# Biostatistics Scope of Work Agreement

## General Information

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| **Investigator** | Jacqueline Kiernan Jacqueline.Kiernan@uchealth.org | **Date** | 10/26/18 |
| **Project Number** | HW7 |  |  |
| **Project Title** | Survey of Back Pain Among Recreational Day Hikers and Backpackers | | |

## Project Cost and Milestones

**Project Type:** Average Data Analysis/Publication

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| **Billing Phase and Milestone** | **Cost** |
| **Phase 1: Project Start Up** Discuss and review project materials, establish timelines, deliverables, and data structures with biostatistician. | $ 450 |
| **Phase 2: Exploratory Analysis** Establish preliminary analysis dataset, run descriptive statistics and graphics, and create a report. | $ 3525 |
| **Phase 3: Comprehensive Analysis** Complete comprehensive analysis and present a report. Additional changes to analysis are anticipated and part of the Project Complete phase. | $ 3525 |
| **Phase 4: Project Complete** Complete final analysis and publication quality figures. | $ 450 |
| **Customization:** | 0 |
| **Total Due** | **$ 7950** |

## Understanding of Project

### Project Description

While there is some literature regarding correlations between back pain and backpack load, fitting, etc. in military personnel and school children, the same research is lacking in recreational hikers and backpackers. The aim of this research is to examine back pain in recreational day hikers and back packers, and to explore correlations between hiking/backpacking experience, backpack load, backpack fit, and activity level in the two groups. The goal is to provide some baseline research for future development of safety guidelines to minimize back pain in recreational hikers and backpackers.

### Timelines/Deadlines

* Abstract Deadline: Currently 12/1/18, although this may be pushed back depending on the amount and quality of the data received by 10/29/18.

### Study Design

A survey designed by PT and wilderness medicine professionals at UC Health was sent to several large recreational hiking and backpacking groups. The survey is split into sections designed to measure activity (e.g. average length of backpacking or hiking trips, weight of backpack, years of experience, etc.), back pain severity and location, backpack fitting, and demographics/anthropometrics. The survey is distributed through REDCap and designed to minimize participant burden. For example, if a participant is only in the day hiking group, they will only answer the questions regarding day hiking and vice-versa. All data is self-reported and anonymous.

### Anticipated Sample Size

56,000 people received the survey and as of 10/16/18 approximately 300 had responded. Investigators are hoping for at least 1000 responses at the close of the survey.

### Descriptive Statistics Desired

* Standard table 1 with demographics and anthropometrics for total cohort and split by day hiker and backpacker groups.
* Comparisons between the two groups for all other variables (backpack load, years of experience, back pain severity and location, etc.).
* Within group comparisons among hikers and backpackers to test correlations between experience, pack fit, pack load, etc. with back pain. For example: Among backpackers, do those who have been professionally fitted experience less severe back pain? Is this the same for day hikers?
* Prevalence of back pain location as a subset of all participants who report pain. For example, among backpackers with back pain, what percentage experience the most pain in their lower back?
* Comparisons between day hikers and backpackers matched by average load weight. For example, among day hikers and backpackers who carry similar loads, do backpackers tend to have more severe back pain?

### Hypothesis

**Primary**

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| **Hypothesis** | Hikers and backpackers who have been professionally fitted will have less severe back pain than those who have not. |
| **Outcome(s)** | Back pain yes/no, back pain severity, etc. (all back pain variables) |
| **Explanatory Variable** | Professionally fitted yes/no, pack features, etc. (all fitting variables) |

**Secondary**

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| **Hypothesis** | There is a load weight cutoff, below which the risk of developing back pain is reduced. |
| **Outcome(s)** | Back pain variables |
| **Explanatory Variable** | Average load weight |

**Tertiary**

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| **Hypothesis** | Experience and professional fitting reduce the risk of back pain, and there is a positive interaction effect between the two (i.e. lots of experience and a professionally fit pack reduces back pain more than either one separately) |
| **Outcome(s)** | Back pain variables |
| **Explanatory Variable** | Experience and fit variables |

### Additional Notes

Not tracking which club the respondents are from. Will provide access to the REDCap database once the study is completed. Require tables, figures, and an explanation of statistical methods. REDCap will help us distinguish between a missing data point and an NA meaning not applicable. Might be worth dichotomizing load weight at some point, but for now we will treat it as continuous. Some people were in both the day hiker and backpacker categories but answered questions separately for each activity. SOW sent to investigator for review 10/25/18 but she will not be able to fully approve it until 11/2/18.

**Approval of Agreement**

By approving this Scope of Work Agreement, you are acknowledging that you have read and agree to the project costs and milestones, timelines, project details, and terms and conditions outlined in this document.

**To approve this Scope of Work Agreement click the button below.**

**Approve Scope of Work Agreement ⏵**[**https://forms.ucdenver.edu/secure/cida\_biostatistics\_consulting\_sow\_approval**](https://forms.ucdenver.edu/secure/cida_biostatistics_consulting_sow_approval)

(If you don’t agree with this Scope of Work Agreement or would like to withdraw your request for CIDA services, please send us an email to [cida@ucdenver.edu](mailto:cida@ucdenver.edu?subject=Don't%20Agree%20with%20CIDA%20Scope%20of%20Work%20Agreement) with a brief explanation.)

## Terms and Conditions

### Clean data requirements - ready for analysis

The data are assumed to be cleaned and ready for analyses unless otherwise agreed upon, and a data dictionary should be provided to the analyst. We strongly encourage the use of [REDCap](http://redcapinfo.ucdenver.edu/) as a data collection and management tool.

### Report writing, abstract and manuscript preparation and revision

A final report will be created with an introduction, statistical methods, and results section. These sections will be close to publication ready. The CIDA biostatistician will edit the methods and results section for publication and read the final version of the manuscript prior to submission. Assuming the biostatistician has provided significant contribution to the manuscript in terms of performing analyses and contributing to the results and methods sections, the biostatistician shall be a co-author on the publication, acknowledging the intellectual contribution of the work.

Assuming no substantial new analysis is needed, the CIDA biostatistician will assist with writing a response to reviewer’s statistical questions, make revisions to the paper and review the final version of any revised manuscript. If substantial new analysis is required, a new scope of work will be created and with costs agreed upon by both parties.

### CIDA Authorship Guidelines

The CIDA abides by the [International Committee of Medical Journal Editors (ICMJE) guidelines concerning authorship](http://www.icmje.org/). Visit our CIDA website to learn more about [CIDA’s authorship policies](http://www.ucdenver.edu/academics/colleges/PublicHealth/research/centers/CBC/Biostatistics-Consulting/Pages/authorship.aspx).

**Specific CIDA guidelines include:**

* The biostatistician performing the analysis will be a co-author on the publication to acknowledge the intellectual contribution to the work. Statistician co-authors will use their primary appointment affiliation on manuscripts and abstracts.
* To maintain study and statistical integrity, data collected for publication and abstracts will only be analyzed after study completion.
* The CIDA biostatistician performs the analysis, collaborates in the structuring of the presentation of the results, and writes the "statistical methods" section of the paper.
* The biostatistician reviews the publication and any revisions prior to submission.
* The biostatistician will assist with revisions, keeping in mind your revision deadlines.

### CIDA’s right to cancel or close out a project

Please approve the Scope of Work (SOW) within 15 days (or prior to anticipated start of work, if less). SOWs not approved within 30 days will be closed. Projects which remain inactive for over 60 days will be closed unless prior arrangements have been made, and a final bill will be sent for work completed.

### CCTSI subsidized projects

If the project cost is subsidized by the Colorado Clinical and Translational Sciences Institute (CCTSI), you are required to cite the CCTSI grant in posters and publications. Please review the [CCTSI’s Citation and CTSA grant language](http://www.ucdenver.edu/research/CCTSI/about/Pages/Cite-Grant.aspx).