

AWARD NUMBER: W81XWH-19-2-0004

TITLE: Precision Metrics for Driving Open- and Closed-Loop Resuscitation Algorithms for Enteral and IV Resuscitation in Burn Casualties

PRINCIPAL INVESTIGATOR: Dr. David Burmeister

CONTRACTING ORGANIZATION: The Geneva Foundation

REPORT DATE: JANUARY 2021

TYPE OF REPORT: ANNUAL

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

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14. ABSTRACT Formula-driven burn resuscitation may deliver too much fluid resulting in significant co-morbidities. An alternative strategy could be the use of enteral fluid resuscitation, which has been explored for decades. In line with this, recent fluid therapy recommendations from the prolonged field care working group only mention in brief that enteral fluids have been studied in burns up to 40% TBSA. In fact, while enteral fluids have been shown to reduce the volumes of IV fluids given, there is a paucity of information regarding fluid type, volumes, and efficacy. A recent randomized controlled trial continues to advocate for oral rehydration post-burn, but this strategy has largely been forgotten by current practice. In short, the need exists for a new personalized approach that incorporates new targets and endpoints for identifying which patients respond to resuscitation (both IV and enteral) versus those that do not. Burn resuscitation is not an exact science, and experienced providers supplement UO with static physiologic measurements (e.g., blood pressure, pulmonary arterial occlusion pressure, cardiac index, etc.). For IV resuscitation, a decision support system based on burn surface area and UO was developed at USAISR and has become commercially available. Both these static measurements as well as the dynamic ones listed above (PPV, SPV, SVV) could be incorporated into existing decision support system algorithms for identifying which patients respond to both enteral and IV fluids. The current proposal will characterize burn-induced changes in functional hemodynamic variables to determine new endpoints that will guide IV and enteral resuscitation.					
15. SUBJECT TERMS Burn, prolonged field care, urine output, arterial waveforms, intravenous resuscitation, endpoints, swine, crystalloid, colloid, third spacing					
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1. INTRODUCTION:

Formula-driven burn resuscitation may deliver too much fluid resulting in significant co-morbidities. An alternative strategy could be the use of enteral fluid resuscitation, which has been explored for decades. In line with this, recent fluid therapy recommendations from the prolonged field care working group only mention in brief that enteral fluids have been studied in burns up to 40% TBSA. In fact, while enteral fluids have been shown to reduce the volumes of IV fluids given, there is a paucity of information regarding fluid type, volumes, and efficacy. A recent randomized controlled trial continues to advocate for oral rehydration post-burn, but this strategy has largely been forgotten by current practice. In short, the need exists for a new personalized approach that incorporates new targets and endpoints for identifying which patients respond to resuscitation (both IV and enteral) versus those that do not. Burn resuscitation is not an exact science, and experienced providers supplement UO with static physiologic measurements (e.g., blood pressure, pulmonary arterial occlusion pressure, cardiac index, etc.). For IV resuscitation, a decision support system based on burn surface area and UO was developed at USAISR (ISR: US Army Institute of Surgical Research) and has become commercially available. Both these static measurements as well as the dynamic ones listed above (PPV, SPV, SVV) could be incorporated into existing decision support system algorithms for identifying which patients respond to both enteral and IV fluids. The current proposal will characterize burn-induced changes in functional hemodynamic variables to determine new endpoints that will guide IV and enteral resuscitation.

2. **KEYWORDS:** Burn, prolonged field care, urine output, arterial waveforms, intravenous resuscitation, endpoints, swine, crystalloid, colloid, third spacing

3. ACCOMPLISHMENTS:

What were the major goals of the project?

Specific Aim 1: Examine temporal changes in dynamic waveform and their relationships with organ (dys)function after thermal injury using a 40% TBSA pig burn model. (0-10 months)

- Objective 1a: Identify the effect of burn injury and standard of care (IV fluids) on dynamic waveforms. (0-7 months)
- Objective 1b: Dosing: Define the relationship between dynamic waveforms and MOD/AKI. (3-10 months)

Specific Aim 2: Use varying levels of IV fluids to alter organ perfusion in a 40% TBSA pig burn model to examine ensuing differences in PPV, SPV, SVV. (10-27 months)

- Objective 2a: Determine if varying levels of IV fluids increase dynamic waveform variability. (10-27 months)
- Objective 2b: Identify the efficacy of oral fluids in maintaining PPV, SVV and SPV. (10-27 months)

Specific Aim 3: Compare traditional resuscitation decision support algorithms (i.e., UO) to new algorithms containing waveform data (e.g., UO+PPV) for the ability to prevent organ damage and maintain organ perfusion in the 40% TBSA porcine burn model. (27-36 months)

- Objective 3a: Perform 12-hour in vivo experiments to compare new algorithms with UO (n=32). (27-36 months)

Deliverables:

- Knowledge products on how burn injury changes arterial waveform derivatives in real time over “ebb” and “flow” phases of burn shock.
- Identification of variables that indicate patient responsiveness to oral resuscitation can revolutionize burn care in prolonged field care scenarios
- Knowledge product indicating which variables will be advantageous to incorporate with decision support systems guiding burn resuscitation
- A refining of existing decision support to generate a personalized resuscitation approach to maximize responsiveness to fluids.
- More efficient burn care and improved outcomes for combat casualties.

What was accomplished under these goals?

Initial work performed at the USAISR included several model development animal, with an unexpectedly high mortality rate. Several nuances to the protocol were worked out, to include initial insight into the changes in arterial waveform variations post-burn (Figure 1) and the relationship to MOD/AKI (Figure 2). The promise of the waveform variations is shown in figure 1, wherein 1 animal displayed large increase in hemodynamic instability concurrent with waveform variations. This addresses objective 1a, wherein burn injury increases parameters such as PPV and SPV to a point, and then becomes wildly unpredictable with hemodynamic instability (i.e., burn shock and poor outcomes).

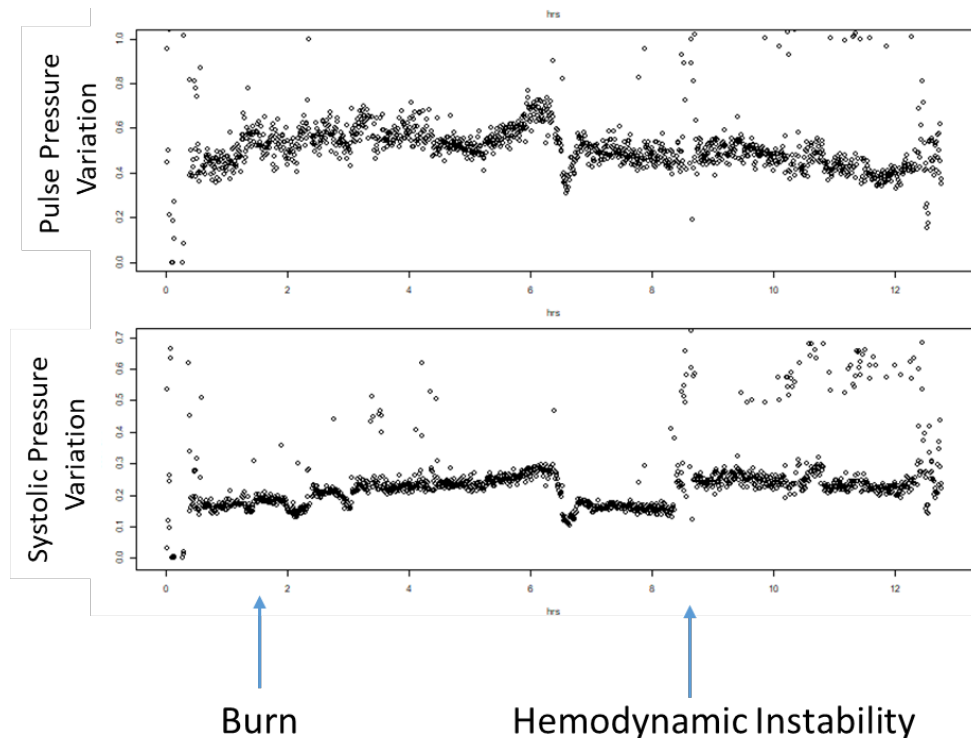
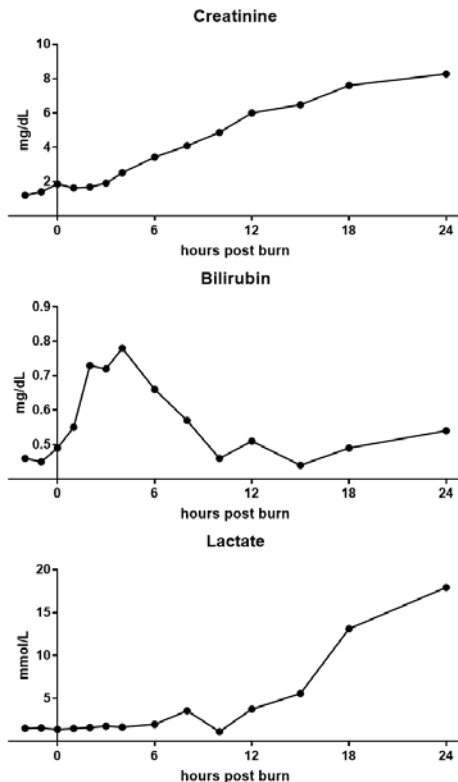


Figure 1. PPV (top) and SPV (bottom) from one animal across study. Increases in the amount of variation is seen progressing slowly after the burn injury, which becomes pronounced as the animal progresses into burn shock. (hemodynamic instability).



At the same time, MOD/AKI parameters from this same animal are shown in Figure 2, which indicates that renal dysfunction (as displayed by creatinine) progressively increases throughout the 24 hour experiment. This is at odds with the liver dysfunction biomarkers (as shown by Bilirubin) which increases in the first 4-6 hours, and then decreases while the animal is in the ICU. Even more, lactate (a marker traditionally used in resuscitation rate decisions) displays a slight normalization around hour 10, which seems to correspond to fluctuations in the arterial waveform variation shown in figure 1. Taken together, waveform variations are likely only indicative of dysfunctions of certain organ systems, and not all, and revealing which ones are susceptible will prove very interesting.

Figure 2. The differing time frames of creatinine, bilirubin, and lactate post-burn are shown for the same animal for which waveform variations are given in Figure 1.

Aside from the experiments shown above, the bulk of the work down for this award in the past year has involved the official transfer of the award from USAISR to Uniformed Services University of the Health Sciences (USU), and then a subsequent subaward to Medstar Research Institute due to concerns of vivarium space. This transfer proved to be no trivial task, and some highlights on the transfer of the award are given here. While this was occurring Dr. Burmeister and the Medstar team worked together to get PI status and access to Medstar for Dr. Burmeister, and also developed a plan for subaward and experiments, to include details similar to the PI's previously published model [1]. This is not meant to be exhaustive, but to give an idea of how time consuming the transfer was, which was likely exacerbated by the COVID-19 pandemic. :

- JAN 2, 2020- Initial email within USAISR to discuss dollar amounts for transfer
- JAN 2020- discussions on feasibility within USU, and game planning for a subaward
- FEB 7, 2020- first subaward budget proposed by Medstar
- FEB 24, 2020- subaward vs. contractor checklist sent to Geneva Foundation decision on appropriate mechanism
- FEB 25, 2020- Email traffic with Contract officer on altering budget and SOW
- FEB 26, 2020- Explicit email to Medstar requesting documents needed for subaward
- MAR 2, 2020- Subaward budget and other documents sent from Medstar
- MAR 4, 2020- Inquiry to science officer about budget
- MAR 10, 2020- 2 separate calls with CDMRP and USAISR on project future
- MAR 17, 2020- Dr. Burmeister signed Geneva site change approval
- MAR 19, 2020- Email to Science office (CDMRP) and contract officer (USAMRAA) for official site change approval and rebudgeting (appended).
- MAR 31, 2020- Notice that CAPT Mosquera was temporarily replaced with Dr. Christie Vu.
- APR 14, 2020- Dr. Burmekster vetted in Medstar's system
- APR 16, 2020- Request from Contract officer for budget clarifications and adjustment.
- MAY 4, 2020- Requested for SOW justification from Science Officer
- MAY 4, 2020- Response to science officer and altered SOW provided to Geneva
- MAY 5, 2020- Discussion between Geneva and Mr. Grenier about budgeting

- MAY 14, 2020 detailed email with budget updates sent to USAMRAA
- MAY 20, 2020- Medstar IACUC approval
- MAY 22, 2020- Email from Dr. Chritie Vu with concerns about budget
- JUN 9, 2020- USU approval for award transfer
- JUN9-JUL9- Discussion between CDMRP and USAMRAA
- JUL 10, 2020- Notification of approved modification to prime award
- JUL 10, 2020- Geneva initiates subaward paperwork with Medstar
- JUL 13, 2020- Medstar provides needed documents
- SEP 21, 2020- Fully executed subaward provided
- OCT 13, 2020- protocol submitted to ACURO
- OCT 19, 2020- ACURO responds with questions.
- OCT 23, 2020- ACURO approval obtained
- NOV 2, 2020- Medstar/USU planning meeting
- NOV 10, 2020- First animal experiment at MEDstar

Since early November, several animals have been run for ensuring feasibility for executing the studies at Medstar. This includes animals that have been over- and under-resuscitated as per Specific Aim 2. Figure 3 shows Burn Navigator readouts for these two animals, indicating the ability to achieve these resuscitative endpoints. This also includes a readout from an animal with adequate resuscitation goals, and shows this was achievable in hours 8-14. Additional parameters such as Central venous pressure (Figure 4) may also be able to inform resuscitation status. Moreover, as of yet unidentified parameters are also being collected. For example, swabs are being taken to examine the microbiome, which has been shown by these investigators to be altered in response to burn trauma [2, 3].

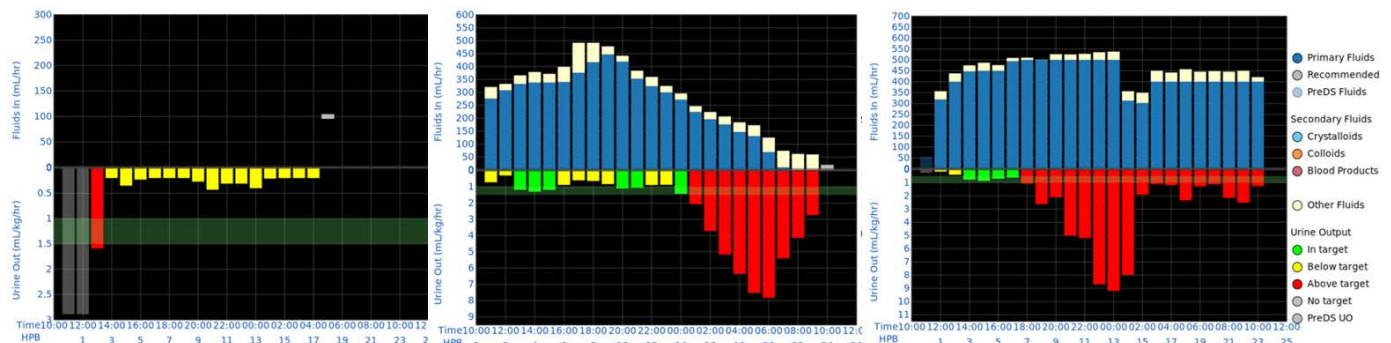


Figure 3. Burn Navigator readouts for an under resuscitated animal (left), and adequate resuscitation (middle) and an over resuscitated animal (right) shows the variations in IV fluid levels which will allow for waveform extremes.

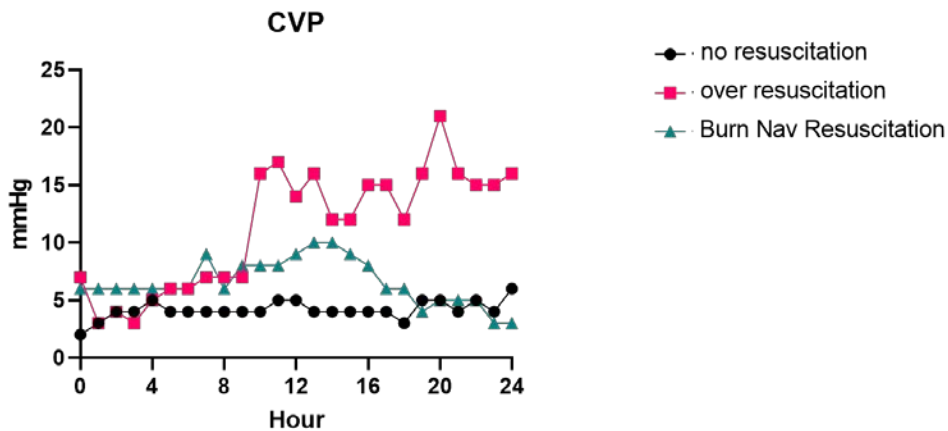


Figure 3. Central Venous Pressure (CVP) appears to be able to stratify resuscitation strategies and could be used in conjunction with arterial waveforms.

What opportunities for training and professional development has the project provided?

While this project was not intended to specifically provide training or professional development, it will allow for training of postdoctoral fellows and residents to get involved with military-relevant research.

How were the results disseminated to communities of interest?

There have not been submitted results as an abstract to date.

What do you plan to do during the next reporting period to accomplish the goals?

With the successful transfer of the prime and sub awards, animal experiments should be able to commence with increased regularity to gather necessary data to satisfy the deliverables. Moreover, with the limited role of ISR in analysis, a new plan will be developed for analysis of the waveforms.

4. IMPACT:

What was the impact on the development of the principal discipline(s) of the project?

Functional hemodynamic measurements (currently ignored in burn resuscitation evaluation) offer hope of predicting patient response to fluid. Specifically, pulse pressure variation (PPV), systolic pressure variation (SPV), and stroke volume variability (SVV) are easily obtained from the aortic waveform and are predictive of volume responsiveness perioperatively. In other patient populations, a resuscitation protocol that included SVV was compared to one that used only UO and MAP and showed decreased hospital length of stay and fewer complications. These variables likely can inform the response to fluids (both oral and IV) in the burn patient.

What was the impact on other disciplines?

While technology guiding fluid levels in other conditions is generally ahead of burns, principles found with this proposal could generally be applied to other conditions requiring fluid. As burn patients

require large volumes of fluids for resuscitation purposes, the usefulness of these informative endpoints may very well be exacerbated.

What was the impact on technology transfer?

None to date, however successful implementation in burn resuscitation will be incorporated with the Burn Resuscitation Decision System-Mobile (BRDSS-M) is an Army-developed, FDA-cleared computerized fluid calculator designed to assist clinicians with fluid resuscitation for burn-injured patients. The Arcos Burn Navigator™ (NSN 6515-01-621-3571; list cost \$14,500, sell price \$12,200) is the only commercial product currently available. With the proof of concept generated within the current proposal, the most attractive variables may be easily incorporated into decision support.

What was the impact on society beyond science and technology?

If successful, this proposal has the potential to improve outcomes of severely injured warfighters. Especially considering the challenges of care in multi-domain operations, optimization of burn resuscitation will help make triage and evacuation decisions and improve the response to injury which can accelerate return to duty rates and enhance the effectiveness of our future military.

5. CHANGES/PROBLEMS:

Changes in approach and reasons for change

An altered SOW has been submitted to account for a change in cost and time for accommodation to new facilities at USU and Medstar. These include a de-emphasis on enteral fluids, and timelines pushed to the right.

Actual or anticipated problems or delays and actions or plans to resolve them

Prior delays in equipment acquisition through USAMRAA has been documented. This made the transfer of this award to USUHS palatable from a time standpoint. However, with the delays also listed below there have been significant time delays.

- 1- The COVID 19 pandemic has delayed the transfer of this award and the start of animal experiments. This may continue into the 2021 calendar year, but will hopefully be resolved soon. This is on top of the massive undertaking of Dr. Burmeister moving agencies and labs halfway across the country.

Changes that had a significant impact on expenditures

The aforementioned transfer to USU impacted the total cost of the award, which resulted in the altered SOW. Specifically, since animal costs are higher at USU, the enteral fluid component of the experimental design (for example) may be removed.

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

Nothing to Report.

Significant changes in use or care of human subjects

Nothing to Report.

Significant changes in use or care of vertebrate animals

Nothing to Report.

Significant changes in use of biohazards and/or select agents

Nothing to Report.

6. PRODUCTS:

Publications, conference papers, and presentations

Nothing to Report.

Journal publications.

Nothing to Report.

Books or other non-periodical, one-time publications.

Nothing to Report.

Other publications, conference papers and presentations.

Nothing to Report.

Website(s) or other Internet site(s)

Nothing to Report.

Technologies or techniques

Nothing to Report.

Inventions, patent applications, and/or licenses

Nothing to Report.

Other Products

Nothing to Report.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS:

What individuals have worked on the project?

Name: David Burmeister

Project Role: PI

Nearest person month worked: 6

Contribution to Project: Dr. Burmeister is providing technical oversight and leadership of the protocol. Specifically, he will oversee regulatory approval, supervise data collection and analysis, and coordinate team meetings to review planning and execution of the study.

Name: Monet Schuler

Project Role: Research Lab Technician III

Nearest person month worked: 3
Contribution to Project: Monet assisted with animal procedures and processed blood/tissue samples.

Name: John Keyloun
Project Role: Resident
Nearest person month worked: 2
Contribution to Project: in charge of injury pattern and ICU care

Name: Adam Reese
Project Role: Resident
Nearest person month worked: 2
Contribution to Project: in charge of injury pattern and ICU care

Name: Lauren Moffatt
Project Role: Research Director
Nearest person month worked: 3
Contribution to Project: Coordination with Medstar team and facilities

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

As mentioned above, Dr. Burmeister will be transitioning to USU.

What other organizations were involved as partners?

Nothing to Report.

8. SPECIAL REPORTING REQUIREMENTS:

COLLABORATIVE AWARDS: N/A

QUAD CHARTS: Attached

9. APPENDICES: Attached

W81XWH-19-2-0004_ISR_Decision Memo.pdf
Site Change and Rebudget Documents

DECISION MEMO

FCMR-SRR

7 November 2019

MEMORANDUM FOR ISR Commander

SUBJECT: Defense Health Program Award # W81XWH-19-2-0004, "Precision Metrics for Driving Open- and Closed-Loop Resuscitation Algorithms for Enteral and IV Resuscitation in Burn Casualties"

1. For DECISION.

2. PURPOSE: This memo is written to seek approval for moving an extramurally-funded award (W81XWH-19-2-0004) to Uniformed Services University of the Health Sciences (USUHS) upon Dr. Burmeister's transfer.

3. RECOMMENDATION(S).

- a. Department Chief (HCRRD) authorizes the transfer of award W81XWH-19-2-0004 to USUHS.

APPROVED MO DISAPPROVED _____ NEED MORE INFO _____

- b. Division Chief (ACCCD) authorizes the transfer of award W81XWH-19-2-0004 to USUHS.

APPROVED APC DISAPPROVED _____ NEED MORE INFO _____

- c. Department Chief (BSTRD) authorizes the transfer of award W81XWH-19-2-0004 to USUHS.

APPROVED RC DISAPPROVED _____ NEED MORE INFO _____

- d. Division Chief (STARD) authorizes the transfer of award W81XWH-19-2-0004 to USUHS.

APPROVED RC ^{Dr. Selmas} DISAPPROVED _____ NEED MORE INFO _____

- e. Research Director authorizes the transfer of award W81XWH-19-2-0004 to USUHS.

APPROVED CEL DISAPPROVED _____ NEED MORE INFO _____

- f. ISR Commander authorizes the transfer of award W81XWH-19-2-0004 to USUHS.

APPROVED [Signature] DISAPPROVED _____ NEED MORE INFO _____

DECISION AUTHORITY [Signature]

4. BACKGROUND.

1. Dr. Burmeister is leaving the ISR for USUHS on in January 2020.
2. He has been working diligently with Drs. Dubick, Christy and Leung to ensure there is a plan in place to keep his intramural and BARDA projects moving.
3. Plans to continue execution of 3 of 4 studies at ISR follows:
 - a. C_019_2020_USAUSR (Resuscitation with Enteral Fluids: A prospective Observational study to Reduce IV-related EdeMa Complications (REFORM Complications)) is a clinical study that Dr. Martini will assume PI duties on. Dr. Burmeister has agreed to continue to be involved with data analysis and interpretation of data generated from this protocol.
 - b. C_011_2019_USAISR (Evaluating Novel Metabolic Stabilizing Agents Incorporated into Limited Volume Resuscitation Fluids Post-Traumatic Injury) will be led by Dr. Evan Ross under the direction of Drs. Christy, Leung, and Martini.
 - c. BARDA project (Examination of Fresh Frozen Plasma as the Sole Resuscitation Fluid for Protection of the Glycocalyx and Mitigation of Endotheliopathy Burns) will require additional personnel to execute. The current plan is to try recruit Dr. Belinda Gomez back to the USAISR execute as the PI (contingent on contract position). She will be supported by Dr. Martini.

4. In addition to these three studies, Dr. Burmeister has a Defense Medical Research and Development Program study (Precision Trauma Care; W81XWH-19-2-0004. FY19 start, 3yPoP with \$1.5M total costs). This award was a split disbursement with Geneva. ISR received \$287,948 in FY20, and will receive \$185,327 in FY21. Due to delays in contracting for equipment, the current status of this award is still in "model development", about 10 months behind schedule. A NCE will be required to complete this study. Dr. Burmeister is requesting permission to take this award with him to USUHS and both Drs. Dubick and Christy have approved at their levels. The Geneva PM has agreed to support the study regardless of site. Additionally, preliminary talks with CDMRP have indicated they would entertain movement of the award, contingent on USAISR approval.

5. DISCUSSION.

- a. Course of Action (COA) 1: Authorize the transfer of award W81XWH-19-2-0004 to USUHS. Advantages- Supports a transition by Dr. Burmeister across agencies while allowing for DoD-related studies to continue. USAISR can focus manpower resources on intramurally-funded projects. Disadvantages- A reduced S&T budget for USAISR.
- b. Course of Action (COA) 2: Do not authorize the transfer of award W81XWH-19-2-0004 to USUHS. Advantages- ISR retains extramural funds as shown above, and Geneva will provide contract manpower as agreed to. Disadvantages- The study is already behind schedule and loss of PI will strain ISR manpower resources further, potentially at the expense of intramural projects.

6. IMPACT. COA 1 will provide less total extramural funds to USAISR, though will allow Dr. Burmeister to pursue research aiming at closing a mission critical knowledge gap. COA 2 will retain more extramural funds at USAISR, with potential risks of under-delivering on intramural projects, not completing the extramural study, and/or having to decline option year funds.

7. The POC for this action is Dr. David Burmeister at 539-9226 or david.m.burmeister3.civ@mail.mil.

MCMR-SRR-RD
SUBJECT: IIMS Pilot Award

Encl

A handwritten signature in black ink, appearing to read "David Burmeister", with a stylized, cursive script.

DAVID BURMEISTER
Research Physiologist
Damage Control Resuscitation



17 March 2020

USAMRAA
Attn: Mr. Kenneth Grenier
820 Chandler St.
Fort Detrick, MD 21702-5014

SUBJECT: Request for Site Change and Rebudget – Award Number: W81XWH-19-2-0004, PI: Dr. David Burmeister

Dear Mr. Grenier,

On behalf of Dr. David Burmeister, The Geneva Foundation respectfully requests approval for a change of primary site as well as the initiation of a new subaward to the above-referenced award. As of January 2020, Dr. Burmeister is now located in the National Capitol Region at USUHS. The USAISR plans to retain \$58,364 to support Dr. Maria Serio-Melvin on this project. The remainder of the funding directly sent to the USAISR has been returned to MRDC for re-disbursement.

Dr. Burmeister plans for the animal work to be completed through a subaward from The Geneva Foundation to MedStar Health Research Institute. Samples and data would then be processed and analyzed at USUHS, the new primary performance site.

Geneva and Dr. Burmeister do not anticipate that these changes will have any negative impact on the completion of the work associated with this award. Dr. Burmeister maintains a strong rapport and regular communication with all staff and key personnel for this project and currently anticipates successful completion of the SOW by the end of the planned period of performance on December 14, 2021.

Please find attached the following documents:

1. Updated SOW (tracked and clean copies)
2. Updated Budget and Justification (USUHS + Geneva costs)
3. Equipment Quotes
4. USUHS Facilities and Resources
5. MedStar Subaward Budget and Justification
6. MedStar Key Personnel biosketches and support pages (3)
7. MedStar Facilities and Resources

If you have any questions, please do not hesitate to reach out. Thank you for your attention to this request.

Sincerely,


Digitally signed by Kathlyn Huson
DN: cn=Kathlyn Huson, o=Geneva
Foundation, ou=GCDW,
email=khuson@genevausa.org, c=US
Date: 2020.03.17 13:39:48 -07'00'

Ms. Kathlyn Huson
Grants and Contracts Director
The Geneva Foundation
Ph: 253-682-3835
khuson@genevausa.org



Dr. David Burmeister
Principal Investigator
USUHS
Ph: 301-295-0742
David.burmeister@usuhs.edu

Title: Precision Metrics for Driving Open and Closed Loop Resuscitation Algorithms for Enteral and IV Resuscitation in Burn Casualties

**STATEMENT OF WORK – 03/12/2020
PROPOSED START DATE OCT 01, 2018**

Site 1:

US Army Institute of Surgical Research
3650 Chambers Pass, Bldg 3610
Fort Sam Houston, TX, 78234
PI: Dr. David Burmeister

Site 2:

MedStar Health Research Institute
108 Irving Street NW
George Hyman Research Building, Rm. 304
Washington, DC 20010
Site PI: Dr. Lauren Moffatt

Summary:

Formula-driven burn resuscitation may deliver too much fluid resulting in significant co-morbidities. An alternative strategy could be the use of enteral fluid resuscitation, which has been explored for decades. In line with this, recent fluid therapy recommendations from the prolonged field care working group only mention in brief that enteral fluids have been studied in burns up to 40% TBSA. In fact, while enteral fluids have been shown to reduce the volumes of IV fluids given, there is a paucity of information regarding fluid type, volumes, and efficacy. A recent randomized controlled trial continues to advocate for oral rehydration post-burn, but this strategy has largely been forgotten by current practice. In short, the need exists for a new personalized approach that incorporates new targets and endpoints for identifying which patients respond to resuscitation (both IV and enteral) versus those that do not. Burn resuscitation is not an exact science, and experienced providers supplement UO with static physiologic measurements (e.g., blood pressure, pulmonary arterial occlusion pressure, cardiac index, etc.). For IV resuscitation, a decision support system based on burn surface area and UO was developed at USAISR and has become commercially available. Both these static measurements as well as the dynamic ones listed above (PPV, SPV, SVV) could be incorporated into existing decision support system algorithms for identifying which patients respond to both enteral and IV fluids. The current proposal will characterize burn-induced changes in functional hemodynamic variables to determine new endpoints that will guide IV and enteral resuscitation.

Specific Aim 1: Examine temporal changes in dynamic waveform and their relationships with organ (dys)function after thermal injury using a 40% TBSA pig burn model.	Timeline (Months)	Site 1	Site 2
Milestone(s) Achieved:			
Local IACUC Approval	0-1	Dr. Burmeister	
ACURO Approval	0-2	Dr. Burmeister	
Major Task 1: Identify the effect of burn injury and standard of care (IV fluids) on dynamic waveforms. Major Task 2: Dosing: Define the relationship between dynamic waveforms and MOD/AKI.			
Subtask 1: Perform 24 hour <i>in vivo</i> experiments with no fluids (n=8)	10-15	Dr. Burmeister	

Title: Precision Metrics for Driving Open and Closed Loop Resuscitation Algorithms for Enteral and IV Resuscitation in Burn Casualties

Subtask 2: Collect data on blood chemistry, blood gas, coagulation, and complete blood cells.	10-15	Dr. Burmeister,	
Subtask 3: Analyze and interpret arterial waveforms.	16-19	Dr. Burmeister, Mr. Vega	
Subtask 4: Correlate Waveforms with organ dysfunction biomarkers	18-21	Dr. Burmeister	
Milestone(s) Achieved: Manuscript submission	24	Drs. Burmeister, Darlington and Wu	
Specific Aim 2: Use varying levels of IV fluids to alter organ perfusion in a 40% TBSA pig burn model to examine ensuing differences in PPV, SPV, SVV.			
Major Task 3: Determine if varying levels of IV fluids increase dynamic waveform variability.			
Subtask 1: Perform 24 hour <i>in vivo</i> experiments with IV fluids- Under, over, and adequately resuscitated (n=24).	21-28	Dr. Burmeister	Drs. Moffatt and Shupp
Subtask 2:Collect data on blood chemistry, blood gas, coagulation, and complete blood cells.	21-28	Drs. Burmeister, TBD Fellow	
Subtask 3: Analyze and interpret arterial waveforms.	22-29	Dr. Burmeister, Mr. Vega	
Major Task 4: Identify the efficacy of oral fluids in maintaining PPV, SVV and SPV.			
Subtask 1: Perform 24 hour <i>in vivo</i> experiments with oral fluids added to adequate resuscitation (n=8).	21-28	Dr. Burmeister	Drs. Moffatt and Shupp
Subtask 2:Collect data on blood chemistry, blood gas, coagulation, and complete blood cells.	21-28	Drs. Burmeister, TBD Fellow	
Subtask 3: Analyze and interpret arterial waveforms.	22-29	Dr. Burmeister, Mr. Vega	
Milestone(s) Achieved:			
Decision point: hemodynamic variables used for comparison in Experiment 3	29	Dr. Burmeister	
Manuscript Submission	29-30	Dr.	

Title: Precision Metrics for Driving Open and Closed Loop Resuscitation Algorithms for Enteral and IV Resuscitation in Burn Casualties

		Burmeister	
Identification of the most informative arterial variable.	29-36	Drs. Burmeister, Salinas and Mr. Baker	
Specific Aim 3: Compare traditional resuscitation decision support algorithms (i.e., UO) to new algorithms containing waveform data (e.g., UO+PPV) for the ability to prevent organ damage and maintain organ perfusion in the 40% TBSA porcine burn model.			
Major Task 5: Perform 24 hour <i>in vivo</i> experiments to compare new algorithms with UO (n=8).	29-36	Dr. Burmeister	Drs. Moffatt and Shupp
Subtask 1: Collect data on blood chemistry, blood gas, coagulation, and complete blood cells.	29-36	Drs. Burmeister, TBD Fellow	
Subtask 2: Compare burn outcomes between UO and newly developed algorithms.	32-36	Dr. Burmeister, Mr. Vega	
Subtask 3: Compare acquired data with clinical data from “Evaluation of the Effectiveness of the Burn Navigator in Improving Resuscitation Outcomes” (Award W81XWH-16-2-0055).	32-36	Drs. Burmeister, Salinas	
Milestone(s) Achieved:			
Manuscript Submission	34-36	Dr. Burmeister, Salinas	Dr. Shupp
Recommendations to burn clinical practice guidelines.	34-36	Dr. Burmeister, Salinas	Dr. Shupp

Specific Aims:

Phase 1 Base: Examine temporal changes in dynamic waveform measurements (e.g., PPV, SPV, SVV) and their relationships with organ (dys)function after thermal injury using a 40% TBSA pig burn model.

Phase 2 Option-I: Use varying levels of IV fluids and employ enteral fluids to alter organ perfusion in a 40% TBSA pig burn model to examine ensuing differences in PPV, SPV, SVV.

Phase 3 Option- II: Compare traditional resuscitation decision support algorithms (i.e., UO) to new algorithms containing waveform data (e.g., UO+PPV) for the ability to prevent organ damage and maintain organ perfusion in the 40% TBSA porcine burn model.

Deliverables:

- Knowledge products on how IV fluids post-burn injury changes arterial waveform derivatives in real time during the acute resuscitation of burn shock.

Title: Precision Metrics for Driving Open and Closed Loop Resuscitation Algorithms for Enteral and IV Resuscitation in Burn Casualties

- b. Identification of variables that indicate patient responsiveness to oral resuscitation can revolutionize burn care in prolonged field care scenarios
- c. Knowledge product indicating which variables will be advantageous to incorporate with decision support systems guiding burn resuscitation
- d. A refining of existing decision support to generate a personalized resuscitation approach to maximize responsiveness to fluids.
- e. More efficient burn care and improved outcomes for combat casualties.

Title: Precision Metrics for Driving Open and Closed Loop Resuscitation Algorithms for Enteral and IV Resuscitation in Burn Casualties
STATEMENT OF WORK –
PROPOSED START DATE OCT 01, 2018

Site 1:
US Army Institute of Surgical Research
3650 Chambers Pass, Bldg 3610
Fort Sam Houston, TX, 78234
PI: [Dr. David Burmeister](#)
Site 2:
[MedStar Health Research Institute](#)
[108 Irving Street NW](#)
[George Hyman Research Building, Rm. 304](#)
[Washington, DC 20010](#)
Site PI: [Dr. Lauren Moffatt](#)

Summary:
Formula-driven burn resuscitation may deliver too much fluid resulting in significant co-morbidities. An alternative strategy could be the use of enteral fluid resuscitation, which has been explored for decades. In line with this, recent fluid therapy recommendations from the prolonged field care working group only mention in brief that enteral fluids have been studied in burns up to 40% TBSA. In fact, while enteral fluids have been shown to reduce the volumes of IV fluids given, there is a paucity of information regarding fluid type, volumes, and efficacy. A recent randomized controlled trial continues to advocate for oral rehydration post-burn, but this strategy has largely been forgotten by current practice. In short, the need exists for a new personalized approach that incorporates new targets and endpoints for identifying which patients respond to resuscitation (both IV and enteral) versus those that do not. Burn resuscitation is not an exact science, and experienced providers supplement UO with static physiologic measurements (e.g., blood pressure, pulmonary arterial occlusion pressure, cardiac index, etc.). For IV resuscitation, a decision support system based on burn surface area and UO was developed at USAISR and has become commercially available. Both these static measurements as well as the dynamic ones listed above (PPV, SPV, SVV) could be incorporated into existing decision support system algorithms for identifying which patients respond to both enteral and IV fluids. The current proposal will characterize burn-induced changes in functional hemodynamic variables to determine new endpoints that will guide IV and enteral resuscitation.

Specific Aim 1: Examine temporal changes in dynamic waveform and their relationships with organ (dys)function after thermal injury using a 40% TBSA pig burn model.	Timeline (Months)	Site 1	Site 2
Milestone(s) Achieved:			
Local IACUC Approval	0-1	Dr. Burmeister	
ACURO Approval	0-2	Dr. Burmeister	
<u>Major Task 1:Identify the effect of burn injury and standard of care (IV fluids) on dynamic waveforms.</u>			
Major Task 2: Dosing: Define the relationship between dynamic waveforms and MOD/AKI.			
Subtask 1:Perform <u>24 hour in vivo</u> experiments with no fluids (n=8)	<u>10-15</u>	Dr. Burmeister	

Title: Precision Metrics for Driving Open and Closed Loop Resuscitation Algorithms for Enteral and IV Resuscitation in Burn Casualties

Subtask 2: Collect data on blood chemistry, blood gas, coagulation, and complete blood cells.	~~10-15~~	~~Dr. Burmeister,~~	
Subtask 3: Analyze and interpret arterial waveforms.	~~16-19~~	~~Dr. Burmeister, Mr. Vega~~	
Subtask 4: Correlate Waveforms with organ dysfunction biomarkers	~~18-21~~	~~Dr. Burmeister~~	
Milestone(s) Achieved: Manuscript submission	~~24~~	~~Drs. Burmeister, Darlington and Wu~~	
Specific Aim 2: Use varying levels of IV fluids to alter organ perfusion in a 40% TBSA pig burn model to examine ensuing differences in PPV, SPV, SVV.			
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Subtask 2: Collect data on blood chemistry, blood gas, coagulation, and complete blood cells.	~~21-28~~	~~Drs. Burmeister, TBD Fellow~~	
Subtask 3: Analyze and interpret arterial waveforms.	~~22-29~~	~~Dr. Burmeister, Mr. Vega~~	
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Subtask 3: Analyze and interpret arterial waveforms.	~~22-29~~	~~Dr. Burmeister, Mr. Vega~~	
Milestone(s) Achieved:			
Decision point: hemodynamic variables used for comparison in Experiment 3	~~29~~	~~Dr. Burmeister~~	
Manuscript Submission	29-30	Dr.	

Title: Precision Metrics for Driving Open and Closed Loop Resuscitation Algorithms for Enteral and IV Resuscitation in Burn Casualties

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Identification of the most informative arterial variable.	~~29-36~~	Drs. Burmeister, Salinas and Mr. Baker	
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Major Task 5: Perform ~~24~~ hour <i>in vivo</i> experiments to compare new algorithms with UO (n= ~~8~~).	~~29-36~~	~~Dr. Burmeister,~~	~~Drs. Moffatt and Shupp~~
Subtask 1: Collect data on blood chemistry, blood gas, coagulation, and complete blood cells.	~~29-36~~	Drs. Burmeister, TBD ~~Fellow~~	
Subtask 2: Compare burn outcomes between UO and newly developed algorithms.	~~32-36~~	Dr. Burmeister, Mr. ~~Vega~~	
Subtask 3: Compare acquired data with clinical data from “Evaluation of the Effectiveness of the Burn Navigator in Improving Resuscitation Outcomes” (Award W81XWH-16-2-0055).	~~32-36~~	Drs. Burmeister, Salinas	
Milestone(s) Achieved:			
Manuscript Submission	34-36	Dr. Burmeister, Salinas	~~Dr. Shupp~~
Recommendations to burn clinical practice guidelines.	34-36	Dr. Burmeister, Salinas	~~Dr. Shupp~~

Specific Aims:

Phase 1 Base: Examine temporal changes in dynamic waveform measurements (e.g., PPV, SPV, SVV) and their relationships with organ (dys)function after thermal injury using a 40% TBSA pig burn model.

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Deliverables:

- a. Knowledge products on how IV fluids post-burn injury changes arterial waveform derivatives in real time during the acute resuscitation of burn shock.

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- b. Identification of variables that indicate patient responsiveness to oral resuscitation can revolutionize burn care in prolonged field care scenarios
- c. Knowledge product indicating which variables will be advantageous to incorporate with decision support systems guiding burn resuscitation
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USU Budget

PI:	Dr. David Burmesister	0.00
Agency:	USAMRAA	
Title:	Precision Metrics for Driving Open- and Closed-Loop Resuscitation Algorithms for Enteral and IV Resuscitation in Burn	
Budget Period:	12/15/2018 - 12/14/2021	
USU On-site Rate:	30.45%	

Federal Personnel						USUHS
Name	Role	Percent Effort	Base Salary	Salary	Fringe (est 25%)	
David Burmeister (Year 2)	PI	40%	-	-	-	-
David Burmeister (Year 3)	PI	40%	-	-	-	-
				-	-	-
				-	-	-
				-	-	-
Subtotal of Federal Personnel (No SCR)						-
Travel						
Sponsor-Required travel (1/year for 2 years)						3,600.00
Conference Travel (1/year for 2 years)						3,600.00
Subtotal of Travel (SCR Base - if Core do not add to SCR Base)						7,200.00
Supplies						
Subtotal of Supplies (SCR Base)						-
Other Expenses (incl'd contracts for goods or services)						
						-
Subtotal of Other Expenses (SCR Base)						-
Contract(s) that Bring "Intellectual Contributions":						
Subtotal of Contracts (No SCR)						-
Equipment						
						-
Subtotal of Equipment (SCR Base)						-
Grants/Sub-Awards						
Geneva Grant/Cooperative Agreement						1,087,952.00
Subtotal of Grants (No SCR)						1,087,952.00
Stipends						
Subtotal of Stipends (No SCR)						-
Direct Costs						1,095,152.00
USUHS SCR Base -- Travel (Unless Core), Supplies, Other Expenses, Equipment						7,200.00
USUHS SCR						2,192.00
Total (Direct Costs + SCR)						1,097,344.00
4.6% Federal Compliance Cost (amt of total award x 4.6%)						52,912.00
Total USU Budget						1,150,256.00

Geneva Research Project Budget

PI: Dr. David Burmesister	USU On-site Rate:	30.45%	30.45%	30.45%	30.45%	30.45%
Agency: USAMRAA	USU Off-site Rate:	3.88%	3.88%	3.88%	3.88%	3.88%
Title: Precision Metrics for Driving Open- and Closed-Loop Research	Geneva Indirect Rate	19.10%	19.10%	19.10%	19.10%	19.10%
Grant/VPR Site # 0.00	WRNMMC Rate:	27.00%	27.00%	27.00%	27.00%	27.00%

		YEAR 1	YEAR 2	YEAR 3	YEAR 4	YEAR 5	TOTAL
Personnel							
Name Enter period (ex. Jan 2019 - Dec 2019) -->							
Total Of ONSITE Personnel (see Geneva Personnel tab for details)		-	154,108.00	158,732.00	-	-	312,840.00
Total Of OFFSITE Personnel (see Geneva Personnel tab for details)		-	-	-	-	-	-
Total Of WRNMMC Personnel (see Geneva Personnel tab for details)		-					-
Subtotal of Personnel		-	154,108.00	158,732.00	-	-	312,840.00
Travel							
Training/Educational	IDC Rate						
Conference- Post	ONSITE		1,800.00	1,800.00			3,600.00
Doc							-
							-
							-
Subtotal of Travel (ONSITE)		-	1,800.00	1,800.00	-	-	3,600.00
Subtotal of Travel (OFFSITE)		-	-	-	-	-	-
TOTAL TRAVEL		-	1,800.00	1,800.00	-	-	3,600.00
Supplies							
Lab Consumables/Disposables	IDC Rate						
ELISA kits	ONSITE		7,000.00	7,000.00			14,000.00
Antibodies	ONSITE		17,000.00	18,000.00			35,000.00
Consumable Office Supplies	ONSITE		6,000.00	6,000.00			12,000.00
Animal Surgery Supplies	ONSITE		200.00	200.00			400.00
Burn Probes, temp controllers, Refrigerator	OFFSITE		37,400.00				37,400.00
	ONSITE		22,750.00				22,750.00
Subtotal of Supplies (ONSITE)		-	52,950.00	31,200.00	-	-	84,150.00
Subtotal of Supplies (OFFSITE)		-	37,400.00	-	-	-	37,400.00
TOTAL SUPPLIES		-	90,350.00	31,200.00	-	-	121,550.00
Equipment							
iStat Analyzer	IDC Rate						
Large Centrifuge	ONSITE		8,311.00				8,311.00
Small Centrifuge	ONSITE		12,899.00				
Microscop	ONSITE		7,486.00				
	ONSITE		45,000.00				45,000.00
Subtotal of Equipment (ONSITE)		-	73,696.00	-	-	-	73,696.00
Subtotal of Equipment (OFFSITE)		-	-	-	-	-	-
TOTAL EQUIPMENT		-	73,696.00	-	-	-	73,696.00
Other Expenses							
Publication Costs	IDC Rate						
	ONSITE		1,000.00	1,000.00			2,000.00
							-
							-
							-
							-
							-
Subtotal of Other Expenses (ONSITE)		-	1,000.00	1,000.00	-	-	2,000.00
Subtotal of Other Expenses (OFFSITE)		-	-	-	-	-	-
TOTAL OTHER EXPENSES		-	1,000.00	1,000.00	-	-	2,000.00
Sub-Contracts (for goods or services)							
							-
							-
							-
							-
TOTAL SUB-CONTRACTS		-	-	-	-	-	-
Sub-Recipient Awards (to other institutions/organizations)							
MedStar			361,413.00				361,413.00
							-
							-
							-
							-
							-
							-
Subtotal of Sub-recipient awards (not included in indirect base)		-	361,413.00	-	-	-	361,413.00
Expenses to be Returned to USU on PO's (ex. LAM Expenses, Supplies, Equipment)							
							-
							-
							-
							-
Subtotal of Expenses to be Returned to USU (USU SCR Onsite base)		-	-	-	-	-	-
Subtotal ONSITE Indirect Base (does not include subawards or equipment)		-	209,858.00	192,732.00	-	-	402,590.00
Subtotal OFFSITE Indirect Base (does not include subawards or equipment)		-	37,400.00	-	-	-	37,400.00
WRNMMC Indirect Base		-	-	-	-	-	-
Total Sub-Contract/Sub-Recipient Costs Eligible for Geneva Indirect		-	25,000.00	-	-	-	25,000.00
USU Onsite Indirect Costs		-	63,902.00	58,687.00	-	-	122,589.00
USU Offsite Indirect Costs		-	1,451.00	-	-	-	1,451.00
WRNMMC Indirect Costs		-	-	-	-	-	-
Subtotal Geneva Indirect Base (Row 71 + 72 + 74)		-	272,258.00	192,732.00	-	-	464,990.00
Geneva Indirect Costs		-	52,001.00	36,812.00	-	-	88,813.00
TOTAL INDIRECT COSTS (Rows 75 + 76 + 77 + 79)		-	117,354.00	95,499.00	-	-	212,853.00
TOTAL ALL DIRECT COSTS		-	682,367.00	192,732.00	-	-	875,099.00
GRAND TOTAL (Rows 80 + 81)		-	799,721.00	288,231.00	-	-	1,087,952.00

Budget Justification: The Geneva Foundation (Award: W81XWH-19-2-0004)

Fringe Benefits Costs: Geneva has a federally negotiated fringe benefit rate (36.1%) that has been approved by our cognizant federal agency, the Office of Naval Research (ONR). This rate was developed under the requirements of the Office of Management and Budget Guidance for Grants and Agreements, 2 CFR 200.

Other Personnel

Principal Investigator, Dr. David Burmeister (effort = 4.8 calendar months). Dr. Burmeister is a doctoral-prepared research scientist with a background in tissue engineering, regenerative medicine, and animal models of thermal injury. He will serve as the PI on the project. Using 40% of his time, Dr. Burmeister will provide technical oversight and leadership of the protocol. Specifically, he will oversee regulatory approval, supervise data collection and analysis, and coordinate team meetings to review planning and execution of the study. He will be responsible for the preparation of technical reports and manuscripts generated by this study. *As a government employee, Dr. Burmeister's salary is paid by the federal government. Therefore, his work on the project will be at no cost to the grant.*

To Be Named, Post-Doctoral Associate II (effort = 7.32 calendar months). A post-doctoral associate is requested for this proposed study. A PhD or MD will be required for this position and s/he should have research experience in molecular science, preferably within the Department of Defense, as well as burn injury in large animal models. This person will collaborate with and assist the PI and research team in the performance of the research study. Specifically, the post-doc will be responsible for the analysis of blood chemistry and blood cell counts, serum ELISAs, western blotting procedures, histopathological analyses. The post-doc will be mentored and supervised under the technical direction of Dr. Burmeister. S/He will also contribute to the drafting and submitting of abstracts, manuscripts and reports for dissemination. *S/He will be an employee of The Geneva Foundation. The salary for this position is consistent with the job title and the area of employment.*

To Be Named, Laboratory Technician III (effort = 12 calendar months). One (1) Laboratory Technician will be needed for this study. S/He will be hired in Year 02. The Laboratory Technician will perform routine laboratory procedures, with oversight and direction from the PI. S/He will assist with set up and preparation of animals for in vivo experiments. The ideal candidate(s) will possess a bachelor's degree in biology or related field and will have experience managing large animal colonies and performing animal experimental procedures. *S/He will be an employee of The Geneva Foundation. The salary for this position is consistent with the job title and the area of employment.*

Equipment

iSTAT Analyzer (\$8,311). An iSTAT analyzer will be needed to analyze blood samples collected from the animals during the experiments.

Eppendorf 5810R Centrifuge and Rotor Packages (\$12,899). A large centrifuge will be needed to spin down samples collected during animal experiments.

Small centrifuge (\$7,486). A small centrifuge will be needed to spin down samples collected during animal experiments.

Microscope (\$45,000). A microscope is needed to analyze samples collected during animal experiments.

Travel

Travel for Training/Educational Conferences (\$3,600). One trip annually for one project team member to attend a training/educational conference for training associated with the protocol is budgeted in years 02-03. This funding will enable the team member to attend workshops and conferences in order to learn new techniques related to the protocol which will enhance his/her training under the mentorship of the PI. The

locations of these meetings are to be determined. Therefore, the location of travel, the number of travel days involved the cost of airfare, lodging expenses, ground transportation costs and per diem costs are not available at this time. The estimated cost of travel is budgeted at \$1,800 per trip. Travel will be coordinated by The Geneva Foundation.

Materials and Supplies

All materials and supplies listed below will be purchased by The Geneva Foundation and shipped to either USAISR, USUHS, or MedStar Health Research Institute unless otherwise noted.

Refrigerator (\$4,503). A small refrigerator is needed to store samples in at controlled temperatures.

Burn Probes (\$12,015). Custom burn probes will need to be fabricated by a machine shop per Dr. Burmeister's design specifications. These probes are needed to create the injury model in the animals.

Temperature Controllers (\$6,232). Temperature controllers will be needed to keep animal and sample conditions stable and viable. This is necessary to maintain the integrity of samples collected for future analysis.

Consumables, disposables and general lab supplies for specimen analysis (\$14,000). Funds are requested to support the cost of general lab supplies, including glassware and plasticware, chemicals and reagents assays, western blot protocols, histopathological analyses, etc. Please see below for a breakdown of costs.

Years 02-03:	Glassware:	\$3,500
	Plasticware:	\$4,000
	Chemicals and Reagents:	\$4,000
	Disposables:	\$2,500
TOTAL		\$14,000

Supplies for animal instrumentation and specimen collection (\$37,400). Funds are requested to support the cost of animal instrumentation and specimen collection, including: general sterile consumables, swabs, sutures, sterile tubes, RNA Protect reagents, formalin, vacutainers, etc.; iStat Cartridges ; and other point-of-care assay reagents and supplies. Estimates are based on product costs available via website or previous purchases from vendors. Please see below for a breakdown of costs:

Year 02:	Sterile Procedure Consumables:	\$8,400
	Specimen Collection & Processing:	\$6,000
	iStat Cartridges:	\$15,000
	Other point of care assay reagents and supplies:	\$8,000
	TOTAL	\$37,400

ELISA Kits (\$35,000). Funds are requested to support the cost of ELISA Kits. Costs are estimated at \$17,000 in year 02, and \$18,000 in year 03 to include shipping.

Antibodies (\$12,000). Funds are requested to support the cost of other antibodies such as CD68. Each antibody is estimated to cost between \$400-\$500. The cost is estimated at \$6,000 in year 02 and year 03.

Consumable Office Supplies (\$400). Funds are requested to support the cost of consumable office supplies associated with administrative functions of the study such as hanging file folders, toner, printer paper, writing utensils, data disks for electronic storage of data, etc. Office supplies are budgeted at \$200 in year 02 and year 03. Consumable office supplies for project use are not calculated as part of The Geneva Foundation's indirect cost rate. Consumable office supplies associated with administrative functions of the study are consistently treated as direct costs and are not charged to federally sponsored agreements as indirect costs.

Other Expenses

Publication Costs (\$2,000). Funds are requested to support costs associated with printing of posters to be presented at local and national meetings, page charges and publication submission costs to journals. The total estimated cost is \$1,000 in year 02 and year 03.

Subaward Funds

In year 02 of the project, \$361,413 will be awarded to MedStar Health Research Institute.

Direct costs of the subaward will include personnel and animal costs, which are based on current pricing from MedStar Health Research Institute Animal Research Facility. The total direct cost is \$278,010.

Indirect costs were calculated at a rate of 30%, which is the MedStar Health Research Institute's current federal negotiated indirect cost rate. This indirect cost rate is applied to a modified total direct cost base that excludes capital expenditures, equipment, alterations and renovations, patient care costs and the portion of each subcontract in excess of \$25,000. The total indirect cost is calculated as \$83,403.

MIPR Funds

The following costs will be sent to the USUHS via a Military Interdepartmental Purchase Request (MIPR).

Years 02-03: \$124,285

The amount previously sent to USAISR via a Military Interdepartmental Purchase Request (MIPR) under this award will cover all costs at USAISR. No additional funding is needed to cover these costs.

The role of The Geneva Foundation

The award will be made to The Geneva Foundation, a non-profit organization that is a nonfederal agency. The Geneva Foundation was established in 1993 with the sole mission to promote and support the advancement of military medicine. Since its inception, The Geneva Foundation has managed over \$378 million in federal and non-federal funds. In 2017, the Foundation supported more than 570 research programs, including industry-sponsored clinical trials, federal and non-federal grants and contracts, and over 270 principal investigators at more than 55 military medical facilities and federal laboratories worldwide.

The Geneva Foundation is uniquely qualified to support and facilitate the achievement of the established goals of the proposed study. Geneva will lend its expertise in post-award management and coordination. Geneva will represent the Principal Investigator by operating not only as the recipient organization, but as a research partner. Geneva research personnel will work on-site under the direction of the Principal Investigator to conduct the research, ensuring that all proposed objectives are met.

The Geneva Foundation is prepared to provide the following services and perform the following activities:

1. Assume full responsibility for the oversight of the research program and award.
2. Provide research staff to conduct the work described in the proposed research program. Geneva's research staff will work on-site with the Principal Investigator.
3. Meet the terms and conditions of the award along with the Principal Investigator.
4. Ensure all applicable regulations and guidelines are maintained.
5. Administer the budget within the guidelines of the sponsor.
6. Purchase supplies and equipment required for the research program.
7. Provide prompt, accurate financial reports to the investigator and sponsor.
8. Supply an accurate inventory of all fixed assets associated with the award.
9. Provide travel services necessary for fulfilling the objectives of the award.

10. Ensure that scientific approval, animal use review, other assurances and reviews of research protocols have been accomplished where required by the DOD, USAMRAA, Federal, State, Local, and site regulations.
11. Ensure that Geneva personnel working at the site are properly credentialed.
12. Ensure that Geneva personnel working at the site meet the Occupational Health and training requirements of the institution.
13. Assist the Principal Investigator in complying with the Sponsor's reporting requirements.
14. Assist the Principal Investigator with preparing manuscripts for publication and other dissemination materials such as abstracts for presentations, posters, copyrighted materials, etc.

Indirect Cost Rate and Fringe Benefit Rate

Geneva's indirect cost rate (19.1%) is a modified total direct cost (MTDC) rate for all activities excluding the portion of subawards costs in excess of \$25,000 and participant support costs. Geneva's fringe benefit rate of 36.1% is applied to total salaries excluding paid time off and holidays. These rates are our provisional rate for 2020 and is approved by the Office of Naval Research (ONR), the Cognizant Federal Agency for The Geneva Foundation.

RATE – TYPE: PROVISIONAL (PROV)

Indirect Rates:

<u>TYPE</u>	<u>FROM</u>	<u>TO</u>	<u>RATE</u>	<u>BASE</u>	<u>APPLICABLE TO</u>	<u>LOCATION</u>
PROV	1/1/19	12/31/19	19.10%	(a)	All activities	All

Fringe Benefits Rates:

<u>TYPE</u>	<u>FROM</u>	<u>TO</u>	<u>RATE</u>	<u>BASE</u>	<u>APPLICABLE TO</u>	<u>LOCATION</u>
PROV	1/1/19	12/31/19	36.10%	(b)	All activities	All

Distribution Bases

- (a) MTDC means all direct salaries and wages, applicable fringe benefits, materials and supplies, services, travel, and up to the first \$25,000 of each subaward (regardless of the period of performance of the subawards under the award). MTDC excludes equipment, capital expenditures, charges for patient care, rental costs, tuition remission, scholarships and fellowships, participant support costs and the portion of each subaward in excess of \$25,000.
- (b) Total Salaries and Wages

Sales Quotation

*Quote Nbr	Creation Date	Due Date	Page
0057-4422-51	02/26/2020		1 of 1
Payment Terms		Delivery Terms	
NET 30 DAYS		DEST	
Valid To		Prepared By	
06/25/2020		MELCH, MICHAEL	
Customer Reference		Sales Representative	
DAVID BURMEISTER/TSG30RPGA/022620		MICHAEL MELCH	
To place an order	Ph: 800-766-7000	Fx: 800-926-1166	
Submitted To:		Customer Account: 912681-002	
DAVID BURMEISTER DAVID.BURMEISTER@USUHS.EDU 301-295-		USUHS ATTN PO _____ 4301 JONES BRIDGE RD BETHESDA MD 20814-4799	



Fisher Scientific

Part of Thermo Fisher Scientific

FISHER SCIENTIFIC COMPANY LLC
4500 TURNBERRY DRIVE
HANOVER PARK IL 60133-5491

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[Click here or go through your purchasing system to fishersci.com quotes](#)

***Please reference this Quote Number on all correspondence.**

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For complete Terms and Conditions, please [click here.](#)

Nbr	Qty	UN	Catalog Number	Description	Unit Price	Extended Price
1	1	EA	TSG30RPGA	TSG REF 30 PNT GLASS 115V/60HZ	4,503.49	4,503.49
			Vendor Catalog # TSG30RPGA This item is being sold as 1 per each GSA# GS07F161BA			



MERCHANDISE TOTAL

4,503.49

NOTES:

FREE SHIPPING TO DOCK

We now offer highly competitive financing with low monthly payments. Please contact your local sales representative for more information.

Tell us about your recent customer service experience by completing a short survey. This should take no longer than three minutes. Enter the link into your browser and enter the passcode: USA-PGH-CS2

<http://survey.medallia.com/fishersci>

**ITM Partners, Ltd.**

5925 Corridor Pkwy
Schertz, TX 78154-3215
Phone: (210) 651-9066
Fax: (210) 651-9067

Quotation**Quote** Uniformed Services University

To: 4301 Jones Bridge Rode
Building 42, Room 3129
Bethesda, MD 20814
United States

Quote Number:	17955	Contact:	David Burmeister
Quote Date:	02/27/20	Expires:	03/28/20
Customer:	USU	Inquiry:	
Salesman:	ITM	Terms:	Net 30 Days
Ship Via:		Phone:	(301) 295-0742
FOB:	Origin	FAX:	
		Delivery:	6-7 Weeks ARO

Payment terms are as shown below. All payments are in U.S. dollars.

1. Fifty percent (50%) of the Cost will be due at the time of contract award, Net-0 days.
2. Balance of Cost (Fifty percent-50%) of each Station upon completion and acceptance, Net -30 days.

<u>Part Number</u>				
<u>Item</u>	<u>Description</u>	<u>Revision</u>	<u>Quantity</u>	<u>Price</u>
1	2104 02 0010 2x2 inch Brass Heating Block		3	\$1,735.00 /EA
2	2104 02 1005 Teflon Nesting Block		3	\$185.00 /EA
3	2104 01 0000 9x15 cm Brass Heating Block		3	\$1,825.00 /EA
4	2104 01 1004 Teflon Nesting Block		3	\$260.00 /EA
Total:				\$12,015.00

Part Number

Item **Description**

Revision

Quantity

Price

All delivery is After Receipt of your purchase Order (ARO), dependent upon ITM's existing workload at the time the PO is received. Payment terms are Net 30 days, U.S. dollars. The above price excludes any applicable packaging, handling, installation or taxes, except as noted above. All payments are to be made via U.S. bank unless prior written arrangements have been established by ITM. Delivery is F.O.B.: Origin. This quote remains valid for thirty (30) days from the date of the transmittal letter. All packaging, if elected, will be in accordance with best commercial practices.

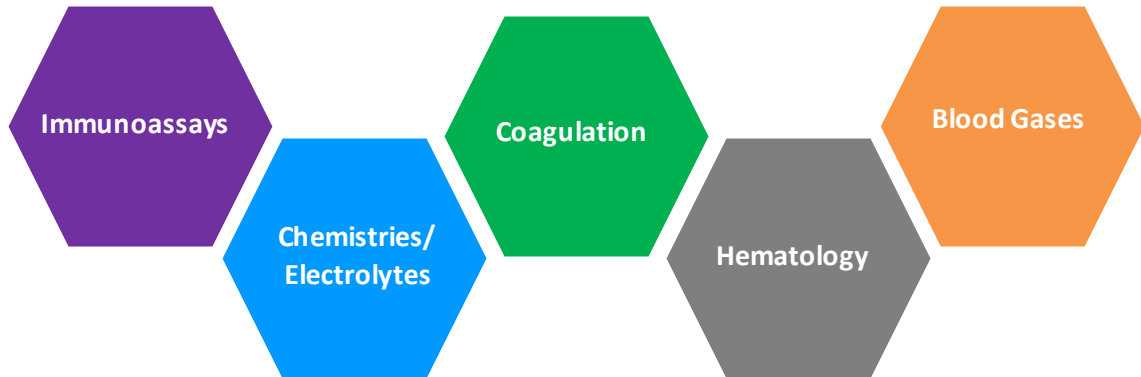
The fabrication by ITM of the above components will be accomplished at our facility in Schertz, Texas consistent with the customer-supplied information. Any anodizing, painting, heat treating, etc. as applicable to this project will be subcontracted to qualified supporting facilities. The customer will be responsible for providing ITM all applicable documentation relating to the product and materials being supported. Any Customer supplied materials will be returned to the Customer upon completion of the contract. ITM reserves the right to re-evaluate this proposal based upon the review of any additional requirements not identified prior to submission of this proposal.

By Weaver, Jeff
ITM Partners, Ltd.



i-STAT Proposal – USUHS

Attn: Prof. David Burmeister



INFORMATION FOR ORDERING ACTIVITIES

ORDERING ADDRESS:

Abbott Laboratories
Point of Care Division
200 Abbott Park Road
Dept. 720Q, Bldg. AMJ23-3
Abbott Park, IL 60064
967474896
Registered – Cage Code 6AWN5

DUNS NUMBER:

CENTRAL CONTRACTOR REGISTRATION (CCR):

Prepared By: Dan Moberly

Prepared: 26 Feb 2020

Valid through: 90 days from date prepared



EXECUTIVE SUMMARY

THE i-STAT SOLUTION

Abbott Point of Care understands the need for fast, accurate, and reliable test results that give health care professionals the confidence they need to make critical patient care decisions. We manufacture the i-STAT System, an advanced, handheld blood analyzer that provides real-time, lab-quality results within minutes to accelerate the patient care decision-making process.

The advanced biosensor technology of the i-STAT System enables patient-side blood testing, so that health care professionals can access real-time, lab quality results within minutes, rather than hours. By accelerating the availability of diagnostic test results, the i-STAT System provides health care professionals with the information they need to make treatment decisions sooner, which may lead to enhanced quality of care and improved departmental efficiency.

Lightweight, portable, and easy to use, the i-STAT System features single-use disposable cartridges that perform a broad menu of the most commonly performed diagnostic tests, including cardiac markers, blood gases, chemistries and electrolytes, lactate, coagulation, and hematology. To perform a test, apply a few drops of blood to the cartridge, and then insert it into the handheld reader. Results are reported in just minutes and easily uploaded to the patient chart.

At Abbott Point of Care, our goal is to provide our customers with products and services that are safe and effective, meet and or exceed customer expectations and are in compliance with worldwide regulatory quality system requirements.

IMPLEMENTATION SERVICES SUMMARY

Implementation Value	Cost to Customer	
\$32,000*	\$0	<i>Cost is based on 160 hours (on average) per implementation.</i>

**All labor and travel expenses are provided at No Charge. Customer is responsible for cartridges utilized during implementation and training.*

Implementation Services are expansive, typically involving 160 hours of dedicated service by various professionals—yet they are offered at no cost. Abbott Point of Care offers these services as part of a commitment to meet your distinct point-of-care testing needs.

A standardized, five-phase process guides your facility's implementation to ensure a smooth, efficient, and successful implementation of the *i-STAT System*. A dedicated Implementation Team will partner with your staff to provide expert guidance and project management for each of the below implementation services:

- Pre-Implementation Meeting and Workflow Design
- Performance Verification
- Data Management and Interfacing
- Clinical Education and Awareness
- Point of Care Coordinator Training
- End User Training
- Go Live Support
- Follow-Up Support



INVESTMENT DETAIL***

CAPITAL

Part #	Product	Cost (EA)	Number Required	Total Cost	Contract #	Contract Type
04P75-01	i-STAT 1 Analyzer	\$6,297.23	1	\$ 6,297.23	GS-07F-0303Y	GSA (also avail on eCat)
06F23-55	i-STAT rechargeable battery pack	\$ 131.23	1	\$ 131.23	N/A	Not on contract - Made in China*
04P74-04	i-Stat Printer Kit	\$ 350.00	1	\$ 350.00	N/A	Not on contract - Made in China*
04P73-04	i-STAT Downloader Recharger Kit	\$1,003.78	1	\$ 1,003.78	GS-07F-0303Y	GSA (also avail on eCat)
06F11-01	i-STAT Elec Simulator	\$ 528.97	1	\$ 528.97	GS-07F-0303Y	GSA (also avail on eCat)
			Grand Total	\$ 8,311.21		* These open market items will also incur a small shipping charge.

*****NOTE:** This proposal is CONFIDENTIAL and does not constitute a contract. All items on this quote are available for procurement in DMLSS/eCAT with the exception of the items marked "OPEN MARKET". Additionally, pricing above for Analyzer/equipment investment matches Abbott GSA pricing (Schedule #: GS-07F-0303Y). Cartridge quotation matches Abbott FSS pricing (Schedule #: V797P-2032D). DMLSS/eCAT pricing may vary slightly from the above pricing. For all pricing inquiries please contact Daniel Moberly at 928-853-4670, daniel.moberly@abbott.com.



CONSUMABLE, CALIBRATOR, & CONTROLS

Consumable, Calibrator and Control cost may vary depending on Laboratory procedure. Estimates provided in this section are based on past experience with similar accounts.

ACCESSORY COST

Consumable Costs typically range between 1-3% of reagent cost. A detailed list of accessories is available upon request.

CALIBRATOR/CONTROL COST

Calibrator and Control Costs typically range between 1-3% of reagent cost.

CALIBRATOR/CONTROL COST

Item #	Description	FSS Price
06F15-01	Calibration Verification	\$39.82
06F12-01	Level 1 Aqueous Control	\$14.33
06F13-01	Level 2 Aqueous Control	\$14.33
06F14-01	Level 3 Aqueous Control	\$14.33
06P17-15	Level 1 Coagulation Control	\$49.16
06P17-16	Level 2 Coagulation Control	\$49.16
06P17-13	PT CTL LV1	\$36.62
06P17-14	PT CTL LV2	\$36.62
06P17-09	i-STAT cTnI Control Level 1	\$164.03
06P17-10	i-STAT cTnI Control Level 2	\$164.03
06P17-11	i-STAT cTnI Control Level 3	\$164.03
06P17-12	i-STAT cTnI Calibration Verification 1-3	\$164.03
06P17-05	i-STAT BNP Control Level 1	\$164.03
06P17-06	i-STAT BNP Control Level 2	\$164.03
06P17-07	i-STAT BNP Control Level 3	\$164.03
06P17-08	i-STAT BNP Calibration Verification 1-3	\$164.03
06F12-14	CHEM8+ Level 1b	\$14.76
06P17-01	i-STAT CK - MB Control Level 1	\$164.03
06P17-02	i-STAT CK - MB Control Level 2	\$164.03



06P17-03	i - STAT CK - MB Control Level 3	\$164.03
06P17-04	i - STAT CK - MB Calibration Verification 1-3	\$164.03
06F12-04	HCT Control Level 1	\$28.70
06F12-06	HCT Control Level 3	\$28.70
05P71-01	TriControls Control Level 1 (10x1.7ml ampule)	\$31.66
05P72-01	TriControls Control Level 2 (10x1.7ml ampule)	\$31.66
05P73-01	TriControls Control Level 3 (10x1.7ml ampule)	\$31.66
05P70-01	Set Levels 1-5 (4 ea, 5 lvl x 1.7ml ampules/box)	\$64.32
02R29-01	bHCG Control Level 1	\$211.65
02R29-02	bHCG Control Level 2	\$211.65
02R29-03	bHCG Control Level 3	\$211.65
05P59-04	bHCG Cal Ver	\$211.65

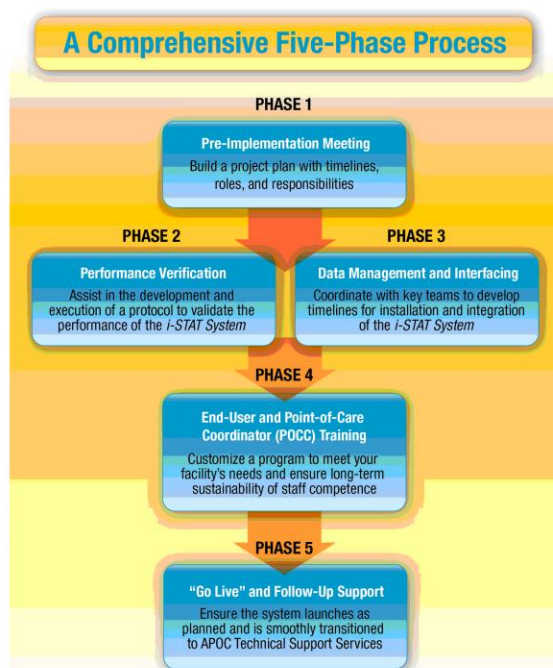


The i-STAT® Implementation Services Value Summary

FEATURES	BENEFITS
Valuable services with invaluable rewards provided at no cost: Implementation Services are varied and expansive, typically involving 160 hours of dedicated service by various professionals—yet they are offered at no cost. Abbott Point of Care offers these services as part of a commitment to meet customers' distinct point-of-care testing needs with innovative solutions in technology, process, and services.	Dedicated, proven, and personalized service for successful implementation of the i-STAT System at your facility—at no cost. With true collaboration and ongoing support, your institution, staff, and patients can derive the greatest value from the <i>i-STAT System</i> .
A comprehensive and proven program: A standardized, five-phase process guides your facility's implementation of the <i>i-STAT System</i> , from planning stages through "Go Live" and beyond. This extensive program includes project planning, performance verification, data management and interfacing, training, and "Go Live" with follow-up support.	Reassurance that your staff will be guided every step of the way, addressing your distinct needs to help ensure a smooth, efficient, and successful implementation of the <i>i-STAT System</i> at your facility.
Process change consulting: The implementation program includes a Clinical Awareness initiative to educate your clinical staff about process changes with the <i>i-STAT System</i> and resultant benefits regarding patient care.	Your staff needs to not only accept but <i>embrace</i> the process changes that come with the <i>i-STAT System</i> —reinforcing implementation within your facility. Our program is far more comprehensive than a typical end user training program and actively involves your clinical staff throughout the process so they will take greater ownership of the system and its continued success.
A dedicated, experienced team: The Implementation and Technical Support teams are experts in their field—offering both clinical and technical expertise, more than 15 years of experience, and a track record of success with thousands of facilities.	Confidence to collaborate with a knowledgeable team of professionals whose collective experience and insights will help ensure that all of your implementation needs are met.
Ongoing, 24/7 technical support: Once your system goes live, you will have access to APOC Technical Support Services 24 hours a day, 7 days a week.	Security in knowing that you and your staff will have access to the support you need, whenever you need it, to reinforce ongoing success with the <i>i-STAT System</i> and the overall success of your POC testing program.



The *i-STAT*® VALUE



HANDHELD SUMMARY

FEATURES	BENEFITS
Portable: The <i>i-STAT</i> handheld is lightweight and portable designed for performing diagnostic laboratory tests at the patient's bedside	Clinicians receive critical patient test results when they need them, where they need them, at the patient's bedside.
Simple: Performing patient testing on the <i>i-STAT</i> System is easy to do. Approved operators can perform a wide range of diagnostic testing required for critical patient decisions directly at the patient's bedside.	Provides bedside test results quickly and efficiently. Complicated steps, procedures and hand-offs associated with traditional laboratory testing are removed from the process, thereby reducing risk of error.
Automated QC: Quality control on the <i>i-STAT</i> System is internal and automated and can be customized to run automatically at intervals set by the laboratory.	Clinicians can focus on the patient and not time consuming quality control or maintenance procedures. The laboratory can have confidence in the accuracy of test results and assure regulatory compliance requirements are being met.
Secure: Programmed with comprehensive and customizable lock-out protocols, the <i>i-STAT</i> System features lock-out options for operators, download intervals, and quality control.	The laboratory maintains control of the testing process and can have confidence that all <i>i-STAT</i> System testing is in compliance with laboratory protocols and guidelines.
One platform. Multiple testing solutions: The <i>i-STAT</i> System performs a wide variety of diagnostic tests required for critical patient decisions such as blood gases, chemistries and electrolytes, lactate, hematology, cardiac markers and coagulation.	Standardization to a single point of care platform can be achieved throughout most critical care areas of the hospital reducing the cost, time and effort associated with managing multiple testing platforms.
Integrated: The <i>i-STAT</i> handheld is equipped with a built-in laser barcode scanner for use in entering operator, patient identification and <i>i-STAT</i> Test Cartridges.	Reduces risk of error by eliminating time spent on manual entry of patient and operator parameters.
Connected: Fully automated, hands free bidirectional communication with the laboratory via a seamless data management system.	Downloading test records is made easy ensuring patient results transfer immediately to the laboratory information system (LIS) and the electronic patient record.

For Intended Use information, see the intended use page.

CHOOSE TRANSFORMATION

Abbott



Enter Operator



Enter Patient



View Results



Transmit



Apply Blood



Insert Cartridge



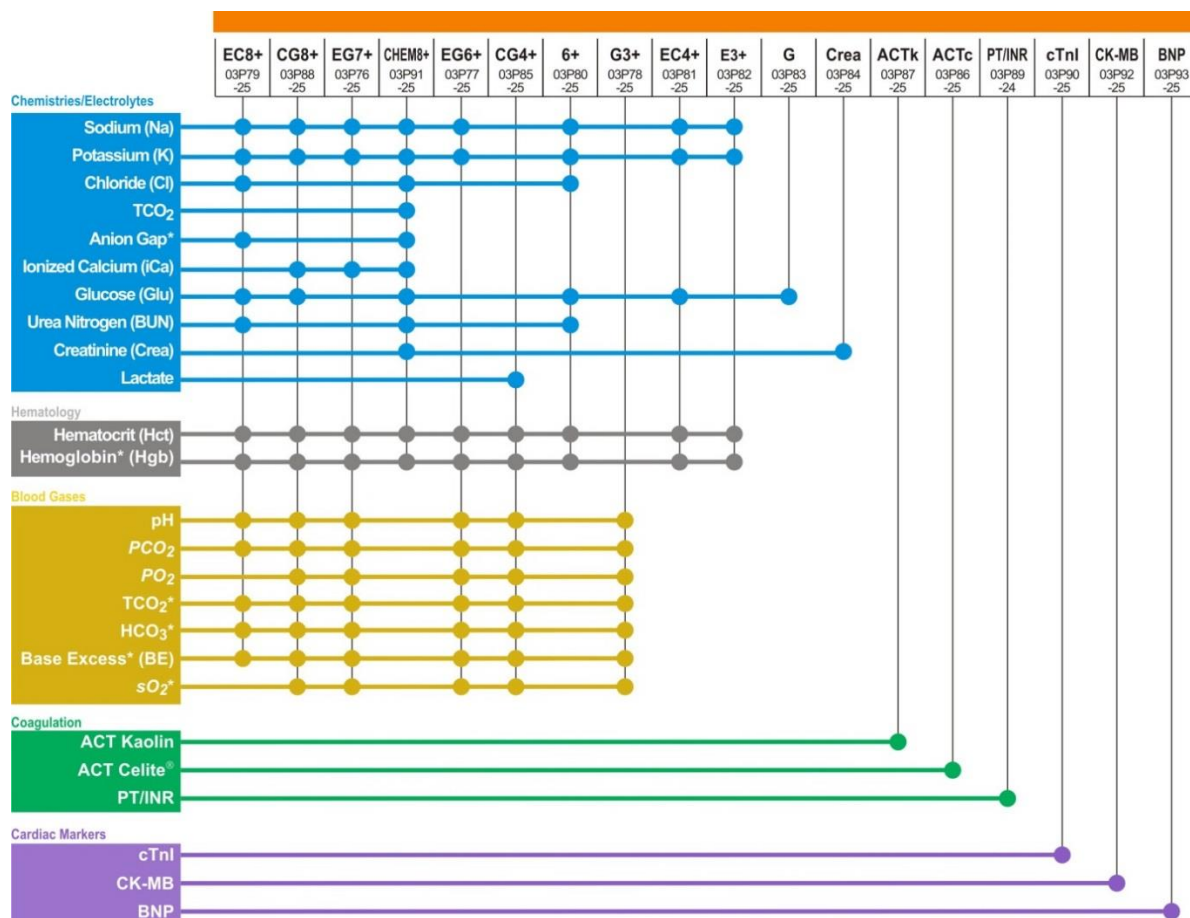
i-STAT® CARTRIDGE TECHNOLOGY

FEATURES	BENEFITS
Small patient sample: Patient sample volume requirements for <i>i-STAT</i> Cartridges range from 17 µL – 95 µL.	May reduce current patient sample volume requirements helping to achieve blood conservation initiatives
Whole blood sample use. Results in minutes. Arterial, venous or capillary samples may be used.	With no sample preparation required, the use of fresh whole blood samples helps ensure a timely and accurate assessment of the patient's condition in just minutes at the patient's bedside.
Automated, internal quality control: Prior to running a test, each cartridge initiates a series of preset quality control diagnostics, from monitoring the quality of the sample to validating the reagent.	Instills confidence in the integrity and accuracy of every test result for the clinician and the laboratory.
Single use, cartridge based, disposable test platform: Test cartridges are used only once, eliminating the need for routine maintenance and calibration procedures.	Minimizes cost and downtime associated with routine maintenance and quality control. Reduces risk of errors from product reagent and sensor degradation commonly associated with <i>multi-use, pack based systems</i> .
Expansive point of care test menu: An extensive menu of tests used by clinicians to make critical patient decisions including blood gases, chemistries and electrolytes, lactate, hematology, cardiac markers and coagulation testing.	Enables the hospital to reduce time, effort and costs associated with managing multiple point of care systems by consolidating critical point of care testing onto a single platform.

For Intended Use information, see the intended use page.

CHOOSE TRANSFORMATION

Abbott



* Calculated

LACTATE – INTENDED USE

The test for lactate, as part of the i-STAT System, is intended for use in the

in vitro quantification of lactate in arterial, venous, or capillary whole blood. The i-STAT lactate test is useful for (1) the diagnosis and treatment of lactic acidosis in conjunction with measurements of blood acid/base status, (2) monitoring tissue hypoxia and strenuous physical exertion, and (3) diagnosis of hyperlactatemia.

COAGULATION – INTENDED USE

ACT Kaolin

The i-STAT Kaolin Activated Clotting Time (KaolinACT) test is an in vitro diagnostic test that uses fresh, whole blood, and is used to monitor high-dose heparin anticoagulation frequently associated with cardiovascular surgery.

ACT Celite®

The i-STAT Celite Activated Clotting Time (CeliteACT) test is an in vitro diagnostic test that uses fresh, whole blood, and is useful for monitoring patients receiving heparin for treatment of pulmonary

CHOOSE TRANSFORMATION

Abbott



embolism or venous thrombosis, and for monitoring anticoagulation therapy in patients undergoing medical procedures such as catheterization, cardiac surgery, surgery, organ transplant, and dialysis.

PT/INR

The i-STAT PT, a prothrombin time test, is useful for monitoring patients receiving oral anticoagulation therapy such as Coumadin® or warfarin.

Coumadin is a registered trademark of Bristol-Myers Squibb.

CARDIAC MARKERS – INTENDED USE

cTnI

The i-STAT cardiac troponin I (cTnI) test is an in vitro diagnostic test for the quantitative measurement of cardiac troponin I (cTnI) in whole blood or plasma. Measurements of cardiac troponin I are used in the diagnosis and treatment of myocardial infarction and as an aid in the risk stratification of patients with acute coronary syndromes with respect to their relative risk of mortality.

CK-MB

The i-STAT CK-MB test is an in vitro diagnostic test for the quantitative measurement of creatine kinase MB mass in whole blood or plasma samples. CK-MB measurements can be used as an aid in the diagnosis and treatment of myocardial infarction (MI).

BNP

The i-STAT BNP test is an in vitro diagnostic test for the quantitative measurement of B-type natriuretic peptide (BNP) in whole blood or plasma samples using EDTA as the anticoagulant. BNP measurements can be used as an aid in the diagnosis and assessment of the severity of congestive heart failure.

From Eye to Insight



No QU-0105596-A

Date 3/3/2020

Valid Until 5/2/2020

UNIFORMED SVCS UNIV

3901 Jones Bridge Rd

Bethesda

Maryland

USA

20814

Dr. David Burmeister

david.burmeister@usuhs.edu

(301) 295-0742

Sales Contact

David White

Phone: 240-499-4009

David.White@leica-microsystems.com

Customer Care Contact

Ms Andrea Lieberman

Phone: 847-405-8162

Fax: 847-236-3009

Andrea.Lieberman@leica-microsystems.com

QUOTATION

DM2500 LED for transmitted light and fluorescence

[See Online](#)

DM2500 for transmitted light and fluorescence
Ergonomic system microscope Leica DM2500 LED with powerful LED transmitted light illumination delivers excellent optical performance for reliable results.

Extremely versatile microscope system for bright field and fluorescence, can be optionally equipped for dark field, phase contrast, polarization contrast, and DIC to suit the needs of modern laboratories. The extremely bright LED light source offers abundant light for applications like DIC that benefit from a substantial illumination.

The microscope configuration includes already the necessary fluorescence outfit like fluorescence illuminator, filter cubes (with Zero-Pixel-Shift for distinct multicolor experiments), and a fluorescence light source.

The ergonomic features like height adjustable focus knobs, symmetrical operation of focus and coaxial drive, optional ergotubes and a wide range of ergonomic accessories help to ensure fatigue-free work at the microscope.

Choice between 6- and 7-fold objective nosepiece offers plenty of positions for different objectives to feature efficient work. The reliable 2- or the optional 3step focusing mechanism allows adaptation of the focusing to the properties of the specimen



- Leica DM2500 LED for Research Applications
- 2-step focussing (coarse/fine), torque adjustment, adjustable focus stop
- 7-fold nosepiece
- Rotating stage, two slides, for DM2000/2500/3000
- Slide holder for rotating stage, 2 slides
- With Object clamp for oil immersion
- XY-stage control standard, left/right
- Rubber focus knobs
- Without filter magazine
- Basic docu tube BDT, mech., 19 CIP
- Tube top (for 1 camera)
- Imaging module 0:100 and 100:0 + 0.7x C-mount
- Transmitted light brightfield (BF)
- Pol contrast (Polarizer, analyser, lambda plate)
- Condenser achr.-apl. (P) with switchable condenser top and aperture diaphragm
- With diffuser for low magnification
- Pair of eyepiece HC PLAN s 10x/22 Br. M
- Filter systems for standard fluorescence applications
- Warranty extension
- Training
- Installation

Microscope Platform

#	Items	Quantity	List Price	Net Price
10	Leica DM2500 LED stand 11888856	1	1,642.00	1,642.00
	Leica DM2500 LED stand for Biology & Medicine, with LED transmitted light illumination with LED lamp housing for constant color temperature, with height-adjustable focus knobs, coaxial coarse-fine focusing with 25 mm z-travel, with adjustable height stop, with integrated stage bracket and condenser holder with centering and height adjustment (with right-and left-hand operation) and clamping screw for condenser. Supply voltage 100-240 V AC, frequency 50/60 Hz			
20	Focusing drive 2-step 11888143	1	684.00	684.00
	Focusing drive 2-step DM2000-3000 for coarse and fine focussing and adjustable focus stop and focus torque adjustment, including focus knobs coarse			
30	Rev. nosepiece 7-fold for DM2000/2500 11888141	1	726.00	726.00
	Objective nosepiece for DM2000/DM2500 for 7 objectives with M25 thread			

#	Items	Quantity	List Price	Net Price
40	Rubber focus knobs for DM2000/2500/3000 11888137 Set of focus knobs fine with rubber surface for DM2000-3000.	1	48.00	48.00
Section Net Subtotal			USD 3,100.00	

Transmitted Light Illumination

#	Items	Quantity	List Price	Net Price
50	Condenser achr.-apl. A 0.9 (P), CC 11501183 Condenser Achr.apl. A 0.9 (P) with switchable condenser head, with color coding for fast and easy adjustment of the aperture diaphragm, for brightfield and polarisation (qualitative), optional equipment for darkfield and phase contrast available, with slot for sliders	1	716.00	716.00
60	Condenser lens CL Pol 11501060 Condenser lens CL, suitable for polarisation, for DM1000/DM2000/DM3000	1	42.00	42.00
70	Diffuser for low magnification 11505219 Diffuser for low magnification (for the condenser top of condensers achr. apl. with switchable top lens). For use with 1.25x - 5x objectives to boost the image quality in particular for H. E. stained samples. The diffuser will be automatically switched into the light path with the magnifications below 10x when the condenser top is moved	1	41.00	41.00
80	Polarizer in mount, 32mm 11505087 Polarizer in mount, 32mm, for interference contrast, polarization contrast and quantitative polarization. Polarizer in holder, diameter 32 mm, for insertion into the filterholder without protective filter.	1	430.00	430.00
90	Analyzer L ICT/P 11555045 Analyser IC/P, non rotatable, for DMLB/DMLP (TL)	1	369.00	369.00
100	Filterholder L f.2 filter 32mm condensor 11505085 Filter holder for max. two filters in mount, 32 mm, under condenser DM1000/DM2000/	1	140.00	140.00

#	Items	Quantity	List Price	Net Price
	DM3000/DM LB/LP/LM			
110	Lambda plate in holder 11513908	1	107.00	107.00
120	Ground plate w/o filter DM2500/DM2700 11888145	1	53.00	53.00
	Stand ground for Leica DM2500 / DM2700 without filtermagazine			
130	Lamp housing LH113 LED 11504199	1	354.00	354.00
	Lamp housing LH113 LED Exchangeable LED Lamp housing with constant color temperature at 4500 K.			
Section Net Subtotal			USD 2,252.00	

Incident Light Fluorescence

#	Items	Quantity	List Price	Net Price
	LED3 11504254	1	6,500.00	6,500.00
140	LED3 is a mercury-free, bright, and versatile solid-state light source offering white light in the 390-680nm range and is well suited for a range of fluorescence microscopy and stereo microscopy applications. LED3 is practically maintenance-free and offers better output stability and longer life time of the lamp than traditional metal-halide lamps. LED3 can be triggered to synchronize illumination with camera exposure and minimize photobleaching. The LED3 Bundle contains: - LED 3 light source - 3mm Liquid-Light-Guide - 24V DC 220W Power Supply - 2mm Hex Allen Wrench - 1x BNC-to-SMB Cable - 1x Adapter plug BNC-to-SMB			
	Fluo Illuminator LRF 4/22 11505235	1	3,416.00	3,416.00
150	Fluorescence illuminator LRF 4/22 for incident fluorescence for DM2000, DM2500, and DM3000, up to eyepiece field of view 22, with 5-position filter cube turret for cubes size "k", cubes are easily exchangeable, with centerable aperture and field diaphragms, with three switchable neutral filters N2, N4 and N16 for intensity reduction, and shutter			

#	Items	Quantity	List Price	Net Price
160	DAPI 390 Filter cube, size K 11533332	1	1,396.00	1,396.00
	DAPI 390 Filter cube, size K Excitation: 395/25 Dichoric: 425 Emission: 460/50 Improved performance with 390nm LEDs			
170	Filter system GFP ET, k 11504164	1	1,474.00	1,474.00
	Filter system GFP ET, size K Excitation: 470/40 Dichroic: 495 Emission: 525/50			
180	Filter system Y3 ET, k 11504169	1	1,474.00	1,474.00
	Filter system Y3 ET, size K Excitation: 545/25 Dichroic: 565 Emission: 605/70			
190	Filter system Y5 ET, k 11504171	1	1,474.00	1,474.00
	Filter System Y5 ET, size K Excitation: 620/60 Dichroic: 660 Emission: 700/75			
Section Net Subtotal			USD 15,734.00	

Microscope Stage				
#	Items	Quantity	List Price	Net Price
200	Object clamp for oil immersion 11505218	1	24.00	24.00
210	XY-stage control standard 11888153	1	84.00	84.00
	X/Y stage control standard for ergostages DM1000/DM2000/DM2500/DM3000 with removable rubber covers			
220	Rotating stage for DM2000/2500/3000 11888188	1	588.00	588.00

#	Items	Quantity	List Price	Net Price
	Rotatable stage for DM1000-DM3000 with right hand operation x/y control, 2 slides option, travel range 76x52mm, with ceramic stage plate, rotatable 110°			
230	Slide holder f. rotating stage, 2 slides 11505242	1	95.00	95.00
	Slide holder for rotating stage DM1000/DM2000/DM2500/DM3000, for two standard slides or one double size slide, easy operation, one hand slide exchange			
Section Net Subtotal			USD 791.00	

Tube and Eyepieces				
#	Items	Quantity	List Price	Net Price
240	Eyepiece HC PLAN s 10x/22 Br. M 11507820	2	278.00	556.00
	Eyepiece HC PLAN s 10x/22 Br. M Eyepieces with 10x magnification and 22mm field of view. Ideal for fatigue-proof screening. Useable with or without glasses. Dioptric adjustment. A reticule can be added.			
250	Basic docu tube BDT, mech., 19 CIP 11505296	1	1,522.00	1,522.00
	Tube BDT 25+V100/50/0, mech. Mechanical documentation tube, with fixed viewing angle 30°, field of view 25, variable beam splitters, 3 beam splitter positions: 100% eyepieces, 50% eyepieces: 50% documentation port 100% documentation port and 19 mm CIP (Camera Imaging Port/ documentation port for full sCMOS chip support)			
260	Tube adapter incl. 1 docu. port 11505161	1	333.00	333.00
	Tube adapter for mounting on documentation tubes BDT (11505146) or MBDT (11505145), with port for 1 documentation device			
270	Imaging module 100/0,0/100 + 0,7xC-mount 11505202	1	1,094.00	1,094.00
	Imaging module for camera adaption on binocular tubes (placed between the stand and the tube), switchable beam splitting: 100%:0%, 0%:100% with integrated and centrable C-mount (0.7x). Port to back (rotatable to side position possible)			
Section Net Subtotal			USD 3,505.00	

Accessories				
#	Items	Quantity	List Price	Net Price
280	Dust cover DML/2000/2500/3000 Fluo/Photo 11501074	1	76.00	76.00
	Dust cover for DM2000/DM2500/DM3000/DM LB with fluorescence or photography / TV			
Section Net Subtotal				USD 76.00

Objectives				
#	Items	Quantity	List Price	Net Price
290	Obj. HI PLAN 4x/0.10 11506226	1	121.00	121.00
	Objective HI PLAN 4x/0.10 Free working distance: 18.0 mm For use with and without Cover Glass			
300	Obj. HC PL FLUOTAR 10x/0.32 11506521	1	1,296.00	1,296.00
	Objective HC PL FLUOTAR 10x/0.32 Semiapochromatic corrected Objective, dry.			
310	Obj. HC PL FLUOTAR 20x/0.55 11506519	1	1,508.00	1,508.00
	Objective HC PL FLUOTAR 20x/0.55 Semiapochromatic corrected objective			
320	Obj. HC PL FLUOTAR 40x/0.80 11506382	1	1,855.00	1,855.00
	Objective HC PL FLUOTAR 40x/0.80 Semiapochromatic corrected objective, dry.			
330	Obj. HC PL FLUOTAR 100x/1.32 OIL 11506525	1	3,522.00	3,522.00
	Objective HC PL FLUOTAR 100x/1.32 OIL Semiapochromatic corrected objective with high numerical aperture and oil immersion.			
340	Type F Immersion liquid, ISO 8036 11513859	1	42.00	42.00
	Type F Immersion liquid, ISO 8036, 10 ml, very low autofluorescence, highly recommended			

#	Items	Quantity	List Price	Net Price
	for Fluorescence applications and all APO objectives			
Section Net Subtotal			USD 8,344.00	

Documentation				
#	Items	Quantity	List Price	Net Price
350	K5 Microscope Camera 11547112 The Leica K5 - small but effective: Despite small-size dimensions of roughly 65 x 65 x 65 mm ³ , the new Leica k5 passive cooled sCMOS camera system provides high quantum efficiency with low readout noise making it suitable for countless applications Main Features: - Resolution: 2048 x 2048 pixels - Pixel size: 6.5µm x 6.5µm - Superior quantum efficiency up to 80% - 21 400 : 1 dynamic range	1	6,350.00	6,350.00
360	HC C-mount adapter 1x for sCMOS 11541551 1x HC C-mount for high performance sCMOS cameras with a sensor diagonal of 18-22mm	1	456.00	456.00
370	Leica DMC4500 Digital Camera & SW Kit 12730517 Leica DMC4500 digital microscope camera with sw kit - USB3 connection - 5Mpixel resolution - 2/3" CCD sensor - Pixel size 3.4 µm x 3.4 µm - Color filter RGB (Bayer) - Color depth 3x12 bits - Exposure time 1msec - 600sec - A/D converter 14 bit - Dynamic range >59dB - Fast live image 1280x960pixel with up to. 18 frames per sec (depending on the PC performance and exposure time) - Gain 1x - 10x - 25MHz/50MHz pixel clock, - Supported operating systems Win7, Win8 and Win10 Camera kit contains: Leica LAS X Software for PC, Leica LAS application suite for PC, USB cable 2.5m with screw-lock connectors, PCI-express card with 2 USB3.0 (screw-lock) Recommended c-mount adapters: Stereo Microscope: 0.63x Compound Microscope: 0.70x No: 12730517	1	5,595.00	5,595.00
Section Net Subtotal			USD 12,401.00	

Service Contract				
#	Items	Quantity	List Price	Net Price
380	1 Day CM Application Training(Image/Dig) 9I_CM_APPLIC1 Introduction to the LAS X software user interface • Data handling and management • Microscope control and camera settings • Single frame image acquisition • Advanced image acquisition workflows (e.g. XY stitching, extended depth of field imaging, XYZ imaging) if applicable • Image annotation • 2D and 3D measurements (if applicable) • Advanced image analysis configurations (e.g. image analysis, phase analysis, grain sizing, etc.) • Configuring and saving user settings	1	1,500.00	1,500.00
390	Service Installation 9I_CM_CLASS_D	1	750.00	750.00
400	Warranty Extension 9WE_CM_CLASS_D Warranty Extension Coverage: -Unless otherwise provided by Leica in writing, Leica warrants for the earlier of 13 months from delivery, or 12 months from date of completion of assembly and installation by Leica consistent with its Leica Microsystems Warranty Policy (available at https://downloads.leica-microsystems.com/Other/Certificates/Leica_US_Warranty_Policy_April_21_2015.pdf) ("Standard Warranty"). Extended warranty coverage starts at the end of the Standard Warranty and can be extended up to 5 years, so long as the instrument remains eligible and warranty coverage is continuous. Included in the extended warranty coverage: -,, All the benefits of the Standard Warranty, including: - Warranty service visits for qualified issues by Leica Microsystems trained and certified field service engineer. - Warranty replacement for service parts, components, Leica-branded Cameras, or modules necessary for repairs excluding consumables and third-party parts. - Unlimited firmware updates and software revisions, when applicable. However, Windows upgrades and third-party software are not included. - Unlimited access to expert Applications and Technology Support Center (M-F 8am-5pm EST). o To submit a request for service, please visit: https://www.leica-microsystems.com/service/ and click "CONTACT US" *,,,Select Inquiry Type: Service, Inquiry Subtype: Technical Support/Repair, and complete the request form. o,, Repairs requests may also be submitted by calling 866-830-0735 Option 2, Monday-Friday 8am-5pm CST.	1	1,999.00	1,999.00

Section Net Subtotal		USD 4,249.00
Quotation Totals		
Subtotal		USD 50,452.00
New Investigator Discount		(13.00%) -6,558.76
Freight & Handling		1,029.00
Grand Total Excluding Taxes		USD 44,922.24

Total open market list price 50,452.00

Total overall discount 13.00%

Terms and Conditions

Currency: USD

Payment Terms: 30 days from date of

Shipping Terms: Ship Point PREPAY & ADD

Lead Time: 30 lbl.workingdays

Valid Until: 5/2/2020

Sales Contact

David White

Phone: 240-499-4009

David.White@leica-microsystems.com

Customer Care Contact

Ms Andrea Lieberman

Phone: 847-405-8162

Fax: 847-236-3009

Andrea.Lieberman@leica-microsystems.com

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Leica's General Terms and Conditions of Sale, available at:

<https://www.e-leica.com/S.nsf/U/tncus>

Exclusively apply to this order unless superseded by the contract referenced above. Any other terms or conditions are null and void.

This Quotation is Acknowledged and Agreed:

Signature of Authorization Buyer Representative:		Date:	
Print Name:		Title:	



MICROSYSTEMS



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Leica Microsystems Inc

1700 Leider Lane

Buffalo Grove, IL 60089

Leica Biosystems and Leica Microsystems are part of Leica Microsystems Inc.

Phone:

800-526-0355

Fax:

847-236-3009

Shopping Cart

 LIVE CHAT  EMAIL CART  PRINT

PRODUCT INFORMATION	UNIT PRICE	QUANTITY	AVAILABILITY	SUBTOTAL
 InnoCal NIST-Traceable Calibration; Thermocouple Meter (Meter) UX-17000-10	\$150.70 USD / EACH	7	Usually Ships in 9 Days	\$1,054.90 USD
Add Accessories for UX-17000-10				
 Digi-Sense TC9100 Benchtop Temperature Controller for Thermocouples; 115 VAC UX-89800-11	\$807.50 USD / EACH	6	In Stock	\$4,845.00 USD You Saved \$855.00 USD
Add Innocal Calibration For UX-89800-11				
Add Accessories for UX-89800-11				

Item Total:	\$5,899.90 USD
Estimated Shipping:	\$178.74 USD
Estimated Tax:	\$10.73 USD
Tariff Surcharge: 	\$142.50 USD
You Saved:	\$855.00 USD
Estimated Total:	\$6,231.87 USD

Sales Quotation

*Quote Nbr	Creation Date	Due Date	Page
0057-4425-63	02/26/2020		1 of 1
Payment Terms		Delivery Terms	
NET 30 DAYS		DEST	
Valid To		Prepared By	
06/25/2020		MELCH, MICHAEL	
Customer Reference		Sales Representative	
DAVID BURMEISTER/X4R/022620		MICHAEL MELCH	
To place an order	Ph: 800-766-7000	Fx: 800-926-1166	
Submitted To:		Customer Account:	
DAVID BURMEISTER 301-295-		USUHS ATTN PO _____ 4301 JONES BRIDGE RD BETHESDA MD 20814-4799	



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FISHER SCIENTIFIC COMPANY LLC
4500 TURNBERRY DRIVE
HANOVER PARK IL 60133-5491

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Nbr	Qty	UN	Catalog Number	Description	Unit Price	Extended Price
1	1	EA	75 016 052	SRVLX4R PRO-MD, 120V TX-1000CC	12,899.17	12,899.17
				Thermo Scientific Sorvall X4R Pro-MD, 120V TX-1000 Cell Culture Package		
				Vendor Catalog # 75016052		
				This item is being sold as 1 per each		
				GSA# GS07F161BA		
				=====		
				Extended warranty available for purchase below:		
				13 100 736 EXT WTY + PM GP CENT CW SPDVAC \$1312.00		
				13 100 706 GROUP 2-D LAB EQUIPMENT INSTAL \$394.00		
				13 100 732 EXT WARRANTY GP CENT CW SPDVAC \$956.00		
				=====		



MERCHANDISE TOTAL

12,899.17

NOTES:

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<http://survey.medallia.com/fishersci>

Sales Quotation

*Quote Nbr	Creation Date	Due Date	Page
0058-4451-51	02/27/2020		1 of 1
Payment Terms		Delivery Terms	
NET 30 DAYS		DEST	
Valid To		Prepared By	
06/26/2020		MELCH, MICHAEL	
Customer Reference		Sales Representative	
DAVID BURMEISTER/5427R/022720		MICHAEL MELCH	
To place an order	Ph: 800-766-7000	Fx: 800-926-1166	
Submitted To:		Customer Account:	
DAVID BURMEISTER 301-295-		USUHS ATTN PO _____ 4301 JONES BRIDGE RD BETHESDA MD 20814-4799	



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Nbr	Qty	UN	Catalog Number	Description	Unit Price	Extended Price
1	1	EA	05 100 155	5427R,24X2ML SB,QL-AT RTR,120V	7,485.86	7,485.86



Centrifuge, Sample Handling; Eppendorf; For high-end research;
Includes Aerosol-tight QuickLock rotor S-24-11-AT; Quiet; Soft-touch
lid closure; Swing-bucket rotor; 16220rpm; wt.: 30 kg; 24x1.5/2mL SB
AT-QL rotor; 120V/50-60Hz
Vendor Catalog # 022620703
This item is being sold as 1 per each
GSA# GS07F161BA

MERCHANDISE TOTAL

7,485.86

NOTES:

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Tell us about your recent customer service experience by completing a short survey. This should take no longer than three minutes. Enter the link into your browser and enter the passcode: USA-PGH-CS2

<http://survey.medallia.com/fishersci>

Facilities, Equipment and other Resources

Laboratory:

The PI has access to shared facilities at Uniformed Services University (USU) and Armed Forces Radiobiology Research Institute (AFRRI) as well as dedicated lab space within AFRRI. The Armed Forces Radiobiology Research Institute (AFRRI) is a tri-service laboratory located on the Walter Reed National Military Medical Center campus in Bethesda, MD that conducts biomedical research in the field of radiobiology for the U.S. Department of Defense. AFRRI's core mission is to research all aspects of prevention, assessment and treatment of radiological injuries that are applicable to military and civilian communities. The Institute collaborates with other federal, civilian and academic institutions. AFRRI is comprised of a main research facility, an animal facility, and a radiation facility supported by a central computer facility, an electronic and hardware shop, a graphics department, and a statistician.

AFRRI laboratory space has ample equipment to serve for molecular laboratory analyses.

Laboratory space within AFRRI has standard laboratory equipment such as bench top micro centrifuges, electronic balances, water baths, warming ovens, pH meters, tissue homogenizers and sonicators. The lab also has multiple -80°C freezers (including one dedicated to the PI), liquid nitrogen storage tanks, standard refrigerators and freezers, shakers and glassware for protein expression, equipment for electrophoresis of DNA and proteins and Western blotting (iBlot, Invitrogen), and transfer systems with appropriate power supplies. Used for the manipulation and analysis of biological samples, the laboratory is equipped with laminar flow hoods, microwaves, HPLC equipment, thermo cyclers, iQ5, Experion, Millipore pure water systems, DNA synthesizers, DNA sequencers and spectrophotometers. Additionally, several PCR machines including a Roche 480 Light Cycler (e.g., for qRT-PCR) and appropriate workstations are available. Additionally, the laboratory has several 37°C CO₂ tissue culture incubators and biological safety cabinets, and refrigerated centrifuges (4°C Thermo, Beckman Coulter), 1 light microscope and 1 phase contrast microscope for cell culture, an ELISA plate washing set-up, an ELISA plate reader (Biotek services), and a microwave.

Other Uniformed Services University (USU) common core equipment available for use: oligonucleotide and peptide synthesis, sequencing, mass spectroscopy, electron microscopy, laser scanning confocal microscopy, flow cytometry BD LSRs, cell sorting equipment, protein sequencer, Luminex systems, mass spectrometer, HPLC systems, array detector, IEF Cell, fluorescence microscope with cooled CCD digital camera, Coulter cell counter, Sorvall RC-5B centrifuges, Beckman L7-65 ultracentrifuges, scintillation counters, UV/Vis spectrometer, Sequence Detection System (for real-time PCR), LKB gamma counter, roller bottle incubator, etc. Equipment and computer analysis programs for behavior studies and magnetic resonance imaging studies are available through the CNRM translational imaging core and pre-clinical studies core.

Shared Resources in the building:

BIC Resources

The USU Biomedical Instrumentation Center (BIC) is located on-site on the ground floor of Building B, easily accessible from the adjacent, attached Building A. It provides a wide variety of services that include oligonucleotide and peptide synthesis, sequencing, mass spectroscopy, electron microscopy, laser scanning confocal microscopy, as well as maintenance of a flow cytometry and cell sorting facility. The BIC recently acquired a new 5-laser Cytex Aurora spectral analyser, significantly expanding our ability to phenotype cells using multiple labeled marker proteins. A BSL-3 facility is available for interdepartmental use and is located in a connected building B. Other specific available equipment includes: protein sequencer, Luminex systems, mass spectrometer, HPLC systems, array detector, IEF Cell, fluorescence microscope with cooled CCD digital camera, Coulter cell counter, Sorvall RC-5B centrifuges, Beckman L7-65 ultracentrifuges, scintillation counters, UV/Vis spectrometer, Sequence Detection System (for real-time PCR), LKB gamma counter, roller bottle incubator,

etc. A CTL Immunospot S6 Ultimate Image analyzer is in an adjacent, connected building, and it is available to USU researchers for ELISPOT and Fluorospot assays.

Bioinformatics Core:

Isilon storage area network cluster (NL400, and X410; 864 TB of solid state and 2.5 TB of hard disk; EMC Corporation, Hopkinton, MA).

Custom designed high performance compute cluster (80 nodes @ dual 12 core 2.5 Ghz, 128 GB each; capable of running 3,840 concurrent processes with 10,240 GB total RAM; Dell, Round Rock, TX)

Spectra Logic Tape Library and Black Pearl Appliance (Spectra Logic Corporation, Boulder, CO)

High performance switches (Cisco Systems, Inc., San Jose, CA)

CHIRP Core Resources

The Collaborative Health Initiative Research Program (CHIRP) at USU is a precision-medicine based collaborative effort between the NHLBI and Department of Defense. Their mission is to identify and characterize genomic alterations in patient specimens in order to enable precision medicine, such as characterizing the molecular etiology of disease, predicting disease risk and outcome, and discovering molecular subtypes of disease. CHIRP applies and develops computational methods for analyzing high throughput sequencing from the CHIRP sequencing core or from CHIRP-affiliated investigators. Bioinformatics Core analysis spans primary level data analysis to biological hypothesis evaluation and exploration. Many Core resources are provided at no cost to individual projects of USU investigators. The CHIRP Core Facilities provide state-of-the-art resources and expertise supporting genomics and epigenomics research requiring next generation sequencing technologies (exome sequencing, RNA-Seq, ChIP-Seq, etc.) and bioinformatics analysis. The resources available in the ~3000 sq ft Laboratory Core include the instruments, personnel and reagents for the biorepository, whole genome sequencing, other next generation sequencing technologies (exome sequencing, RNA-Seq, ChIP-Seq, etc.), digital/RT-PCR platforms for DNA and RNA analysis as well as platforms for proteomic analysis including mass spectrometers and protein microarray printers and laser scanners.

CHIRP Core Equipment

Laboratory Core

Genomics

HiSeq X Ten Next Generation Sequencers (Illumina, San Diego, CA)

HiSeq 3000 Sequencer (Illumina, San Diego, CA)

NextSeq 500 Sequencer (Illumina, San Diego, CA)

Neoprep Library Preparation System (Illumina, San Diego, CA)

cBot Cluster Generation Systems (Illumina, San Diego, CA)

QiaSymphony Automated Sample Preparation System (Qiagen, Germantown, MD)

Hamilton STAR Robotic Liquid Handling Workstations (Hamilton Robotics, Reno, NV)

Covaris LE220 Ultrasonicator (Covaris, Woburn, MA)

Fragment Analyzer (Advanced Analytics, Ankeny, IA)

Light Cycler 480 (Hoffman La-Roche, Basel, Switzerland)

7900 HT Fast Real-Time PCR System (ThermoFisher, Grand Island, NY)

Eight -80° freezers

Two liquid nitrogen storage devices.

GenoLogics Clarity X LIMS System (GenoLogics, Victoria, BC, Canada)

Proteomics

MesoScale® Sector Imager 6000 Multiplexed ELISA platform (MesoScale Discovery, Gaithersburg, MD);

2470 Microarray Printer (Aushon Biosystems, Billerica, MA)

InnoScan 710-IR Infrared Scanner (Innopsys, Carbonne, France)

GenePix 400B Microarray Scanner (Molecular Devices, Sunnyvale, CA)
Typhoon® 9410 (GE Healthcare, Piscataway, NJ).
ChemiDoc Multiplex Imaging System (Bio-rad, Hercules, CA)
ABI Voyager MALDI-TOF (ThermoFisher, Grand Island, NY)
ABI QSTAR LC MS/MS (ThermoFisher, Grand Island, NY)
Agilent 1100 Microflow HPLC (Agilent Technologies, Santa Clara, CA)

Scientific Environment:

Uniformed Services University is located on the grounds of the Walter Reed Bethesda Hospital and is adjacent to the NIH campus. This provides a stimulating scientific environment and allows collaboration with scientists both here and on the NIH campus. The Department of Medicine has an excellent scientific atmosphere, consisting of both clinicians and scientists. It holds weekly informal seminars by each faculty member on his/her own research activities and outside investigators to present their work. USU/AFRRI is also in close proximity of the National Library of Medicine located on the National Institutes of Health campus.

[Check Form for Errors](#)[Save](#)**RESEARCH & RELATED BUDGET - Budget Period 1**

OMB Number: 4040-0001

Expiration Date: 6/30/2016

ORGANIZATIONAL DUNS:**Enter name of Organization:****Budget Type:**☐ Project☒ Subaward/Consortium**Budget Period: 1****Start Date:****End Date:****A. Senior/Key Person**

Prefix	First	Middle	Last	Suffix	Base Salary (\$)	Months			Requested Salary (\$)	Fringe Benefits (\$)	Funds Requested (\$)
						Cal.	Acad.	Sum.			
	Jeffrey		Shupp	MD	185,000.00	0.24			3,700.00	710.00	4,410.00

Project Role:

	Lauren		Moffatt	PhD	126,672.00	1.20			12,667.00	2,432.00	15,099.00
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Project Role:

	Melissa		McLawhorn	RN	96,616.00	1.20			9,662.00	1,855.00	11,517.00
--	---------	--	-----------	----	-----------	------	--	--	----------	----------	-----------

Project Role:**Additional Senior Key Persons:**[Add Attachment](#)[Delete Attachment](#)[View Attachment](#)**Total Funds requested for all Senior Key Persons in the attached file****Total Senior/Key Person**

31,026.00

B. Other Personnel

Number of Personnel	Project Role	Cal.	Months		Requested Salary (\$)	Fringe Benefits (\$)	Funds Requested (\$)
			Acad.	Sum.			
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
1	Fellow	12.00			52,000.00	9,984.00	61,984.00

Total Number Other Personnel**Total Other Personnel**

61,984.00

Total Salary, Wages and Fringe Benefits (A+B)

93,010.00

C. Equipment Description

List items and dollar amount for each item exceeding \$5,000

Equipment item	Funds Requested (\$)
Additional Equipment:	Add Attachment Delete Attachment View Attachment
Total funds requested for all equipment listed in the attached file	
Total Equipment	

D. Travel

	Funds Requested (\$)
1. Domestic Travel Costs (Incl. Canada, Mexico and U.S. Possessions)	
2. Foreign Travel Costs	
Total Travel Cost	

E. Participant/Trainee Support Costs

	Funds Requested (\$)
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other	
Number of Participants/Trainees	Total Participant/Trainee Support Costs

F. Other Direct Costs

		Funds Requested (\$)
1.	Materials and Supplies	
2.	Publication Costs	
3.	Consultant Services	
4.	ADP/Computer Services	
5.	Subawards/Consortium/Contractual Costs	
6.	Equipment or Facility Rental/User Fees	
7.	Alterations and Renovations	
8.	Animals	185,000.00
9.		
10.		
Total Other Direct Costs		185,000.00

G. Direct Costs

		Funds Requested (\$)
Total Direct Costs (A thru F)		278,010.00

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base (\$)	Funds Requested (\$)
Subaward MTDC	30.00	278,810.00	83,403.00
Total Indirect Costs			83,403.00

Cognizant Federal Agency
(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs

		Funds Requested (\$)
Total Direct and Indirect Institutional Costs (G + H)		361,413.00

J. Fee

		Funds Requested (\$)

K. Budget Justification

(Only attach one file.)

Add Attachment

Delete Attachment

View Attachment

RESEARCH & RELATED BUDGET - Cumulative Budget

		Totals (\$)
Section A, Senior/Key Person		31,026.00
Section B, Other Personnel		61,984.00
Total Number Other Personnel	1	
Total Salary, Wages and Fringe Benefits (A+B)		93,010.00
Section C, Equipment		
Section D, Travel		
1. Domestic		
2. Foreign		
Section E, Participant/Trainee Support Costs		
1. Tuition/Fees/Health Insurance		
2. Stipends		
3. Travel		
4. Subsistence		
5. Other		
6. Number of Participants/Trainees		
Section F, Other Direct Costs		185,000.00
1. Materials and Supplies		
2. Publication Costs		
3. Consultant Services		
4. ADP/Computer Services		
5. Subawards/Consortium/Contractual Costs		
6. Equipment or Facility Rental/User Fees		
7. Alterations and Renovations		
8. Other 1	185,000.00	
9. Other 2		
10. Other 3		
Section G, Direct Costs (A thru F)		278,010.00
Section H, Indirect Costs		83,403.00
Section I, Total Direct and Indirect Costs (G + H)		361,413.00
Section J, Fee		

Budget Justification

Prime: PI Burmeister, USUHS

Site: MedStar Health Research Institute (MHRI), Site PI Jeffrey W. Shupp, MD

PERSONNEL

Key personnel

1. Jeffrey W. Shupp, MD (PRINCIPAL INVESTIGATOR- 2% or 0.24 CALENDAR MONTHS EFFORT): Dr. Shupp will be the PI overseeing this project at MHRI and will be responsible for overseeing the performance of the animal models (specifically the surgeries and procedures), as well as the sampling, data collection, and assays for this site. He will guide interpretation of data and translatability to clinical experience. He will provide direction and guidance on site protocols, data analysis, and participate in any subsequent manuscript writing and publication in collaboration with Dr. Burmeister. He will ensure coordination of efforts of his team members and will interface with any relevant collaborators and be responsive to Geneva Foundation or DoD requests for reporting or information.
2. Lauren Moffatt, PhD (Laboratory and Administrative Director- 10% or 1.2 CALENDAR MONTHS EFFORT): Dr. Moffatt will work closely with the PI and study teams under Drs. Shupp and Burmeister to ensure overall study progress and compliance with the study protocol(s) and all institutional, study- and DoD-level compliance processes. She will ensure appropriate resource allocation to ensure study success and will closely oversee laboratory sample processing and assays as well as animal procedures. She will work closely with the nurse, technician, and fellow to troubleshoot animal protocols and procedures, and will oversee data collection, analysis, and interpretation. Additionally, she will assist with interactions with other PIs, and assist with manuscript and report writing.
3. Melissa McLawhorn, RN BSN (Nurse- 10% or 1.2 CALENDAR MONTHS EFFORT): Ms. McLawhorn will be providing oversight and technical management of the critical care for the animal model. She will apply her background as an ICU/Burn/Trauma nurse to monitor anesthesia, drug delivery, resuscitation and ICU-level care of the animals. She will work closely with the technician and surgical fellow as well as the team under Dr. Burmeister, to successfully complete the procedures and protocols and ensure compliance. She will also participate in clinical and point of care data generation and interpretation.

Other Personnel

1. TBD (SURGICAL FELLOW- 100% or 12.0 CALENDAR MONTHS EFFORT): The surgical fellow will work in coordination with the technician, nurse, and Laboratory Director, as well as the study team under Dr. Burmeister, to perform the technical aspects of the animal surgeries/procedures, and will assist with data collection, analysis, and interpretation. The surgical fellow will provide technical guidance as well as clinical expertise to ensure translatability and proper techniques.

Fringe Benefits

MHRI institutional rate of 19.2% fringe benefits on salaries have been applied in the salaries budgeted.

ANIMAL

Animal costs are based on current pricing (2020) available from MedStar Health Research Institute Animal Research Facility staff.

Animal Acquisition: Cost per animal, administrative fees, and transport from the vendor
Estimate ~\$800/animal x 40 animals =

Budget Justification

Prime: PI Burmeister, USUHS

Site: MedStar Health Research Institute (MHRI), Site PI Jeffrey W. Shupp, MD

Animal Husbandry: \$20/animal/day for basic husbandry including health and wellness observations. Also includes any veterinary required interventions, medications, and carcass disposal. We expect ~7 days of facility acclimation prior to acute procedures.

Estimate ~\$520/animal (acclimation time and carcass disposal) x 40 animals =

Animal Procedure/OR use: Covers use of the equipment, drugs, materials (sheets, table covers, gauze, PPE, tubing, etc.), monitoring, etc. available for support in the pre-clinical ICU; ~\$1.50/minute depending on complexity/procedure type and duration. Each estimate includes ~4 hours of setup time for each animal to include gaining access, etc.

48 Hour Animals (n=8) =

24 Hour Animals (n=32) =

Estimate =

Additional non-formulary drugs: \$353/animal x 40 animals =

GRANT TOTAL ANIMAL COSTS:

INDIRECT COSTS

A 30% indirect cost rate is applied to a modified total direct cost base that excludes capital expenditures, equipment, alterations and renovations, patient care costs and the portion of each subcontract in excess of

Biographical Sketch

Provide the following information for each individual included in the Research & Related Senior/Key Person Profile (Expanded) Form.			
NAME MCLAWHORN, MELISSA M.		POSITION TITLE PROGRAM MANAGER	
EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training).			
INSTITUTION AND LOCATION	DEGREE (IF APPLICABLE)	YEAR(S)	FIELD OF STUDY
University of North Carolina, Chapel Hill, NC	BS	2002-2006	Political Science and Psychology
East Carolina University, Greenville, NC	BS	2007-2009	Nursing

RESEARCH AND PROFESSIONAL EXPERIENCE:

Positions and Employment

2005	Research Assistant, Department of Psychology, University of North Carolina, Chapel Hill, NC
2008	Nurse Extern, Pitt County Memorial Hospital; Greenville, NC
2009-2012	Registered Nurse, Baylor University Medical Center; Dallas, TX
2012-2015	Registered Nurse, MedStar Washington Hospital Center, MedSTAR Trauma Unit, Washington, DC
2013-2015	Research Assistant, Firefighters' Burn and Surgical Research Laboratory, MedStar Washington Hospital Center/MedStar Health Research Institute, Washington, DC
2015-	Program Manager, Firefighters' Burn and Surgical Research Laboratory, MedStar Washington Hospital Center/MedStar Health Research Institute, Washington, DC

Other Experience and Professional Memberships

Member, Psi Chi – Psychology Honor Society

Member, Sigma Theta Tau – Nursing Honor Society

Member, American Burn Association (ABA) (2015-)

Member, ABA Committee on Elderly Care (2017-)

RESEARCH AND PROFESSIONAL EXPERIENCE (CONTINUED). PAGE LIMITATIONS APPLY. DO NOT EXCEED 5 PAGES FOR THE ENTIRE BIOGRAPHICAL SKETCH PER INDIVIDUAL.

RECENT PUBLICATIONS

1: Stiles CE, McLawhorn MM, Nosanov LB, Paul JL, Shupp JW. Burn Injuries in Patients with Paralysis: A National Perspective on Injury Patterns and Outcomes. J Burn Care Res. 2017 Dec 27;39(1):15-20. doi: 10.1093/jbcr/irx003. PubMed PMID: 29596679.

2: Walters ES, Curtin K, McLawhorn MM, Lee K, Shupp JW. Follow the Blue Feet: Nurse Implemented Postoperative MOBILITY Program. J Burn Care Res. 2017 Dec 27;39(1):54-59. doi: 10.1093/jbcr/irx001. PubMed PMID: 29596678.

3: Nosanov LB, McLawhorn MM, Hassan L, Travis TE, Tejiram S, Johnson LS, Moffatt LT, Shupp JW. Graft loss: Review of a single burn center's experience and proposal of a graft loss grading scale. J Surg Res. 2017 Aug;216:185-190. doi: 10.1016/j.jss.2017.05.004. Epub 2017 May 8. PubMed PMID: 28807206.

4: Nosanov LB, McLawhorn MM, Vigiola Cruz M, Chen JH, Shupp JW. A National Perspective on ECMO Utilization Use in Patients with Burn Injury. J Burn Care Res. 2017 Dec 27;39(1):10-14. doi: 10.1097/BCR.0000000000000555. PubMed PMID: 28368919.

5: Chung KK, Coates EC, Hickerson WL, Arnold-Ross AL, Caruso DM, Albrecht M, Arnoldo BD, Howard C, Johnson LS, McLawhorn MM, Friedman B, Sprague AM, Mosier MJ, Conrad PF, Smith DJ Jr, Karlinski RA, Aden JK, Mann-Salinas EA, Wolf SE; Randomized controlled Evaluation of high-volume hemofiltration in adult burn patients with Septic shock and acute kidney injury (RESCUE) Investigators. J Burn Care Res. 2018 Oct 23;39(6):1017-1021. doi: 10.1093/jbcr/iry036. PubMed PMID: 29931223.

6: Bravo MC, Tejiram S, McLawhorn MM, Moffatt LT, Orfeo T, Jett-Tilton M, Pusateri AE, Shupp JW, Brummel-Ziedins KE. Utilizing Plasma Composition Data to Help Determine Procoagulant Dynamics in Patients with Thermal Injury: A Computational Assessment. Mil Med. 2019 Mar 1;184(Suppl 1):392-399. doi: 10.1093/milmed/usy397. PubMed PMID: 30901410.

Biographical Sketch

Provide the following information for each individual included in the Research & Related Senior/Key Person Profile (Expanded) Form.

NAME MOFFATT, LAUREN T	POSITION TITLE DIRECTOR, BURN AND SURGICAL RESEARCH LAB		
EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training).			
INSTITUTION AND LOCATION	DEGREE (IF APPLICABLE)	YEAR(S)	FIELD OF STUDY
University of Maryland, College Park, MD	BS	1999-2003	Environmental Science and Policy
Universtiy of Massachusetts, Amherst, MA	PhD	2003-2008	Animal Biotechnology and Biomedical Sciences

RESEARCH AND PROFESSIONAL EXPERIENCE:

Positions and Employment

2000-2003	Research Technician, Entomology/Stream Ecology, University of Maryland, College Park, MD
2001-2002	Educator, Catoctin Wildlife Preserve and Zoo, Thurmont, MD
2002-2003	Veterinary Assistant, Kenilworth Animal Medical Center, Riverdale, MD
2003-2008	Graduate Research Assistant, Department of Veterinary and Animal Sciences, University of Massachusetts, Amherst, MA
2008-2010	Coordinator, Berkshire Environmental Resource Center, Massachusetts College of Liberal Arts, North Adams, MA
2010-2012	Scientist, Firefighters' Burn and Surgical Research Laboratory, MedStar Washington Hospital Center (MWHC), MedStar Health Research Institute (MHRI), Washington, DC
2012-	Director, Firefighters' Burn and Surgical Research Laboratory, MWHC/MHRI, Washington, DC
2015-2019	Instructor, Department of Biochemistry and Molecular and Cellular Biology, Georgetown University School of Medicine, Washington, DC
2019-	Assistant Professor, Department of Biochemistry and Molecular and Cellular Biology, Georgetown University School of Medicine, Washington, DC
2019-	Assistant Professor, Department of Surgery, Georgetown University School of Medicine, Washington, DC

Other Experience and Professional Memberships

- Member, Society of Environmental Toxicology and Chemistry (2003-2009)
- Member, American Burn Association (ABA) (2010-)
 - ABA Research Committee (2014-), Vice Chair (2015-2018), Chair (2018-)
- Member, American Society for Microbiology (2011-)
- Member, Wound Healing Society (WHS) (2011-)
 - WHS Awards Committee (2019-)

RESEARCH AND PROFESSIONAL EXPERIENCE (CONTINUED). PAGE LIMITATIONS APPLY. DO NOT EXCEED 5 PAGES FOR THE ENTIRE BIOGRAPHICAL SKETCH PER INDIVIDUAL.

Member, Surgical Infection Society (2014-)
-SIS Awards Committee (2019-)
Member, Public Responsibility in Medicine and Research (2013-)
Member, Association for Academic Surgery (2014-)
Member, Shock Society (2019-)
Member, Institutional Animal Care and Use Committee (MHRI, 2010-2013)
Chair, Institutional Animal Care and Use Committee (MHRI, 2013-)

Honors

2001-2003 University of Maryland College of Agriculture and Natural Resources Ambassador
2003 University of Maryland College of Agriculture and Natural Resources Commencement
Speaker
2005-2008 University of Massachusetts College of Natural Resources and the Environment, Lotta
Crabtree Fellowship
2007 University of Massachusetts Graduate School Travel Grant
2007 Massachusetts Water Resources Research Center (WRRC) USGS Student Research
Grant
2007 Massachusetts WRRC 4th Annual Meeting, Best Student Poster Award
2011 MedStar Health Research Institute Manager of the Quarter, Spirit of Excellence Award

RECENT PUBLICATIONS (2017-) OUT OF A TOTAL OF 48 TO DATE

- 1: Nisar S, Roberson JL, Carney BC, Alkhalil A, Moffatt LT, Shupp JW. Further Histological and Cellular Characterization of Hidradenitis Suppurativa in 11 Patients. Eplasty. 2019 Dec 3;19:e21. eCollection 2019. PubMed PMID: 31885764; PubMed Central PMCID: PMC6916621.
- 2: Ball RL, Keyloun JW, Brummel-Ziedins K, Orfeo T, Palmieri TL, Johnson LS, Moffatt LT, Pusateri AE, Shupp JW. Burn-Induced Coagulopathies: A Comprehensive Review. Shock. 2019 Nov 19. doi: 10.1097/SHK.0000000000001484. [Epub ahead of print] PubMed PMID: 31804296.
- 3: Carney BC, Dougherty RD, Moffatt LT, Simbulan-Rosenthal CM, Shupp JW, Rosenthal DS. Promoter methylation status in pro-opiomelanocortin (POMC) does not contribute to dyspigmentation in hypertrophic scar. J Burn Care Res. 2019 Sep 21. pii: irz168. doi: 10.1093/jbcr/irz168. [Epub ahead of print] PubMed PMID: 31541238.
- 4: Carney BC, Chen JH, Kent RA, Rummani M, Alkhalil A, Moffatt LT, Rosenthal DS, Shupp JW. Reactive Oxygen Species Scavenging Potential Contributes to Hypertrophic Scar Formation. J Surg Res. 2019 Dec;244:312-323. doi: 10.1016/j.jss.2019.06.006. Epub 2019 Jul 11. PubMed PMID: 31302330.
- 5: Bravo MC, Tejiram S, McLawhorn MM, Moffatt LT, Orfeo T, Jett-Tilton M, Pusateri AE, Shupp JW, Brummel-Ziedins KE. Utilizing Plasma Composition Data to Help Determine Procoagulant Dynamics in Patients with Thermal Injury: A Computational Assessment. Mil Med. 2019 Mar 1;184(Suppl 1):392-399. doi:

10.1093/milmed/usy397. PubMed PMID: 30901410.

6: Prinzeze NJ, Ardanuy JG, Carney BC, Moffatt LT, Shupp JW. Photobiomodulation Elicits a Differential Cytokine Response in a Cultured Analogue of Human Skin. *Eplasty*. 2019 Mar 1;19:e3. eCollection 2019. PubMed PMID: 30858901; PubMed Central PMCID: PMC6404725.

7: Alkhalil A, Carney BC, Travis TE, Muhie S, Miller SA, Ramella-Roman JC, Ghassemi P, Hammamieh R, Jett M, Moffatt LT, Shupp JW. Dyspigmented hypertrophic scars: Beyond skin color. *Pigment Cell Melanoma Res*. 2019 Sep;32(5):643-656. doi: 10.1111/pcmr.12780. Epub 2019 Apr 5. PubMed PMID: 30849202; PubMed Central PMCID: PMC6697599.

8: Vigiola Cruz M, Carney BC, Luker JN, Monger KW, Vazquez JS, Moffatt LT, Johnson LS, Shupp JW. Plasma Ameliorates Endothelial Dysfunction in Burn Injury. *J Surg Res*. 2019 Jan;233:459-466. doi: 10.1016/j.jss.2018.08.027. Epub 2018 Sep 22. PubMed PMID: 30502286.

9: Shupp JW, Brummel-Ziedins KE, Cohen MJ, Freeman K, Hammamieh R, Mudunuri US, Orfeo T, Moffatt LT, Brownstein BH, Mann KG, Jett M, Pusateri AE. Assessment of Coagulation Homeostasis in Blunt, Penetrating, and Thermal Trauma: Guidance for a Multicenter Systems Biology Approach. *Shock*. 2019 Oct;52(1S Suppl 1):84-91. doi: 10.1097/SHK.0000000000001275. PubMed PMID: 30339633; PubMed Central PMCID: PMC6472988.

10: Alkhalil A, Carney BC, Travis TE, Muhie S, Miller SA, Ramella-Roman JC, Ghassemi P, Hammamieh R, Jett M, Moffatt LT, Shupp JW. Key Cell Functions are Modulated by Compression in an Animal Model of Hypertrophic Scar. *Wounds*. 2018 Dec;30(12):353-362. Epub 2018 Sep 30. PubMed PMID: 30304713.

11: Carney BC, Chen JH, Luker JN, Alkhalil A, Jo DY, Travis TE, Moffatt LT, Simbulan-Rosenthal CM, Rosenthal DS, Shupp JW. Pigmentation Diathesis of Hypertrophic Scar: An Examination of Known Signaling Pathways to Elucidate the Molecular Pathophysiology of Injury-Related Dyschromia. *J Burn Care Res*. 2019 Jan 1;40(1):58-71. doi: 10.1093/jbcr/iry045. PubMed PMID: 30189005.

12: Luker JN, Vigiola Cruz M, Carney BC, Day A, Moffatt LT, Johnson LS, Shupp JW. Shedding of the endothelial glycocalyx is quantitatively proportional to burn injury severity. *Ann Burns Fire Disasters*. 2018 Mar 31;31(1):17-22. PubMed PMID: 30174566; PubMed Central PMCID: PMC6116655.

13: Travis TE, Ghassemi P, Prinzeze NJ, Moffatt LT, Carney BC, Alkhalil A, Ramella-Roman JC, Shupp JW. Matrix Metalloproteinases Are Differentially Regulated and Responsive to Compression Therapy in a Red Duroc Model of Hypertrophic Scar. *Eplasty*. 2018 Jan 5;18:e1. eCollection 2018. PubMed PMID: 29375731; PubMed Central PMCID: PMC5765626.

14: Prinzeze NJ, Mann YVL, Feric TG, Currie TR, Carney BC, Moffatt LT, Loew MH, Shupp JW. Heat transfer analysis and resolution quantification of active dynamic thermography through human skin. *Lasers Surg Med*. 2018 Jan 25. doi: 10.1002/lsm.22790. [Epub ahead of print] PubMed PMID: 29369378.

- 15: Chen JH, Nosanov LB, Carney BC, Vigiola Cruz M, Moffatt LT, Shupp JW. Patient and social characteristics contributing to disparities in outcomes after burn injury: application of database research to minority health in the burn population. *Am J Surg*. 2018 Nov;216(5):863-868. doi: 10.1016/j.amjsurg.2018.01.028. Epub 2018 Jan 31. PubMed PMID: 29366485.
- 16: Cruz MV, Luker JN, Carney BC, Brummel-Ziedins KE, Bravo MC, Orfeo T, Chen JH, Moffatt LT, Shupp JW. Reference ranges for rotational thromboelastometry in male Sprague Dawley rats. *Thromb J*. 2017 Dec 28;15:31. doi: 10.1186/s12959-017-0154-0. eCollection 2017. PubMed PMID: 29299031; PubMed Central PMCID: PMC5747092.
- 17: Day A, Alkhalil A, Carney BC, Hoffman HN, Moffatt LT, Shupp JW. Disruption of Biofilms and Neutralization of Bacteria Using Hypochlorous Acid Solution: An In Vivo and In Vitro Evaluation. *Adv Skin Wound Care*. 2017 Dec;30(12):543-551. doi: 10.1097/01.ASW.0000526607.80113.66. PubMed PMID: 29140837.
- 18: Shupp JW, Prior SM, Jo DY, Moffatt LT, Mann KG, Butenas S. Analysis of factor Xla, factor IXa and tissue factor activity in burn patients. *Burns*. 2018 Mar;44(2):436-444. doi: 10.1016/j.burns.2017.08.003. Epub 2017 Oct 9. PubMed PMID: 29032977; PubMed Central PMCID: PMC5844776.
- 19: Nosanov LB, Jo DY, Randad PR, Moffatt LT, Carney BC, Ortiz RT, Shupp JW. Effectiveness of a Glycylcycline Antibiotic for Reducing the Pathogenicity of Superantigen-Producing Methicillin-Resistant *Staphylococcus aureus* in Burn Wounds. *Eplasty*. 2017 Sep 7;17:e27. eCollection 2017. PubMed PMID: 28943993; PubMed Central PMCID: PMC5600145.
- 20: Nosanov LB, McLawhorn MM, Hassan L, Travis TE, Tejiram S, Johnson LS, Moffatt LT, Shupp JW. Graft loss: Review of a single burn center's experience and proposal of a graft loss grading scale. *J Surg Res*. 2017 Aug;216:185-190. doi: 10.1016/j.jss.2017.05.004. Epub 2017 May 8. PubMed PMID: 28807206.
- 21: Alkhalil A, Day A, Monger KW, Zhang J, Carney BC, Hoffman HN, Moffatt LT, Shupp JW. Hydroconductive and silver-impregnated foam dressings: a comparison. *J Wound Care*. 2017 Jul 1;26(Sup7):S15-S22. doi: 10.12968/jowc.2017.26.Sup7.S15. PubMed PMID: 28704172.
- 22: Tejiram S, Johnson LS, Mete M, Desale S, Johnson K, Zhang J, Moffatt LT, Shupp JW. Screening nasal swabs for methicillin resistant *Staphylococcus aureus*: A regional burn center's experience. *Burns*. 2017 Jun;43(4):771-779. doi: 10.1016/j.burns.2017.01.009. Epub 2017 Apr 12. PubMed PMID: 28412131.
- 23: Carney BC, Liu Z, Alkhalil A, Travis TE, Ramella-Roman J, Moffatt LT, Shupp JW. Elastin Is Differentially Regulated by Pressure Therapy in a Porcine Model of Hypertrophic Scar. *J Burn Care Res*. 2017 Jan/Feb;38(1):28-35. doi: 10.1097/BCR.0000000000000413. PubMed PMID: 28009695.

Biographical Sketch

Provide the following information for each individual included in the Research & Related Senior/Key Person Profile (Expanded) Form.

NAME SHUPP, JEFFREY W.	POSITION TITLE DIRECTOR, THE BURN CENTER		
EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training).			
INSTITUTION AND LOCATION	DEGREE (IF APPLICABLE)	YEAR(S)	FIELD OF STUDY
University of Maryland, College Park, MD	BS	1997-2001	Neurobiology and Physiology
Medical College of Virginia, Virginia Commonwealth University, School of Medicine, Richmond, VA	MD	2002-2006	Doctor Of Medicine
MedStar Washington Hospital Center, Surgical Residency, Washington, DC		2006-2014	Surgery
MedStar Washington Hospital Center, Burn Surgery Fellowship, Washington, DC		2009-2011	Burn Surgery, Burn and Surgical Research
RESEARCH AND PROFESSIONAL EXPERIENCE:			
Positions and Employment			
2002-04	Instructor in Gross Anatomy, School of Pharmacy, Medical College of Virginia/VCU, Richmond, VA		
2002-06	Medical Technologist, Lab Services, Department of Pathology, Medical College of Virginia/VCU, Richmond, VA		
2002-10	Scientific Consultant, Walter Reed Army Institute of Research, Div. of Pathology, Washington DC		
2009-12	Director, Firefighters' Burn and Surgical Research Laboratory, MHRI/MWHC, Washington, DC		
2012-	Director, Burn and Surgical Research, MHRI/MWHC, Washington DC		
2010-	Assistant Professor, Biomedical Engineering, Catholic University of America, Washington, DC		
2013-16	Instructor in Surgery, Department of Surgery, Uniformed Services University of the Health Sciences, Bethesda, MD		
2014-	Attending Surgeon, Dept. of Surgery, Burns/Trauma Section, MWHC, Washington, DC		
2014-	Director, The Burn Center, Dept. of Surgery, Burns/Trauma Section, MWHC, Washington, DC		
2015-	Director, Center for Wound Healing, Dept. of Surgery, MWHC, Washington, DC		
2015-	Attending Surgeon, Trauma and Burn Division, Pediatric Surgery, Children's National Medical Center, Washington, DC		
2018-	Associate Professor of Surgery, Georgetown University School of Medicine Washington, DC		
2018-	Associate Professor of Biochemistry, Georgetown University School of Medicine Washington, DC		

RESEARCH AND PROFESSIONAL EXPERIENCE (CONTINUED). PAGE LIMITATIONS APPLY. DO NOT EXCEED 5 PAGES FOR THE ENTIRE BIOGRAPHICAL SKETCH PER INDIVIDUAL.

Other Experience and Professional Memberships

Member of: Society of Experimental Biology and Medicine, American Society of Biochemistry and Molecular Biology, Association of Academic Surgery, American Society for Laser Medicine and Surgery, Shock Society, American Medical Association, American College of Surgeons, American Burn Association (Research Committee 2009-present, Vice Chair 2014-2015, Chair 2015-2018; Committee on Technology 2012; Government Affairs Committee 2017-2020), Wound Healing Society (Program Committee 2019-), Surgical Infection Society (Awards Committee 2017-)

Member, Institutional Review Board, MWHC/MHRI (2012-2018)

Member, Scientific Review Committee, MWHC/MHRI (2012-2018)

Physician Engagement Executive Committee, MWHC

National Rehabilitation Hospital, Physical Medicine and Rehabilitation Residency Review Committee

Peer Reviewer, *Journal of Burn Care and Research*

Peer Reviewer, *Burns*

Peer Reviewer, *Journal of Molecular Biology and Medicine*

Peer Reviewer, *Wound Repair and Regeneration*

Scientific Reviewer, Armed Forces Institute of Regenerative Medicine

Scientific Reviewer, Intramural Grant Programs, USAISR

Honors

2000	American Society of Biochemistry and Molecular Biology Travel Fellowship
2001	Society of Experimental Biology and Medicine, Young Investigator of the Year
2001	Invention of the Year Finalist, University of Maryland, College Park, MD
2003	Medical College of Virginia Research Honors Day Speaker, Richmond, VA
2007	Superior Resident in Transplant Surgery, Washington Hospital Center, Washington, DC
2008	Surgical Intensive Care Resident of the Year, Washington Hospital Center, Washington, DC
2008	Nurses' Choice Physician Collaboration Award, Washington Hospital Center, Washington
2008	Dept. of Surgery Research Competition First Place, Washington Hospital Center, Washington, DC
2009	Research Day First Place Poster Presentation, Washington Hospital Center, Washington, DC
2009	Region #3 Committee on Trauma Oral Presentation—Second Place, University of Maryland Hospital
2010	American Society of Microbiology Post-Doctoral Fellow Travel Award, ICAAC Meeting—Boston, MA
2011	Region #3 Committee on Trauma Oral Presentation—First Place Basic Science, Medical College of Virginia/VCU
2012	Superior Resident in Vascular Surgery, MedStar Washington Hospital Center, Washington, DC
2012	Region #3 Committee on Trauma Oral Presentation—First Place Basic Science, Christiana Hospital, DE
2013	Most Outstanding Resident in Trauma Surgery, MedStar Washington Hospital Center, Washington, DC
2013	Chairman's Leadership Award, MedStar Washington Hospital Center, Washington, DC
2014	American Burn Association Traveling Fellowship Award

RECENT RELEVANT PUBLICATIONS FROM 2017- OUT OF A TOTAL OF 101 TO DATE

1: Johnson LS, Travis TE, Shupp JW. What Is the Value of a Burn Surgery Rotation in Surgical Residency? *Am Surg*. 2019 Dec 1;85(12):1314-1317. PubMed PMID: 31908211.

2: Nisar S, Roberson JL, Carney BC, Alkhalil A, Moffatt LT, Shupp JW. Further Histological and Cellular Characterization of Hidradenitis Suppurativa in 11 Patients. *Eplasty*. 2019 Dec 3;19:e21. eCollection 2019. PubMed PMID: 31885764; PubMed Central PMCID: PMC6916621.

3: Gómez BI, Dubick MA, Schmidt EP, Shupp JW, Burmeister DM. Plasma and Urinary Glycosaminoglycans as Evidence for Endotheliopathy in a Swine Burn Model. *J Surg Res*. 2019 Dec 13;248:28-37. doi: 10.1016/j.jss.2019.11.006. [Epub ahead of print] PubMed PMID: 31841734.

4: Ball RL, Keyloun JW, Brummel-Ziedins K, Orfeo T, Palmieri TL, Johnson LS, Moffatt LT, Pusateri AE, Shupp JW. Burn-Induced Coagulopathies: A Comprehensive Review. *Shock*. 2019 Nov 19. doi: 10.1097/SHK.0000000000001484. [Epub ahead of print] PubMed PMID: 31804296.

5: Nisar S, Roberson JL, Travis TE, Johnson LS, Shupp JW. Extensive hidradenitis suppurativa with dorsal foot involvement: a case report. *J Surg Case Rep*. 2019 Nov 29;2019(11):rjz349. doi: 10.1093/jscr/rjz349. eCollection 2019 Nov. PubMed PMID: 31803468; PubMed Central PMCID: PMC6883906.

6: O'Brien KF, Saardi KM, Johnson LS, Shupp JW, Rodic N, Pasioka HB. Recommendations for Prevention of Drug Re-Exposure in Toxic Epidermal Necrolysis. *J Drugs Dermatol*. 2019 Oct 1;18(10):1049-1052. PubMed PMID: 31603634.

7: Carney BC, Dougherty RD, Moffatt LT, Simbulan-Rosenthal CM, Shupp JW, Rosenthal DS. Promoter methylation status in pro-opiomelanocortin (POMC) does not contribute to dyspigmentation in hypertrophic scar. *J Burn Care Res*. 2019 Sep 21. pii: irz168. doi: 10.1093/jbcr/irz168. [Epub ahead of print] PubMed PMID: 31541238.

8: Carney BC, Chen JH, Kent RA, Rummani M, Alkhalil A, Moffatt LT, Rosenthal DS, Shupp JW. Reactive Oxygen Species Scavenging Potential Contributes to Hypertrophic Scar Formation. *J Surg Res*. 2019 Dec;244:312-323. doi: 10.1016/j.jss.2019.06.006. Epub 2019 Jul 11. PubMed PMID: 31302330.

9: Dyamenahalli K, Garg G, Shupp JW, Kuprys PV, Choudhry MA, Kovacs EJ. Inhalation Injury: Unmet Clinical Needs and Future Research. *J Burn Care Res*. 2019 Aug 14;40(5):570-584. doi: 10.1093/jbcr/irz055. PubMed PMID: 31214710; PubMed Central PMCID: PMC6939826.

10: Bravo MC, Tejiram S, McLawhorn MM, Moffatt LT, Orfeo T, Jett-Tilton M, Pusateri AE, Shupp JW, Brummel-Ziedins KE. Utilizing Plasma Composition Data to Help Determine Procoagulant Dynamics in Patients with Thermal Injury: A Computational Assessment. *Mil Med*. 2019 Mar 1;184(Suppl 1):392-399. doi: 10.1093/milmed/usy397. PubMed PMID: 30901410.

- 11: Kent RA, Shupp J, Fernandez S, Prinzeze N, DeKlotz CMC. Effectiveness of Early Laser Treatment in Surgical Scar Minimization: A Systematic Review and Meta-analysis. *Dermatol Surg.* 2019 Mar 18. doi: 10.1097/DSS.0000000000001887. [Epub ahead of print] PubMed PMID: 30893164.
- 12: Prinzeze NJ, Ardanuy JG, Carney BC, Moffatt LT, Shupp JW. Photobiomodulation Elicits a Differential Cytokine Response in a Cultured Analogue of Human Skin. *Eplasty.* 2019 Mar 1;19:e3. eCollection 2019. PubMed PMID: 30858901; PubMed Central PMCID: PMC6404725.
- 13: Alkhalil A, Carney BC, Travis TE, Muhie S, Miller SA, Ramella-Roman JC, Ghassemi P, Hammamieh R, Jett M, Moffatt LT, Shupp JW. Dyspigmented hypertrophic scars: Beyond skin color. *Pigment Cell Melanoma Res.* 2019 Sep;32(5):643-656. doi: 10.1111/pcmr.12780. Epub 2019 Apr 5. PubMed PMID: 30849202; PubMed Central PMCID: PMC6697599.
- 14: Holmes JH 4th, Molnar JA, Shupp JW, Hickerson WL, King BT, Foster KN, Cairns BA, Carter JE. Demonstration of the safety and effectiveness of the RECELL(®) System combined with split-thickness meshed autografts for the reduction of donor skin to treat mixed-depth burn injuries. *Burns.* 2019 Jun;45(4):772-782. doi: 10.1016/j.burns.2018.11.002. Epub 2018 Dec 19. PubMed PMID: 30578048.
- 15: Vigiola Cruz M, Carney BC, Luker JN, Monger KW, Vazquez JS, Moffatt LT, Johnson LS, Shupp JW. Plasma Ameliorates Endothelial Dysfunction in Burn Injury. *J Surg Res.* 2019 Jan;233:459-466. doi: 10.1016/j.jss.2018.08.027. Epub 2018 Sep 22. PubMed PMID: 30502286.
- 16: Linnstaedt SD, Pan Y, Mauck MC, Sullivan J, Zhou CY, Jung L, Rueckeis CA, Blount JD, Carson MS, Tungate AS, Kurz MC, Hendry PL, Lewandowski C, D'Anza T, Datner E, Bell K, Lechner M, Shupp JW, Cairns BA, McLean SA. Evaluation of the Association Between Genetic Variants in Circadian Rhythm Genes and Posttraumatic Stress Symptoms Identifies a Potential Functional Allele in the Transcription Factor TEF. *Front Psychiatry.* 2018 Nov 15;9:597. doi: 10.3389/fpsy.2018.00597. eCollection 2018. PubMed PMID: 30498461; PubMed Central PMCID: PMC6249322.
- 17: Shupp JW, Brummel-Ziedins KE, Cohen MJ, Freeman K, Hammamieh R, Mudunuri US, Orfeo T, Moffatt LT, Brownstein BH, Mann KG, Jett M, Pusateri AE. Assessment of Coagulation Homeostasis in Blunt, Penetrating, and Thermal Trauma: Guidance for a Multicenter Systems Biology Approach. *Shock.* 2019 Oct;52(1S Suppl 1):84-91. doi: 10.1097/SHK.0000000000001275. PubMed PMID: 30339633; PubMed Central PMCID: PMC6472988.
- 18: Alkhalil A, Carney BC, Travis TE, Muhie S, Miller SA, Ramella-Roman JC, Ghassemi P, Hammamieh R, Jett M, Moffatt LT, Shupp JW. Key Cell Functions are Modulated by Compression in an Animal Model of Hypertrophic Scar. *Wounds.* 2018 Dec;30(12):353-362. Epub 2018 Sep 30. PubMed PMID: 30304713.
- 19: Johnson LS, Jordan MH, Shupp JW. Contemplating a Career in Burn Surgery: Data From the 2016 Burn Physician Survey. *J Burn Care Res.* 2018 Oct 23;39(6):863-868. doi: 10.1093/jbcr/iry047. PubMed PMID: 30202971.

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McLawhorn, MM**ACTIVE**

n/a (Shupp) Inventive Government Solutions, LLC Collection of Lung Ultrasound Images for Algorithm Training and Testing Using a hand-held ultrasound system, coordinator will collect LUS images from adult patients suffering from pulmonary disease (pneumonia, pleural effusion, empyema, pneumothorax) and pediatric patients suffering from pulmonary disease (pneumonia with consolidation). Role: Project Manager	12/01/19 – 06/01/20	1.0 calendar months
BA190086 (Shupp) Department of the Army Identification of mechanisms underlying the effects of plasma inclusive resuscitation in major thermal injury on hemostasis and vascular homeostasis. This prospective observational study aims to characterize the role of FFP in resuscitation of the burn injured patient undergoing shock. Specifically it is meant to determine whether FFP can be implicated in any inflammatory or coagulopathic processes, impacting patient outcomes. Role: Project Manager	09/01/19-09/01/23	2.0 calendar months
n/a (Shupp) Acell A Prospective, Randomized, Controlled Trial Comparing Cytal Wound Matrix 1-Layer to Standard of Care (SOC) in the Management of Diabetic Foot Ulcers (DFUs) This clinical trial aims to evaluate the Cytal Wound Matrix 1-Layer intervention to standard of care intervention in patients presenting with diabetic foot ulcers. Role: Project Manager	07/01/19 – 09/01/20 Per Patient Costs	0.5 calendar months
n/a (Shupp) Kerecis Ltd. Fish Skin Compared to Cadaver Skin as a Temporary Covering for Full Thickness Burns: An early Feasibility Trial To determine, if treatment with Kerecis Omega3 Wound is safe as an alternative to cadaver skin as temporary coverage for debrided full thickness burns prior to closure with split thickness skin grafts. Role: Project Manager	08/01/18 – 08/01/20 Per Patient Costs	0.5 calendar months
n/a (Trankiem) Atox Bio Ltd. Phase 2 Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study To Evaluate The Safety And Efficacy Of Reltecimod As Compared To Placebo In Addition To Standard Of Care In Patients With Sepsis-Associated Acute Kidney Injury (Sa-Aki) The objective of this clinical trial is to demonstrate the safety and tolerance of the investigational drug when given as a single dose in patients with abdominal sepsis associated acute kidney injuries. Role: Project Manager	05/24/18 – 12/31/20 Per Patient Costs	0.5 calendar months
n/a (Shupp) Avita Medical Americas, LLC CTP001-8: A Prospective, Multicenter, Single-Arm, Observational Study of the Safety and Clinical Performance of RES (Regenerative Epithelial Suspension) Prepared with the ReCell Device Combined with Meshed Skin Graft in the treatment of Acute Burn Injuries This study is aimed at demonstrating the effectiveness of a device used to create a “spray-on” skin cell suspension in reducing required donor site areas for grafting of burn wounds. Role: Project Manager	12/01/17 – 12/01/21 Per Patient Costs	0.5 calendar months
n/a (Shupp) Mediowound Ltd.	04/26/17 – 09/30/20 Per Patient Costs	0.25 calendar months

A multicenter, multinational, randomized, controlled, assessor blinded study, performed in subjects with thermal burns, to evaluate the efficacy and safety of NexoBrid compared to Gel Vehicle and compared to Standard of Care

This study is intended to demonstrate effectiveness of NexoBrid treatment over placebo control and standard of care in thermally burned subjects.

Role: Project Manager

n/a (Shupp)	04/24/17 – 06/01/20	0.5 calendar months
Stratatech Corporation	Per Patient Costs	
StrataGraft® Skin Tissue in the Promotion of Autologous Skin Regeneration of Complex Skin Defects Due to Thermal Burns That Contain Intact Dermal Elements		
This goal of this clinical trial is to assess the efficacy and safety of StrataGraft skin tissue in promoting autologous skin tissue regeneration of complex skin defects due to thermal burns.		
Role: Project Manager		

W81XWH-16-C-0202 (Shupp)	04/24/17 – 02/28/20	0.5 calendar months
Stratatech Corporation via DoD	Per Patient Costs	
An Open-Label, Controlled, Randomized, Multicenter, Dose Escalation Study Evaluating The Safety, Tolerability, And Efficacy Of Single Or Multiple Applications Of Stratagraft® Skin Tissue As An Alternative To Autografting Fullthickness Complex Skin Defects		
This clinical trial evaluates Stratagraft tissue in the setting of a full thickness injury to promote healing.		
Role: Project Manager		

INACTIVE

CIHR190808 (Heyland)	08/03/16 – 08/28/19	0.5 calendar months
Canadian Institutes of Health		
The RE-ENERGIZE Study: A RandomizEd trial of ENTERal Glutamine to minimIZE thermal injury		
The goal of this project is to assess the effect of enteral glutamine on 6-month mortality in patients with severe burn injury.		
Role: Project Manager		

n/a (Sava)	09/01/15 – 12/31/19	0.5 calendar months
Atox Bio Ltd.	Per Patient Costs	
Phase III, Randomized, Double-Blind, Placebo-Controlled , Parallel-Group, Study of AB103 as Compared to Placebo in Patients With Necrotizing Soft Tissue Infections (NSTI)		
The objective of this clinical trial is to demonstrate the efficacy of the investigational drug as compared to placebo when given as a single dose in patients with necrotizing soft tissue injuries.		
Role: Project Manager		

W911NF-17-1-0594 (Shupp)	10/01/17 – 09/30/19	1.5 calendar months
Department of the Army		
Biphasic Coagulopathies and Endotheliopathy in Burn Injured Patients: An Analysis of Mechanisms and Interplay		
This study is aimed at assessing coagulopathic conditions in samples collected previously from burn patients and assaying for molecular indicators of endothelial dysfunction to determine possible points of interface or synergism that may lead to altered outcomes in these patients.		
Role: Project Manager		

HHSO100201000002C (Shupp)	04/26/17 – 12/31/19	0.25 calendar months
ASELL via BARDA	Per Patient Costs	
Evaluation of the CytoRADx System as a Biodosimeter for Special Human Populations		
The goal of this pilot study is to provide information on the performance of the CytoRADx system on special populations including burns, traumatic injury, and sepsis.		
Role: Project Manager		

n/a (Shupp)	04/01/18 – 07/31/21[Closed 2019]	0.5 calendar months
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Cytori Therapeutics Per Patient Costs
 Safety and Feasibility of Adipose Derived Regenerative Cells (ADRCs) in the Treatment of Deep Partial Thickness and Full Thickness Thermal Wounds
 The objective of this study is to evaluate preliminary safety and feasibility of adipose-derived regenerative cells (ADRCs) delivered intravenously for the treatment of full thickness and deep partial thickness thermal wounds in addition to standard of care.
 Role: Project Manager

HU0001-17-2-0008 (Beachkofsky) 11/01/18 – 10/31/19 0.36 calendar months
 USUHS

Comprehensive Genomic Analysis of Cutaneous Adverse Drug Reactions
 This grants objective is to prospectively collect blood, blister fluid, and tissue from patients with Steven Johnson's Syndrome to characterize this disease process via changes in gene expression.
 Role: Project Manager

W81XWH-11-1-0840 Shupp (PI) 08/01/15 – 10/01/17 1.0 calendar months
 Arteriocyte, Inc. via DoD

Use of Autologous Platelet Rich Plasma (PRP) Gel as an Adjunct to the Treatment of Deep 2nd and 3rd Degree Burns
 The goal of this study is to demonstrate the safety of, and potential for improved healing with using patient autologous PRP concurrent with skin grafting for more severe injuries.
 Role: Coordinator

W911QY-15-C-00251 (Shupp) 04/17/15 – 04/17/18 2.0 calendar months
 Department of the Navy

Determining the Chronology of Occult and Gross Coagulopathy in Thermally Injured Patients: A Systems Biology Approach.
 The goal of this study is to examine coagulopathies in burn patients at time points proximal to injury and throughout the hospital course using systems biology methods and serial blood sampling.
 Role: Project Manager

HHSO10020130020C (Shupp) 07/23/14 – 10/31/17 1.0 calendar months
 Arteriocyte, Inc. via BARDA

Arteriocyte's Magellan Autologous Platelet Rich Plasma (PRP) Based Therapy for Burn Wounds
 The goal of this project is to demonstrate the safety of, and potential for improved healing with, patient autologous PRP as a "biologic dressing" for burn wounds.
 Role: Coordinator

PENDING

n/a (Shupp) 02/2020 – 01/2022 1.0 calendar months
 Avita Medical Americas, LLC \$Per patient enrollment

Evaluation of Healing Following Use of the RECELL® Device for Treatment of Acute Thermal Burns
 The overall purpose of this study is to evaluate healing in patients undergoing treatment of acute thermal burns using the RECELL Device by photo documentation and histological assessment. The documentation gathered from this study will be used to develop visual aids and tools for training purposes.
 Role: Project Manager

HHSO100201000002C (Shupp) TBD 0.16 calendar months
 ASELL via BARDA Per Patient Costs

Clinical Validation of the CytoRADx System as a Biodosimeter for Special Human Populations
 The goal of this study validate the results from the CytoRADx system on special populations.
 Role: Project Manager

OVERLAP

None

MOFFATT, LT**ACTIVE**

n/a (Shupp) 12/01/19 – 04/01/20 1.0 calendar months
Avita Medical Americas, LLC
The use of Negative Pressure Wound Therapy (NPWT) on Recell-Treated Excised and Autografted Full Thickness Burns
The purpose of the study is to evaluate the use of NPWT over Recell + mSTSG-treated excised burn wound beds. To accomplish this, a burn, excise, mSTSG + Recell model will be utilized in two duroc pigs.
Role: Investigator

n/a (Shupp) 12/01/19 – 06/01/20 0.5 calendar months
Inventive Government Solutions, LLC
Collection of Lung Ultrasound Images for Algorithm Training and Testing
Using a hand-held ultrasound system, coordinator will collect LUS images from adult patients suffering from pulmonary disease (pneumonia, pleural effusion, empyema, pneumothorax) and pediatric patients suffering from pulmonary disease (pneumonia with consolidation).
Role: Sub-Investigator

BA190086 (Shupp) 09/01/19-09/01/23 2.0 calendar months
Department of the Army Identification of mechanisms underlying the effects of plasma inclusive resuscitation in major thermal injury on hemostasis and vascular homeostasis.
This prospective observational study aims to characterize the rold of FFP in resuscitation of the burn injured patient undergoing shock. Specifically it is meant to determine whether FFP can be implicated in any inflammatory or coagulopathic processes, impacting patient outcomes.
Role: Scientist/Project Manager

n/a (Shupp) 12/01/17 – 12/01/21 0.5 calendar months
Avita Medical Americas, LLC Per Patient Costs
CTP001-8: A Prospective, Multicenter, Single-Arm, Observational Study of the Safety and Clinical Performance of RES (Regenerative Epithelial Suspension) Prepared with the ReCell Device Combined with Meshed Skin Graft in the treatment of Acute Burn Injuries This study is aimed at demonstrating the effectiveness of a device used to create a “spray-on” skin cell suspension in reducing required donor site areas for grafting of burn wounds.
Role: Investigator

n/a (Shupp) 04/24/17 – 06/01/20 0.25 calendar months
Stratatech Corporation Per Patient Costs
StrataGraft® Skin Tissue in the Promotion of Autologous Skin Regeneration of Complex Skin Defects Due to Thermal Burns That Contain Intact Dermal Elements
This goal of this clinical trial is to assess the efficacy and safety of StrataGraft skin tissue in promoting autologous skin tissue regeneration of complex skin defects due to thermal burns.
Role: Site Sub-Investigator

INACTIVE

W911NF-17-1-0594 (Shupp) 10/01/17 – 09/30/19 2.0 calendar months
Department of the Army
Biphasic Coagulopathies and Endotheliopathy in Burn Injured Patients: An Analysis of Mechanisms and Interplay
This study is aimed at assessing coagulopathic conditions in samples collected previously from burn patients and assaying for molecular indicators of endothelial dysfunction to determine possible points of interface or synergism that may lead to altered outcomes in these patients.
Role: Site Sub-Investigator

HHSO100201000002C (Shupp) ASELL via BARDA Evaluation of the CytoRADx System as a Biodosimeter for Special Human Populations The goal of this pilot study is to provide information on the performance of the CytoRADx system on special populations including burns, traumatic injury, and sepsis. Role: Site Sub-Investigator	04/26/17 – 12/31/19 Per Patient Costs	0.25 calendar months
n/a (Moffatt) Avita Medical Americas, LLC Enzyme Performance Comparison between Recombinantly-sourced and Animal-derived Trypsin as Measured by Cell Disaggregation and Cell Viability in Human Skin Samples The purpose of this laboratory study was to determine whether a non-animal derived source of trypsin (enzyme) can be procured (and/or prepared according to AVITA Medical's specifications), which performs in an equivalent manner to the enzyme currently in use in the RECELL® system Role: Investigator	04/01/19 – 12/01/19	1.0 calendar months
n/a (Moffatt) Avita Medical Americas, LLC Comparison of Cell Viability in RES™ Derived from Fresh Skin Samples Sourced Directly (Operating Room to Lab) or Indirectly (Operating Room to Vendor to Lab) Analyzed Up to a 7 Day Time Frame The purpose of this laboratory study was to characterize the RES generated in the RECELL® system from both fresh skin samples and those skin samples provided from a vendor. Role: Investigator	04/01/19 – 12/01/19	1.0 calendar months
n/a (Shupp) Cytori Therapeutics Safety and Feasibility of Adipose Derived Regenerative Cells (ADRCs) in the Treatment of Deep Partial Thickness and Full Thickness Thermal Wounds The objective of this study is to evaluate preliminary safety and feasibility of adipose-derived regenerative cells (ADRCs) delivered intravenously for the treatment of full thickness and deep partial thickness thermal wounds in addition to standard of care. Role: Site Sub-Investigator	04/01/18 – 07/31/21[Closed 2019] Per Patient Costs	1.0 calendar months
n/a (Shupp) Prometic Life Sciences Examination of the Ability of a Plasminogen Formulation to Salvage Burn Wound Progression/Conversion and Viability of the Zone of Stasis This study is aimed at assessing the effects of an IV formulation of plasminogen on burn wound progression, and secondarily, burn wound healing. Role: Co-Investigator	12/01/17 – 12/01/18	1.0 calendar months
n/a (Shupp) Biospecifics Technologies, Inc. Impact of a Novel Injectable Collagenase Formulation on Hypertrophic Scar This study is aimed at assessing the effectiveness of a collagenase formulation on mitigating the pathologic symptoms associated with hypertrophic scars using a duroc pig model for hypertrophic scar. Role: Co-Investigator	11/01/17 – 11/01/18	1.5 calendar months
1 R01 AR070851-01A1 (Brash) NIH/NIAMS Chemiexcitation: A New Mode of Skin Disease The purpose of this project is to determine the chemistry underlying UV-induced chemiexcitation in mammalian cells, investigate whether it can be induced by other stimuli such as inflammation, and investigate the range of diseases in which it participates. Role: Sub-Investigator	09/01/17 – 07/31/19	1.5 calendar months

W81XWH-11-1-0840 Shupp (PI) 08/01/15-10/01/17 0.24 calendar months
 Arteriocyte, Inc. via DoD patient
 Use of Autologous Platelet Rich Plasma (PRP) Gel as an Adjunct to the Treatment of Deep 2nd and 3rd Degree Burns
 The goal of this study is to demonstrate the safety of, and potential for improved healing with using patient autologous PRP concurrent with skin grafting for more severe injuries.
 Role: Site Sub-Investigator

W911QY-15-C-00251 (Shupp) 04/17/15 – 04/17/18 2.0 calendar months
 Department of the Navy
 Determining the Chronology of Occult and Gross Coagulopathy in Thermally Injured Patients: A Systems Biology Approach.
 The goal of this study is to examine coagulopathies in burn patients at time points proximal to injury and throughout the hospital course using systems biology methods and serial blood sampling.
 Role: Site Sub-Investigator

HHSO10020130020C (Shupp) 07/23/14 – 10/31/17 0.24 calendar months
 Arteriocyte, Inc. via BARDA
 Arteriocyte's Magellan Autologous Platelet Rich Plasma (PRP) Based Therapy for Burn Wounds
 The goal of this project is to demonstrate the safety of, and potential for improved healing with, patient autologous PRP as a "biologic dressing" for burn wounds.
 Role: Site Sub-Investigator

PENDING

n/a (Shupp) 02/2020 – 06/2020 0.25 calendar months Avita
 Medical Americas, LLC
 RECELL® Autologous Cell Harvesting Device (RECELL® Device) Non-Cellular Characterization
 Determining the feasibility of accurately and reliably identifying specific proteins and non-cellular components present in Spray-On Skin™ Cells (RES™) prepared using the RECELL® System on fresh human skin samples or sourced skin samples.
 Role: Project manager

n/a (Shupp) 02/2020 – 01/2022 0.5 calendar months
 Avita Medical Americas, LLC \$Per patient enrollment
 Evaluation of Healing Following Use of the RECELL® Device for Treatment of Acute Thermal Burns
 The overall purpose of this is study to evaluate healing in patients undergoing treatment of acute thermal burns using the RECELL Device by photo documentation and histological assessment. The documentation gathered from this study will be used to develop visual aids and tools for training purposes.
 Role: Laboratory assay manager

BA160347 (Shupp) TBD 1.5 calendar months
 Department of the Army TBD
 Mouse Feeder Cell-Free Human Epidermal Culture and its Application in Strategies to Treat Burn Injury
 This study is aimed to determine whether the use of a novel defined culture medium will allow rapidly generated and expanded patient-specific epidermal cultures (without the need for feeder cells).
 Role: Sub-Investigator

OVERLAP

None

SHUPP, J.W.

ACTIVE

n/a (Shupp) Avita Medical Americas, LLC The use of Negative Pressure Wound Therapy (NPWT) on Recell-Treated Excised and Autografted Full Thickness Burns The purpose of the study is to evaluate the use of NPWT over Recell + mSTSG-treated excised burn wound beds. To accomplish this, a burn, excise, mSTSG + Recell model will be utilized in two duroc pigs. Role: PI	12/01/19 – 04/01/20	0.2 calendar months
n/a (Shupp) Inventive Government Solutions, LLC Collection of Lung Ultrasound Images for Algorithm Training and Testing Using a hand-held ultrasound system, coordinator will collect LUS images from adult patients suffering from pulmonary disease (pneumonia, pleural effusion, empyema, pneumothorax) and pediatric patients suffering from pulmonary disease (pneumonia with consolidation). Role: Site PI	12/01/19 – 06/01/20	0.1 calendar months
BA190086 (Shupp) Department of the Army Identification of mechanisms underlying the effects of plasma inclusive resuscitation in major thermal injury on hemostasis and vascular homeostasis. This prospective observational study aims to characterize the role of FFP in resuscitation of the burn injured patient undergoing shock. Specifically it is meant to determine whether FFP can be implicated in any inflammatory or coagulopathic processes, impacting patient outcomes. Role: PI	09/01/19-09/01/23	1.0 calendar months
n/a (Shupp) Acell A Prospective, Randomized, Controlled Trial Comparing Cytal Wound Matrix 1-Layer to Standard of Care (SOC) in the Management of Diabetic Foot Ulcers (DFUs) This clinical trial aims to evaluate the Cytal Wound Matrix 1-Layer intervention to standard of care intervention in patients presenting with diabetic foot ulcers. Role: Site PI	07/01/19 – 09/01/20 Per Patient Costs	0.24 calendar months
n/a (Shupp) Kerecis Ltd. Fish Skin Compared to Cadaver Skin as a Temporary Covering for Full Thickness Burns: An early Feasibility Trial To determine, if treatment with Kerecis Omega3 Wound is safe as an alternative to cadaver skin as temporary coverage for debrided full thickness burns prior to closure with split thickness skin grafts. Role: Site PI	08/01/18 – 08/01/20 Per Patient Costs	0.24 calendar months
n/a (Trankiem) Atox Bio Ltd. Phase 2 Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study To Evaluate The Safety And Efficacy Of Reltecimod As Compared To Placebo In Addition To Standard Of Care In Patients With Sepsis-Associated Acute Kidney Injury (SA-AKI) The objective of this clinical trial is to demonstrate the safety and tolerance of the investigational drug when given as a single dose in patients with abdominal sepsis associated acute kidney injuries. Role: Site Sub-Investigator	05/24/18 – 12/31/20 Per Patient Costs	0.16 calendar months
n/a (Shupp) Avita Medical Americas, LLC Continued Access: ReCell® in the Treatment of Acute Burn Injuries	12/01/17 – 12/01/21 Per Patient Costs	0.24 calendar months

A Prospective, Multicenter, Single-Arm, Observational Study of the Safety and Clinical Performance of RES (Regenerative Epithelial Suspension) Prepared with the ReCell Device Combined with Meshed Skin Graft in the treatment of Acute Burn Injuries

This study is aimed at demonstrating the effectiveness of a device used to create a "spray-on" skin cell suspension in reducing required donor site areas for grafting of burn wounds.

Role: Project Manager

Role: Site PI

n/a (Shupp) 04/24/17 – 06/01/20 0.16 calendar months
Stratatech Corporation Per Patient Costs
StrataGraft® Skin Tissue in the Promotion of Autologous Skin Regeneration of Complex Skin Defects Due to Thermal Burns That Contain Intact Dermal Elements
This goal of this clinical trial is to assess the efficacy and safety of StrataGraft skin tissue in promoting autologous skin tissue regeneration of complex skin defects due to thermal burns.
Role: Site PI

W81XWH-16-C-0202 (Shupp) 04/24/17 – 02/28/20 0.24 calendar months
Stratatech Corporation via DoD Per Patient Costs
An Open-Label, Controlled, Randomized, Multicenter, Dose Escalation Study Evaluating The Safety, Tolerability, And Efficacy Of Single Or Multiple Applications Of Stratagraft® Skin Tissue As An Alternative To Autografting Fullthickness Complex Skin Defects
This clinical trial evaluates Stratagraft tissue in the setting of a full thickness injury to promote healing.
Role: Site PI

n/a (Shupp) 04/26/17 – 09/30/20 0.16 calendar months
Mediowound Ltd. Per Patient Costs
A multicenter, multinational, randomized, controlled, assessor blinded study, performed in subjects with thermal burns, to evaluate the efficacy and safety of NexoBrid compared to Gel Vehicle and compared to Standard of Care
This study is intended to demonstrate effectiveness of NexoBrid treatment over placebo control and standard of care in thermally burned subjects.
Role: Site PI

INACTIVE

HHSO100201000002C (Shupp) 04/26/17 – 12/31/19 0.16 calendar months
ASELL via BARDA Per Patient Costs
Evaluation of the CytoRADx System as a Biodosimeter for Special Human Populations
The goal of this pilot study is to provide information on the performance of the CytoRADx system on special populations including burns, traumatic injury, and sepsis.
Role: Site PI

CIHR190808 (Heyland) 08/03/16 – 08/28/19 0.24 calendar months
Canadian Institutes of Health
The RE-ENERGIZE Study: A RandomizEd trial of ENtERal Glutamine to minimIze thermal injury
The goal of this project is to assess the effect of enteral glutamine on 6-month mortality in patients with severe burn injury.
Role: Site PI

n/a (Sava) 09/01/15 – 12/31/19 0.16 calendar months
Atox Bio Ltd. Per Patient Costs
Phase III, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Study of AB103 as Compared to Placebo in Patients With Necrotizing Soft Tissue Infections (NSTI)
The objective of this clinical trial is to demonstrate the efficacy of the investigational drug as compared to placebo when given as a single dose in patients with necrotizing soft tissue injuries.
Role: Site Sub-Investigator

W911NF-17-1-0594 (Shupp)	10/01/17 – 09/30/19	1.0 calendar months
Department of the Army		
Biphasic Coagulopathies and Endotheliopathy in Burn Injured Patients: An Analysis of Mechanisms and Interplay		
This study is aimed at assessing coagulopathic conditions in samples collected previously from burn patients and assaying for molecular indicators of endothelial dysfunction to determine possible points of interface or synergism that may lead to altered outcomes in these patients.		
Role: Site PI		
n/a (Shupp)	04/01/18 – 07/31/21 [Closed 2019]	0.24 calendar months
Cytori Therapeutics		
Per Patient Costs		
Safety and Feasibility of Adipose Derived Regenerative Cells (ADRCs) in the Treatment of Deep Partial Thickness and Full Thickness Thermal Wounds		
The objective of this study is to evaluate preliminary safety and feasibility of adipose-derived regenerative cells (ADRCs) delivered intravenously for the treatment of full thickness and deep partial thickness thermal wounds in addition to standard of care.		
Role: Site PI		
HU0001-17-2-0008 (Beachkofsky)	11/01/18 – 10/31/19	0.1 calendar months USUHS
Comprehensive Genomic Analysis of Cutaneous Adverse Drug Reactions		
This grants objective is to prospectively collect blood, blister fluid, and tissue from patients with Steven Johnson's Syndrome to characterize this disease process via changes in gene expression.		
Role: Site Sub-Investigator		
n/a (Shupp)	01/01/18 – 06/30/18	0.25 calendar months
Avita Medical Americas, LLC		
ReCell® Autologous Cell Harvesting Device Assessment of Elevated Incubation Temperatures on RES		
RES characterization assays will be performed so that Avita Medical can provide ReCell customers with detailed information assessing the effect an elevated incubation temperature may have on the RES with respect to cell viability, apoptotic activity and cell phenotypes.		
Role: PI		
n/a (Shupp)	12/01/17 – 12/01/18	0.25 calendar months
Prometic Life Sciences		
Examination of the Ability of a Plasminogen Formulation to Salvage Burn Wound Progression/Conversion and Viability of the Zone of Stasis		
This study is aimed at assessing the effects of an IV formulation of plasminogen on burn wound progression, and secondarily, burn wound healing.		
Role: PI		
n/a (Shupp)	11/01/17 – 11/01/18	0.25 calendar months
Biospecifics Technologies, Inc.		
Impact of a Novel Injectable Collagenase Formulation on Hypertrophic Scar		
This study is aimed at assessing the effectiveness of a collagenase formulation on mitigating the pathologic symptoms associated with hypertrophic scars using a duroc pig model for hypertrophic scar.		
Role: PI		
1 R01 AR070851-01A1 (Brash)	09/01/17 – 07/31/18	0.25 calendar months
NIH/NIAMS		
Chemiexcitation: A New Mode of Skin Disease		
The purpose of this project is to determine the chemistry underlying UV-induced chemiexcitation in mammalian cells, investigate whether it can be induced by other stimuli such as inflammation, and investigate the range of diseases in which it participates.		
Role: Sub-Investigator		

W81XWH-11-1-0840 (Shupp) 08/01/15 – 10/01/17 0.24 calendar months
 Arteriocyte, Inc. via DoD patient
 Use of Autologous Platelet Rich Plasma (PRP) Gel as an Adjunct to the Treatment of Deep 2nd and 3rd Degree Burns
 The goal of this study is to demonstrate the safety of, and potential for improved healing with using patient autologous PRP concurrent with skin grafting for more severe injuries.
 Role: Site PI

W911QY-15-C-00251 (Shupp) 04/17/15 – 04/17/18 1.0 calendar months
 Department of the Navy
 Determining the Chronology of Occult and Gross Coagulopathy in Thermally Injured Patients: A Systems Biology Approach.
 The goal of this study is to examine coagulopathies in burn patients at time points proximal to injury and throughout the hospital course using systems biology methods and serial blood sampling.
 Role: Site PI

HHSO10020130020C (Shupp) 07/23/14 – 10/31/17 0.24 calendar months
 Arteriocyte, Inc. via BARDA
 Arteriocyte's Magellan Autologous Platelet Rich Plasma (PRP) Based Therapy for Burn Wounds
 The goal of this project is to demonstrate the safety of, and potential for improved healing with, patient autologous PRP as a "biologic dressing" for burn wounds.
 Role: Site PI

PENDING

n/a (Shupp) 02/2020 – 06/2020 0.25 calendar months Avita
 Medical Americas, LLC
 RECELL® Autologous Cell Harvesting Device (RECELL® Device) Non-Cellular Characterization
 Determining the feasibility of accurately and reliably identifying specific proteins and non-cellular components present in Spray-On Skin™ Cells (RES™) prepared using the RECELL® System on fresh human skin samples or sourced skin samples.
 Role: PI

n/a (Shupp) 02/2020 – 01/2022 0.5 calendar months
 Avita Medical Americas, LLC \$Per patient enrollment
 Evaluation of Healing Following Use of the RECELL® Device for Treatment of Acute Thermal Burns
 The overall purpose of this is study to evaluate healing in patients undergoing treatment of acute thermal burns using the RECELL Device by photo documentation and histological assessment. The documentation gathered from this study will be used to develop visual aids and tools for training purposes.
 Role: PI

BA160347 (Shupp) TBD 0.5 calendar months
 Department of the Army TBD
 Mouse Feeder Cell-Free Human Epidermal Culture and its Application in Strategies to Treat Burn Injury
 This study is aimed to determine whether the use of a novel defined culture medium will allow rapidly generated and expanded patient-specific epidermal cultures (without the need for feeder cells).
 Role: PI

HHSO100201000002C (Shupp) TBD 0.16 calendar months
 ASELL via BARDA Per Patient Costs
 Clinical Validation of the CytoRADx System as a Biodosimeter for Special Human Populations
 The goal of this study validate the results from the CytoRADx system on special populations.
 Role: Site PI

OVERLAP

None

Facilities and Other Resources

MedStar Health Research Institute (MHRI)/MedStar Washington Hospital Center (MWHC) – Jeffrey W. Shupp, MD

Laboratory:

The George Hyman Research Building (GHRB) is located on the campus of the MedStar Health System's largest hospital, MWHC. The GHRB is the major pre-clinical research facility of MHRI and has approximately 13,500 square feet of research and laboratory space, along with administrative offices and common space. The Firefighters' Burn and Surgical Research Lab (FBSRL) is housed within the GHRB and totals over 6,500 square feet of laboratory and office space. The FBSRL has access to equipment and materials as described in the equipment documentation provided as part of this application. Dr. Shupp also has access to a large medical library, shared equipment rooms, autoclaves, ice machine, dry ice, and liquid nitrogen. An optics work area is maintained, including an optics bench with associated equipment and materials.

The FBSRL has experience and expertise in these areas, which are the primary research focus and interest: 1) microbiology of surgical, traumatic, and chronic wounds; 2) wound healing after cutaneous trauma and burn; 3) biophotonics/bioimaging to non-invasively diagnose disease pathology; 4) burn pathophysiology; 4) systems biology and integrated studies aimed at the host response to physical and environmental trauma. The FBSRL is staffed by the principal investigator, two Ph.D.-level Scientists, 3 full time technicians, 2 part time technicians, and surgical research fellows, medical students, and undergraduate students. Approximately 1/3 of the 5,000 square feet of laboratory space is maintained at a Biosafety II Level for work with human pathogens and ex-vivo human specimens including a dedicated blood and tissue processing lab.

Clinical:

The clinical components of the Burn and Surgical Research team, under Dr. Shupp, are lead by a full time, dedicated Clinical Research Program Manager who is an RN, a Clinical Research Coordinator, and part-time Clinical Research Assistant. The Burn Center at MWHC is the only adult burn treatment center in the Washington metropolitan area. Physicians, other clinicians, and scientists from this center are active nationally and internationally in areas ranging from improved organization of care to basic science research. With over 600 admissions annually our center cares for an array of thermal, electrical and chemical injuries as well as soft tissue lesions such as those caused by TENS making it one of the top-10 busiest burn centers in North America. Patients at the Burn Center also receive rehabilitation and post-surgical care with a goal of social reintegration and effective management of scarring and other conditions. The facility, which is conveniently located on the same campus as our pre-clinical laboratory, has a patient population that has been successfully studied by our group for previous work, with patient data and specimens accessible on campus by appropriately trained study staff (with IRB approval). The Burn Center houses several outpatient clinic and rehabilitation rooms that may be utilized for conducting follow-up visits for research. Moreover, expertise from physicians, nurses, and other providers may be easily accessed when interpreting and determining translatability of findings.

Animal:

Research space includes an AAALAC accredited, PHS assured, and USDA certified vivarium and a fully equipped pre-clinical surgical suite, which are both capable of accommodating large and small animal models and both GLP and non-GLP studies. These facilities are located on the ground and first floors of the GHRB. They consist of two large animal rooms (swine; current capacity 19 pens), two rabbit rooms, five small animal rooms, one small animal isolation room, one treatment/procedure room, three storage rooms, one cage wash/autoclave room, a large animal prep area, one necropsy room, a technician office, one investigator laboratory room, and a locker room. The large animal surgery facility (consisting of two cardiac catheterization/surgery suites, a general surgery suite, surgical scrub area, and recovery room) is located on the first floor of the GHRB. Our staff has access to this facility and to a wide array of animal housing and husbandry services as well as fluoroscopy suites and microsurgery capabilities.

Computer:

Dedicated technology infrastructure is in place, including over 20 PC and Mac workstations connected to redundant servers specifically used for FBSRL research. Workstations are outfitted with up to date statistical and data analysis software (including ImageJ, Zeiss Zen, GraphPad Prism, and SAS) and all are connected to a dedicated, redundant server. Multiple printers, scanners, and laptops are also available for use. A secure wireless network is in place in the FBSRL.

Office:

The investigator has an 800 sq. ft. office located in MWHC and the research staff have dedicated office spaces totaling approximately 1,000 sq. ft. in the GHRB. Fax machines, copiers, and laser printers are available in the offices and a private conference room is maintained by the investigator and research staff.

Other:

MHRI's robust research support infrastructure includes a biostatistics, data analysis, and epidemiological department, an institutional review board (IRB), an institutional animal care and use committee (IACUC), and an office of research integrity, all of which are accessible. A full-service research pharmacy provides investigators with a broad range of services including secure storage of pharmaceutical and biological materials, preparation and dispensing of study medications, patient randomization, and drug accountability documentation. Previous work from Dr. Shupp's group has allowed for extensive collaborative relationships with each of the mentioned groups within MHRI.

Equipment

MedStar Health Research Institute (MHRI)/MedStar Washington Hospital Center (MWHC) – Jeffrey W. Shupp, MD

The FBSRL has access to a dark room, tissue culture facilities, a histology core lab, analytical chemistry lab, platelet core lab, and flow cytometry core. The tissue culture facilities consist of three biosafety cabinets and 2 laminar flow hoods, four water-jacketed CO₂ incubators, a Motic AE21 inverted microscope, a Nikon reverse phase microscope, as well as refrigerators, freezers and bench-top centrifuges. The general laboratory space is outfitted with a fume hood for general work, a Millipore Direct-Q 3 Ultrapure water system, five refrigerated centrifuges, five -80C freezers, six -20C freezers, and two cryostorage vessels. There are also dedicated bacteriology hoods and incubators, as well as an entire dedicated laboratory room for human sample processing for clinical studies. The histology core lab is equipped with tissue embedding and sectioning devices including a Leica TP 1020 Automated Tissue Embedder, a Shandon Electronic Cryostat and a Leica RM2125RT Sectioner, as well as dedicated staining and microscopy equipment. The microscopy equipment includes an Olympus BX41, a Nikon Eclipse TE2000S fluorescence microscope, and a Zeiss AxioImager A2 with fluorescence capabilities. The analytical chemistry facility is outfitted with a Shimadzu HPLC system capable of protein separation, purification, and quantification. The lab also has ample access to wet and dry baths, incubators, shakers, pH meters, analytical balances, blotting equipment, plate readers and gel imagers, as well as cytofluorometers, thermocyclers (2 BioRad CFX96 Real Time System, BioRad C1000, and an MJ Research PTC100). The molecular biology area has sophisticated tissue processing equipment including a Qiagen Tissuelyser system, a Nanodrop 2000C, an Agilent Bioanalyzer, a Molecular Devices Filtermax F5 Plate reader, and a QIAcube for automated RNA, DNA and protein extraction. The lab has access to shared resources including a ROTEMdelta (TEM systems) and a TEG 5000 (Haemonetics).

The FBSRL has laser Doppler imaging (Moor LDI-THB), laser perfusion imaging (Moor FLPI), in-vivo confocal microscopy (Lucid VivaScope 1500), and in vivo imaging (Xenogen IVIS System) capabilities.

The MHRI animal facility offers a fully equipped pre-clinical surgical suite and procedure rooms. The major surgical support equipment available in this facility includes: autoclaves, gas anesthesia machines, ventilators,

vital signs monitoring equipment (including electrocardiographs, pulse oximeters, and thermometers), fluoroscopes, defibrillators, operating room tables/lights, animal warming units, lifts, transport cages, and electro-surgery devices. The FBSRL also maintains an electric dermatome (Zimmer), a CO₂ laser (Cynosure®) and dedicated surgical instruments for both large and small animal procedures.