

AWARD NUMBER: W81XWH1990005

TITLE: Assessment of Psychological and Physiological Effects of Augmented Reality: System for Honing Augmented Reality Psychological Suitability (SHARPS)

PRINCIPAL INVESTIGATOR: Dr. Jennifer Riley

PERFORMING ORGANIZATION: Design Interactive

REPORT DATE: April 25, 2020

TYPE OF REPORT: Annual Report

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

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6. AUTHOR(S) Claire Hughes E-Mail: claire.hughes@designinteractive.net			5d. PROJECT NUMBER MT190006		
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7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Design Interactive, Inc. 3504 Lake Lynda Dr, Ste 400 Orlando, FL 32817			8. PERFORMING ORGANIZATION REPORT 2018-677-003		
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14. ABSTRACT The System for Honing Augmented Reality Psychological Suitability (SHARPS) effort seeks to assess psychological impacts of AR on end-user training behavior in a combat casualty care context, which has the potential to lead to increased AR training efficacy and safety. Specifically, the effort will apply interrelated bio-behavioral measures to evaluate AR Psychological Suitability in terms of AR Training Receptivity and AR Training System Efficacy. Results from the assessment will be used to evaluate the psychological impact of AR exposure and develop design guidelines, usability criteria, and best practices guides to ensure AR is safe and effective to use for military medical training.					
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TABLE OF CONTENTS

	<u>Page</u>
Annual Technical Report	4
1. Project Status	5
a. Accomplishments	
b. Reportable Outcomes	
c. Progress Detail	
2. Future Plans	6
3. Problems / Issues	7
a. Current Problems / Issues	
b. Anticipated Problems / Issues	
4. Financial Health	7
5. Personnel Effort	7
6. Protocol and Activity Status.....	7
a. Human Use Regulatory Protocols	
b. Use of Human Cadavers for RDT&E, Education or Training	
c. Animal Use Regulatory Protocols	
Annual Business Report	9
1. Current Staff	10
2. Current Expenditures.....	10
3. Status of Milestones.....	11
4. Deviation from Project Plan.....	11

Annual Technical Status Report for

Assessment of Psychological and Physiological Effects of Augmented Reality: System for Honing Augmented Reality Psychological Suitability (SHARPS)

Research Project No. MTEC 2018-677-003

EGS# MT190006

Reporting Period: 01 MAY '19 – 25 APR '20

MTEC Research Project Awardee

Dr. Kay Stanney, Program Manager

Dr. Jennifer Riley, Principal Investigator

Claire Hughes, Project Manager

Deirdre Maietta, Project Management Officer

Dr. Cali Fidopiastis, Chief Scientist

Peyton Bailey, Research Associate

Nicole Taranta, Data Scientist

Lindsey Lee, Research Intern

Jack Reckmeyer, Research Intern

Research Project Technical POC

Claire Hughes

Design Interactive, Inc.

3504 Lake Lynda Dr. Suite 400

Orlando, FL 32817

407-706-0977

Email address: Claire.Hughes@designinteractive.net

Submitted: April 25, 2020



1. Project Status

a. Accomplishments

Objective 1: Human Subjects Study Planning

- Milestone 1: Award Executed with MTEC
 - Complete 5/1/2019
- Milestone 2: Kickoff Meeting, Project Planning, and Stakeholder Brainstorm
 - Complete 5/16/2019
- Milestone 3: Quarterly Report 1 (April – June)
 - Complete 7/25/2019
- Milestone 4: Develop Human Subjects Study Protocol
 - Complete 08/01/2019
- Milestone 5: IRB/HRPO Submitted
 - Complete 10/23/2019
- Milestone 6: Administrative Review to Approve Continuation to Objective 2
 - Complete 10/17/2019
- Milestone 7: Quarterly Report 2 (July – September)
 - Complete 10/25/2019
- Milestone 8: Experimental Equipment Set up and Tested
 - Complete 11/15/2019
- Milestone 9: Pilot Testing Complete
 - Complete 12/02/2019
- Milestone 10: Quarterly Report 3 (October – December)
 - Complete 1/25/2020
- Milestone 11: Annual Report 1
 - Complete 4/25/2020

b. Reportable Outcomes

N/A

c. Progress Detail

Objective 1: Human Subjects Study Planning

Objective 1 resulted in a human subjects study plan that is ready for study execution and is now complete. The following milestones were completed during this reporting period:

- Milestone 2: Kickoff Meeting, Project Planning, and Stakeholder Brainstorm: Complete
 - Stakeholder requirements were gathered, and project planned occurred at the kickoff meeting on 5/16/2019.
 - Literature review was completed 6/30/2019.
- Milestone 3: Quarterly Report 1 (April – June): Complete
 - A quarterly report was generated for April – June and was submitted to MTEC on 7/25/2019.
- Milestone 4: Develop Human Subjects Study Protocol: Complete
 - Study design prepared, completed, and submitted on 8/1/2019.
- Milestone 5: IRB/HRPO Submitted: Complete

- IRB submission was made to Copernicus IRB and approval was received in September 2019 and subsequently, HRPO submission was prepared, with submission to HRPO on 10/23/2019.
- HRPO Approval was received 1/10/2020
- Milestone 6: Administrative Review to Approve Continuation to Objective 2: Complete
 - A meeting was held with DI's Senior Vice President of Shared Services Karen Gibbons to review the IRB approved protocol and approve continuation to Objective 2. This meeting resulted in administrative approval to commence study activities, and a signed copy of this report was submitted to MTEC on 10/17/2019.
- Milestone 7: Quarterly Report 2 (July – September): Complete
 - A quarterly report was generated for July – September and submitted to MTEC on 10/25/2019.

Objective 2: Human Study Assessment Execution

Objective 2 will result in an assessment of how AR exposure impacts psychological state. The following milestones have been completed toward this objective during this reporting period:

- Milestone 8: Experimental Lab Set up and Tested: Complete
 - The experimental lab has been set up with all the necessary equipment. A report describing the set up and testing that has been completed was submitted to MTEC on 11/15/2019. This report included photographs of the different experimental stations that are being utilized throughout the study, as well as a description of each station and its purpose.
- Milestone 9: Pilot Testing: Complete
 - The pilot study was completed between 11/25/2019 and 11/27/2019. A report on the process results and data collection was generated and submitted to MTEC on 12/2/2019. Due to the delay in HRPO approval, in order to maintain the proposed study schedule , we determined that additional lab space and an additional set of equipment needed to be purchased and set up so that we can run four (4) participants per day instead of the planned two (2) participants per day..
- Milestone 10: Quarterly Report 3 (October – December): Complete
 - A quarterly report was generated for October – December and submitted to MTEC on 1/25/2020.
- Milestone 11: Annual Report 1: Complete
 - An annual report was generated for May 2019 – April 2020 and submitted to MTEC on 4/25/2020.

2. Future Plans

During the next quarter, the following Milestones are planned:

Objective 2: Human Study Assessment Execution

- Milestone 12: Data Collection Set 1—in progress as of 4/13/20
- Milestone 13: Data Collection Set 2
- Milestone 14: Quarterly Report 4 (April – June)

3. Problems / Issues

a. Current Problems / Issues

The outbreak of COVID-19 has delayed data collection. Modification 3 was requested and approved to move Milestones 12 and 13 by 30 days. These milestones are on track for delivery by the new date of 6/1/20, as we have begun running internal participants.

b. Anticipated Problems / Issues

The outbreak of COVID-19 has delayed data collection, but at this time has not impacted any scheduled milestones beyond those noted in 3a above. We will continue to monitor the situation and report any impacts.

4. Financial Health

The project is financially on track.

5. Personnel Effort

Personnel	Role	Percent Effort
Kay Stanney, PhD	Program Manager	5%
Jennifer Riley, PhD	Principal Investigator	5%
Claire Hughes	Project Manager	22%
Deirdre Maietta	Project Management Officer	7%
Cali Fidopiastis, PhD	Chief Scientist	5%
Peyton Bailey	Research Associate	16%
Nicole Taranta	Data Scientist	16%
Lindsey Lee	Research Intern	12%
Jack Reckmeyer	Research Intern	12%

6. Protocol and Activity Status

a. Human Use Regulatory Protocols

TOTAL PROTOCOLS: One (1) human subjects research protocol will be required to complete the Statement of Work.

PROTOCOLS:

Protocol [HRPO Assigned Number]: E01200.1a

Title: Assessment of Psychological and Physiological Effects of Augmented Reality (APPEAR): System for Honing Augmented Reality Psychological Suitability (SHARPS)

Target required for clinical significance: N/A



Target approved for clinical significance: N/A

Submitted to and Approved by:

- Copernicus Group Independent Review Board; Approved 10/11/2019
- U.S. Army Medical Research and Development Command Human Research Protection Office; Approved 01/10/2020

STATUS:

- Recruitment: 17
- Enrollment: 17
- Excluded after Informed Consent: 0
- Drop Out during Experiment: 1
- Administrative, Technical, Logistical Issues: None

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

TOTAL ACTIVITIES: No RDT&E, education or training activities involving human cadavers will be performed to complete the Statement of Work (SOW).

ACTIVITIES: N/A

c. Animal Use Regulatory Protocols

TOTAL PROTOCOLS: No animal use research will be performed to complete the Statement of Work.

PROTOCOLS: N/A

STATUS: N/A

Annual Business Status Report for

Assessment of Psychological and Physiological Effects of Augmented Reality: System for Honing Augmented Reality Psychological Suitability (SHARPS)

Research Project No. MTEC 2018-677-003

EGS# MT190006

Reporting Period: 01 MAY '19 – 25 APR '20

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Email address: Claire.Hughes@designinteractive.net

Submitted: April 25, 2020



1. CURRENT STAFF

<i>Personnel</i>	<i>% of Effort on project</i>
Program Manager	5%
Principal Investigator	5%
Project Manager	22%
Project Management Officer	7%
Chief Scientist	5%
Research Associate	16%
Data Scientist	16%
Research Intern	12%
Research Intern	12%

2. CURRENT EXPENDITURES

A. Cost Reimbursable Contracts: N/A

B. Fixed Priced Contracts:

MTEC Milestone Number	Milestone Description	Due Date	Government Funds
1	Award Executed with MTEC	5/1/2019	\$0
2	Kickoff Meeting, Project Planning, and Stakeholder Brainstorm	5/24/2019	\$50,000
3	Quarterly Report 1 (April-June)	7/25/2019	\$0
4	Study Design Complete	8/1/2019	\$100,000
5	IRB Submitted	9/2/2019	\$100,000
6	Administrative Review to Approve Continuation to Task/Objective 2	10/18/2019	\$58,664
7	Quarterly Report 2 (July - September)	10/25/2019	\$0
8	Experimental Equipment Set Up and Tested	11/15/2019	\$100,000
9	Pilot Testing Complete	12/5/2019	\$150,000
10	Quarterly Report 3 (October – December)	1/25/2020	\$0
11	Annual Report 1	4/25/2020	\$0
	Total Expenditures		\$558,664.00

C. Cost Share Contributions: N/A

3. STATUS OF MILESTONES

MTEC Milestone Number	Milestone Description	Due Date	% Completed this Reporting Period	Cumulative % Complete
1	Award Executed with MTEC	5/1/2019	100%	100%
2	Kickoff Meeting, Project Planning, and Stakeholder Brainstorm	5/24/2019	100%	100%
3	Quarterly Report 1 (April – June)	7/25/2019	100%	100%
4	Study Design Complete	8/1/2019	100%	100%
5	IRB Submitted	9/2/2019	100%	100%
6	Administrative Review to Approve Continuation to Task/Objective 2	10/18/2019	100%	100%
7	Quarterly Report 2 (July – September)	10/25/2019	100%	100%
8	Experimental Equipment Set Up and Tested	11/15/2019	100%	100%
9	Pilot Testing Complete	12/5/2019	100%	100%
10	Quarterly Report 3 (October – December)	1/25/2020	100%	100%
11	Annual Report 1	4/25/2020	100%	100%
12	Data Collection Set 1 Complete	6/1/2020	60%	60%
13	Data Collection Set 2 Complete	6/1/2020	0%	0%
14	Quarterly Report 4 (April – June)	7/25/2020	0%	0%
15	Data Collection Set 3 Complete	8/20/2020	0%	0%
16	Quarterly Reports 5 (July – September)	10/25/2020	0%	0%
17	Data Collection Complete	10/30/2020	0%	0%
18	Quarterly Report 6 (October – December)	1/25/2021	0%	0%
19	Data Analysis Complete	3/1/2021	0%	0%
20	Out Brief and Report Results	4/30/2021	0%	0%
21	Final Technical and Business Status Report	4/30/2021	0%	0%

4. DEVIATION FROM PROJECT PLAN

- Modification 1 was approved on December 19, 2019 moving Milestone 11 from 2/3/2020 to 5/1/2020 due to a delay in HRPO approval.
- Modification 2 was approved on March 12, 2020 adding the HRPO Approval Memorandum as Attachment C to the contract.
- Modification 3 was approved on April 10, 2020 to increase the incremental funding to \$1,249,999 and move Milestones 12 and 13 from 5/1/2020 to 6/1/2020 due to the impact of COVID-19.