

Building a Consortium

Acute Effects of Neurotrauma Consortium (AENC)

This document describes the time line of events that led to the development of the AENC, from concept to final entity. The main focus of effort has been on the appropriate mechanisms for governance with focus on the Army's Medical Research and Materiel Command (MRMC), the General Leonard Wood Army Community Hospital (GLWACH), the Maneuver Support Center of Excellence (MSCoE), Phelps County Regional Medical Center (PCRMC), the Leonard Wood Institute (LWI) and the various universities conducting Acute Traumatic Brain Injury (TBI) research. This Chronological method helps one understand the complexity of AENC, from the start.

March 2016 – The GLWACH with assistance from PCRMC hosted the first research Summit meeting on 1 April with tours of the installation and meetings that followed. Roughly 70 people attended the first meeting, split into 4 focus groups: Governance, Protection, Identification, Treatments.

2nd Quarter 2016 – Various MOU's, MOA's and Cooperative Agreements were explored, none fit. Word of the Summit reached MRMC, to the Brain Health Research Program Coordinator, COL Sid Hinds. COL Hinds immediately visited FLW, PCRMC, and Missouri S&T, then tasked the GLWACH Commander to find a way to develop a research group to focus on the Acute side of TBI's, offering up a Medical Master Cooperative Research and Development Agreement (CRADA). This document requires participation of an off-post, non-profit medical entity. The CRADA also holds significant HiPPA requirements, thus the need to partner with PCRMC. Further, because LWI is already in the research field, with the Post and Army Research Lab's, they were a natural fit. Developed White Paper for COL Hinds to brief MRMC leadership the Acute TBI research was a very real possibility. MRMC moved very quickly and revised their master CRADA to allow for a three way agreement as MRMC, LWI and PCRMC.

3rd Quarter 2016 – Initial development of MOU and Membership Agreement for Universities to join AENC. Significant coordination and documentation for all of the players.

4th Quarter 2016 - Developing lists of researchers, significant editing of the Membership Agreement and MOU. MOU is designed to coordinate approval efforts and actions between GLWACH, MSCoE and PCRMC. Finalizing CRADA with MRMC and LWI, significant coordination effort to bring the parties together, on the same page. Also brief to the PCRMC Board of Trustees to bring them up to speed on TBI research with GLWACH.

1st Quarter 2017 – Signing of the CRADA, which allows all parties to talk and communicate more openly. This document is a numbered and registered 10 year authorization to conduct medical research on Fort Leonard Wood. This action drove the need to develop a template for researchers to submit proposals for review. The template became part of the draft Membership Agreement. Significant editing and coordination of Membership Agreement

throughout the quarter. In fact, the continued edit and rewrite of the Membership Agreement consumed the rest of the year and became the strongest focus of the AENC team. Further coordination with the GLWACH and MSCoE (Garrison Command) for the MOU was also a primary function during this period. Significant planning for Spring TBI Symposium for the GLWACH and Conclave for the AENC. Finalize MOU, submit Dr. Ma's initial "test" research proposal. This effort pointed out considerable roadblocks and challenges within the FLW approval process. Great support from GLWACH Commander, coordination through installation levels greatest challenge. Support letter referencing the numbered MOU was provided for Dr. Ma's proposal. Support letter from AENC with reference to numbered CRADA provided. Strong effort to bring in PCRMC speakers for Army's TBI symposium and AENC initial board meeting.

2nd Quarter 2017 – April 12 AENC Conclave meeting. Presentation to Installation Strategic Sustainment Planning group. (ISSP) Continue meeting and briefing GLWACH Command group, Develop AENC brochure, initiate Webpage development. Expand engagement with the Universities, prior to issuing Membership Agreement and after issuing MA. Critical to develop the numbers of soldiers and civilians with Acute TBI's at hospitals in the area. Discovered accurate coding and capture of mTBI's is lacking. Developing a champion within MSCoE is both very difficult and critical to success of AENC. Each individual developed has been highly interested, yet has proven to be moderately supportive because of their regular jobs. Considerable editing and coordination of MA through UMC and Wash U.

3rd Quarter 2017 – The Membership Agreement negotiations with 6 Universities has taken an inordinate amount of administrative time. Coordination of each change can be overwhelming, yet must be maintained for transparency and credibility. Marketing of AENC to others began prior to signing of MA. University medical researchers need to collaborate with Engineering schools and vice versa. Prep of generic briefing slides. Researchers pay little attention to the critical understanding of the background, they just want to know about the money available and the target area of research. Must pitch "How the AENC can help you". Membership Agreement signed by LWI, PCRMC, Wash U and SLU. SLU subsequently dropped out. Press releases coordinated with signatories, their PAO and especially with the FLW PAO.

4th Quarter 2017 – More follow-up and marketing of Membership Agreement to potential other schools in MU System. Change to MA, 1st amendment to revise the compensation section, away from 1% fee to actual consulting start-up fee, IRB fee and closing out fee. Missouri Health Professionals (UMC) and System GC approved of the Membership Agreement and 1st Amendment, signed in December. Once completed and active, the Membership Agreement can be shared with other institutions to determine interest.

1st Quarter 2018 – UMKC and Missouri S&T signed the Membership Agreement. S&T had a false start in Dec, but signed in Jan. First project (Brainscope) reviewed and approved by the AENC team, submitted scoring and approval comments to MSCoE for Business Review of training brigades.

