BUDGET JUSTIFICATION – PROJECT 3 – BIOMARKERS OF HUMAN EPILEPTOGENESIS AFTER TRAUMATIC BRAIN INJURY

Personnel:

Paul Vespa will serve as Principal Investigator at 2.4 calendar months in Yrs 1 and 2, 0.9 calendar months in Yr 3, and 2.4 calendar months in Yrs 4 and 5, to oversee all development work associated with Project 3 at the UCLA campus, serve on the principal management team for all Projects, coordinate with all collaborating institutions for this Project, evaluate EEG records, and supervise all clinical activities in the intensive care setting at UCLA. Dr. Vespa's employment reflects anticipated workload changes, wherein time in earlier years must be devoted to programmatic flow and optimization, while later years will require added effort for analyses, interpretations, and preparations for presentations and manuscripts. Benefits are calculated at 28% of base salary.

Ben Ellingson will serve as Co-Investigator at 1.2 calendar months in Yrs 1 and 5, at 1.48 calendar months in Yr 2, 0.24 calendar months in Yr 3, 1.68 calendar months in Yr 4, and 1.2 calendar months in Yr 5, to assist with planning, coding and execution of MRI sequences, and coordination and concordance of MRI data collection and recording across collaborating institutions. Dr. Ellingson's employment reflects anticipated workload changes, wherein time in earlier years must be devoted to programmatic flow and optimization, while later years will require added effort for analyses, interpretations, and preparations for presentations and manuscripts. Benefits are calculated at 27% of base salary.

Manuel Blanco will serve as Co-Investigator at 0.96 calendar months in Yrs 1 and 2, .0.2 calendar months in Yr 3, and 1.8 calendar months in Yrs 4 and 5, to assist in preparing all clinical activities in the intensive care setting at UCLA, and to coordinate MRI phantom studies across all collaborating institutions, including scheduling, shipping, MRI protocol and quality assurance. Dr. Blanco's employment reflects anticipated workload changes, wherein time in earlier years must be devoted to programmatic flow and optimization, while later years will require added effort for analyses, interpretations, and preparations for presentations and manuscripts. Benefits are calculated at 37% of base salary.

Rick Staba will serve as Co-Investigator at 1.2 calendar months during Yrs 1, 2, 4 and 5, and 0.24 calendar months in Yr 3, to provide specific expertise in basic and clinical epileptology, to provide EEG analysis and technical algorithms for pHFO and rHFOs, and to evaluate EEG records. Dr. Staba's employment reflects anticipated workload changes, wherein time in earlier years must be devoted to programmatic flow and optimization, while later years will require added effort for analyses, interpretations, and preparations for presentations and manuscripts. Benefits are calculated at 54.6% of base salary.

Martin Monti will serve as Co- Investigator at 1.44 calendar months in Yrs 1, 2 and 4, 0.24 calendar months in Yr 3, and 1.3 calendar months in Yr 5, to provide specific expertise in clinical MRI studies, including their design, parameter specifications, post-processing and interpretation. Dr. Monti will oversee the parameter specifications and data interpretation for all MRI phantom studies. Dr. Monti's employment reflects anticipated workload changes, wherein time in earlier years must be devoted to programmatic flow and optimization, while later years will require added effort for analyses, interpretations, and preparations for presentations and manuscripts. Benefits are calculated at 34% of base salary.

Equipment:

MRI Phantom studies: A specialized high-reliability MRI phantom suitable for use in all collaborating institutions is needed in Yr 1 to provide a single uniform reference base for all MRI studies, to assure that post-processing and interpretation across MRI machines properly incorporates machine-specific characteristics and variabilities. This device will be shipped once in Yr 1 and again once in Yr 2 from UCLA to each collaborator together with a single mandatory MRI parameter set to generate key reference datasets with known characteristics; the device will be returned to UCLA and results of the MRI phantom test session will be downloaded and interpreted at UCLA.

Inpatient costs:

Inpatient costs are based on N = 4/yr with 2yr follow-up, and include all research-related costs for EEG and MRI data collection. The total per patient cost is estimated at $1500 for each of EEG and MRI.

	Per patient	Year 1	Year 2	Year 3	Year 4	Year 5	Total DC
Inpatient Costs:							
cEEG ICU monitoring	1500	6000	6000	7500	9000	9000	37500

Travel:

Clinical investigators will travel to an annual face-to-face meeting to assure uniform management of clinical methods and data processing, to review data analytics, and to deliberate on case exceptions and complications. More frequent cross-institutional conferencing will occur by Skype or WebEx using institutional electronic conference technologies.

Other expenses:

Technology Infrastructure service (TIF). TIF is a consistently-applied direct charge that is assessed to each and every campus activity unit, regardless of funding source, including units identified as individual grant and contract awards. The TIF pays for campus communication services on the basis of a monthly accounting of actual usage data. These costs are charged as direct costs and are not recovered as indirect costs. This is calculated at $33.28 per FTE per month, which is mandated by the University to be part of the direct costs of grants.

Shipping charges are estimated for regular annual shipment by common carrier of the specialized MRI phantom device to and from each of 12 collaborating sites @ $208.33.

Shipping Equipment to 12 clinical sites round trip	208.333333	2,500.
Scan on the MRI Phantom equipment 12 sites	416.6666667	5,000.

Scan of the MRI phantom will be conducted once each year during Yrs 1 and 2 at all 12 collaborating sites @ $416.66 for standard MRI facility charges.

Clinical costs are based on N=4/yr during Yrs 1 and 2, 5/yr in Yr 3, and 6/yr in Yrs 4 and 5, with follow-up to 2 years for enrollees in Yrs 1 through 3 and up to 1 year for enrollees in Yr 3. These costs include enrollment, acute biomarker collection across 3 days, blood draws across 3 months, telephone continuity calls across 24 months, outpatient research EEG at 6 months, data entry for chronic epilepsy, and computerized neurophysiologic testing with specialized software (Cogstate Brain Injury Batter, New Haven CT). Clinical costs are based on a per patient total of $4000.

	Per patient	Year 1	Year 2	Year 3	Year 4	Year 5	Total DC
Other Costs:							
Enrollment	243	971	971	1,214	1,457	1,457	6,071
TBI Common data elements	343	1,371	1,371	1,714	2,057	2,057	8,571
Acute Biomarker collection (d1,3,5)	243	971	971	1,214	1,457	1,457	6,071
Blood Draws for soluble biomarkers 1, 3, 6, months	643	2,571	2,571	3,214	3,857	3,857	16,071
Telephone continuity calls (6, 12, 18, 24 months)	543	2,171	2,171	2,714	3,257	3,257	13,571
Outpatient Research EEG at 6 months	643	2,571	2,571	3,214	3,857	3,857	16,071
Chronic Epilepsy Data Entry	343	1,371	1,371	1,714	2,057	2,057	8,571
Cogstate Computer testing	1,000	4,000	4,000	5,000	6,000	6,000	25,000
Total per PTs	**4,000**	**16,000**	**16,000**	**20,000**	**24,000**	**24,000**	**99,999**

Indirect costs:

Indirect costs are calculated at 54% of eligible items, which include personnel and other expenses but exclude equipment and inpatient costs.