SUMMARY STATEMENT

PROGRAM CONTACT: [redacted]

(Privileged Communication)

Release Date: **10/26/2018**
Revised Date:

Application Number: **1 R01 DC017174-01A1**

Principal Investigators (Listed Alphabetically):

CHERNEY, LEORA R
HEINEMANN, ALLEN WALTER (Contact)

Applicant Organization: REHABILITATION INSTITUTE OF CHICAGO

Review Group: **LCOM**
Language and Communication Study Section

Meeting Date: **10/18/2018**
Council: **JAN 2019**
Requested Start: **04/01/2019**

RFA/PA: **PA18-287**
PCC: **VS01**

Project Title: **Defining Trajectories of Linguistic, Cognitive-Communicative and Quality of Life Outcomes in Aphasia**
SRG Action: **Impact Score:17 Percentile:5**
Next Steps: **Visit https://grants.nih.gov/grants/next_steps.htm**
Human Subjects: **30-Human subjects involved - Certified, no SRG concerns**
Animal Subjects: **10-No live vertebrate animals involved for competing appl.**
Gender: **1A-Both genders, scientifically acceptable**
Minority: **1A-Minorities and non-minorities, scientifically acceptable**
Children: **3A-No children included, scientifically acceptable**

Project Year	Direct Costs Requested	Estimated Total Cost
1	[redacted]	[redacted]
2		
3		
4		
5		
TOTAL	[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.

1R01DC017174-01A1 Heinemann, Allen

RESUME AND SUMMARY OF DISCUSSION: This application proposes a project to investigate and model linguistic, cognitive-communicative, and quality of life (QoL) outcome trajectories in people with aphasia following a stroke. This large, innovative project addresses a critical barrier to prognosis and treatment and if successful would be paradigm shifting in approaches to aphasia recovery. The investigative team and environment are outstanding. The approach is rigorous, with the inclusion of genotype and a highly sophisticated data analysis plan noted as particular strengths. The panel noted only minor weaknesses, including that the application is only partially responsive to prior concerns about how the project will handle the large amount of data, and that there is a potential for bias in the sample. Overall, this project addresses a highly significant research area and is likely to exert a large, sustained impact on the treatment of aphasia.

DESCRIPTION (provided by applicant): Stroke imposes significant burdens on the health and quality of life of survivors and their caregivers, and presents a major public health issue in terms of healthcare costs and lost productivity. Aphasia adds to the cost of stroke-related care. Many stroke survivors with aphasia receive therapy in inpatient rehabilitation facilities. However, aphasia recovery is variable and there is limited evidence on the benefits of inpatient rehabilitation on outcomes. The objective of this study is to describe the trajectories of linguistic, cognitive-communicative, and health-related quality of life (QoL) outcomes following stroke in persons with aphasia during inpatient and outpatient rehabilitation to 18 months following stroke. A sample of 300 consecutively-admitted stroke patients with aphasia recruited at three Midwestern rehabilitation hospitals will complete measures of linguistic and cognitive-communicative performance, and the Quality of Life in Neurological Disorders (Neuro-QoL) Measurement System instruments during rehabilitation and at 6-,12-, and 18- months post-stroke. We will model outcomes as individual and group trajectories, allowing us to develop individual predictions which could inform clinical planning and decision-making for new patients. The Specific Aims are to: Aim 1: Establish a prospective cohort of stroke patients with aphasia, and define their typical trajectory of linguistic, cognitive-communicative, and health-related QoL recovery at admission to and discharge from the IRF, and at 6, 12, and 18 months post onset. Aim 2: Identify factors that are associated with linguistic, cognitive-communicative, and health-related QoL outcomes from among the following: patient factors including demographic and clinical characteristics related to stroke and aphasia; treatment variables including inpatient and outpatient aphasia therapy characteristics and informal aphasia services; and biomarkers, including genetic and neuroimaging biomarkers. Aim 3: Evaluate the stability of the models of linguistic, cognitive-communicative, and health-related QoL outcomes recovery that are developed from Aims 1 and 2. This study is innovative in its use of (1) standardized assessments that measure not only linguistic outcomes but also communication and QoL outcomes; (2) patient-centered, self-report instruments such as Neuro-QoL to detect clinically important change through 18 months post-stroke; (3) individual growth curve analysis to describe recovery trajectories and examine associations between demographic, lesion, aphasia, genetic, and speech and language therapy characteristics; (4) biomarkers that have been implicated in promoting neuroplasticity; (5) resting state functional magnetic resonance imaging to evaluate the association between network pathology and recovery from aphasia; (6) information on type, amount, and duration of aphasia treatment provided in clinical settings; and (7) information on informal aphasia services following discharge from formal therapy.

PUBLIC HEALTH RELEVANCE: This study describes trajectories of linguistic, cognitive-communicative, and health-related QoL outcomes during inpatient and outpatient rehabilitation to 18 months in a sample of 300 adults with aphasia using demographic, lesion, aphasia, genetic polymorphisms, and speech and language therapy characteristics as predictors.

CRITIQUE 1

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

Overall Impact: This resubmitted multi-site study from an accomplished pair of PIs, leading a large and multi-faceted investigative team, aims to measure the trajectory of aphasia recovery across multiple dimensions over an 18-month window during the course of typical rehabilitation for stroke survivors. Determining the typical path of recovery over longer time periods is key to formulating prognosis statements and evaluating the effectiveness of aphasia treatments – this evidence is currently systematically lacking in the aphasia-treatment literature, representing a significant barrier to progress. If successful, this project would represent a key step toward attaining these critical healthcare goals. The proposed study will collect a wide range of measures – including clinical treatment records, multiple genomic measures, and both functional and structural neuroimaging measures – and relate them to language-impairment, communicative participation and health-related quality of life outcomes in a large sample of stroke survivors. The project is ambitious but feasible given the multi-site collaboration, and the measures to be collected (particularly the language/communicative outcomes and the genomic measures) are well selected and rigorous. The proposed analysis plans are well thought out and innovative; the use of multiple genomic measures relevant to neuroplasticity (key to stroke recovery) is also noteworthy and innovative. Furthermore, the plan to examine how dosage of standard-of-care aphasia rehabilitation impacts recovery is rare and is another noteworthy strength of the proposal. These notable strengths are somewhat offset by a lack of theoretical innovation and impact, and by some underspecified or unclear aspects of the approach, particularly related to the analysis plans. There are also some concerns regarding the management and coordination of this large, multi-site investigative team. However, these weaknesses only somewhat qualify enthusiasm for this ambitious proposal's high potential clinical impact.

1. Significance:

Strengths

- Understanding the trajectory of aphasia recovery in detail and over extended time-windows (longer than 6-12 months) is of very high clinical significance – it is key to formulating prognosis statements and to evaluating the effectiveness of aphasia treatments. If successful, this project would represent a significant step toward attaining this critical healthcare goal.
- Identifying factors (both treatment-related and person-related) that are predictive of ultimate outcomes and the slope (trajectory) of recovery would significantly advance personalized aphasia intervention – this is a significant strength.
- Measuring recovery of not only language and communicative function but health-related quality of life (QoL) is unusual among aphasia studies, and a noteworthy strength.
- Focus on the contribution of aphasia treatment as provided in "real-world" clinical settings to language/communicative and QoL outcomes is rare and noteworthy.
- Premise: Preliminary clinical data from a large sample of stroke survivors (n=71) compellingly demonstrates that there is natural significant variation in language-treatment, motivating aim to examine the impact of such variation on outcomes.

Weaknesses

- The proposed model of the factors that interact to predict recovery (Fig. 2) is descriptive rather than substantive, and does not provide insight or make predictions regarding the relative weight or importance of the multiple factors that may contribute to recovery.

- The proposal's specific hypotheses and predictions regarding the impact of different factors on language, communicative, and QoL recovery (see Approach: Aims and Hypotheses, especially Hypothesis 1, Hypotheses 2a-c) are for the most part intuitive and unsurprising. This reduces the significance of the proposal's theoretical contributions (although this is offset by the study's high potential clinical significance).
- No hypotheses are proposed regarding which of the multiple sets of neuroimaging measures (functional and structural, targeting both grey and white matter) is likely to be associated with recovery, despite significant discussion in the aphasia and neuroimaging literature regarding the neural substrates of aphasia recovery. This is not a fatal flaw, but it again detracts from the theoretical significance and impact of the proposal.
- Premise: Preliminary data related to the rs-fMRI and lesion-related measures (from a sample of 8 PWA) remain sparse and somewhat uncompelling.

2. Investigator(s):

Strengths

- MPI Cherney is a renowned expert in the study of aphasia and aphasia recovery and is well-positioned to lead aphasia-specific aspects the study.
- MPI Heinemann has significant experience in stroke recovery, in study of quality of life post-stroke, and with multi-site studies, and he has a record of collaboration with MPI Cherney.
- Co-I Kozlowski provides key expertise in person-level growth curve analyses (a core analytical method to be used to model recovery).
- Co-I Baliki brings key expertise in neuroimaging methods, including recent work with PI Cherney on neuroimaging in stroke.
- The specific roles and contributions of the investigators are better specified in this revised application.

Weaknesses

- The study team is very large, and there are concerns regarding how effective study-team management and coordination will be maintained, both within and across sites.
- The study team appears to include senior/key personnel who are not listed as such, like Rosalind Hurwitz (research SLP at SRAL, who will devote 6 calendar months effort and will oversee aphasia-related training across all sites), co-I [redacted] (biostatistician at Northwestern), and Site Coordinator Roberta Virva (Mary Free Bed site). These may be oversights but they reinforce concerns regarding coordination and management of the large, multi-site study team.

3. Innovation:

Strengths

- Proposed very large sample size (n=300 in final sample) and very broad array of variables to be collected (treatment history; multiple genomic assays; rs-fMRI; demographic, health, and other person-level variables) represents a very significant novel contribution – this data set would be unique in the study of aphasia recovery.
- Plan to study the impact of genomic factors related to neuroplasticity on aphasia recovery (in particular, the joint influence of multiple genomic factors) is highly innovative.

- Use of individual growth-curve analyses to model recovery is innovative.
- Following stroke survivors for 18 months and evaluating their trajectory of recovery over such an extended period is novel and noteworthy.

Weaknesses

- Use of rs-fMRI and white-matter imaging to study aphasia and aphasia recovery is only modestly innovative.

4. Approach:

Strengths

- The study has ample resources for participant recruitment and referral across the three sites, ensuring feasibility – this is a significant strength.
- The proposal uses a broad and well-chosen mix of measures (including impairment- and participation-focused, surrogate- and patient-reported) to characterize the language and communicative function and the health-related QoL of participants – this is a significant strength.
- The plan to capture clinical data regarding treatment dosage and to use those data for models relating treatment to recovery is clever, and a significant strength.
- The analysis approach for Aim 2 – first fitting separate multilevel individual growth-curve models of outcome variables for the demographic, treatment-related, neuroimaging, and genomic measures (treated the measures as fixed effects), and then building more complex models based on combinations of these fixed effects, assessing changes in model fit as a way of estimating which combination of factors explains the most variance – is clever (although see concerns below regarding multiple comparisons associated with this analysis strategy). This is a strength.
- The plan to use multifactor dimensionality reduction methods to identify patterns in the genomic measures, and to reduce the number of genomic predictor variables, appears sound and would seem to be a strength.
- The plan to use bootstrapping and cross-validation to assess the stability of fitted models is a strength.
- Rigor: Chosen language, communication, and QoL measures are well validated and have strong measurement properties.
- Rigor: There are detailed plans for characterizing the variability in the sample, along multiple dimensions, and assessing the impact of this variability on outcomes

Weaknesses

- The proposal still has not addressed the concern (raised in the previous round of reviews) that there may be sample bias due to attrition -- i.e., people with poorer overall health or greater numbers of comorbidities will be more likely to be among those who drop out – and that this will bias limit generalizability of the findings. Especially given the proposal's strong health-service-delivery focus and clinical significance, this is a notable weakness.
- The sample size for proposed individual growth-curve analyses are below those recommended for this analysis method (n=300 instead of 500, as noted in the proposal); this is not a fatal flaw, but does suggest that the study may be underpowered to detect effects of interest, and no alternative analysis plan is provided. This is a moderate weakness.
- The proposed model of the factors that condition aphasia recovery (Figure 2) is implicitly a mediation model, claiming that person-level characteristics have both direct and indirect effects

(mediated through treatment) on outcomes. This model would be most appropriately tested through SEM analysis, which would permit quantification of the weight of the different links in the model, as well as direct assessment of this mediation claim; however, no such plan is proposed. This is a moderate (addressable) weakness.

- The analysis plan for the neuroimaging measures remains underspecified. Some indication is provided regarding the set of anatomical and functional measures to be collected (see Table 5) and the processing pipeline for these measures is now described in the Approach. However, it is unclear whether the measures will be fit to separate models to address Aim 2c, or whether some dimension-reduction methods will be used for neuroimaging measures to create omnibus measures for fitting individual growth curves. This is a modest (addressable) weakness.
- The analysis plan related to demographic measures is also underspecified. Under Table 3, the proposal notes that the NINDS Common Data Elements will be collected, but this set is not fully specified, and it is unclear whether the measures will be fit to separate models to address Aim 2a or whether (as for neuroimaging measures) dimension-reduction methods will be used for demographic data. This is a modest (addressable) weakness.
- The analysis plan involves fitting separate individual growth curve models for each primary and secondary outcome (there appear to be 15 such outcomes, given Table 3). No plan is provided to correct for multiple comparisons across these models (this is necessary, given that the different outcomes are taken from the same sample and are likely collinear). Similarly, there is no plan to correct for multiple comparisons across the multiple models used to test Aim 2 hypotheses. This is an addressable weakness. However, correcting for these multiple comparisons (using family-wide error methods, for example) will again reduce the power of the analyses to detect effects of interest, hampering the study's ability to provide definitive answers to the important clinical questions it is posing.

5. Environment:

Strengths

- The Shirley Ryan Ability Lab provides a superb environment for large-scale studies of stroke recovery and aphasia recovery, and is well-suited to serve as lead site in the proposed multi-site collaboration.
- Facilities and support for genomic and neuroimaging procedures are excellent.
- The partner sites (Alexian Brothers and Mary Free Bed Rehabilitation Hospitals) have a history of collaboration with the lead site.

Weaknesses

- No major weaknesses noted.

Study Timeline:

Not applicable (No Clinical Trials)

Protections for Human Subjects:

Acceptable Risks and/or Adequate Protections

- No concerns noted.

Data and Safety Monitoring Plan (Applicable for Clinical Trials Only):

Acceptable

- No concerns noted.

Inclusion of Women, Minorities and Children:

- Sex/Gender: Distribution justified scientifically
- Race/Ethnicity: Distribution justified scientifically
- For NIH-Defined Phase III trials, Plans for valid design and analysis: Not applicable
- Inclusion/Exclusion of Children under 18: Excluding ages <18; justified scientifically
- The distribution of race/ethnicity across sites is well described and characterized.

Vertebrate Animals:

Not Applicable (No Vertebrate Animals)

Biohazards:

Not Applicable (No Biohazards)

Resubmission:

- This resubmission has been responsive to the previous round of reviews, providing helpful additional details regarding genomic testing and rs-fMRI procedures, an explicit model of factors that may contribute to stroke recovery, and modified analysis plans.

Resource Sharing Plans:

Acceptable

- Plans to ensure confidentiality of participants and to establish data-use agreements are somewhat underspecified but appear adequate.

Authentication of Key Biological and/or Chemical Resources:

Not Applicable (No Relevant Resources)

Budget and Period of Support:

Recommend as Requested

CRITIQUE 2

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

Overall Impact: This resubmitted multiple PI plan comes from a talented team of researchers with complementary expertise in the measurement of aphasia and neuropsychosocial outcomes post stroke.

The investigators were particularly responsive to the initial critique, adding essential rigor to a proposal with many extant strengths. Long-term disability is a major concern in the trajectory of recovery from post-stroke aphasia. The investigators note that only about 25% of the variance in functional recovery is attributable to therapy intensity. Therefore, there exists a compelling public health need to develop a broader understanding of the predictors of recovery. This is an essential step toward developing effective, personalized medicine approaches to rehabilitation. This holistic perspective is a major strength of the premise of the research. The investigators are characterizing longitudinal change under the auspices of a path model integrating numerous biomarkers, including genotype and resting state fMRI. Rigor and reproducibility are both high, and the potential contribution to theory is excellent.

1. Significance:

Strengths

- Much remains unclear about the trajectory of aphasia recovery and the role(s) of specific biomarkers. Previous work on treatment outcomes in aphasia has focused almost exclusively on dose and treatment efficacy. The current proposal situates treatment as just one variable among many others that conspire to influence outcomes in post stroke aphasia. This holistic approach is a major advance for a field that has shown limitations in treatment effectiveness.

Weaknesses

- No major weaknesses noted.

2. Investigator(s):

Strengths

- The MPI plan includes complementary expertise in the measurement of outcomes and aphasia treatment. The investigative team is world class. There is perhaps no stronger or better suited group to undertake this complex project.

Weaknesses

- No major weaknesses noted.

3. Innovation:

Strengths

- The perspective of nesting patients within a systems level framework integrating multiple biomarkers is exceptionally innovative.

Weaknesses

- Although not an explicit weakness, the measures used to track longitudinal change are well-worn (e.g., rsFMRI).

4. Approach:

Strengths

- Sample size and diversity of the metrics are major strengths of the approach.
- The use of linear mixed effects models is an added strength of the statistical approach.
- The multi-site data collection proposal improves sample representativeness.

Weaknesses

- The overarching model (Figure 2) seems more like a crude box-and-arrow approach then a testable path model.

5. Environment:

Strengths

- The research will take place at the Rehabilitation Institute of Chicago, with tertiary data collection at two additional centers. The environment is exceptional both in terms of research infrastructure and the supportive intellectual community. An added strength is a well-established patient recruiting pipeline.

Weaknesses

- No major weaknesses noted.

Study Timeline:

Strengths

- The study timeline is extremely detailed, and although ambitious, the goals appear achievable for this talented group.

Weaknesses

- No major weaknesses noted.

Protections for Human Subjects:

Acceptable Risks and/or Adequate Protections

- Primary risks include MRI, fatigue, and data confidentiality. These risks appear to be well-mitigated.

Data and Safety Monitoring Plan (Applicable for Clinical Trials Only):

Acceptable

- The DSMP is well-planned and comprehensive.

Inclusion of Women, Minorities and Children:

- Sex/Gender: Distribution justified scientifically
- Race/Ethnicity: Distribution justified scientifically
- For NIH-Defined Phase III trials, Plans for valid design and analysis: Not applicable
- Inclusion/Exclusion of Children under 18: Excluding ages <18; justified scientifically
- Reasonable exclusion of children; recruitment based on population demographics for three sites.

Vertebrate Animals:

Not Applicable (No Vertebrate Animals)

Biohazards:

Not Applicable (No Biohazards)

Resubmission:

- The resubmission was highly responsive to the initial round of reviews.

Authentication of Key Biological and/or Chemical Resources:

Acceptable

Budget and Period of Support:

Recommended budget modifications or possible overlap identified:

- Multi-site, MPI study - expenses reasonably justified

CRITIQUE 3

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

Overall Impact: Aphasia is a particularly devastating result of stroke that significantly affects quality of life, but studies are often focused on impairment-based treatments rather than more holistic considerations, and assess beginning and ending timepoints rather than modeling individual trajectories. This proposal evaluates the effects of multiple environmental and biologic variables to predict treatment response over time, and would be a valuable contribution to the guidance of effective and efficient therapy. The proposal is responsive to previous review.

1. Significance:

Strengths

- Focus on quality of life rather than just correction of deficits
- Aphasia decreases quality of life when physical effects of stroke and other factors are controlled, but response to treatment is harder to predict. Evidence-based modeling of trajectory will be valuable in guiding treatment planning. This study provides a comprehensive study with large sample size.

Weaknesses

- No major weaknesses noted.

2. Investigator(s):

Strengths

- Dr. Heinemann has expertise in stroke rehabilitation and quality of life assessments, and Co-PI Dr. Cherney has complementary expertise in aphasia therapy. They are well qualified to lead this study and have a history of productive collaboration. A multiple PI agreement is in place. Dr. Domenighetti has previous experience in the study of neural plasticity and SNP analysis of

candidate genes, and Dr. Baliki brings experience in neuroimaging. The rest of the team has the clinical and statistical experience necessary for the project.

Weaknesses

- No major weaknesses noted.

3. Innovation:

Strengths

- The project is innovative in its scope, including language and quality of life outcomes and a variety of environmental and biologic variables that can predict the trajectory of response to therapy, and the large size of the study population should give more reliable results.

Weaknesses

- No major weaknesses noted.

4. Approach:

Strengths

- Use of trajectory modeling allows for more comprehensive analysis of the effects of covariates on improvement, resulting in better prediction and identification of plateaus in improvement
- Power analyses are discussed, citing the limitations of methods to calculate power in a this type of growth curve modeling study, but showing that the sample size is likely to be sufficient
- Preliminary data on brain lesion characteristics and connectivity are available that support the modeling approach

Weaknesses

- Validation in a separate population would be ideal, but the bootstrapping analyses would identifiy problems in the model.

5. Environment:

Strengths

- The inclusion of three facilities will assure that there is a sufficient number of participants, and their relative proximity aids in communication across sites so that the procedures are consistent.

Weaknesses

- No major weaknesses noted.

Study Timeline:

Strengths

- The timeline is provided and is realistic.

Weaknesses

- No major weaknesses noted.

Protections for Human Subjects:

Acceptable Risks and/or Adequate Protections

- The research involves minimal risk and includes assessments that would be typical for stroke patients. Appropriate protections are in place to maintain confidentiality of the data.

Data and Safety Monitoring Plan (Applicable for Clinical Trials Only):

Acceptable

- A Data Safety and Monitoring Committee will be created even though this is not a clinical trial.

Inclusion of Women, Minorities and Children:

- Sex/Gender: Distribution justified scientifically
- Race/Ethnicity: Distribution justified scientifically
- For NIH-Defined Phase III trials, Plans for valid design and analysis: Not applicable
- Inclusion/Exclusion of Children under 18: Excluding ages <18; justified scientifically
- There are no restrictions by sex/gender nor race/ethnicity, so these should be adequately represented. Adults are included and it is anticipated that most will be over 50 since this is the population most likely to experience stroke.

Vertebrate Animals:

Not Applicable (No Vertebrate Animals)

Biohazards:

Not Applicable (No Biohazards)

Resubmission:

- The resubmission is responsive to previous critiques

Resource Sharing Plans:

Acceptable

- A data sharing plan is included and is appropriate.

Authentication of Key Biological and/or Chemical Resources:

Not Applicable (No Relevant Resources)

Budget and Period of Support:

Recommend as Requested

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:

PROTECTION OF HUMAN SUBJECTS: ACCEPTABLE

INCLUSION OF WOMEN PLAN: ACCEPTABLE

INCLUSION OF MINORITIES PLAN: ACCEPTABLE

INCLUSION OF CHILDREN PLAN: ACCEPTABLE

COMMITTEE BUDGET RECOMMENDATIONS: The budget was recommended as requested.

Footnotes for 1 R01 DC017174-01A1; PI Name: Heinemann, Allen Walter

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.

MEETING ROSTER

Language and Communication Study Section
Biobehavioral and Behavioral Processes Integrated Review Group
CENTER FOR SCIENTIFIC REVIEW
LCOM
10/18/2018 - 10/19/2018

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.

CHAIRPERSON(S)

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MEMBERS

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SCIENTIFIC REVIEW OFFICER

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EXTRAMURAL SUPPORT ASSISTANT

[redacted]

* Temporary Member. For grant app cat ons, temporary members may part c pate n the ent re meet ng or may rev ew on y se ected app cat ons as needed.

Consu tants are requ red to absent themse ves from the room dur ng the rev ew of any app cat on f the r presence wou d const tute or appear to const tute a conf ct of nterest.