

AWARD NUMBER: W81XWH-15-9-0001-0005

TITLE: **Electroceutical technology against bacterial drug resistance.**

PRINCIPAL INVESTIGATOR: Sashwati Roy, PhD

PERFORMING ORGANIZATION: Indiana University School of Medicine, Indianapolis, IN

REPORT DATE: April 25, 2020

Revision submitted: June 15, 2020

TYPE OF REPORT: Annual Report (revised)

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

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<b>1. REPORT DATE</b> 04/25/2020		<b>2. REPORT TYPE</b> Annual		<b>3. DATES COVERED</b> 03/19/2019 - 03/20/2019	
<b>4. TITLE AND SUBTITLE</b>  Electroceutical technology against bacterial drug resistance.				<b>5a. CONTRACT NUMBER</b> W81XWH-15-9-0001	
				<b>5b. GRANT NUMBER</b> N/A	
				<b>5c. PROGRAM ELEMENT NUMBER</b>	
<b>6. AUTHOR(S)</b>  Sashwati Roy (PI) Co-I: Chandan K. Sen, PhD, Gayle M Gordillo, MD, Savita Khanna Post Doc: Dolly Khona, PhD, Nandini Ghosh, PhD, Vinoj Gopalakrishan, PhD  E-Mail (PI): Roysa@iu.edu				<b>5d. PROJECT NUMBER</b> MT17002.18	
				<b>5e. TASK NUMBER</b> W81XWH-15-9-0001-0005	
				<b>5f. WORK UNIT NUMBER</b> N/A	
<b>7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)</b>  Indiana University School of Medicine 444A MRLB; 975 Walnut Street Indianapolis, IN				<b>8. PERFORMING ORGANIZATION RE PORT</b>  2019-328-001	
<b>9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)</b>  U.S. Army Medical Research and Development Command Fort Detrick, Maryland 21702-5012				<b>10. SPONSOR/MONITOR'S ACRONYM(S)</b> MTEC/MIDRP	
				<b>11. SPONSOR/MONITOR'S REPORT NUMBER(S)</b> N/A	
<b>12. DISTRIBUTION / AVAILABILITY STATEMENT</b>  Approved for Public Release; Distribution Unlimited					
<b>13. SUPPLEMENTARY NOTES</b>					
<b>14. ABSTRACT</b> The objective of this work is to develop EDT <sub>lo</sub> and EDT <sub>hi</sub> wound dressings against bacteria and fungal biofilm infections as MTEC Technology for prototype acceleration. Resilience, DoD). Two sp aims have been proposed: <b>Aim 1.</b> Demonstrate the ability of optimized electroceutical EDT dressings to eliminate mixed species, multi-drug resistant infection in an invitro assay and porcine burn infection model. <b>Aim 2.</b> Conduct a pilot study to test whether infected wound closure in a pair-matched setting is improved using optimized EDT treatment compared to standard of care (SoC).					
<b>15. SUBJECT TERMS</b>					
<b>16. SECURITY CLASSIFICATION OF:</b>			<b>17. LIMITATION OF ABSTRACT</b>	<b>18. NUMBER</b>	<b>19a. NAME OF RESPONSIBLE PERSON</b> Sashwati Roy
<b>a. REPORT</b>	<b>b. ABSTRACT</b>	<b>c. THIS PAGE</b>			<b>19b. TELEPHONE NUMBER</b> (include area code)
Unclassified	Unclassified	Unclassified	Unclassified	15	317-278-2706

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Annual Technical Status Report for  
Electroceutical technology against bacterial drug resistance  
Research Project No. MTEC-17-02-PA-18  
EGS#  
Reporting Period: Effective Date – 04.25.2020

MTEC Research Project Awardee  
Sashwati Roy, PhD  
Co-I: Chandan K. Sen, PhD, Gayle M Gordillo, MD, Savita Khanna  
Post Doc: Dolly Khona, PhD, Nandini Ghosh, PhD, Vinoj Gopalakrishan, PhD

Research Project Technical POC  
Sashwati Roy  
Indiana University School of Medicine  
444A MRLB; 975 Walnut Street Indianapolis, IN  
Tel: 317-278-2706; Email: roysa@iu.edu

Submitted: 04.29.2020

Revised Submitted: 06.15.2020



## 2. Project Status

## a. Accomplishments

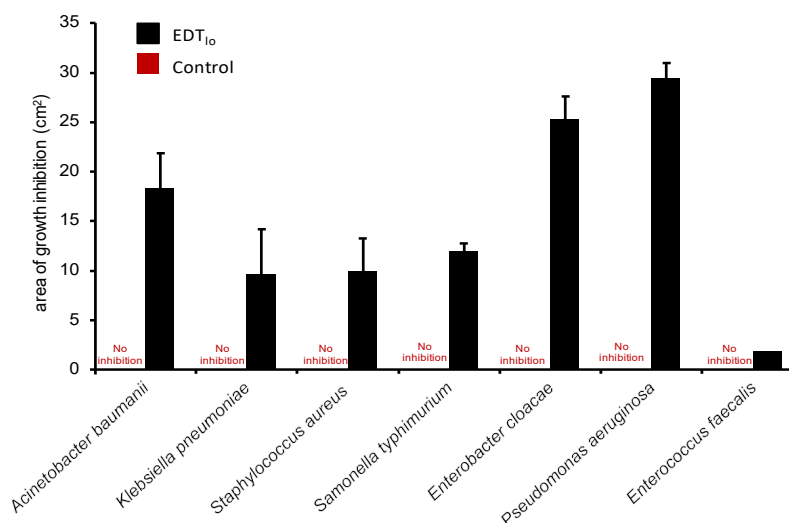
The Table below indicates the status of all milestone within the past year.

<b>MTEC Milestone #</b>	<b>Sow Task Number</b>	<b>Significant Event/ Accomplishments</b>	<b>Due Date</b>	<b>Milestone status</b>
1	1	In vitro testing of EDT on the viability of the drug resistant strains tested either in planktonic or biofilm mode of growth used independently or in combination with antibiotic.	6/21/2019	Complete
2	2	DoD ACURO submission	04/30/2019	Complete
3		Quarterly Reports 1 (March-June, Technical and Business Reports)	7/25/2019	Complete
4		Quarterly Report 2 (June- Sept, Technical and Business Reports)	10/25/2019	Complete
5	3	Preclinical porcine wound studies testing efficacy of EDT on the persistence of infection in wounds infected by drug resistant strains in planktonic/biofilm mode.	10/29/2019	Ongoing*
6	4	Preclinical porcine wound studies testing efficacy of EDT as compared to SoC on wound closure of burn wounds infected by drug resistant strains in planktonic/biofilm mode.	11/29/2019	Ongoing*
7		Quarterly Report 3 (September-Dec, Technical and Business Reports)	1/25/2020	Complete
8	5	Data analysis	2/29/2020	Ongoing*
9		Quarterly Report 4 (Dec-March, Technical and Business Reports)	4/25/2020	Complete

*Note: Due to COVID-19 disruption in animal related experiments, n=2 additional pigs to achieve statistical goal remain pending. The work will resume as soon as the experiments are resumed back at the Institution.*

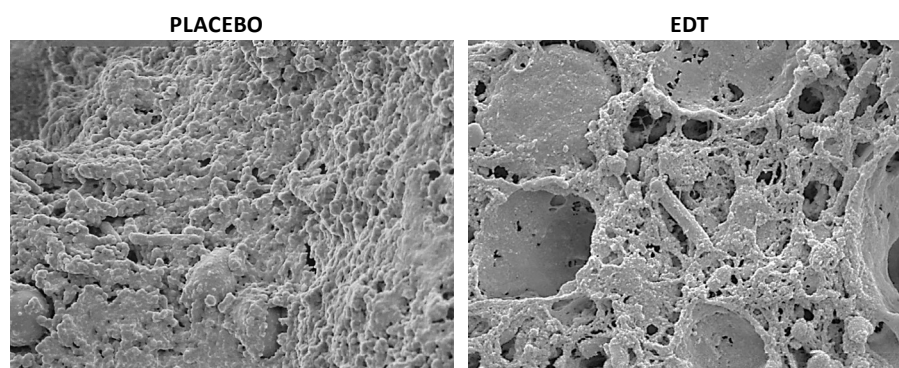
## b. Reportable Outcomes

1. The in vitro studies testing efficacy of ABR on MDR infection (Aim 1 in vitro studies). Data attached as Figure 1.



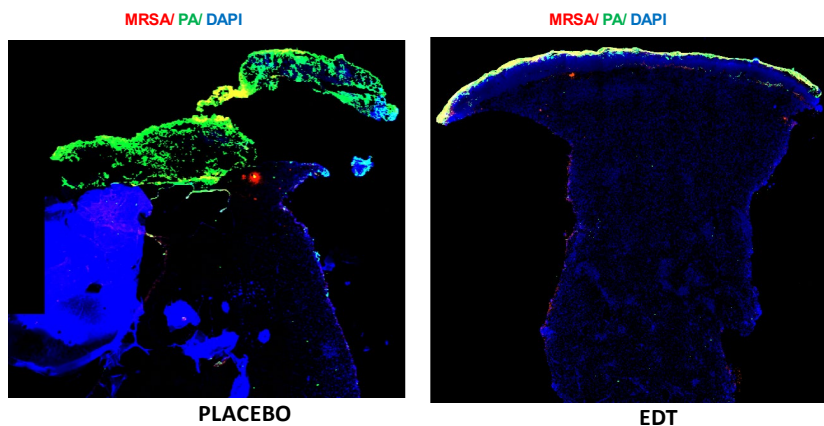
**Figure 1. Agar biofilm growth inhibition assay.** The EDT<sub>10</sub> dressing was embedded in a thin (5 mm) layer of agar. Each of the antibiotics resistant (ABR) bacterial strain inoculum was then evenly spread on the agar and the plate was incubated at 37°C overnight. The zone of inhibition (clear zone, no bacterial growth) was quantitated. The viability test of the 8 different ABR strains treated with EDT<sub>10</sub> or placebo (control) revealed that EDT<sub>10</sub> was highly effective against 7 out of eight ABR bacteria as compared to the placebo group.

2. The porcine studies are progressing as per timeline and we have already completed 3 pigs with EDT and placebo treatments, the last two pigs studies were ongoing while COVID-19 disruption started and the studies were stalled. The experiments and analysis will resume as soon as the Institution reopens. Biofilm infection data (SEM and confocal) has been presented in Figures 2 & 3 (see attachments).



**Figure 2. Scanning electron microscopy images of wound biofilm.** Porcine burn wounds (2 × 2 sq inch) were subjected to biofilm infection on day 3 post-burn with *P. aeruginosa* PAO1 and *S. aureus* USA 300 (MRSA). The burn wounds were treated with EDT<sub>hi</sub> 28 d post-infection followed by EDT<sub>lo</sub> until the end of the study. The EDT dressings were changed twice a week throughout the duration of the study (d56). Scanning electron microscope (SEM) images of wound biopsies on days 14 post inoculation from pig burn wounds infected with mix biofilm infection MRSA and PA. The wounds were treated with Placebo or EDT. Note the thick aggregates of bacteria (cocci) encased in extrapolymeric matrix (EPS) characteristic of bacterial biofilm in placebo group, such thick biofilm was not observed in EDT treated group. Placebo group included treatment with EDT<sub>hi</sub> (power off) and EDT<sub>lo</sub> (silver only) dressings.

MRSA, Methicillin-resistant staphylococcus aureus; PA, *Pseudomonas, aeruginosa*.

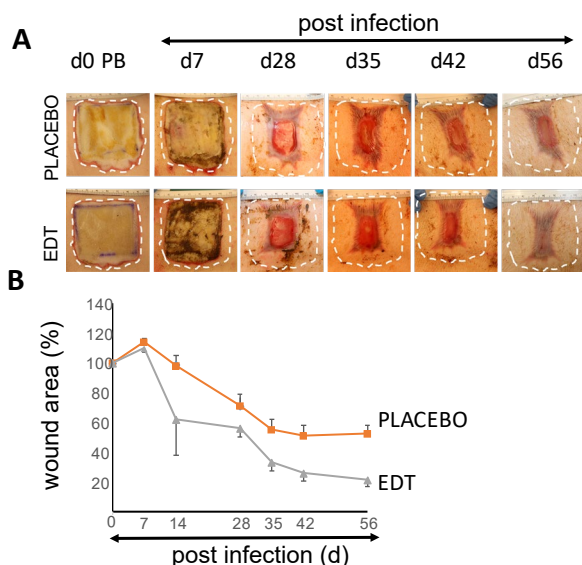


**Figure 3.** Confocal microscopy fluorescence images. images Porcine burn wounds ( $2 \times 2$  sq inch) were subjected to biofilm infection on day 3 post-burn with *P. aeruginosa* PAO1 and *S. aureus* USA 300. The burn wounds were treated with EDT<sub>hi</sub> 28 d post-infection followed by EDT<sub>lo</sub> until the end of the study. The EDT dressings were changed twice a week throughout the duration of the study (d56). **A.** Representative

confocal fluorescence microscopy images of wound biopsies on days 14 post inoculation from pig burn wounds infected with mix infection MRSA and PA. The wounds were treated with Placebo or EDT. Placebo group included treatment with EDT<sub>hi</sub> (power off) and EDT<sub>lo</sub> (silver only) dressings. MRSA & PA infection was observed using anti-PA antibody (green), anti-*S. aureus* (red) and counter staining with nuclear stain DAPI (blue). *Note reduced staining in treated wounds on the surface indicating diminished infection following treatment.*

MRSA, Methicillin-resistant staphylococcus aureus; PA, *Pseudomonas, aeruginosa*

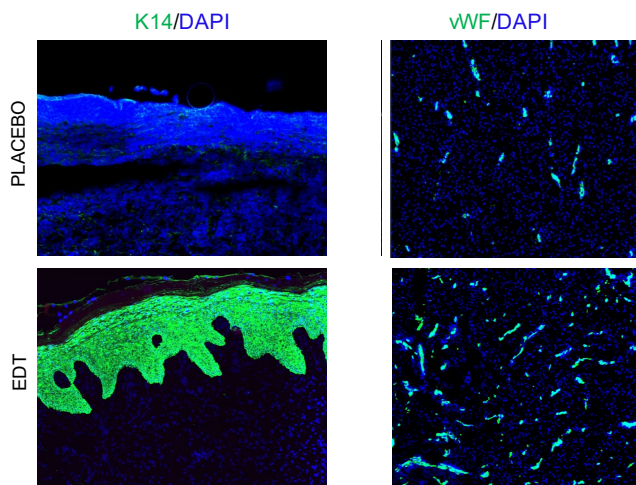
3. Wound closure data (Figure 4) and wound reepithelialization and neovascularization data (Figure 5) has been presented.



**Figure 4. Effect of EDT treatment on wound closure in burn wounds with mixed biofilm infection.** Porcine burn wounds ( $2 \times 2$  sq inch) were subjected to biofilm infection on day 3 post-burn with *P. aeruginosa* PAO1 and *S. aureus* USA 300. The burn wounds were treated with EDT<sub>hi</sub> 28 d post-infection followed by EDT<sub>lo</sub> until the end of the study. The EDT dressings were changed twice a week throughout the duration of the study (d56). **A.** Representative wound images in porcine burn wounds infected with mixed biofilm infection described above. **B.** Average % wound area in three groups Data are mean  $\pm$  SEM ( $n = 3$ ).

Placebo group included treatment with EDT<sub>hi</sub> (power off) and EDT<sub>lo</sub> (silver only) dressings. A clear trend in improved wound closure was noted in EDT treatment group.

*Note: this is an ongoing study, because of Covid-19, n=2 pigs remain to be completed, therefore, the data is trend only and not conclusive.*



**Figure 5. Effect of EDT treatment on wound reepithelialization and neovascularization in burn wounds with mixed biofilm infection.**

Porcine burn wounds ( $2 \times 2$  sq inch) were subjected to biofilm infection on day 3 post-burn with *P. aeruginosa* PAO1 and *S. aureus* USA 300. The burn wounds were treated with EDT<sub>hi</sub> 28 d post-infection followed by EDT<sub>lo</sub> until the end of the study. The EDT dressings were changed twice a week throughout the duration of the study (d56).

**A.** Representative K14 (keratinocytes, green) and DAPI (nuclear, blue) micrographs from wound sections on d56 post infection. **B.** Representative vWF (endothelial cells/vessels, green) and DAPI (nuclear, blue) micrographs from wound sections on d56 post infection. Placebo group included treatment with EDT<sub>hi</sub> (power off) and EDT<sub>lo</sub> (silver only) dressings.

4. The data thus far indicate a favorable outcome of EDT treatment on
  - a. Biofilm infection control
  - b. wound closure and reepithelialization/vascularization
5. If successful, these studies will finalize a clinical treatment protocol using EDT that can then be tested in a clinical study.

a. Progress Detail

Describe each Statement of Work (SOW) task or logical segment of work on which effort was expended during this quarterly reporting period only. Description shall include pertinent data and graphs in sufficient detail to explain any significant results achieved or problems encountered. A succinct description of the methodology used shall be provided.

For task numbers 1, 3 & 4 Figures with detailed legends (descriptions & methods) have been provided as attachments.

2. Future Plans

Present a brief statement of plans or milestones planned for the next quarter. If any of the plans deviate from the original approved SOW (e.g., new or modified tasks, objectives, experiments, etc), they will require review by the Grants Officer's Representative and final approval by USAMRAA Grants Officer through an award modification prior to initiating any changes.

**We have already initiated work for the expanded scope (task #6) - *In vitro* testing of the efficacy of EDT on the planktonic and on biofilm mode for candida albicans.**

3. Problems / Issues

Any change that is substantially different from the original approved SOW (e.g., new or modified tasks, objectives, experiments, etc.) will require review by the Grants Officer's Representative and final approval by USAMRAA Grants Officer through an award modification prior to initiating any changes.

## a. Current Problems / Issues

Provide a description of current problems or issues that may impede performance or progress of this project along with proposed corrective action. This may include administrative, technical, and/or logistical issues.

**Due to Covid-19 related closures, there are some delays anticipated. The completion of the next tasks will be dependent on when IU allows the research work including animal experiments to resume.**

For an award that includes the recruitment of human subjects for clinical research or a clinical trial, discuss any problems or barriers encountered, if applicable, and what has been done to mitigate those issues. Discussion may highlight enrollment problems, retention problems, and actions taken to increase enrollment and/or improve retention.

## b. Anticipated Problems / Issues

Provide a description of anticipated problems or issues that have a potential to impede performance or progress. Also provide course of actions planned to mitigate problems or to take should the problem materialize.

**See Comment above about the delays in completing tasks due to COVID-19 related closures.**

## 4. Financial Health

Comment on the financial health of the study. Was the study financially on track during this quarterly reporting period and cumulatively for completion as proposed within the period of performance? If not, describe the cause(s), whether this will have a short-term or long-term impact, the likelihood this can be overcome, and provide remediation strategy. Provide amount expended this quarter and cumulatively. State if there was any major equipment procured, sub-award implemented, and/or travel conducted.

**We are on track with our budget and anticipate no problems in moving forward. No major equipment was purchased on this award for last quarter.**

## 5. Personnel Effort

Provide names of current staff along with their roles and percent effort of each on this project. Add additional rows if necessary to list the complete team. If there is more than one project on this award, breakdown according to each project (one table per project).

Personnel	Role	Percent Effort
Principal Investigator	PI	5%
Chandan K. Sen	Co-I	5%
Gayle Gordillo	Co-I	1%
Shomita Steiner	Project Manager	30%
Savita Khanna	Co-I	5%
Suman Santra	Post Doc	30%
Nandini Ghosh	Post Doc	25%
Dolly Khona	Post Doc	60%
Mahadeo Gorain	Post Doc	25%

## 6. Protocol and Activity Status

For awards involving the use of human subjects, use of human cadavers, and/or use of animal subjects, prepare a



summary in accordance with the following subsections. For all other awards, including those involving the use of human anatomical substances (such as tissue or cells or identifiable private information), mark as directed below.

a. Human Use Regulatory Protocols

**TOTAL PROTOCOLS:** State the total number of human use protocols required to complete this project (e.g., 5 human subject research protocols will be required to complete the Statement of Work.”). If not applicable, write “No human subjects research will be performed to complete the Statement of Work.”

**Not applicable – no human subjects proposed**

**PROTOCOLS:** List all human use protocols to be performed to complete the project, and include approved target number for clinical significance, followed by type of submission and type of approval with associated dates, and performance status for each.

Protocol [HRPO Assigned Number]:

Title:

Target required for clinical significance:

Target approved for clinical significance:

Submitted to and Approved by:

Provide bullet point list of protocol development, submission, amendments, and approvals (include IRB in addition to HRPO).

**STATUS:** Provide bullet point list of performance and/or progress status relating to the above protocol and discuss recruitment number, enrollment number, drop outs, disqualified, etc. Discuss any administrative, technical, or logistical issues that may impact performance or progress of the study (e.g. slow enrollment, large dropouts, or adverse events) for the above HPRO approved protocol.

b. Use of Human Cadavers for RDT&E, Education or Training

“Cadaver” is defined as a deceased person or portion thereof, and is synonymous with the terms “human cadaver” and “post-mortem human subject” or “PMHS.” The term includes organs, tissue, eyes, bones, arteries or other specimens obtained from an individual upon or after death. The term “cadaver” does not include portions of an individual person, such as organs, tissue or blood, that were removed while the individual was alive (for example, if a living person donated tissue for use in future research protocols, that tissue is not considered a “cadaver” under this policy, regardless of whether the donor is living or deceased at the time of tissue use).

**TOTAL ACTIVITIES:** State the total number of RDT&E, education or training activities that will involve cadavers. If not applicable, write “No RDT&E, education or training activities involving human cadavers will be performed to complete the Statement of Work (SOW).”

**ACTIVITIES:** Provide the following information in a bulleted list for all RDT&E, education or training activities involving human cadavers conducted or supported during the quarter:

- Title of the RDT&E, education or training activity
- SOW task/aim associated with the activity
- Date the activity was conducted
- Identification of the organization’s responsible individual (e.g., PI or individual primarily

responsible for the activity's conduct)

- Brief description of the use(s) of cadavers in the activity and the total number of cadavers used during the reporting period
- Brief description of the Department of Army organization's involvement in the activity
- Status of document submission and approvals
- Problems encountered in the procurement, inventory, use, storage, transfer, transportation and disposition of cadavers used for RDT&E, education or training. Examples of problems include but are not limited to: loss of confidentiality of cadaveric donors, breach of security, significant deviation from the approved protocol, failure to comply with state laws and/or institutional policies and public relations issues.

c. Animal Use Regulatory Protocols

TOTAL PROTOCOLS: State the total number of animal use protocols required to complete this project (e.g., 2 animal use research protocols will be required to complete the Statement of Work.). If not applicable, write "No animal use research will be performed to complete the Statement of Work."

PROTOCOLS: List all animal use protocols to be performed to complete the project, include approved target number for statistical significance, followed by type of submission and type of approval with associated dates, and performance status for each.

Protocol [ACURO Assigned Number]: **MT17002.18**

Title: **Electroceutical Technology Against Bacterial Drug Resistance**

Target required for statistical significance: n=5

Target approved for statistical significance: n=5

Submitted to and Approved by: **Submitted to ACURO and approved by ACURO USAMRDC Proposal Number MT17002.18 entitled, on July 23rd, 2019**

Provide bullet point list of protocol development, submission, amendments, and approvals (include IACUC in addition to ACURO).

**II IACUC approved protocol # 18048 - Tilted - Dermal wound healing treatment**

STATUS: Provide bullet point list of performance and/or progress status relating to the above protocol and discuss any administrative, technical, or logistical issues that may impact performance or progress of the study (e.g. animal use protocol need revision to minimize animal suffering, animal protocol modification to include additional staff) for the above ACURO approved protocol.

Annual Business Status Report for

Electroceutical technology against bacterial drug resistance

Research Project No. MTEC-17-02-PA-18

EGS#

Reporting Period: Effective Date – 04.25.2020

MTEC Research Project Awardee

Sashwati Roy, PhD

Co-I: Chandan K. Sen, PhD, Gayle M Gordillo, MD, Savita Khanna

Post Doc: Dolly Khona, PhD, Nandini Ghosh, PhD, Vinoj Gopalakrishan, PhD

Research Project Technical POC

Sashwati Roy

Indiana University School of Medicine

444A MRLB; 975 Walnut Street Indianapolis, IN

Tel: 317-278-2706; Email: roysa@iu.edu

Submitted: 04.29.2020

Revised Submitted: 06.15.2020

## 1. CURRENT STAFF

<i>Personnel</i>	<i>% of Effort on project</i>
Program Manager	
Principal Investigator	
Project Manager	
Project Management Officer	
Contracting	
Management Assistant	

## 2. CURRENT EXPENDITURES

DIRECTIONS: FILL OUT TABLE A OR B DEPENDING ON CONTRACT TYPE. TABLE A IS FOR COST REIMBURSABLE CONTRACTS AND TABLE B IS FOR FIX PRICED CONTRACTS.

A. Cost Reimbursable Contracts: Complete only if your contract is Cost Reimbursable or Cost Plus Fixed Fee.

Expenditures should be reflective of cost incurred to date, not exceeding awarded project ceiling. Expenditures should coincide with the latest invoice for the reporting period. For cost reimbursable contracts please use the table below.

<i>Contract Expenditures</i>	<i>Current QTR Expenditures</i>	<i>Cumulative To Date Expenditures</i>
Labor (Personnel and Fringe)	\$	\$
Supplies/Materials	\$	\$
Travel	\$	\$
Equipment	\$	\$
Subcontractors and Consultants	\$	\$
Other Direct Costs	\$	\$
Indirect Costs	\$	\$
Total	\$	\$

## B. Fixed Priced Contracts: Complete only if your contract is Fixed Priced.

Expenditures should be reflective of milestones that are 100% complete and invoiced for. Milestones reported below should correspond to the Milestone Payment Schedule in the Project Award. Milestones can only be invoiced for if they are 100% Complete. Expenditures should coincide with the latest invoice for the reporting period. For fixed priced contracts please use the table below.

MTEC Milestone Number	Milestone Description	Due Date	Government Funds
1	Task – 1 In vitro testing of EDT on the viability of the drug resistant strains tested either in planktonic or biofilm mode of growth used independently or in combination with antibiotic	06/30/2019	\$41,985
2	DoD ACURO Submission	04/30/2019	
3	Quarterly Report 1 (March – June, Technical and Business Reports)	7/25/2019	
4	Quarterly Report 2 (July – September, Technical and Business Report)	10/25/2019	
6	Preclinical porcine wound studies testing efficacy of EDT on the persistence of infection in wounds infected by drug resistant strains in planktonic/biofilm mode.	10/25/2019	\$69,545
5	Receive DoD ACURO approval		
7	Preclinical porcine wound studies testing efficacy of EDT as compared to SoC on wound closure of burn wounds infected by drug resistant strains in planktonic/biofilm mode	12/21/2019	\$41,820
8	Quarterly Report 3 (October – December, Technical and Business Reports)	01/25/2020	
10	Annual Report (March – March, Technical and Business Reports)	04/25/2020	
	Total Expenditures		\$153,350

## C. Cost Share Contributions: Complete only if you're reporting Cost Share:

Cost sharing includes any costs a reasonable person would incur to carry out (necessary to) proposed projects' statements of work not directly paid for by the Government. There are two types of cost sharing: (1) Cash: Outlays of funds to perform the proposed project. Cash includes labor, materials, new equipment, and relevant subcontractor efforts. Sources include new IR&D funds, profit or fee from another contract, overhead or capital equipment expense pool. (2) In-Kind: Reasonable value of in-place equipment, materials or other property used in performance of the proposed project. All cash or in-kind cost sharing availability must be clearly and convincingly demonstrated by the Offeror. The Offeror will be required to provide financial reporting with appropriate visibility into expenditures of Government funds vs. private funds.

Funding Source (Cash)	This Period	Cumulative to Date
Cash	\$0.00	\$0.00
Labor Dollars	\$0.00	\$0.00
Indirect Labor Rates (Overhead/Fringe Benefits)	\$24,450	\$23,340.00
Travel	\$0.00	\$0.00
General & Administrative Services	\$0.00	\$10,000.00
Equipment (New)	\$0.00	\$0.00
Material	\$15,550	\$31,715.00
Other Direct Costs	\$0.00	\$0.00
Other *	\$0.00	\$0.00
Sub-Total	\$40,000.00	\$71,000.00
Funding Source (In-Kind)	This Period	Cumulative to Date
Use of Existing Equipment (Estimated fair market value)	\$20,000	\$29,000.00
Use of Existing Software (Estimated fair market value)	\$0.00	\$0.00
Intellectual Property (Estimated fair market Value)	\$0.00	\$0.00
Space (Land or buildings)	\$0.00	\$0.00
Sub-Total	\$20,000.00	\$29,000.00
Cost Share Total	\$60,000.00	\$100,000.00

### 3. STATUS OF MILESTONES – FILL OUT FOR ALL CONTRACT TYPES (all project milestones are to be included)

All project milestones from the Milestone Payment Schedule, in the project award, should be accounted for below.

MTEC Milestone Number	Milestone Description	Due Date	% Completed this Reporting Period	Cumulative % Complete
1	In vitro testing of EDT on the viability of the drug resistant strains tested either in planktonic or biofilm mode of growth used	6/21/2019		

	independently or in combination with antibiotic.			
2	DoD ACURO submission	4/30/2019		
3	Quarterly Reports 1 (March - June, Technical and Business Reports)	7/25/2019		
4	Quarterly Report 2 ( <b>June</b> -September, Technical and Business Reports)	10/25/2019		
5	Receive DoD ACURO approval	7/30/2019		
6	Preclinical porcine wound studies testing efficacy of EDT on the persistence of infection in wounds infected by drug resistant strains in planktonic/biofilm mode.	<b>10/29/2019</b>		
7	Preclinical porcine wound studies testing efficacy of EDT as compared to SoC on wound closure of burn wounds infected by drug resistant strains in planktonic/biofilm mode.	<b>11/29/2019</b>		
8	Quarterly Report 3 (October - December, Technical and Business Reports)	01/25/2020		
9	Data analysis	03/21/2020		
10	<b>Annual Report</b>	<b>4/25/2020</b>		
11	<b><i>In vitro testing of the efficacy of EDT on the planktonic and on biofilm mode for candida albicans</i></b>	<b>5/29/2020</b>		
12	<b><i>Quarterly Report 4 (March-June, Technical and Business Reports)</i></b>	<b>7/25/2020</b>		
13	<b><i>Quarterly Report 5 (June-Sept, Technical and Business Reports)</i></b>	<b>10/25/2020</b>		
14	<b><i>Preclinical porcine wound studies testing efficacy of EDT on the persistence of infection in wounds infected by CA infection.</i></b>	<b>10/29/2020</b>		
15	<b><i>Data analysis</i></b>	<b>12/29/2021</b>		
16	<b><i>Quarterly Report 6 (Sept-Dec, Technical and Business Reports)</i></b>	<b>01/25/2021</b>		
17	Pre submission meeting with FDA and Preparation/submission of FDA 510(k)	<b>02/28/2021</b>		

	application			
<b>18</b>	Final Reports	<b>04/25/2021</b>		

#### 4. DEVIATION FROM PROJECT PLAN

Any major deviations from the agreed to project plan shall be explained with a discussion of proposed actions to address the deviations.

**Please name this annual report file as EGS#\_Annual Report\_Y# (For example MT160001.01\_Annual Report\_Y2)**  
**Please submit as a PDF file.**  
**Please make sure to fill in the page number on page 3 Table of Contents.**  
**Don't forget to submit an updated Quad Chart as well. Please name the Quad chart file as EGS#\_Quad Chart\_Y#.**