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SUMMARY STATEMENT

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(Privileged Communication)

Release Date: **11/16/2018**
Revised Date:

Application Number: **1 R44 AG062014-01A1**

Principal Investigator

WANG, VICTOR

Applicant Organization: CARE.COACH CORPORATION

Review Group: **ZRG1 ETTN-G (12)**
Center for Scientific Review Special Emphasis Panel
Small Business: Aging and Development, Auditory, Vision and Low Vision Technologies

Meeting Date: **11/08/2018**
Council: **JAN 2019**
Requested Start: **04/01/2019**

RFA/PA: **PAR18-186**
PCC: **2CTECPB**

Project Title: **A Specialized Automatic Speech Recognition and Conversational Platform to Enable Socially Assistive Robots for Persons with Mild-to-Moderate Alzheimer's Disease and Related Dementia**

SRG Action: **Impact Score:20**

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	[redacted]	[redacted]
3	[redacted]	[redacted]
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.

1R44AG062014-01A1 WANG, VICTOR

RESUME AND SUMMARY OF DISCUSSION: This Fast Track application is focused on improving an existing human-operated socially assistive robot (SAR)-like avatar called care.coach by refining the automatic speech recognition (ASR) engine for conversing with elderly and Alzheimer's disease (AD) patients. The developed platform will have a large subset of interactions automated to make it more cost effective although the human-in-the-loop will maintain the personalizing aspect of the system. The previous submission received mixed ratings for the fall prevention efficacy of the develop system being largely unclear and, in the current submission, the PI has put in a valid effort to clarify the point that the primary goal is to develop a conversational means to engage the ADRD patients, which is deemed clinically significant by reviewers. The research team has been strengthened with additions of an ASR expert and an NLG expert. The revised research plan is well thought through, scientifically rigorous, and is equipped with strong preliminary data, clear Phase I milestones, and adequate discussions of potential pitfalls and alternative approaches. The PI is also well positioned to lead the research effort as he has ownership of relevant patents. Having the data of [redacted] is also noted as a strength. Minor weaknesses raised by reviewers include no preliminary data demonstrating long-term receptivity of the care.coach avatar to AD patients, no in-depth discussion or planning for possible varied patient responses to automated versus human interactions using the developed system, and no effort planned for improving the voice quality using features such as noise cancelling in the current studies. Despite these minor shortcomings in the research plan, the review committee as a whole is overwhelmingly supportive of this much improved FastTrack application and thus recommends it with an outstanding level of enthusiasm.

DESCRIPTION (provided by applicant): 1 in 3 seniors in the United States dies with dementia, of which Alzheimer's disease (AD) is the most common form. AD patients suffer from decreased ability to meaningfully communicate and interact, which causes significant stress and burden for both professional caregivers and family members. Socially assistive robots (SARs) have been designed to promote therapeutic interaction and communication. Unfortunately, artificial intelligence (AI) has long been challenged by the speech of elderly persons, who exhibit age-related voice tremors, hesitations, imprecise production of consonants, increased variability of fundamental frequency, and other barriers that can be exacerbated by the neurological changes associated with AD, further complicated by common environmental noises such as the ceiling fan, television, etc. Because of the resulting poor real-world speech and language understanding by available SAR technologies, scarce human caregivers are often required to guide AD patients through SAR interactions, limiting SARs to small deployments, mostly as part of research studies. Unlike existing approaches relying purely on AI, care coach is developing a SAR-like avatar that converses with elderly and AD patients through truly natural speech. Each avatar is controlled by a 24x7 team of trained human staff who can cost-effectively monitor and engage 12 or more patients sequentially (2 simultaneously) through the audio/visual feeds from the patient's avatar device. The staff communicate with each patient by sending text commands which are converted into the avatar's voice through a speech synthesis engine. The staff contribute to the system their human abilities for speech and natural language processing (NLP) and for generating free-form conversational responses to help patients build personal relationships with the avatar. The staff are guided by a software-driven expert system embedded into their work interface, which is programmed with evidence-based prompting and protocols to support healthy behaviors and self-care. This SBIR Fast-Track project will leverage the unique data generated by our human- in-the-loop platform to develop new ASR capabilities, enabling fully automatic conversational protocols to engage and support AD patients without human intervention. We aim in Phase I to leverage our unique prior work dataset to train an automatic speech recognition (ASR) engine to enable the understanding of certain types of elderly and AD patient speech more successfully than any currently available engine. We aim in Phase II to incorporate this new engine along with an NLP module into our existing human-in-the-loop avatar system, recruiting a population of AD patients to further train and validate with during a 2-year human subjects study so that we can demonstrate full automation of a significant portion of our avatar conversations with mild- to-moderate level AD patients. Thus, we will improve the commercial

scalability of our avatars, while validating our new ASR/NLP engine as the most accurate platform for enabling the next generation of AD-focused SARs.

PUBLIC HEALTH RELEVANCE: Artificial intelligence (AI) has long been challenged by the speech of elderly persons, and especially persons with dementia, due to age-related voice tremors, hesitations, imprecise production of consonants, increased variability of fundamental frequency, and other barriers. Unlike existing approaches to socially assistive robots (SARs) relying purely on limited AI for conversation, care coac has been commercializing a SAR-like avatar that converses with elderly and AD patients through truly natural speech, powered by a 24x7 team of trained human staff. The unique data sets that our solution enables us to gather at commercial scale will be leveraged in this SBIR project to develop an automatic speech recognition (ASR) and natural language processing (NLP) engine that is best-in-class for AD applications, improving the commercial scalability of our avatars by reducing our dependence on human staff, while serving as a new AI platform for enabling the next generation of AD- focused, conversational SARs.

CRITIQUE 1

Significance: 4
Investigator(s): 3
Innovation: 4
Approach: 3
Environment: 2

Overall Impact: People with Alzheimer's Disease (AD) need additional care. Since the number of AD patients is increasing, that is straining our healthcare system. To address this problem, a combined approach of human health advocate combined with a socially assistive robot could monitor numerous patients effectively. The robot would need to be able to perform automatic speech recognition (ASR), which is a non-trivial task for older talkers. Therefore, the purpose of this proposal is to develop ASR capabilities for older people (including those with AD) and integrate that technology into the existing care.coach system, which currently has humans monitor multiple patients. The overall approach has strong scientific rigor, the team should be capable of performing the proposed work, and the environment is good for performing the work. Minor weaknesses only slightly diminished enthusiasm for the project.

1. Significance:

Strengths

- Alzheimer's Disease (AD) is a major and growing problem straining our health care system.
- Socially assistive robots (SARS) could provide help in patient care, providing health care advice, and social interactions to people with AD. There is currently a request for proposals on this topic from NIA.
- However, SARS would need to perform automatic speech recognition (ASR), which is difficult because speech production in older individuals deviates greatly from how younger people produce speech. It is a substantial hurdle to overcome.
- This proposal aims to overcome ASR for older talkers with AD by using a deep neural network approach.
- If this can be done, then the care coach system, which has health advocates monitoring several patients at one time, would be relieved of needing to monitor all visual and auditory inputs form multiple patients. The pairing of humans and an SAR-like approach has a higher likelihood of success.

- Therefore, the scientific premise of the proposal is sound.
- The proposed project already has good commercial potential, building off existing products. There is also a commercial contract in place with the Alzheimer's Association.

Weaknesses

- Technically the use of a human-in-loop approach of care coach with ASR technology isn't quite an SAR. However, this is a minor weakness. This is still an acceptable solution to this problem.
- It is unclear if older individuals would remain engaged in this system (a care coach avatar).
- Despite the clarification in the Introduction to the proposal, it is still unclear what care coach provided to the elderly people to reduce their fall rates. Was it simply that they were used, which reduced the delirium? And if so, it is unclear how this supports the current proposal, which aims to develop SAR for older people with AD.

2. Investigator(s):

Strengths

- Wang, PI and CEO of care coach, has experience with human-machine interfaces, and is highly productive and successful as an entrepreneur.
- The rest of the team has depth and breadth in clinical, research, and gerontology experience.
- Addition of Makatcheve and Hararti addresses previous weakness of expertise in ASR and natural language production.

Weaknesses

- None noted.

3. Innovation:

Strengths

- Present SARS usually have limited functionality, are high cost, and are usually designed for research use. Providing a relatively low-cost, commercially available SAR that has broad functionality is innovative.
- Expanding care coach, a human-in-loop system, by including AI and ASR is innovative.

Weaknesses

- Expanding the already existing care coach limits innovation.

4. Approach:

Strengths

- Combining AI with a human-in-loop system is a good approach to solving this problem.
- Phase I attempts to solve the ASR problem for speech production in older adults. Aim 1 is about building a training data set; aim 2 is about training a deep neural network to perform the ASR. The goal to achieve less than 25%-word error identification rate is probably appropriate for this stage, with the future goal of better performance as the product moves closer to commercialization.
- Use of [redacted] of recorded material for database and training a strength.
- Issue of considering dealing with background noise in alternative strategies is appropriate, as this is difficult for ASR and healthcare facilities are often noisy environments.

- Phase II will integrate the ASR with current care coach and perform a human subjects study over 2 years. It addresses the problem that the questions of the care coach are intended to be yes/no answers, but AD patients tend to provide longer answers. The goal is to develop a keyword database to address this issue. Further validation is also an aim of phase II.
- A two-year observational study is appropriate and a strength because it will be in collaboration with a strong team at Indiana University. It provides a potential larger pool of research participants and it would be possible to collect more recordings for the ASR training.
- Overall the Aims, expectations, benchmarks, acknowledgment of potential problems, and alternative strategies are appropriate, giving this proposal high scientific rigor.
- The commercialization plan and commercialization potential of this product are strong.

Weaknesses

- Dealing with the background noise problem is non-trivial and slow down the overall timeline.
- Unclear if a sufficient database can be developed from the scripted interactions for the care coach. Boredom from those interactions are a concern.

5. Environment:

Strengths

- Environments and facilities appropriate for the proposed work.

Weaknesses

- None noted.

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

Acceptable

- Applying for fast track appropriate for this application. Integration of technology in phase II not entirely dependent of success of phase I.

Protections for Human Subjects

Acceptable Risks and Adequate Protections

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; not justified scientifically

Vertebrate Animals:

Not Applicable (No Vertebrate Animals)

Biohazards:

Not Applicable (No Biohazards)

Resource Sharing Plans:

Acceptable

Authentication of Key Biological and/or Chemical Resources:

Not Applicable (No Relevant Resources)

Budget and Period of Support:

Recommend as Requested

CRITIQUE 2

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

Overall Impact: This resubmitted fast-track application proposes to enhance an existing socially assistive robot/agent system for elderly and AD patients by incorporating automatic speech recognition technology into existing conversational protocols. The proposed research expands on the capabilities of an existing, successful commercial patient engagement system developed by the investigators. This expansion will increase staff efficiency and provide a natural language interface for the users, thus helping to build and maintain a personal relationship with the patient and increase overall system success. A significant strength of the proposed development work is access to [redacted] of conversations between avatars and older adult users which can be used for deep neural network (DNN) training of the speech recognition system. The proposal is very well written. The plan is based on solid ASR approaches giving it strong scientific premise and is executed in a rigorous manner. The investigators have been highly responsive to previous comments. Enthusiasm for this project is high, as is its projected overall impact.

1. Significance:

Strengths

- The important and growing problem of providing care and support to the expanding population of aging adults with Alzheimer's Disease (AD) is addressed by this project.
- The proposed research expands on the capabilities of an existing, successful commercial patient engagement system developed by the investigators. This expansion will increase staff efficiency and provide a natural language interface for the users. In addition, similar techniques have been used in other SAR related systems. Consequently, the scientific premise of the project is strong.
- The investigators' approach is to employ a remote team of "health advocates" thereby keeping a human "in the loop", thus helping to build and maintain a personal relationship with the patient and increase the likelihood of success.
- This approach also increases the efficiency of the advocates by allowing one individual staff member to interact with multiple (up to 12) patients.
- The goal to incorporate an avatar using natural speech will further enhance the relationship with the patient.

- This solution has the potential for broader application in other systems.
- Investigators hold intellectual property rights based on patent filings.
- System has strong potential for long-term and broad-based usage in other research projects.

Weaknesses

- None noted.

2. Investigator(s):

Strengths

- The investigators have appropriate and sufficient backgrounds to conduct the proposed work.
- Dr. Maxim Makatchev will advise on NLP, NL generation, dialog management, and machine learning.
- Dr. Amir Harati will serve as a consultant to the PI and technical team on automatic speech recognition and machine learning.
- Drs. Makatchev and Harati, both consultants to the project, have collaborated on a previous project involving human-robot interaction for a family social robot.
- It is worth noting that the principals at care coach are young new investigators. All are well qualified for their respective roles. The success of care coach to date speaks to the energy and vitality that they bring to the project. They have appropriately augmented their team's pool of skills with the addition of Drs. Makatchev and Harati as consultants.

Weaknesses

- None noted.

3. Innovation:

Strengths

- The combination of SAR-delivered automated/scripted interactions with a real-time human caregiver/interaction partner is an innovative strength.
- Use of a unique training set of AD language is novel for a SAR system.

Weaknesses

- None noted.

4. Approach:

Strengths

- The proposal is extremely well written and organized. The approaches, methods, and analyses are logically described and are appropriate to accomplish the aims. Scientific rigor is strong.
- Potential problems and alternative strategies are discussed.
- Milestones for each phase of the project are provided and are appropriate.
- A significant strength of proposed development work is access to [redacted] of conversations between avatars and older adult users which can be used for deep neural network (DNN) training of the speech recognition system.
- The collaboration with Indiana University and Eskenazi Health/Regenstrief Institute to conduct the two-year observational study is a strength given the expertise and experience of proposed

collaborators and access to a large pool of potential research participants and additional ASR training data.

Weaknesses

- It is unclear why more proactive steps (noise cancellation, better microphone placement, etc.) have not been taken in ensuring audio quality in the basic avatar system already.

5. Environment:

Strengths

- Facilities appear adequate for the proposed research.

Weaknesses

- None noted.

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

Acceptable

- The Phase I application specifies clear, appropriate, measurable goals (milestones) that should be achieved prior to initiating Phase II.

Protections for Human Subjects

Acceptable Risks and Adequate Protections

- Risks are appropriately considered, and data protection is adequate

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

Not Applicable (No Clinical Trials)

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

Vertebrate Animals:

Not Applicable (No Vertebrate Animals)

Biohazards:

Not Applicable (No Biohazards)

Budget and Period of Support:

Recommend as Requested

CRITIQUE 3

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

Overall Impact: As with the original submission, this fast-track resubmission application aims to enhance a human-in-the-loop socially assisted robot (SAR) monitoring and care delivery tool, care coach, to include a greater proportion of interactions that are automated. Currently, the care coach system uses human agents to interact with, and monitor, the activities of care coach elder adult users through crafting text to speech interaction elements in interactions with remote users. The applicants propose to use natural language processing (NLP) keyword extraction techniques to program the SAR system to perform affirmative/negative intent parsing allowing automation of a greater proportion of interactions between the SAR and the human participant. Specifically, the applicants propose to use already collected interaction data and deep neural network processing to train a speech recognition system to recognize interaction content which can be processed via automatic scripts. Following development of this system, the applicants propose to use the enhanced system in two-year observational study to assess the ability of the system to meet a goal of one-third of interactions processed automatically without deteriorations in quality or user perceptions. The care coach system offers one solution for the need for cost-effective monitoring and interaction approaches for individuals with Alzheimer's Disease (AD) or other dementias. The human-in-the-loop artificial intelligence (AI) approach is innovative and the strong human element has great potential for "humanizing" and "personalizing" computer-human interactions. The commercialization plan is sound and there is limited competition for their unique human-in-the-loop AI process. The research and development approach are generally sound in drawing upon a large database of already collected computer-human interactions, extant open source speech recognition software, and testing in a longitudinal observational study of individuals with mild-moderate AD. Enthusiasm is still slightly dampened in this resubmission due to an underdeveloped plan for monitoring and evaluating the quality of interactions and users' perceptions of automated vs. non-automated interactions, as well as how interest in interacting with the system might change over extended use. Nonetheless, the proposed work has the potential to enhance the care coach system which has significantly applicability to the care of older adults including those with AD or other dementias.

1. Significance:

Strengths

- Major strength: Alzheimer's Disease (AD) and other dementias are a prevalent and growing health condition that puts considerable strain on healthcare and caregiving systems. Socially assistive robots (SARS) and computer applications show promise in assisting in the care monitoring, care, and social interaction of those with AD and other dementias. The care.coach model of a remote caregiver who can guide computerized avatar interactions with a care recipient provides a potentially more personalized form of care as compared to a fully automated SAR interaction.
- Major strength: The proposal to automate a subset of interactions with care recipients via natural speech would allow a cost-effective expansion of this form of monitoring and care and potentially extend this technology to other SAR systems.
- Major strength: The use of remote staff who serve as interaction/care agents will facilitate expansion of care coach to serve a large number of users.
- Major strength: The applicants already have patents in place for some components/processes of the care coach platform.

Weaknesses

- Minor-major weakness: As previously indicated, the value of this system is dependent upon the receptivity of the user and care providers (e.g., family caregivers, hospitals, residential care facilities) to interact and utilize the system. The pilot study results do not indicate prior demonstration of long-term interaction with a care coach avatar. It is not clear how likely it is that the attention of a user could be held over long periods of time thereby potentially eliminating the effectiveness of this tool. This concern is minimized somewhat with preliminary data that indicates favorable responses to the system by hospital staff and family caregivers.
- Minor-major weakness: As previously indicated, it would be useful to see data or an analysis plan for addressing whether users' perceptions of the system vary with degree of scripted/automated vs. human interaction. Applicants may be successfully in automating a significant proportion of interactions but with resulting declines in the effectiveness of the system for target recipients.
- Minor weakness: There is still little attention given to a plan for monitoring the quality of staff-client interactions given future projected growth of care coach human advocates/staff.

2. Investigator(s):

Strengths

- Major strengths: PI, Wang, CEO of care coach, has a high level of productivity and experience as a relatively junior investigator and entrepreneur. He is PI on Department of Defense and NIH grants that focus on the use of digital avatars in patient populations. Chief Technology Officer, Deng and Program Manager, Weng, have the relevant expertise and experience for their respective roles.
- Major strength: Dr. Boustani, Professor, Indiana University, Founding Director and Chief Innovation and Implementation Officer of the Center for Brain Care Innovation at Eskenazi Health, and PI of the Great Lakes Practice Transformation Network, is well suited to oversee implementation of the observational study proposed for Phase II activities. He has a distinguished profile of publications and federal grant funding.
- Major strength: Dr. Wexler, Associate Professor of Nursing, and Dr. Drury, Professor of Nursing, at Pace University, note experience as a co-investigators on previous technology grants in older adult populations. They have collaborated on previous research on the care coach system.
- Major strength: Drs. Torbati and Makatchev were added with the resubmission to enhance expertise in the team in natural language processing.

Weaknesses

- No significant weaknesses noted in the investigative team.

3. Innovation:

Strengths

- The key innovation of the care coach system lies in its combination of SAR-delivered automated/scripted interactions with a real-time human caregiver/interaction partner ("human-in-the-loop AI system).

Weaknesses

- None noted.

4. Approach:

Strengths

- Major strength: A significant strength of proposed development work is access to [redacted] of conversations between avatars and older adult users which can be used for deep neural network (DNN) training of the speech recognition system. Use of an open source and currently deployed speech recognition system (e.g., Mozilla DeepSpeech) should facilitate timely DNN analysis and development.
- Major strength: Collaborating with Indiana University and Eskenazi Health/Regenstrief Institute to conduct the two-year observational study is a strength given the expertise and experience of proposed collaborators and access to a large pool of potential research participants.
- Major strength: Benchmarks for success and potential pitfalls along with solutions are clearly outlined in the proposal.

Weaknesses

- Major weakness: There is still a concern of how the applicants will address potential boredom and fatigue on the part of participants with a greater proportion of scripted interactions. The addition of two members to the team with expertise in natural language processing is a positive revision but little detail is still providing as to how the quality of interactions and users' perceptions of scripted vs. non-scripted interactions will be monitored and evaluated.

5. Environment:

Strengths

- The environments are excellent for carrying out proposed activities.

Weaknesses

- None noted.

Protections for Human Subjects

Acceptable Risks and Adequate Protections

- One concern is the withdrawal of the care coach system after such a prolonged period of use. The applicants note an additional 3-month period to decrease usage and wean off the system but if the system does provide the monitoring and interaction that it purports, it seems that a more ethical plan would be continuous access to the system until no longer needed or wanted by the participant or a reduced-fee continuation of the system. This resubmission application does emphasize that the withdrawal plan will be repeatedly emphasized to prospective participants as part of informed consent and description of study procedures.

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:
- Inclusion/Exclusion of Children under 18: Excluding ages <18;justified scientifically

Vertebrate Animals:

Not Applicable (No Vertebrate Animals)

Biohazards:

Not Applicable (No Biohazards)

Resource Sharing Plans:

Acceptable

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 R44 AG062014-01A1; PI Name: Wang, Victor

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

Center for Scientific Review Special Emphasis Panel
CENTER FOR SCIENTIFIC REVIEW
Small Business: Aging and Development, Auditory, Vision and Low Vision Technologies
ZRG1 ETTN-G (12)
11/08/2018 - 11/09/2018

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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