Biostatistics Scope of Work Agreement

General Information

Investigator	Sabrina Newman sabrina.newman@ucdenver.edu	**Date**	2/22/2018
Project Number	P1291Newman		
Project Title	CEPS program to evaluate teledermatology in the ED		

Project Cost and Milestones

Project Type: CEPS Analysis

Billing Phase and Milestone	Cost
Phase 1: Project Start Up Discuss and review project materials, establish timelines, deliverables, and data structures with biostatistician.	$ 400
Phase 2: Exploratory Data Analysis Establish preliminary analysis dataset, run descriptive statistics and graphics, and create a report.	$ 2100
Phase 3: Comprehensive Analysis Complete comprehensive analysis and present a report. Additional changes to analysis are anticipated and part of the Project Complete phase.	$ 2100
Phase 4: Project Complete Complete final analysis and publication quality figures.	$ 400
Total Due	**$ 5000**

Understanding of Project

Project Description

The goal of this Clinical Effectiveness and Patient Safety (CEPS) project is to evaluate the feasibility and reliability of a store-and-forward teledermatology system at UCH for the diagnosis and triage of Emergency Department (ED) patients requiring outpatient dermatology follow-up. Currently, when an ED patient has a non-urgent dermatology issue, the ED will refer the patient to the derm urgent care, which has an approximate 7 week wait time. To improve this wait time and provide patients with more timely care, teledermatology has been proposed; in this setting, ED providers photograph the area of concern and forward images along with notes to the teledermatologist for assessment, diagnosis, and treatment plan. The ultimate goal is to move toward the teledermatology system for most cases, and reduce in-person visits, and consequently time to appointment, for those needing in-person care. To assess this process and determine when and how teledermatology can be implemented, the investigators have implemented a prospective evaluation to study the following outcomes:

- Descriptive statistics on feasibility and quality outcomes:

  - Is the dermatologist providing telehealth comfortable managing the case?
  - Was image quality and information provided by ED enough to make a diagnosis?
  - Time to in-person consultation
- Return on investment
  - Diagnosis errors – ED docs make a diagnosis (as well as telederm and in-person) – how often do they make an inaccurate diagnosis compared to in-person?
  - How many in-person visits would be required per telederm not feeling comfortable managing the case?
- ED length of stay – compare LOS between those who are referred to derm clinic vs those who are not referred
- Concordance between diagnoses in-person and using teledermatology (in-person is the gold standard)

Potential Additional Analyses include:

- Comparison of show vs no-show – coordinator is looking into whether we can get the information on the no-shows.
- Descriptives on the patient survey

Timelines/Deadlines

The CEPs program funding runs out in June, but there is an option of an extension. Accrual has been slower than anticipated for this project, with only approximately 30 patients enrolled (estimated 90-120). The investigator is exploring possibilities for extensions and new timelines. CIDA will reach out to her during the last week in April to confirm timing, or make alternative plans.

The current time frame is: Study enrollment will end in June / July, and we will begin on data analysis in early-to-mid August (the investigator will be on maternity leave until early August, so start date will be dependent on when she returns). CIDA will reach out to her in early August to confirm timing.

Additional Notes

We estimated this project to be on the smaller side of a CEPS project, however, if the additional analyses are included or project is larger than originally scoped, notify project management as the investigator has additional funds to cover more work.

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 ▸

(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 cbc.project@ucdenver.edu with a brief explanation.)

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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 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. Visit our CIDA website to learn more about CIDA's authorship policies.

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.