Annual Technical Progress Report Format Front Cover

Award Number:	W81XWH1910023
Log Number:	E00705.1a
Project Title:	Biopsychosocial Mechanisms of Chronic Pain Recovery and Maintenance
Principal Investigator Names:	1. Krista Highland, PhD
Principal Investigators Organization and Address:	1. USU, 11300 Rockville Pike, Suite 709, Rockville, MD 20852
Principal Investigator Phone and Email:	301-400-4237 khighland@dvcipm.org
Report Date:	9OCT2020
Report Period:	30SEP2019-29SEP2020

Email the report and any other attachments to the Grants Officer's Representative (GOR) and Grants Specialist at the email addresses specified in the award document. Name the file with the award number, followed by "SemiAnnTechProgReport Month Year."

If you have questions, contact the GOR.

1. **Accomplishments:** The PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency Grants Officer whenever there are significant changes in the project or its direction.

What were the major goals of the project?

Milestone 1: Gain IRB approval: **Achieved 24APR2020**
Milestone 2: Identification of psychosocial and behavioral factors distinguishing groups [original target date 1MAY2020] **[ON HOLD d/t COVID19]**
Milestone 3: All samples banked and aliquoted. [original target date 1MAY2021]
Milestone 4: Manuscript on the biopsychosocial predictors of chronic pain maintenance and recovery. Depending on results, there will likely be a need to divide results into 2-3 manuscripts. [original target date 1SEPT2021]
Milestone 5: Manuscript on serum-saliva biomarkers in chronic pain maintenance and recovery [original target date 30APR2022]

What was accomplished under these goals?

1) Major Activities: Conducted Co-PI team meetings. Obtained IRB approval. Obtained and in the process of submitting Biobank Sample Request Form.
2) Specific Objectives: Obtain Biobank specimens – **[ON HOLD d/t COVID19]**
3) Significant Results/Key Outcomes: None to date
4) Other achievements: None to date

We will not be achieving the Milestone 2 in the intended time frame due to ongoing COVID Pandemic disruptions and IRB delays for the Pain Registry Biobank's IRB at NMC-SD and MAMC (e.g., Biobank specimens originally planned to be collected/ready for this study were not obtained due to ssubstantial delays with the IRB and ceasing enrollment at NMC-SD; intended recruitment was closed indefinitely at MAMC due to substantial delays with IRB and logistics planning).

Describe the Regulatory Protocol and Activity Status (if applicable).

(a) ***Human Use Regulatory Protocols***

TOTAL PROTOCOLS: 2

No human subjects research will be performed to complete the Statement of Work. However, we are providing the information regarding the **exempt** protocol approvals here: On April 24th, the USU IRB provided the following: "Protocol DBS.2020.075 (Ref #921933), entitled "Biopsychosocial Mechanisms of Chronic Pain Recovery and Maintenance" was reviewed by the Uniformed Services University's Human Research Protections Program (HRPP) Office and determined to be considered research not involving human subjects as defined by 32 CFR 219.102(e) because the research involves the analysis of de-identified data not collected for the purposes of this study. As such, this protocol does not require Institutional Review Board (IRB) review."

PROTOCOL (_ 1 of _2 total):

Protocol [HRPO Assigned Number]: Protocol DBS.2020.075 (Ref #921933)
Title: Biopsychosocial Mechanisms of Chronic Pain Recovery and Maintenance
Target required for clinical significance: n/a
Target approved for clinical significance: n/a

SUBMITTED TO AND APPROVED BY:

1. 16DEC2019: Submitted to USU IRB for Exempt Determination Review
2. Jan2020: Dr. Highland reached out to USU IRB to inquire as to the delay in approval; USU IRB indicated that USU had not approved Dr. Highland's PI Waiver due to their contractor status. USU IRB suggested Dr. Highland identify an alternative PI who was a civilian or military employee USU. Dr. Highland identified Dr. Arlene Hudson to serve as the protocol PI.
3. 13JAN2020: Resubmitted the protocol with Dr. Hudson as the PI.
4. 20FEB2020: USU IRB provided administrative stipulations
5. 4MAR2020: Resubmitted the protocol
6. 24APR2020: Dr. Highland inquired as to the delay in approval. IRB assigned a new analyst
7. 24APR2020: IRB Exemption Determination received

PROTOCOL (_2 of _2 total):

Protocol [HRPO Assigned Number]: WRAIR 2665

Title: Biopsychosocial Mechanisms of Chronic Pain Recovery and Maintenance

Target required for clinical significance: Not Human Subjects Research

Target approved for clinical significance: Not Human Subjects Research

SUBMITTED TO AND APPROVED BY: WRAIR Human Research Protections Office
503 Robert Grant Avenue, Silver Spring, MD 20910

Commented [KH1]: Please place your protocol information here.

STATUS OF BOTH PROTOCOLS:

(i) Number of samples requested/original planned target: 0/150

(ii) Report amendments submitted to the IRB and USAMRMC HRPO for review: 0

(iii) Adverse event/unanticipated problems involving risks to subjects or others and actions or plans for mitigation: None

(b) Use of Human Cadavers for Research Development Test & Evaluation (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).**

(c) Animal Use Regulatory Protocols
TOTAL PROTOCOL(S):

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

What do you plan to do during the next reporting period to accomplish the goals and objectives?
Describe briefly what you plan to do during the next reporting period to accomplish the goals and objectives.

1. Engage in strategic planning with Pain Registry Biobank managers to determine timelines and future expectations of sample obtainment
2. Submit sample request form, working carefully with the Pain Registry Biobank managers to ensure completeness
3. Clean and analyze data by establishing R code to the highest replicability standards in data informatics
4. Obtain samples; ensure transfer procedures with Pain Registry Biobank managers to ensure sample integrity

2. Products: List any products resulting from the project during the reporting period. If there are no products to report for the current quarter, state "Nothing to report."

Examples of products include:

- *publications, conference papers, and presentations;*
- *website(s) or other Internet site(s);*
- *technologies or techniques;*
- *inventions, patent applications, and/or licenses; and*
- *other products, such as data or databases, biospecimen collections, germplasm, audio or video products, software, models, educational aids or curricula, instruments or equipment, data and research material, clinical or educational interventions, or new business creation.*

Nothing to report.

3. Participants & Other Collaborating Organizations

What individuals have worked on the project?
Provide the following information for: (1) Project Directors (PDs)/ PIs; and (2) each person who has worked at least one person month per year on the project during the reporting period, regardless of the source of compensation (a person month equals approximately 160 hours of effort).

Provide the name and identify the role the person played in the project. Indicate the nearest whole person month (Calendar, Academic, Summer) that the individual worked on the project. Show the most senior role in which the person worked on the project for any significant length of time. For example, if an undergraduate student graduated, entered graduate school, and continued to work on the project, show that person as a graduate student, preferably explaining the change in involvement.

Describe how this person contributed to the project. If information is unchanged from a previous submission, provide the name only and indicate "no change."

Commented [KH2]: Please add your information in the yellow highlighted sections.

Name: Krista Highland
Project Role: Co-PI
Research Identifier: NA
Nearest person month worked: 1.8
Contribution to Project: no change

Name: Germaine Herrera
Project Role: Protocol Coordinator
Research Identifier: NA
Nearest person month worked: 6.0
Contribution to Project: no change

Name: Mary Jo Lindl
Project Role: Research Activity Coordinator
Research Identifier: NA
Nearest person month worked: 6.0
Contribution to Project: no change

Name: Dr. John Clifford
Project Role: Former PI
Research Identifier:NA
Nearest person month worked:
Contribution to Project: HRPO initial approval(USAMRICD)
Name: Dr. Rasha Hammamieh
Project Role: Current PI
Research Identifier: NA
Nearest person month worked: 0.6
Contribution to Project:Overall Supervision,

Name: Dr. Aarti Gautam
Project Role: Project Co-I
Research Identifier:NA
Nearest person month worked: 0.6
Contribution to Project: Agreement paperwork and HRPO transition to WRAIR

4. **Changes/Problems:** The PD/PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency Grants Officer whenever there are significant changes in the project or its direction. If not previously reported in writing, provide the following additional information or state, "Nothing to Report," if applicable:

a. Actual Problems or delays and actions to resolve them

Commented [KH3]: Anything to add?

Provide a description of current problems or issues that may impede performance or progress of this project along with proposed corrective action. Also describe changes during the reporting period that may have had a significant impact on expenditures, for example, delays in hiring staff or favorable developments that enable meeting objectives at less cost than anticipated.

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.

Current problems:

1. Pain Registry Biobank planned enrollment sites and recruitment rate have been delayed due to IRB and logistic challenges.
2. Though NMC-SD Pain Registry Biobank site was recruiting, recruitment was then halted at NMC-SD (Pain Clinic) due to COVID19 Pandemic.

To mitigate these challenges, the PI has worked extensively with the Pain Registry Biobank to develop logistics for recruitment to enabler fastidious recruitment whenever the COVID19 Pandemic impact is no longer present. However, it is noted that the timeline for which this will occur (e.g., 6-18 months) is unclear.

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.

The COVID19 Pandemic is likely to have a large impact on the timeline of this study, not only for obtainment of samples, but also the continued progress on other study aims and goals; as employee time and laboratory access will be limited (COVID-related studies are taking precedent in the current environment; as such, there will be a deluge of backlog items that the study team will need to complete once operations are back to normal).

5. Special Reporting Requirements:

Quad Charts: If applicable, the Quad Chart (available on https://www.usamraa.army.mil) should be updated and submitted with attachments.

n/a