PI meetings, proposals should budget for at least two (2) meetings per Phase to engage with the Government IV&V team and to support IV&V efficacy assessments as well as for attending the actual IV&V assessments at the end of Phase 1 and Phase 2.
- Regular teleconference meetings will be scheduled with the Government Team for progress reporting as well as problem identification and mitigation.
- Proposers should anticipate at least one site visit per phase by the DARPA Program Manager during which they will have the opportunity to demonstrate progress towards agreed-upon milestones. This is in addition to end of Phase demonstrations.
- Proposers should provide a clear understanding of the cost, risk, and organizational expertise to be used within each proposed effort. Proposals must include detailed pricing and a Statement of Work (SOW) for the Phase I Base effort and a detailed SOW and separately priced Option for Phase II. Proposals that do not include a separately priced Option for Phase II may be deemed non-conforming and removed from consideration.

Monthly financial reports: Performers are required to provide financial status updates. The prime Performer shall include information for itself and all subawardees/subcontractors. These reports shall be in the form of an editable Microsoft (MS) Excel™ file (templates will be provided) and shall provide financial data including, but not limited to:

- Program spend plan by Phase and task
- Incurred program expenditures to date by Phase and task
- Invoiced program expenditures to date by Phase and task

Deliverables

All products – material and otherwise – to be provided to the Government as outcomes from conducted research should be defined in the proposal. Performers need to allot time and budget

to fulfill obligations for the transmission of report documentation. In addition to the financial reporting requirements above, performers will be expected to provide at a minimum the following deliverables:

- Monthly progress reports, including both technical and financial updates.
- Comprehensive quarterly technical reports due within ten days of the end of the given quarter, describing progress made on the specific milestones as laid out in the SOW.
- Regular updates on progress towards FDA milestones (see Table 2).
- System elements to be provided to the IV&V team for evaluation, see Section 1.5 and Table 2.
- Draft System Requirements Document at end of Phase I.
- Final System Requirements Document following System Requirements Review.
- Preliminary Design Review materials following Preliminary Design Review.
- Regular engagements and delivery of material to the Government IV&V team to support their assessments, see Sections 1.2, 1.3 and 1.5 for more details regarding the IV&V effort goals and timing.
- A phase completion report for each phase, summarizing the research done including, but not restricted to, progress towards program metrics and milestones (see Tables 1 and 2).
    - End of Phase I report must include progress towards using a single cannula to provide closed loop resuscitation with bleeding and oxygenation support (with bleeding and oxygenation either achieved simultaneously or via decoupled tests, see Section 1.2.1 and Tables 1 and 2 for details regarding timing of end of phase demonstrations and program metrics).
- Copies of published papers and presentations (e.g., conference abstracts), provided each month.
- Final Program Report: When the final funding Phase closes out, performer teams must provide a final report summarizing all research activities and outcomes during the program; publications, research presentations, patent applications that result from the research pursued; and any additional deliverables requested by the contracting agent for this program.
- Other negotiated deliverables specific to the objectives of the individual efforts. These may include registered reports; experimental protocols; publications; data management plan; intermediate and final versions of software libraries, code, and APIs, including documentation and user manuals; and/or a comprehensive assemblage of design documents, models, modeling data and results, and experimental validation data.

1.5. INDEPENDENT VERIFICATION AND VALIDATION (IV&V)

GOLDEVAC will include Government-led IV&V efforts to provide independent assessments of the GOLDEVAC cannulas and oxygenation capabilities as well as offering subject matter expert insights into areas of particular interest to the Department of Defense regarding appropriate animal models to simulate military relevant injuries. At the end of Phase I and Phase II (Section 1.3), technology will be evaluated in a large animal (e.g., porcine) model. These evaluations will be performed by the IV&V team, at an IV&V-managed site.

The performer will be present for IV&V testing and can support the training and setup of their GOLDEVAC system as needed. There is no expectation that the GOLDEVAC breadboard

system needs to be at a maturity level suitable for complete handover to the IV&V team for installation and setup without any assistance from the performer team, though it is expected that during evaluation tests the system will either be fully automated or the performer will present the IV&V team with specific clinical algorithms to control resuscitation and gas exchange. The IV&V team will coordinate with the performer at regular intervals as outlined in Section 1.3 to determine the logistical and clinical requirements to install and operate the breadboard GOLDEVAC system, and to confer on data outputs, standards, and handover plans suitable to ensure adequate review of system performance during the evaluation. It is anticipated that performers will utilize standard protocols for data curation and export compatible with DoD medical databases, as will be defined by the IV&V team. For planning purposes, the IV&V assessments can be estimated as occurring across the span of a week, one month prior to the end of Phase I and Phase II (see Table 2) at a CONUS location selected by the IV&V team, with the devices to be delivered one month prior to the assessment. Performers will also need provide all necessary hardware (sensors, actuators, etc.) and software (with documentation) necessary to use the cannulas, as well as to provide technical support in the use of the systems to the IV&V team.

1.5.1. Injury Models

GOLDEVAC performers' injury management will be evaluated by the IV&V team using a large animal (e.g., porcine) model. Hemorrhage injury models in both Phase I and Phase II, and the lung injury model in Phase II, will follow established protocols managed by the IV&V team. The hemorrhage model will consist of major organ laceration yielding uncontrolled hemorrhage for six hours in Phase I. There is no lung injury model in Phase I, and instead oxygenation support will be evaluated by demonstrating a minimum oxygen transfer rate for a period of 24 hours. In Phase II, animals will be subjected to a lung injury in concert with a controlled hemorrhage (removal of a fixed volume of blood over one or more intervals) over the first six hours of the experiment. Details of the lung injury model will be developed early in Phase 2 but will likely follow a smoke inhalation protocol sufficient to induce acute respiratory distress syndrome (ARDS) with a partial pressure of oxygen arterial blood to fraction of inspiratory oxygen concentration (P/F) ratio of between 100 (categorized as severe ARDS) and 300 (categorized as mild ARDS). The Phase II IV&V assessment will continue for 42 hours beyond the six-hour controlled hemorrhage, for a total of 48 hours.

1.6. ETHICAL, LEGAL, AND SOCIETAL IMPLICATIONS (ELSI)

As part of their proposals, efforts should consider potential Ethical, Legal, and Societal Implications (ELSI) of their approaches. Proposals should provide strategies for considering the potential societal and legal impacts of the outcomes of the GOLDEVAC program so that efforts are positioned to offer feedback to DARPA that highlights areas in which GOLDEVAC could generate ELSI concerns (e.g., GOLDEVAC cannulas being compatible with and usable by diverse demographic populations). Efforts must account for participating in DARPA-supported ELSI meetings. For planning purposes, proposals should budget for one (hybrid) ELSI meeting per year, with the in-person component located in Washington DC metropolitan area.

2. Evaluation Criteria

- Proposals will be evaluated using the following criteria listed in ***descending order of importance***: Overall Scientific and Technical Merit; Proposer's Capabilities and/or Related Experience; Potential Contribution and Relevance to the DARPA Mission; and Cost Realism.

    - **Overall Scientific and Technical Merit**: The proposed technical approach is innovative, feasible, achievable, and complete. The proposed technical team has the expertise and experience to accomplish the proposed tasks. Task descriptions and associated technical elements provided are complete and in a logical sequence with all proposed deliverables clearly defined such that a final outcome that achieves the goal can be expected as a result of award. The proposal identifies major technical risks and planned mitigation efforts are clearly defined and feasible.

    - **Proposer's Capabilities and/or Related Experience:** The proposer's prior experience in similar efforts clearly demonstrates an ability to deliver products that meet the proposed technical performance within the proposed budget and schedule. The proposed team has the expertise to manage the cost and schedule. Similar efforts completed/ongoing by the proposer in this area are fully described including identification of other Government sponsors.

    - **Potential Contribution and Relevance to the DARPA Mission:** The potential contributions of the proposed effort bolster the national security technology base and support DARPA's mission to make pivotal early technology investments that create or prevent technological surprise. The proposed intellectual property restrictions (if any) will not significantly impact the Government's ability to transition the technology.

    - **Cost Realism**: The proposed costs are realistic for the technical and management approach and accurately reflect the technical goals and objectives of the solicitation. The proposed costs are consistent with the proposer's Statement of Work and reflect a sufficient understanding of the costs and level of effort needed to successfully accomplish the proposed technical approach. The costs for the prime proposer and proposed sub awardees are substantiated by the details provided in the proposal (e.g., the type and number of labor hours proposed per task, the types and quantities of materials, equipment and fabrication costs, travel and any other applicable costs and the basis for the estimates).

      It is expected that the effort will leverage all available relevant prior research in order to obtain the maximum benefit from the available funding. For efforts with a likelihood of commercial application, appropriate direct cost sharing may be a positive factor in the evaluation. DARPA recognizes that undue emphasis on cost may motivate proposers to offer low-risk ideas with minimum uncertainty and to staff the effort with junior personnel in order to be in a more competitive posture. DARPA discourages such cost strategies.

- Unless otherwise specified in this announcement, for additional information on how DARPA reviews and evaluates proposals through the Scientific Review Process, please visit: Proposer Instructions and General Terms and Conditions.

3. Submission Information

- This announcement allows for multiple award instrument types to be awarded to include Procurement Contracts, Cooperative Agreements, and Other Transactions. Some award instrument types have specific cost-sharing requirements. The following websites are incorporated by reference and contain additional information regarding overall proposer instructions, general terms and conditions, and each specific award instrument type.

  - **Proposer Instructions and General Terms and Conditions**: Proposer Instructions and General Terms and Conditions
  - **Procurement Contracts**: Proposer Instructions: Procurement Contracts
  - **Assistance (Cooperative Agreements)**: Proposer Instructions: Grants/Cooperative Agreements
  - **Other Transaction agreements**: Proposer Instructions: Other Transactions

  - This announcement contains an abstract phase. Abstracts are strongly encouraged but not required. Abstracts are due **April 24, 2024** at 4:00 p.m. Eastern Daylight Time, as stated in the Overview section. Additional instructions for abstract submission are contained within **Attachments A and B**.

  - Full proposals are due **June 4, 2024** at 4:00 p.m. Eastern Daylight Time, as stated in the Overview section. **Attachments C, D, E, and F** contain specific instructions and templates and constitute a full proposal submission. Please visit Proposer Instructions and General Terms and Conditions for specific information regarding submission methods through the Broad Agency Announcement Tool (BAAT) or Grants.gov, as applicable. (Proposers requesting Procurement Contracts or Other Transactions for Prototype must submit proposals through BAAT. If requesting a Cooperative Agreement or Other Transaction for Research, proposals must be submitted through grants.gov.)

  - **Submissions may not be sent by fax or e-mail; any so sent will be disregarded.**

  - **BAA Attachments**:
  - **(required) Attachment A**: Abstract Summary Slide Template
  - **(required) Attachment B**: Abstract Instructions and Template
  - **(required) Attachment C**: Proposal Summary Slide Template
  - **(required) Attachment D**: Proposal Instructions and Volume I Template (Technical and Management)
  - **(required) Attachment E**: Proposal Instructions and Volume II Template (Cost)
  - **(required) Attachment F**: MS Excel™ DARPA Standard Cost Proposal Spreadsheet

4. Special Considerations

- This announcement, stated attachments, and websites incorporated by reference constitute the entire solicitation. In the event of a discrepancy between the announcement, attachments, or websites, the announcement shall take precedence.

- All responsible sources capable of satisfying the Government's needs, including both U.S. and non U.S. sources, may submit a proposal that shall be considered by DARPA. Historically Black Colleges and Universities, Small Businesses, Small Disadvantaged Businesses and Minority Institutions are encouraged to submit proposals and join others in submitting proposals; however, no portion of this announcement will be set aside for these organizations' participation due to the impracticality of reserving discrete or severable areas of this research for exclusive competition among these entities. Non-U.S. organizations and/or individuals may participate to the extent that such participants comply with any necessary nondisclosure agreements, security regulations, export control laws, and other governing statutes applicable under the circumstances.

- As of the time of publication of this solicitation, all proposal submissions are anticipated to be unclassified.

- Federally Funded Research and Development Centers (FFRDCs), University Affiliated Research Centers, and Government entities interested in participating in the GOLDEVAC program or proposing to this BAA should first contact the Agency Point of Contact (POC) listed in the Overview section prior to the Abstract due date to discuss eligibility. Complete information regarding eligibility can be found at Proposer Instructions and General Terms and Conditions.

- As of the date of publication of this solicitation, the Government expects that program goals as described herein may be met by proposed efforts for fundamental research and non-fundamental research. Some proposed research may present a high likelihood of disclosing performance characteristics of military systems or manufacturing technologies that are unique and critical to defense. Based on the anticipated type of proposer (e.g., university or industry) and the nature of the solicited work, the Government expects that some awards will include restrictions on the resultant research that will require the awardee to seek DARPA permission before publishing any information or results relative to the program. For additional information on fundamental research, please visit Proposer Instructions and General Terms and Conditions.

  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. This language can be found at Proposer Instructions and General Terms and Conditions.

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 subawardee's effort may be fundamental research. It is also possible that the research performed by a potential awardee is fundamental research while its proposed subawardee'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.

- DARPA's Fundamental Research Risk-Based Security Review Process (formerly CFIP) is an adaptive risk management security program designed to help protect the critical technology and performer intellectual property associated with DARPA's research projects by identifying the possible vectors of undue foreign influence. The DARPA team will create risk assessments of all proposed Senior/Key Personnel selected for negotiation of a fundamental research grant or cooperative agreement award. The risk assessment process will be conducted separately from the DARPA scientific review process and adjudicated prior to final award. For additional information on this process, please visit Proposer Instructions: Grants/Cooperative Agreements.

- Proposals will include Animal Use. As such, the proposed research must comply with the approval procedures detailed at Human Subjects and Animal Subjects Research, to include providing the information specified therein as required for proposal submission.

- DARPAConnect offers free resources to potential performers to help them navigate DARPA, including "Understanding DARPA Award Vehicles and Solicitations," "Making the Most of Proposers Days," and "Tips for DARPA Proposal Success." Join DARPAConnect at www.DARPAConnect.us to leverage on-demand learning and networking resources.

- DARPA has streamlined our Broad Agency Announcements and is interested in your feedback on this new format. Please send any comments to DARPAsolicitations@darpa.mil