



## **Sample Application for Small Business Funding**

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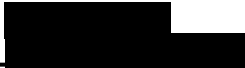
**SUMMARY STATEMENT**

**PROGRAM CONTACT:**  
**BRADLEY WISE**

( Privileged Communication )

*Release Date:* 11/23/2018

*Revised Date:*



*Application Number:* 1 R42 AG062026-01A1

**Principal Investigators (Listed Alphabetically):**

**FISCHL, BRUCE**  
**WIGHTON, PAUL (Contact)**

**Applicant Organization: CORTICOMETRICS, LLC**

*Review Group:* ZRG1 SBIB-T (10)  
Center for Scientific Review Special Emphasis Panel  
Small Business: Medical Imaging

*Meeting Date:* 11/15/2018  
*Council:* JAN 2019  
*Requested Start:* 05/01/2019

*RFA/PA:* PAS18-188  
*PCC:* 3BFBRBW

*Project Title:* Unbiased longitudinal neuromorphometry for clinical decision support

*SRG Action:* Impact Score:20  
*Next Steps:* Visit [https://grants.nih.gov/grants/next\\_steps.htm](https://grants.nih.gov/grants/next_steps.htm)  
**Human Subjects:** 10-No human subjects involved  
**Animal Subjects:** 10-No live vertebrate animals involved for competing appl.

Project Year	Direct Costs Requested	Estimated Total Cost
1	[REDACTED]	[REDACTED]
2	[REDACTED]	[REDACTED]
3	[REDACTED]	[REDACTED]
<b>TOTAL</b>	[REDACTED]	[REDACTED]

**ADMINISTRATIVE BUDGET NOTE:** The budget shown is the requested budget and has not been adjusted to reflect any recommendations made by reviewers. If an award is planned, the costs will be calculated by Institute grants management staff based on the recommendations outlined below in the COMMITTEE BUDGET RECOMMENDATIONS section.

## **1R42AG062026-01A1 Wighton, Paul**

**RESUME AND SUMMARY OF DISCUSSION:** In this very strong Fast Track STTR proposal, investigators seek to advance and commercialize a longitudinal, neuro-morphometric image processing pipeline for radiology, neurology and related clinical fields using MRI data and modern software practices such as docker and common workflow language (CWL). The study section lauded the sound scientific premise and significance of the proposal due to its potential in helping clinicians quantitatively assess and interpret changes in brain MRI data and identifying effective treatment early in the stages of Alzheimer's disease. Previous reviewer's comments were addressed effectively by adding functionalities for segmentation of hippocampal subfields and amygdalar nuclei and for longitudinal prediction of the onset of Alzheimer's disease. Other clear advantages of this focused proposal include a well-thought out innovative approach with solid preliminary data, rigorous assessment criteria and technical foundation by an excellent team of investigators and collaborators. Overall, the study section enthusiastically agreed that this technology could potentially advance a clinically useful neuro-morphometric longitudinal analysis stream with more statistical power than is currently available commercially.

**DESCRIPTION (provided by applicant):** Normal human neuroanatomy is incredibly variable, and increases with age. This impedes the ability of neuroimaging to detect effects in neurological conditions such as Alzheimer's disease (AD), Huntington's disease (HD), multiple sclerosis (MS) and schizophrenia. Most of the recently available state-of-the-art quantitative imaging tools still use cross-sectional methods to analyze repeated scans. These tools lack the sensitivity to monitor subtle progressive changes because such approaches do not account for the large intrinsic variability of normal neuroanatomy. The goal of this project is to commercialize a longitudinal, neuro-morphometric image processing pipeline for use in radiology, neurology and related clinical fields. The successful completion of this project will result in a clinically useful neuro-morphometric longitudinal analysis stream with more statistical power than is currently available commercially. This increase in power will directly translate into an enhanced ability to detect and assess progression at both the individual and group levels. It will also alleviate a major pain point in current longitudinal neuroradiology reading workflows, reducing radiology report turnaround times (RTAT).

**PUBLIC HEALTH RELEVANCE:** The proposed project will develop software to help clinicians quantitatively assess and interpret changes in brain MRI data in a way that integrates seamlessly into an existing clinical workflow. It will help radiologists detect changes to brain structures earlier and more accurately, in neurological conditions such as Alzheimer's disease (AD), Huntington's disease (HD), multiple sclerosis (MS) and schizophrenia. The resulting efforts will translate into an enhanced ability to detect and assess disease progression, and reduce radiology report turnaround time.

### **CRITIQUE 1**

Significance: 2  
Investigator(s): 1  
Innovation: 3  
Approach: 2  
Environment: 1

**Overall Impact:** This is a resubmission of a Fast-Track STTR application, the investigators seek to optimize Freesurfer for longitudinal analysis. The software will be hardened with modern software practices such as docker and common workflow language (CWL). The software will allow radiologists to more conveniently leverage the benefits of longitudinal imaging. Scientific premise is solid, building upon the team's extensive experience and expertise in this area. The project is scientifically rigorous with carefully worked out details on how the aims are going to be achieved. The team is very competent

to carry out the research. Previous concerns on innovation are addressed by adding functionalities for segmentation of hippocampal subfields and amygdalar nuclei and for longitudinal prediction of the onset of Alzheimer's disease.

### **1. Significance:**

#### **Strengths**

- Most quantitative imaging tools are still cross-sectional not longitudinal.
- Cross-sectional studies confounded by large inter-subject variability in neuroanatomy.
- Technology will increase sensitivity in detecting subtle disease progression.
- Technology will increase report turnaround times (RTAT).
- Help radiologists avoid having to find comparable slices for longitudinal follow-up scans.

#### **Weaknesses**

- Nothing major.

### **2. Investigator(s):**

#### **Strengths**

- The investigators are very strong and have the relevant expertise and experience to carry out the proposed research.

#### **Weaknesses**

- Nothing major.

### **3. Innovation:**

#### **Strengths**

- Longitudinal analysis pipeline.
- Modern software deployment using docker.
- Integration with AutoRegister.
- Midspace registration.

#### **Weaknesses**

- Some of these techniques were developed quite some time ago, but additional functionalities are now added in response to previous comments, including new tools for segmentation of hippocampal subfields and amygdalar nuclei and for longitudinal prediction of the onset of Alzheimer's disease.

### **4. Approach:**

#### **Strengths**

- The research plan is scientifically rigorous with carefully worked out experimental plans.
- Use of state-of-the-art software deployment techniques (docker, CWL, etc.).
- Solid software development practices.
- Speed optimization for clinical use, aiming 15 minutes total execution time.

- Integration of the longitudinal pipeline with slice-prescriptioning using the AutoRegister tool, which is developed by the same company (CortioMetrics).

**Weaknesses**

- Nothing major.

**5. Environment:**

**Strengths**

- Excellent.

**Weaknesses**

- Nothing major.

**Phase II (Type 2 R42 and Type 2 R44 applications):**

**Direct Phase II (Type 1 R44 applications-See Face Page):**

**Fast Track (Type 1 R42 and Type 1 R44 applications):**

**Protections for Human Subjects**

Not Applicable (No Human Subjects)

**Inclusion of Women, Minorities and Children:**

- Sex/Gender:
- Race/Ethnicity:
- For NIH-Defined Phase III trials, Plans for valid design and analysis:
- Inclusion/Exclusion of Children under 18:

**Vertebrate Animals:**

Not Applicable (No Vertebrate Animals)

**Biohazards:**

Not Applicable (No Biohazards)

**Resource Sharing Plans:**

Acceptable

**Budget and Period of Support:**

Recommend as Requested

## CRITIQUE 2

Significance: 1  
Investigator(s): 1  
Innovation: 2  
Approach: 2  
Environment: 1

**Overall Impact:** This Fast Track application will develop further and commercialize a software environment and pipeline that describes longitudinal changes in brain structures as seen in MRI. Those image-based biomarkers may be helpful in identifying effective treatment early in the stages of Alzheimer's disease, and thus could have a powerful influence on the field. The overall project is rigorous (though details of the validation process are minimal) and the investigators are experienced and expert. They will seek FDA approval and have had preliminary discussions there; this work will focus on validation in accord with those discussions. The commercialization plan makes no estimate of the potential market nor of the additional funds required to bring the product to market.

### 1. Significance:

#### Strengths

- Longitudinal analysis of brain structures, especially including subregions of the hippocampus and the amygdala, will help to identify and track early signs of Alzheimer's disease. This could yield a four-fold improvement in discrimination compared to cross-sectional methods.
- This biomarker may be helpful in identifying effective treatments.

#### Weaknesses

- None noted

#### Addition to the review criteria: "Is there a strong scientific premise?" Yes

- Specifically, has the applicant:
  - **Provided sufficient justification for the proposed work?** Yes
  - **Cited appropriate work and/or preliminary data?** Yes
  - **Appropriately identified strengths and weaknesses in prior work in the field?** Yes
  - **Proposed to fill a significant gap in the field?** Yes

### 2. Investigator(s):

#### Strengths

- Excellent team: Wighton for software and Fischl for algorithms and analysis

#### Weaknesses

- None noted

### 3. Innovation:

#### Strengths

- The use of FreeSurfer and attention to "inverse consistency" in time-series image data will reduce bias

- Their approach to registration is robust and has demonstrated value

#### **Weaknesses**

- None noted

#### **4. Approach:**

##### **Strengths**

- Construction of an integrated software environment and pipeline for the analysis, using docker and CWL.

##### **Weaknesses**

- The work will explore methods "to predict a subject's neuromorphometrics at an arbitrary time in the future from as little as a single timepoint." No definition of, or approach to, the methods is given, nor is any theoretical basis identified. (The discussion in Phase 2, Subaim 1.3 does not provide that information.)

**Rigor -- Addition to review criteria: Are there "strategies to ensure a robust and unbiased approach, as appropriate for the work proposed?"** Likely

**Possible considerations, if appropriate for the scientific field and research question, include plans for:**

- **determining group sizes** There is no mention of group sizes
- **analyzing anticipated results** A reference to earlier work is given; but no details are included here
- **reducing bias** Unknown
- **ensuring independent and blinded measurements** Yes
- **improving precision and reducing variability** Unknown
- **including or excluding research subjects** Unknown
- **managing missing data** N/A

#### **5. Environment:**

##### **Strengths**

- Excellent

##### **Weaknesses**

- None noted

#### **Fast Track (Type 1 R42 and Type 1 R44 applications):**

Acceptable

- Suitable for Fast Track: reasonable goals identified for Phases I and II

#### **Protections for Human Subjects**

Acceptable Risks and Adequate Protections

- Deidentified retrospective data are being used.

**Inclusion of Women, Minorities and Children:**

- Sex/Gender:
- Race/Ethnicity:
- For NIH-Defined Phase III trials, Plans for valid design and analysis:
- Inclusion/Exclusion of Children under 18:

**Vertebrate Animals:**

Not Applicable (No Vertebrate Animals)

**Biohazards:**

Not Applicable (No Biohazards)

**Budget and Period of Support:**

Recommend as Requested

**CRITIQUE 3**

Significance: 3

Investigator(s): 1

Innovation: 2

Approach: 3

Environment: 1

**Overall Impact:** This is a very strong application from a very experienced and well-known group of applicants to commercialize aspects of their FreeSurfer pipeline to improve serial studies in neuroradiology with applications to neurodegenerative diseases such as Alzheimer's disease. This application will expand on current neuromorphometric tools in FreeSurfer for the purpose of detecting volumetric change in serial images of patients. The underlying scientific premise is that a joint analysis of longitudinal data will improve the sensitivity of detecting significant changes compared to standard cross-sectional analyses. Overall, the Phase I component of this application is very well designed with appropriate milestones. By the end of Phase I we will have a reimplemented and documented software package together with a quantitative assessment of its performance to milestones that have already been arrived at following initial consultations with the FDA. In some respects, the main issue with Phase I is that it feels overly ambitious, but that is a risk the investigators can take. Phase II is a little less well designed and it is unclear how much of this work will contribute to the overall product – in some respects Phase I is the whole project here. The response to the reviews from the previous submission was adequate, though there remain questions as to whether structural changes have the sensitivity to significantly help with disease detection. Some of the methods are also somewhat old (though would be ground breaking considering the state of what is available clinically) and may be some of the computational optimization could make use of some of the emerging deep learning techniques that are becoming available. One can imagine training a neural network with the output of FreeSurfer to replace the whole process, or at least to significantly speed it up. Deep learning is no panacea and may have other issues.



**Phase II (Type 2 R42 and Type 2 R44 applications):**

**Direct Phase II (Type 1 R44 applications-See Face Page):**

**Fast Track (Type 1 R42 and Type 1 R44 applications):**

**Protections for Human Subjects**

**Inclusion of Women, Minorities and Children:**

- Sex/Gender:
- Race/Ethnicity:
- For NIH-Defined Phase III trials, Plans for valid design and analysis:
- Inclusion/Exclusion of Children under 18:

**Vertebrate Animals:**

**Budget and Period of Support:**

Recommended budget modifications or possible overlap identified:

**THE FOLLOWING SECTIONS WERE PREPARED BY THE SCIENTIFIC REVIEW OFFICER TO SUMMARIZE THE OUTCOME OF DISCUSSIONS OF THE REVIEW COMMITTEE, OR REVIEWERS' WRITTEN CRITIQUES, ON THE FOLLOWING ISSUES:**

**COMMITTEE BUDGET RECOMMENDATIONS: The budget was recommended as requested.**

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Footnotes for 1 R42 AG062026-01A1; PI Name: Wighton, Paul

NIH has modified its policy regarding the receipt of resubmissions (amended applications). See Guide Notice NOT-OD-14-074 at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-074.html>. The impact/priority score is calculated after discussion of an application by averaging the overall scores (1-9) given by all voting reviewers on the committee and multiplying by 10. The criterion scores are submitted prior to the meeting by the individual reviewers assigned to an application, and are not discussed specifically at the review meeting or calculated into the overall impact score. Some applications also receive a percentile ranking. For details on the review process, see [http://grants.nih.gov/grants/peer\\_review\\_process.htm#scoring](http://grants.nih.gov/grants/peer_review_process.htm#scoring).

## MEETING ROSTER

### Center for Scientific Review Special Emphasis Panel CENTER FOR SCIENTIFIC REVIEW Small Business: Medical Imaging

ZRG1 SBIB-T (10)  
11/15/2018 - 11/16/2018

**Notice of NIH Policy to All Applicants:** Meeting rosters are provided for information purposes only. Applicant investigators and institutional officials must not communicate directly with study section members about an application before or after the review. Failure to observe this policy will create a serious breach of integrity in the peer review process, and may lead to actions outlined in NOT-OD-14-073 at <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-073.html> and NOT-OD-15-106 at <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-106.html>, including removal of the application from immediate review.

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