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MISSION CONNECT MILD TBI TRANSLATIONAL RESEARCH CONSORTIUM

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The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.
We assisted with the development of the human subject’s proposals and the clinical protocol. Worked with PIs to develop procedures for reliability analysis.

15. SUBJECT TERMS
Human subjects, clinical protocol, reliability analysis
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Introduction

As statistician for specific aims 2 and 3.1, my group will work mainly with PIs and data for these aims, although we will be available to consult on statistics and design issues for any of the PIs and the Scientific Steering Committee. Our purpose is to assist in matters of design, data collection, data management, and to provide, as requested, data analyses for the PIs. In addition we will aid in the dissemination of results. During the first year of the project we expect our work will mainly be in form of advisement on issues of design and data collection, assistance in setting up data bases and developing programs to aid in data cleaning. During years 2 through 4, we will continue advising on data collection and design issues as well as begin the process of cleaning the data in preparation for data analysis. We are also prepared to do data analyses where they might be required for publications based on initial data collections. However, most of the data analyses will take place in the final year when all relevant data has been collected.

Body of the Report

As no data has been collected yet, our primary tasks for the first year have been to advise the PIs on matters of the clinical protocol and preparation of the human subject’s applications. We have also advised collaborating investigators on issues of data management and organization, as part of the design of the Case Report Forms and the automated data collection/management system. In addition, we have worked with Dr. Levin’s team to establish a mechanism by which reliability of the data collected as part of the clinical protocol will be evaluated for reliability.

Key Research Accomplishments

- The clinical protocol was completed with some assistance from our group.
- The human subject’s proposals were completed with some assistance from our group.
- Development of procedures for determining interrater reliability.

Reportable outcomes

Abstract for Military Health Research Forum 2009 on using computer simulations for determining power for research hypotheses.
Conclusions

In the absence of any data being collected as yet, we have been involved primarily in data collection preparation activities. However, these activities are important as the preparations must be completed before any data can be collected.

References

None

Appendices

None