DPA26BZ06-NV025
Noninvasive Detection and Localization of Occult Hemorrhage
Frequently Asked Questions (FAQs)

1. Anatomical localization: For the Phase I requirement to "accurately identify the anatomical source of bleeding," what level of anatomical specificity is expected? For example, would localization to clinically meaningful anatomical regions such as the liver region, spleen region, pelvis, and retroperitoneal region satisfy the Phase I proof-of-concept objective, or is identification of the specific injured organ or vascular structure expected?
   A: The Phase I capability should establish the potential of the hardware for anatomical localization, when coupled with appropriate data processing algorithms. This topic call is not looking to replicate the capabilities of a Focused Assessment with Sonography in Trauma (FAST) exam, which can already provide regional bleeding insights; rather, this work should inform the capabilities needed to enhance the system for the Phase II use cases of determining bleeding in specific vascular structures, per the solicitation. If the Phase I work establishes a credible path to the Phase II objectives, but the Phase I performance is limited to more coarse (regional) localization as the system is being refined, this would be considered. However, a proposal pursuing this path would need to provide strong justification for how the challenge of moving from coarse to fine localization would be achievable within the project timelines.

2. Semi-quantitative hemorrhage-rate estimation: May "semi-quantitative estimation of bleeding rate" in Phase I be implemented as predefined, clinically meaningful rate categories—for example, slow, intermediate, and rapid bleeding—associated with validated physical flow-rate ranges, or is a continuous numerical estimate of bleeding rate expected?
   A: Yes. Phase I may be implemented as predefined clinically meaningful rate categories such as slow, intermediate, and rapid, if those categories are tied to validated flow-rate ranges and quantitative performance metrics. The solicitation expressly allows quantitative or semi-quantitative estimation and emphasizes distinguishing slow bleeding from rapidly expanding hemorrhage.

3. Challenging anatomical conditions: For a Phase I effort using a physical phantom testbed, should the proof-of-concept demonstration experimentally address each of the specifically identified challenges, that is retroperitoneal hemorrhage and hemorrhage obscured by bone or bowel, or may Phase I experimentally address a representative subset while identifying the remaining conditions as limitations to be characterized during broader Phase II validation?
   A: Phase I may reasonably address a representative subset of challenging conditions in a physical phantom testbed, provided the proposal clearly identifies the remaining conditions as limitations and lays out a credible Phase II validation plan. The solicitation says Phase I should establish capabilities and limitations for a limited set of representative injury types; it does not explicitly require experimental demonstration of every listed challenge in Phase I.