

**AWARD NUMBER:** W81XWH-19-1-0861

**TITLE:** TRACK-TBI Epileptogenesis Project (TRACK-TBI EPI)

**PRINCIPAL INVESTIGATOR:** Ramon Diaz-Arrastia, MD, PhD

**CONTRACTING ORGANIZATION:** University of Pennsylvania

**REPORT DATE:** OCTOBER 2020

**TYPE OF REPORT:** Annual Report

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Fort Detrick, Maryland 21702-5012

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<b>6. AUTHOR(S)</b>  Ramon Diaz-Arrastia, MD, PhD  E-Mail: ramon.diaz-arrastia@penmedicine.upenn.edu				<b>5d. PROJECT NUMBER</b>	
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<b>13. SUPPLEMENTARY NOTES</b>					
<b>14. ABSTRACT</b> Post-traumatic epilepsy is a common complication of traumatic brain injury (TBI), occurring in up to 20% of civilian patients and as many as 50% of military service members who suffer severe brain trauma, and 3-5% of those who suffer moderate TBI. A sophisticated understanding of the subtypes of epilepsy resulting from brain trauma will be required to successfully develop anti-epileptogenic therapies. We propose to extend the follow-up (FU) period of TRACK-TBI participants from the current 1 year post injury to 5 years post injury (Aim 1). This will allow identification of >90% of participants who will eventually develop PTE. The FU period for SD-2 participants will be extended from the current 6 months post injury to 2 years post-injury (Aim 2), using the same structured telephone interview. This will allow identification of 75% of subjects who will eventually develop PTE. Participants who screen as possible PTE will be invited for an in-depth clinical evaluation with an epileptologist at each site (Aim 3), which will be conducted in-person. TRACK-TBI has enrolled 2722 subjects with TBI from 2/2014 - 7/2018, and SD-2 started enrolling subjects in 2017. This in-person evaluation will include a multi-modal MRI study, as well as collection of blood to measure biomarkers of neurodegeneration and inflammation.					
<b>15. SUBJECT TERMS</b> Magnetic resonance imaging; Biomarkers; Electroencephalography; Epileptogenesis					
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**1. INTRODUCTION:** *Narrative that briefly (one paragraph) describes the subject, purpose and scope of the research.*

Post-traumatic epilepsy is a common complication of traumatic brain injury (TBI), occurring in up to 20% of civilian patients and as many as 50% of military service members who suffer severe brain trauma, and 3-5% of those who suffer moderate TBI. A sophisticated understanding of the subtypes of epilepsy resulting from brain trauma will be required to successfully develop anti-epileptogenic therapies. We propose to extend the follow-up (FU) period of TRACK-TBI participants from the current 1 year post injury to 5 years post injury (Aim 1). This will allow identification of >90% of participants who will eventually develop PTE. The FU period for SD-2 participants will be extended from the current 6 months post injury to 2 years post-injury (Aim 2), using the same structured telephone interview. This will allow identification of 75% of subjects who will eventually develop PTE. Participants who screen as possible PTE will be invited for an in-depth clinical evaluation with an epileptologist at each site (Aim 3), which will be conducted in-person. TRACK-TBI has enrolled 2722 subjects with TBI from 2/2014 – 7/2018, and SD-2 started enrolling subjects in 2017. This in-person evaluation will include a multi-modal MRI study, as well as collection of blood to measure biomarkers of neurodegeneration and inflammation.

**2. KEYWORDS:** *Provide a brief list of keywords (limit to 20 words).*

Magnetic resonance imaging; Biomarkers; Electroencephalography; Epileptogenesis

**3. ACCOMPLISHMENTS:** *The PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency grants official whenever there are significant changes in the project or its direction.*

**What were the major goals of the project?**

*List the major goals of the project as stated in the approved SOW. If the application listed milestones/target dates for important activities or phases of the project, identify these dates and show actual completion dates or the percentage of completion.*

**Specific aim 1: Telephone follow-up for all TRACK-TBI and SD-II participants.**

**1a: TRACK-TBI.** We will extend the follow-up period of 2963 TRACK-TBI participants to 5 years, which will allow ascertainment of PTE in >90% of those who will eventually develop post-traumatic seizures. **1b: SD-II.** We will extend follow-up these severe TBI patients enrolled in SD-II through 2 years after injury, identifying over 75% of those who eventually will develop PTE.

**Specific aim 2: To conduct specialist epileptologist evaluation for TBI patients from both studies who screen positive for PTE.** Participants from both TRACK-TBI and SD-II studies who answer YES to screening questions for PTE will be invited for in-person evaluations by expert epileptologist at each sites.

**Specific aim 3: Obtain existing data from the acute and subacute post-injury period for PTE participants and controls.** We will access existing, prospectively collected data from the acute and subacute period after injury. Such data will be obtained for participants adjudicated to have PTE, as well as a matched control sample who had similar injuries but did not develop PTE. This information includes details injury severity, acute neuroimaging (with cranial CT), multimodality MRI assessments (at 2 weeks and 6 months), and trajectory of recovery over the first year after injury.

**Specific aim 4: To measure candidate blood biomarkers** to determine if they are prognostic for epileptogenesis. Samples collected at 5 years (for TRACK-TBI participants) and 2 years (for SD-II) participants will be assayed for a panel of candidate proteomic biomarkers of epileptogenesis. collected at 1, 3, 5, 14, and 180 days after injury.

*For this reporting period describe: 1) major activities; 2) specific objectives; 3) significant results or key outcomes, including major findings, developments, or conclusions (both positive and negative); and/or 4) other achievements. Include a discussion of stated goals not met. Description shall include pertinent data and graphs in sufficient detail to explain any significant results achieved. A succinct description of the methodology used shall be provided. As the project progresses to completion, the emphasis in reporting in this section should shift from reporting activities to reporting accomplishments.*

**Major Task 1:** During the first year of this project, we have completed most of the Milestone 1 tasks (Study startup, regulatory agreements, staff recruitment, and training).

- (1). We have completed the TRACK-TBI EPI Protocol, Manual of Operations, and Informed Consent Form.
- (2). We have obtained IRB approval for TRACK-TBI EPI study from the University of Pennsylvania IRB, which will serve as the single central IRB for this project.
- (3). We have submitted the required documentation to HRPO on 5/8/2020 for second level approval. We have diligently responded to requests for additional documentation and clarifications from HRPO, although final HRPO approval has not yet been received.
- (4). We have established subcontracts between Penn and the University of California, San Francisco, Univ. of Pittsburgh, the University of California, San Diego.
- (5). Working with the TRACK-TBI Data Coordinating Center at UCSF, we have finalized the TRACK-TBI EPI specific Case Report Forms and Database fields.
- (6). We have completed the qualification of MRI instruments at each of the TRACK-TBI Clinical Sites.
- (7). We have contracted with Quesgen, Inc, the Data Repository for TRACK-TBI, to modify the database to include data variables specific to TRACK-TBI EPI.
- (8). We have recruited expert epileptologists at each of the TRACK-TBI Clinical Sites, and training on the on the DISCOVER structured assessments has started. We are awaiting until we are within 2 weeks of launching the project at each site before final DISCOVER training is completed.
- (9). Working with investigators on the TRACK-TBI LONG project, we trained study staff at each of the TRACK-TBI Sites for the in-person TRACK-TBI LONG evaluations.
- (10). We have reviewed existing TRACK-TBI Outcome Data (for 6 and 12 months after injury) and identified participants who screen positive for post-traumatic epilepsy. Analysis of this data was submitted for publication to a peer-reviewed neurological journal (Burke et al, JAMA Neurology [submitted]—included in Appendix)
- (11). We have finalized the TRACK-TBI LONG MRI acquisition parameters, and have implemented this at several of the clinical sites.

**Major Task 2:** Although we have yet to receive HRPO approval to spend funds from this project, we have leveraged the ongoing TRACK-TBI LONG study (funded through a philanthropic gift to UCSF from the National Football League) and have already completed telephone follow-up assessments on 1221 participants from the TRACK-TBI U01 and SD-II studies. This surpasses our target of 350 telephone evaluations within the first year of the project.

Upon discussions with Dr. Geoff Manley and the rest of the TRACK-TBI Executive Committee, we will use funds from the TRACK-TBI EPI, once we obtain HRPO approval, to complete the planned telephone assessments (target n=2000) and to obtain a second telephone assessment from participants who have already been contacted. This will allow longitudinal evaluations and will pick up additional participants to develop post-traumatic epilepsy.

We are poised to start in-person Epilepsy Clinic visits within the 1<sup>st</sup> Quarter of 2021. This will correspond to the time when in-person evaluations for research projects will be possible at most sites, as many of the sites have been unable to schedule in-person research visits due to COVID-19 restrictions.

**What opportunities for training and professional development has the project provided?**

*If the project was not intended to provide training and professional development opportunities or there is nothing significant to report during this reporting period, state “Nothing to Report.”*

*Describe opportunities for training and professional development provided to anyone who worked on the project or anyone who was involved in the activities supported by the project. “Training” activities are those in which individuals with advanced professional skills and experience assist others in attaining greater proficiency. Training activities may include, for example, courses or one-on-one work with a mentor. “Professional development” activities result in increased knowledge or skill in one’s area of expertise and may include workshops, conferences, seminars, study groups, and individual study. Include participation in conferences, workshops, and seminars not listed under major activities.*

This project was not intended to provide training and professional development opportunities. However, Dr. James Gugger, Instructor in Neurology at the University of Pennsylvania, has joined Dr. Diaz-Arrastia’s research group at a post-doctoral fellow, with an interest in developing a research program on post-traumatic epilepsy. Dr. Gugger was awarded a highly competitive Fellowship from the American Epilepsy Society to work with Dr. Diaz-Arrastia’s group, and the TRACK-TBI EPI data will provide an excellent opportunity for Dr. Gugger’s professional development, primarily relating to analysis of MRI and blood biomarker measurements.

**How were the results disseminated to communities of interest?**

*If there is nothing significant to report during this reporting period, state “Nothing to Report.”*

*Describe how the results were disseminated to communities of interest. Include any outreach activities that were undertaken to reach members of communities who are not usually aware of these project activities, for the purpose of enhancing public understanding and increasing interest in learning and careers in science, technology, and the humanities.*

Dr. Diaz-Arrastia gave a presentation to the Patient and Caregiver Support Group of the Epilepsy Society of South Eastern Pennsylvania, during which he discussed the ongoing research at the University of Pennsylvania. Dr. Diaz-Arrastia also gave a presentation to the TBI Patient Support Group at the University of Pennsylvania, focused on the long-term consequences of TBI, which include post-traumatic epilepsy.

**What do you plan to do during the next reporting period to accomplish the goals?**

*If this is the final report, state “Nothing to Report.”*

*Describe briefly what you plan to do during the next reporting period to accomplish the goals and objectives.*

We expect to obtain HRPO approval for launching the clinical activities of this project within the first quarter of 2021. Since we have completed staff recruitment and training in most of the procedures, we expect that enrollment will proceed efficiently at all the clinical sites.  
We will carefully (1). Monitor CRF completion, to insure that complete and clean data is being entered into the TRACK-TBI EPI database. When appropriate, data queries will be sent to the clinical sites, to insure accuracy.  
(2). Monitor the transfer and the quality of the MRI scans obtained, which will be sent to the MRI Core at UCSF.  
(3). Monitor the transfer and quality of blood specimens (serum, plasma, DNA, PAXGene) collected as part of this project and sent to the TRACK-TBI Biospecimen Repository at the university of Pittsburgh

- 4. IMPACT:** *Describe distinctive contributions, major accomplishments, innovations, successes, or any change in practice or behavior that has come about as a result of the project relative to:*

**What was the impact on the development of the principal discipline(s) of the project?**

*If there is nothing significant to report during this reporting period, state “Nothing to Report.”*

*Describe how findings, results, techniques that were developed or extended, or other products from the project made an impact or are likely to make an impact on the base of knowledge, theory, and research in the principal disciplinary field(s) of the project. Summarize using language that an intelligent lay audience can understand (Scientific American style).*

Nothing to Report. This project is in its early stages.

**What was the impact on other disciplines?**

*If there is nothing significant to report during this reporting period, state “Nothing to Report.”*

*Describe how the findings, results, or techniques that were developed or improved, or other products from the project made an impact or are likely to make an impact on other disciplines.*

Nothing to Report. This project is in its early stages.

**What was the impact on technology transfer?**

*If there is nothing significant to report during this reporting period, state “Nothing to Report.”*

*Describe ways in which the project made an impact, or is likely to make an impact, on commercial technology or public use, including:*

- *transfer of results to entities in government or industry;*
- *instances where the research has led to the initiation of a start-up company; or*
- *adoption of new practices.*

Nothing to Report. This project is in its early stages.

**What was the impact on society beyond science and technology?**

*If there is nothing significant to report during this reporting period, state “Nothing to Report.”*

*Describe how results from the project made an impact, or are likely to make an impact, beyond the bounds of science, engineering, and the academic world on areas such as:*

- *improving public knowledge, attitudes, skills, and abilities;*
- *changing behavior, practices, decision making, policies (including regulatory policies), or social actions; or*
- *improving social, economic, civic, or environmental conditions.*

Nothing to Report. This project is in its early stages.

**5. CHANGES/PROBLEMS:** *The PD/PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency grants official whenever there are significant changes in the project or its direction. If not previously reported in writing, provide the following additional information or state, "Nothing to Report," if applicable:*

Nothing to Report.

It is possible that, given delays due to HRPO approval and COVID-19 restrictions, that re-budgeting will be necessary during Year 2 of this project. We will obtain written approval from CDMRP before any re-budgeting is done.

**Actual or anticipated problems or delays and actions or plans to resolve them**

*Describe problems or delays encountered during the reporting period and actions or plans to resolve them.*

- (1). COVID-19 restrictions are anticipated to continue to slow the in-person evaluations. We are anticipating that these will be lifted by the end of the 2<sup>nd</sup> quarter of 2021.
- (2). Staff turnover in the Penn Department of Neurology Business Office have delayed the subcontracting with all the clinical sites. The delay due to this has been less than 2 months, due to parallel delays in completing the TRACK-TBI LONG Outcome Assessment procedures.

**Changes that had a significant impact on expenditures**

*Describe changes during the reporting period that may have had a significant impact on expenditures, for example, delays in hiring staff or favorable developments that enable meeting objectives at less cost than anticipated.*

Due to the factors outlined above, our expenditures are lower than anticipated by this point in the project. Fortunately, we have been able to leverage work done through the TRACK-TBI LONG project (funded by a philanthropic grant from the National Football League) to complete >1200 telephone assessments. We expect that the carry-forward funds will be spent over the next 12 months, with the need for minor re-budgeting.

**Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents**

*Describe significant deviations, unexpected outcomes, or changes in approved protocols for the use or care of human subjects, vertebrate animals, biohazards, and/or select agents during the reporting period. If required, were these changes approved by the applicable institution committee (or equivalent) and reported to the agency? Also specify the applicable Institutional Review Board/Institutional Animal Care and Use Committee approval dates.*

**Significant changes in use or care of human subjects**

No significant changes.

**Significant changes in use or care of vertebrate animals**

Not applicable. This project does not utilize vertebrate animals.

### Significant changes in use of biohazards and/or select agents

Not applicable.

**6. PRODUCTS:** *List any products resulting from the project during the reporting period. If there is nothing to report under a particular item, state “Nothing to Report.”*

- **Publications, conference papers, and presentations**

*Report only the major publication(s) resulting from the work under this award.*

**Journal publications.** *List peer-reviewed articles or papers appearing in scientific, technical, or professional journals. Identify for each publication: Author(s); title; journal; volume: year; page numbers; status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

J Burke, J Gugger, K Ding, et al, Effect of late post-traumatic seizures on outcomes after traumatic brain injury over the first year: a TRACK-TBI study. *JAMA Neurology* [submitted, under review, December 2020]

**Books or other non-periodical, one-time publications.** *Report any book, monograph, dissertation, abstract, or the like published as or in a separate publication, rather than a periodical or series. Include any significant publication in the proceedings of a one-time conference or in the report of a one-time study, commission, or the like. Identify for each one-time publication: author(s); title; editor; title of collection, if applicable; bibliographic information; year; type of publication (e.g., book, thesis or dissertation); status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

None

**Other publications, conference papers and presentations.** *Identify any other publications, conference papers and/or presentations not reported above. Specify the status of the publication as noted above. List presentations made during the last year (international, national, local societies, military meetings, etc.). Use an asterisk (\*) if presentation produced a manuscript.*

J Gugger, J Burke, K Ding, et al, The effect of post-traumatic epilepsy on outcomes after traumatic brain injury: a TRACK-TBI study [Abstract]. Presented at the American Epilepsy Society Annual Meeting, December 6, 2020 (Virtual)

- **Website(s) or other Internet site(s)**

List the URL for any Internet site(s) that disseminates the results of the research activities. A short description of each site should be provided. It is not necessary to include the publications already specified above in this section.

None.

- **Technologies or techniques**

Identify technologies or techniques that resulted from the research activities. Describe the technologies or techniques were shared.

None.

- **Inventions, patent applications, and/or licenses**

Identify inventions, patent applications with date, and/or licenses that have resulted from the research. Submission of this information as part of an interim research performance progress report is not a substitute for any other invention reporting required under the terms and conditions of an award.

None.

- **Other Products**

Identify any other reportable outcomes that were developed under this project. Reportable outcomes are defined as a research result that is or relates to a product, scientific advance, or research tool that makes a meaningful contribution toward the understanding, prevention, diagnosis, prognosis, treatment and /or rehabilitation of a disease, injury or condition, or to improve the quality of life. Examples include:

- data or databases;
- physical collections;
- audio or video products;
- software;
- models;
- educational aids or curricula;
- instruments or equipment;
- research material (e.g., Germplasm; cell lines, DNA probes, animal models);
- clinical interventions;
- new business creation; and
- other.

None.

## 7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

### What individuals have worked on the project?

Provide the following information for: (1) PDs/PIs; and (2) each person who has worked at least one person month per year on the project during the reporting period, regardless of the source of compensation (a person month equals approximately 160 hours of effort). If information is unchanged from a previous submission, provide the name only and indicate “no change”.

#### Example:

Name: Mary Smith  
Project Role: Graduate Student  
Researcher Identifier (e.g. ORCID ID): 1234567  
Nearest person month worked: 5

Contribution to Project: Ms. Smith has performed work in the area of combined error-control and constrained coding.

Funding Support: The Ford Foundation (Complete only if the funding support is provided from other than this award.)

Name: Ramon Diaz-Arrastia, MD, PhD (University of Pennsylvania)

Project Role: Principal Investigator

Months worked: 1

Contribution to Project: Dr. Diaz-Arrastia has supervised the work of Ms. Dabrowski in preparing the TRACK-TBI EPI MOP, ICF, in revising the protocol based on comments from the Penn IRB. Dr. Diaz-Arrastia has also coordinated with Drs. Manley and Lowenstein and the TRACK-TBI Executive Committee regarding identification and recruitment of expert epileptologists at each TRACK-TBI Clinical Site. Finally, Dr. Diaz-Arrastia has worked with UCSF Staff for developing the TRACK-TBI EPI-specific CRFs and database fields. With colleagues at Penn and UCSF, he participated in the FITBIR orientation start-up call for this project.

Name: Cian Dabrowski, MA (University of Pennsylvania)

Project Role: Project Manager, TRACK-TBI EPI

Months worked: 3

Contribution to Project: Ms. Dabrowski has worked under Dr. Diaz-Arrastia's direction in completing the Protocol, Manual of Operations, Informed Consent Form, and Case Report Forms. She completed the IRB submission and approval process at the University of Pennsylvania IRB, and has managed the HRPO submission process. She has also interphased with UCSF staff exploiting the built-in synergies between the TRACK-TBI EPI project and the ongoing TRACK-TBI LONG.

Name: Sabrina Taylor, PhD (University of California, San Francisco)

Project Role: Project Manager, TRACK-TBI

Months worked: 1

Contribution to Project: Dr. Taylor has coordinated incorporated the TRACK-TBI EPI protocol into the larger TRACK-TBI LONG effort, working closely with Drs. Diaz-Arrastia and Manley, and Ms. Dabrowski. The Protocol, MOP, ICF forms have all been completed as part of this effort. Dr. Taylor has also coordinated the IRB ceding process at 15 clinical sites, which will cede to the University of Pennsylvania IRB (which will function as the central IRB for this project).

Name: James Burke, MD, PhD (University of California, San Francisco)

Project Role: Post-doctoral fellow

Months worked: 1

Contribution to Project: Dr. Burke is a neurosurgery resident at UCSF. He has worked closely with Drs. Diaz-Arrastia and Manley analyzing the 12 month outcome data from the TRACK-TBI U01 Project, and confirmed that the NINDS Epilepsy Screening Questionnaire is sensitive and specific as a screening tool for PTE. This analysis was presented in abstract form at the American Epilepsy Society meeting, and a manuscript was submitted for publication to *JAMA Neurology*.

Name: James Gugger, MD, PharmD (University of Pennsylvania)

Project Role: Post-doctoral Fellow

Months worked: 1

Contribution to Project: Dr. Gugger is an Epileptologist and post-doctoral fellow at Penn. He is supported by an American Epilepsy Society Post-doctoral fellowship to study post-traumatic epilepsy. He worked closely with Dr. Diaz-Arrastia and Burke in the analysis of the results of the NINDS PTE screening questionnaire from the TRACK-TBI U01 project, and was involved in preparing this manuscript for publication.

Name: Vibeke Brink (QuesGen Systems)

Project Role: Database specialist

Months worked: 1

Contribution to Project: Ms. Brink is a database specialist who has developed the TRACK-TBI Research Database and Case Report Forms. She has worked to create the TRACK-TBI LONG Case Report Forms (CRFs) and Database, and have created the unique TRACK-TBI EPI CRFs.

**Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?**

*If there is nothing significant to report during this reporting period, state “Nothing to Report.”*

*If the active support has changed for the PD/PI(s) or senior/key personnel, then describe what the change has been. Changes may occur, for example, if a previously active grant has closed and/or if a previously pending grant is now active. Annotate this information so it is clear what has changed from the previous submission. Submission of other support information is not necessary for pending changes or for changes in the level of effort for active support reported previously. The awarding agency may require prior written approval if a change in active other support significantly impacts the effort on the project that is the subject of the project report.*

Nothing to report.

**What other organizations were involved as partners?**

*If there is nothing significant to report during this reporting period, state “Nothing to Report.”*

*Describe partner organizations – academic institutions, other nonprofits, industrial or commercial firms, state or local governments, schools or school systems, or other organizations (foreign or domestic) – that were involved with the project. Partner organizations may have provided financial or in-kind support, supplied facilities or equipment, collaborated in the research, exchanged personnel, or otherwise contributed.*

*Provide the following information for each partnership:*

Organization Name:

Location of Organization: (if foreign location list country)

Partner's contribution to the project (identify one or more)

- *Financial support;*
- *In-kind support (e.g., partner makes software, computers, equipment, etc., available to project staff);*
- *Facilities (e.g., project staff use the partner's facilities for project activities);*
- *Collaboration (e.g., partner's staff work with project staff on the project);*
- *Personnel exchanges (e.g., project staff and/or partner's staff use each other's facilities, work at each other's site); and*
- *Other.*

Organization Name: University of California, San Francisco

Location of Organization: San Francisco, California

Partner's contribution to the project: Collaboration. UCSF houses the Clinical Coordinating Center and Neuroimaging Core for the TRACK-TBI Project. Investigators at UCSF (Drs. Manley and Taylor) have played key roles in finalizing the TRACK-TBI LONG Outcomes Assessment Battery, Protocol, and MOP, which will be adopted in the TRACK-TBI EPI project.

Organization Name: University of Pittsburgh Medical Center

Location of Organization: Pittsburgh, Pennsylvania

Partner's contribution to the project: Collaboration. The University of Pittsburgh houses the TRACK-TBI Biorepository. Investigators at Pitt (Dr. Puccio) has adapted the TRACK-TBI Biorepository procedures to accept samples from the TRACK-TBI EPI project.

Organization Name: University of California, San Diego

Location of Organization: San Diego, California

Partner's contribution to the project: Collaboration. UCSD houses the Biostatistical Core for the TRACK-TBI Project. Dr. Jain and her collaborators have played a key role in developing the Analytical Plan for TRACK-TBI EPI, in conjunction with the TRACK-TBI LONG project.

Organization Name: QuesGen Systems, Inc

Location of Organization: Burlingame, California

Partner's contribution to Coordinating Center and Neuroimaging Core for the TRACK-TBI Database. Investigators at QuesGen have worked to create the TRACK-TBI LONG Case Report Forms (CRFs) and Database, and have created the unique TRACK-TBI EPI CRFs.

## **8. SPECIAL REPORTING REQUIREMENTS**

### **COLLABORATIVE AWARDS:**

### **QUAD CHARTS:**

**9. APPENDICES:** *Attach all appendices that contain information that supplements, clarifies or supports the text. Examples include original copies of journal articles, reprints of manuscripts and abstracts, a curriculum vitae, patent applications, study questionnaires, and surveys, etc.*

(1). PDFs of the following are attached.

J Burke, J Gugger, K Ding, et al, Effect of late post-traumatic seizures on outcomes after traumatic brain injury over the first year: a TRACK-TBI study. *JAMA Neurology* [submitted, under review, December 2020]

J Gugger, J Burke, K Ding, et al, The effect of post-traumatic epilepsy on outcomes after traumatic brain injury: a TRACK-TBI study [Abstract]. Presented at the American Epilepsy Society Annual Meeting, December 6, 2020 (Virtual)

(2). TRACK-TBI LONG Manual of Operations

(3). DISCOVER Interview