

#### Tasks Required of the Expert Panel

#### Panel Tasks

- Task I: Survey existent technologies and products
- Task II: Develop preliminary selection/inclusion criteria for preproposals
- Task III: Describe products with the capability to be developed for combat use
- Task IV: Advise what criteria should be used to evaluate the potential technologies/products
- Task V: Prioritize the current products
- Task VI: Suggest how to further evaluate the leading candidates
- Task VII: Communicate process and findings

#### Sponsor Responsibilities

- Provide all available information
- Review Draft Final Report for factual accuracy and compliance to the Scope of Work



# Tasks Required of the Expert Panel Task I

#### Survey existent technologies and products

- W81XWY-BAA-AFRRF: public call for information on Candidate Technologies for Advanced First-Responder Resuscitation Fluids (AFRRF)
  - LSRO has assembled a database of Pre-Proposal responses
- Review LSRO literature search for completeness



## Tasks Required of the Expert Panel Task II

Develop preliminary selection/inclusion criteria for preproposals

- Product Requirements: Potential to improve fluid resuscitation in combat injury situations, e.g.
  - Fluid conservative treatment with hypotensive endpoints
  - Stable for prolonged periods at ambient temperatures (≤130°F)
  - May support oxygen carrying capacity
  - Mitigates or negates post-shock, post-resuscitation syndromes
  - Compatible with blood products
  - Suitable for administration by first responder medical personnel
  - No mental or physical post-resuscitation impairment
  - No impairment of coagulation capability



# Tasks Required of the Expert Panel Task II (cont.)

#### Develop preliminary selection/inclusion criteria for pre-proposals

- Inclusion criteria to consider:
  - Has the potential to:
    - Increase survival in an extended evacuation situation
    - Reduce morbidity in an extended evacuation situation
  - Meets one or more of the example requirements
- Exclusion criteria
  - Monitoring devices will not be reviewed
  - Devices that assist fluid resuscitation will not be reviewed



# Tasks Required of the Expert Panel Task III

Describe products with the capability to be developed for the intended purposes

• A list of all candidate technologies meeting the inclusion criteria will be supplied to the Sponsor



## Tasks Required of the Expert Panel Task IV

- Advise what criteria should be used to evaluate the potential technologies/products
- Develop a standard evaluation system based on generally accepted scientific criteria
- Set standards of evidence for weighting the candidates
  - Include:
    - Phase of development
    - Non-military development resources (market)
    - Scientific merit
- Sponsor will have the opportunity to review and comment on the evaluation system and standards of evidence



# Tasks Required of the Expert Panel Task V

#### Prioritize the current products

- Utilize the evaluation system to prioritize the pre-proposals that were submitted
- Rank highest those products most warranting an investment of Sponsor resources



# Tasks Required of the Expert Panel Task VI

Suggest how to further evaluate the leading candidates

- Additional types of experiments that might indicate functionality in a combat injury environment
  - Broad stroke, general
  - In vivo and in vitro testing
  - Potential criteria for reviewing future fluids
  - Sponsor acknowledges the lack of a "validated pre-clinical trauma model" and does NOT expect the panel to debate this matter
  - Sponsor acknowledges the need to perform experiments in multiple species prior to human use



## Tasks Required of the Expert Panel Task VII

#### Communicate process and findings

- In the Final Report, include:
  - Selection algorithm for inclusion of pre-proposals
  - List of all candidate technologies meeting the inclusion criteria
  - Details of the evaluation system for ranking pre-proposals
  - Prioritized list, including weighted scorecards, of pre-proposals
  - Additional experiments to support the utility of the product in a combat injury environment
  - Potential criteria for evaluation of future resuscitation fluids/technologies for use in a combat injury environment
  - Likely FDA approvable civilian indication that is analogous to the combat indication
  - Data/literature cited
- Level of detail to include in the Final Report



#### Sponsor Responsibilities

- Provide all available information
- Be accessible for questions
- Review Draft Final Report for factual accuracy and compliance to the Scope of Work