Summary Minutes

The 133rd Meeting

NATIONAL ADVISORY COUNCIL ON AGING

January 19, 2018
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Attachment A: Roster of the National Advisory Council on Aging

Attachment B: Director’s Status Report to Council
The 133rd meeting of the National Advisory Council on Aging (NACA) was convened on Friday, January 19, 2018, at 4 p.m. Dr. Richard Hodes, Director, National Institute on Aging (NIA), presided. In light of uncertainty surrounding a government shutdown, this meeting was convened by teleconference to address essential matters requiring Council approval.

In accordance with the provisions of Public Law 92–463, the meeting was closed to the public on Friday, January 19, from 4 p.m. to 4:30 p.m. for the review, discussion, and evaluation of grant applications in accordance with the provisions set forth in Sections 552(b)(c)(4) and 552(b)(c)(6), Title 5, U.S. Code and Section 10(d) of Public Law 92–463.1 The meeting was open to the public on Friday, January 19, from 4:30 p.m. to 6:10 p.m.

**Council Participants:**
Dr. David A. Bennett  
Dr. Maria Carrillo  
Dr. Eileen M. Crimmins  
Dr. Steven R. Cummings  
Dr. J. Taylor Harden  
Dr. David M. Holtzman  
Dr. James L. Kirkland  
Dr. Stephen B. Kritchevsky  
Dr. Terrie E. Moffitt  
Dr. Charles P. Mouton  
Dr. Anne B. Newman  
Ms. Susan K. Peschin  
Dr. Reisa A. Sperling  
Dr. Debra Bailey Whitman

**Council Members Absent:**  
Dr. Raynard S. Kington  
Dr. Richard Mayeux  
Dr. Thomas A. Rando

**Ex Officio Participants:**  
Dr. Richard M. Allman, Veterans Health Administration

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1 For the record, it is noted that members absented themselves from the meeting when the Council discussed applications (a) from their respective institutions or (b) in which a conflict of interest may have occurred. This procedure only applied to applications that were discussed individually, not to “en bloc” actions.
Absent Ex Officio Participants:
Dr. Kenneth G. Pugh, National Naval Medical Center
Dr. Jane Tilly, Administration for Community Living
Mr. Edwin Walker, Administration on Aging

The Council Roster, which gives titles, affiliations, and terms of appointment, is appended to these minutes as attachment A.

In Addition to NIA Staff, Other Federal Employees Present:
Dr. Valerie Durrant, Center for Scientific Review (CSR)
Dr. Rene Etcheberrigaray, CSR

Members of the Public Present:
Mr. James Appleby, Gerontological Society of America
Ms. Meryl Comer, Geoffrey Beene Foundation Alzheimer’s Initiative
Dr. Alison Goate, Icahn School of Medicine at Mount Sinai
Dr. Rose Maria Li, Rose Li and Associates, Inc.
Dr. Clifford Rosen, Maine Medical Center Research Institute
Dr. Amy Wagers, Harvard University

I. REVIEW OF APPLICATIONS

This portion of the meeting was closed to the public, in accordance with the determination that it concerned matters exempt from mandatory disclosure under Sections 552(b)(c)(4) and 552(b)(c)(6), Title 5, U.S. Code and Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix).\(^2\)

A total of 1411 applications requesting $3,010,953,842 for all years underwent initial review. The Council recommended 761 awards for a total of $1,544,600,753 for all years. The actual funding of the awards recommended is determined by the availability of funds, percentile ranks, priority scores, and program relevance.

II. CALL TO ORDER

Dr. Hodes welcomed members to the open session of the 133rd NACA meeting and called the meeting to order at 4:30 p.m. on Friday, January 19, 2018. In light of uncertainty surrounding a government shutdown, this meeting was convened by teleconference to minimize delays in actions requiring Council approval. Dr. Hodes thanked Council members for their flexibility. To accommodate discussions by the Working Group on Program, Dr. Hodes did not give a formal status report.

\(^2\) For the record, it is noted that members absented themselves from the meeting when the Council discussed applications (a) from their respective institutions or (b) in which a conflict of interest may have occurred. This procedure applied only to applications that were discussed individually, not to “en bloc” actions.
A. Future Meeting Dates

May 22–23, 2018 (Tuesday and Wednesday, Building 31)
September 11–12, 2018 (Tuesday and Wednesday, 6001 Executive Blvd)
January 29–30, 2019 (Tuesday and Wednesday, Building 31)
May 21–22, 2019 (Tuesday and Wednesday, Building 31)
September 10–11, 2019 (Tuesday and Wednesday, 6001 Executive Blvd)

B. Consideration of Minutes of the Last Meeting

The minutes of the September 2017 meeting were considered. A motion to approve the minutes was made, seconded, and passed.

III. WORKING GROUP ON PROGRAM

A. RFA/RFP Concept Clearances

Dr. Eileen Crimmins reported that the Working Group reviewed 26 concepts.

Proposals for Which Working Group Reviewers Raised No Issues or Concerns

Dr. Crimmins noted a group of nine concept proposals for which the primary reviewers raised no concerns.

- Geroscience Approaches to Animal Models of Alzheimer’s Disease (AD)
- Interventions Testing Program Renewal
- Selection, Production, Characterization and Distribution of Cultured Cells of Research in Aging (contract renewal)
- Disparities in Quality and Access to Dementia Care
- Improving the Lives of Persons with Dementia: Impacts on Persons with Dementia, Families, and Communities
- National Health and Aging Trends Study (NHATS) (U01 renewal)
- Data-driven Approaches to Understand the Molecular Mechanisms of NPS in Alzheimer’s and Related Dementias (ADRD)
- Deciphering Glycosylation Code of AD
- Endosomal Log Jam

A motion was forwarded and seconded to approve this group en bloc. The motion passed unanimously.
**Proposals for Which Reviewers Had Comments to Be Considered by Program Staff**

Dr. Crimmins noted a second group of proposals for which the primary reviewers made comments to be accounted for by NIA program staff. A motion was forwarded and seconded to approve these concepts *en bloc*, with the comments noted.

**Testing Lifespan/Healthspan-Extension Interventions in the Models of AD/ADRD**

This concept proposes to use a Small Business Innovation Research/Small Business Technology Transfer mechanism to encourage the small business community to test Food and Drug Administration (FDA)-approved agents in models for their effects on AD and ADRD gene alleles, cognitive behavioral genotypes, and cellular properties. This is part of a general effort by the National Institute of Mental Health to prolong lifespan and healthspan. Working Group reviewers were supportive of the proposal but expressed concern about testing agents in *in vitro* systems. They noted that such testing could lead to artifacts and be difficult unless the agents’ effects are validated *in vivo*. Program staff agreed with this concern and noted that the emphasis of the proposal will focus on *in vivo* testing. However, *in vitro* testing is included in the concept proposal to accommodate applicants who propose potentially valuable assays.

**AD/ADR D Health Care Systems Research Collaboratory**

This concept proposes to bring together a collaboratory to develop pragmatic trials assessing interventions within health care systems that would help people with AD and ADRD. Working Group reviewers supported this concept but wanted more discussion on how the collaboratory would interact with new and existing NIA-supported AD/ADRD-focused centers. One reviewer noted that the Working Group had reviewed three different Center grant applications and that interactions between these initiatives and existing AD centers should be considered in the context of pragmatic trials. Program staff responded that NIA will encourage the different initiatives to identify and leverage commonalities. They also noted that each proposed Center grant program is likely to fund more than one Center.

**Centers on the Demography and Economics of Aging (P30): Renewal and AD/ADRD Expansion**

This concept proposes to renew this P30 program, which has focused on interaction between demographic and economic factors in the social determinants of health, and to expand it to include new AD- and ADRD-focused Centers. At present, there are 11 funded Centers. One Working Group reviewer noted her own training at one of these Centers and expressed support for renewal and expansion of the program. The second reviewer asked for clarification on whether there would be overlap between existing Centers, which can expand to include family demography for ADRD, and new ADRD-focused Centers.

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3 Dr. Crimmins recused herself from discussion on this concept proposal. Dr. Anne Newman served as Working Group on Program Chair during this discussion.
High-Priority Behavioral and Social Research Networks

The Division of Behavioral and Social Research (DBSR) has developed research networks as an effective mechanism for encouraging rapidly emerging subfields in aging research. This concept proposes to bring together multidisciplinary teams from different institutions to build these fields, with the ultimate aim to develop science enough that the field can transfer from network funding to more conventional funding mechanisms such as R01s and Center and training grants. DBSR has funded four networks so far. The proposed concept will invite those networks to renew and expand, and it will invite other networks to apply. One reviewer suggested that the request for applications (RFA) articulate how networks will know when it is time to move toward more conventional funding mechanisms and how that will happen. The second reviewer added that the RFA should describe plans for dissemination of findings and additional participation.

Research Network on Telomeres as Sentinels of Environmental Exposures, Psychosocial Stress, and Disease Susceptibility

Several researchers have investigated telomeres as markers of biological age, but so far, the empirical evidence has been contradictory. It is unclear whether confusing results arise from differences in assays and sample collection and storage methods. The proposed concept arises from a workshop report describing important issues and the types of groups, research, assays, and resources to clarify the role of telomeres as markers of biological age. There was some disagreement between reviewers. One reviewer supported the idea of a research network and noted that the workshop showed that several investigators are willing to devote their time and energy to such a network. In written comments, Dr. Thomas Rando, who was absent from the meeting, questioned whether it would be better to support such efforts through standard, investigator-initiated applications and a series of workshops, rather than through a research network mechanism. Dr. Rando expressed concerns about potential competition between groups, how an interdisciplinary network would be formed, and who would make decisions about who would participate in such a network. Drs. Steven Cummings and Anne Newman also noted that a lot of work on the use of telomere measures to predict outcomes remains unpublished. They encouraged NIA to reach out to institutions that have conducted these studies, dig into negative results that have not been published, and explore other potential reasons for publication bias.

Program staff responded that the design of the proposed concept includes two linked initiatives, one of which is a network that will coordinate multi-investigator competition on methods studies to encourage study participation. Laboratories would submit competing applications, and the network would serve as a central hub to coordinate systematic reviews, implementation of methods studies, dissemination of findings, and the building of transdisciplinary bridges. Publication bias would be addressed specifically within this initiative.

Roybal Translational Center Renewal and AD/ADRD Care Expansion

The Roybal Translational Centers program is an ongoing program that supports 11 centers. The program has been productive, particularly in assessing health care system interventions and in

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4 Dr. Crimmins recused herself from discussion on this concept proposal. Dr. Anne Newman served as Working Group on Program Chair during this discussion.
changing health care systems practices. This concept proposes to renew the Roybal program, add a Coordinating Center, and expand the program to include Centers focused on AD and ADRD. Working Group reviewers agreed that this is an excellent program, but they wanted clarification on how the expanded program will interact with existing NIA-supported, AD/ADRD-focused Center programs and with other Centers focused on health care practices. One reviewer noted that such interactions could provide another opportunity for Roybal Centers to provide expertise in translation and development of practical solutions, which is what they do best.

**AD Translational Center for Structural and Chemical Biology**

This concept proposes to form a Center to design, develop, and disseminate tools to support target-enabling packages for a series of alternative therapeutic targets emerging from such initiatives as the Accelerating Medicines Program in AD (AMP-AD), Molecular Mechanisms of the Vascular Etiology of AD (M2OVE-AD), and Resilience-AD. The proposed Center would initiate early-stage drug discovery campaigns to identify small molecules and biologics focused on these targets, with the ultimate goal of providing chemical leads for the private sector to develop further. The Center would be staffed by an interdisciplinary team with expertise in data science, network biology, structural genomics, and drug discovery and development. One Working Group reviewer agreed that such an interdisciplinary effort is needed within the academic community in the United States. However, he noted that it was not clear whether this concept would fund only one Center. In written comments, Dr. Richard Mayeux noted several important steps that are needed: articulation of a functional assessment of genes and loci related to AD; an understanding of the cellular effects of AD mutations and the over- or underexpression of AD-related genes; a description of the function of pathways in which groups of AD-related genes cluster; and promotion of interaction between this center and the AMP-AD, M2OVE-AD, and Resilience-AD initiatives.

Program staff responded that, depending on funding, the concept would support up to two Centers. Each would have core components in administration, bioinformatics/data management, structural biology, assay development, and medicinal chemistry. The assay core will work with the bioinformatics core on assessing the functional effects of alterations in AD-related genes, both *in vitro* and *in vivo*. The Centers also will work with the MODEL-AD program on functional assessments. The AMP-AD, M2OVE-AD, and Resilience-AD consortia are already working to understand the functional pathways in which AD-related genes cluster. NIA expects that there will be ample opportunity for the AD genetics community to interact with the proposed Centers.

In response to questions from the Council, program staff noted that the other AD-focused consortia are generating a large group of targets and that the bioinformatics core in the proposed Centers would be expected to prioritize the ones that would be explored by the structural biology and medicinal chemistry cores.

**Balance Testing Pilot in the National Health and Nutrition Examination Survey (NHANES)**

This concept proposes to add to an existing contract with NHANES to pilot test balance measures, including a modified Romberg Test, the Dynamic Visual Acuity Test, and a visual contrast-sensitivity test, for inclusion in future NHANES rounds. Reviewers supported the
concept, but one asked whether these assessments would be done as part of existing in-home assessments and why the proposed sample was so small. Program staff clarified that these balance measures would be added to testing that is already a part of the current NHANES round. If pilot testing is successful, balance testing would be a full component for the 2019-2020 round.

Collaborative Studies on AD and ADRD

This concept proposes to foster collaborative projects across several high-profile investments within the NIA portfolio. Working Group reviewers supported the concept. However, they asked whether the funding opportunity announcement (FOA) would require participation of one or more existing AD Centers and non-AD entities. They also noted that several resources named in the concept reside at institutions with existing AD Centers, and they asked how these resources would be leveraged for this concept. One reviewer expressed concern about the amount of money needed to support the collection and integration of new data and samples from existing cohorts and studies.

Program staff responded that the FOA will not require participation by existing AD Centers. They also noted that harmonizing data or samples is not an overarching goal of the concept; some national cell repositories for existing AD initiatives already collect and harmonize samples and data. However, applications that propose such harmonization and request sufficient funds for that effort will be reviewed under this FOA. The FOA will specify available resources, and applicants will specify in their applications which ones they want to use.

Examining Factors Related to Recruitment and Retention in Aging Research

This concept aims to apply science to understanding challenges in recruitment, particularly for large clinical trials and research projects. Working Group reviewers supported the concept, but they noted the importance of including researchers with expertise in studying diversity and cultural barriers to participation. They also questioned whether the concept would allow ongoing studies to study recruitment on a time-limited basis, and they suggested that the concept include cost-effectiveness and cost-benefit evaluations for various recruitment strategies.

NIA Small Research Grant Program for Investigators New to AD and ADRD Research

The proposed concept builds on the success of the Grants for Early Medical/Surgical Specialists Transition to Aging Research and similar programs to attract clinicians and others who have not had experience in AD/ADRD research. Working Group reviewers supported the concept but questioned whether the small grants would impede applicants’ eligibility for new or early-stage investigator R01 awards. They also questioned whether mentorship and training would be included in these small research grants. Dr. Robin Barr responded that these small grants would likely be R03 awards and would therefore not impede applicants’ eligibility for new or early-stage investigator awards.

Integrative -Omics to Enhance Therapeutics Development for Healthy Aging

The proposed concept arises from an August 2017 workshop on integrative -omics approaches to build on genome-wide association and other genetic studies on the determinants of longevity. The RFA would encourage research that would employ proteomics, metabolomics, and systems
biology to identify the biological basis of healthy longevity. One Working Group reviewer supported the idea and suggested that the initiative coordinate with similar efforts, such as the Rotterdam and Framingham studies, that are integrating -omics across cohorts for similar endpoints. Dr. Mayeux’s written comments suggested that the initiative include a rare-variant search in collective cohorts, proper phenotyping for dementia that is not limited solely to historical information, and connections with other efforts in AD genetics.

Program staff agreed on the need to coordinate with similar activities and noted that the RFA will provide instruction on how to do so. Staff also noted ongoing work in the Longevity Consortium and anticipated that investigators from this consortium would be attracted to the proposed concept. Program staff also agreed with Dr. Mayeux’s comments. Instructions for more descriptive phenotyping will be included in the RFA. Staff also anticipated a large amount of interaction between this initiative and AMP-AD.

**NIA Information Resource Centers Contract**

This concept extends the contract for the AD Education and Referral Center and the NIA Information Center, both of which respond to thousands of information requests, receive millions of visits, and distribute materials. These Centers are an integral part of information sharing for NIA. NIA is constantly reviewing and revising the Centers contract. Both Working Group reviewers supported this concept. In response to their questions, program staff noted that program reviews for each Center include a set of deliverables for each year and that the reviews have raised no concerns.

**Proposals Requiring Further Discussion**

The final group of proposals required further detailed discussion. The Council voted on each of these independently.

**Registry for Identification, Evaluation, and Tracking of Older Persons with Superior Cognitive Performance for their Chronological Age**

The most recent Cognitive Aging Summit described a subset of older adults who have maintained superior cognitive performance even at advanced ages. The proposed RFA will support the development of a registry that will include enough of such individuals from around the country to facilitate study of this rare phenotype. Working Group reviewers supported the general idea but believed that the concept as presented was vague. It was not clear whose data would be collected, what scientific goals would be pursued, or the types of studies that would be conducted using the registry. They also expressed concern that this would be such a rare phenotype that accumulating the number of individuals needed for research might be difficult. The reviewers suggested a staged approach, with a period for investigators to ask and prioritize scientific questions and establish feasibility protocols. They also emphasized the importance of defining “cognitive super-agers” and what might be important to know about early versus late life for this population, compared with non-super-agers. One reviewer also questioned whether a registry was the best approach to studying this population.

In response, program staff anticipated that the FOA would direct applicants not only to discuss how they would enroll participants into the registry, but also to propose research that would use
the registry. Staff also noted that the few groups who have been studying this population in the United States have slightly differing definitions for cognitive super-agers; the staff expressed the hope that the registry would aid in establishing a common, standard definition. Program staff agreed on the need for a staged approach and suggested that the initial stage would involve collecting data and establishing a common definition and phenotype. They also noted that information on more than 150 cognitive super-agers has been collected across research groups, but that a registry would aid in increasing this number even further.

Dr. Terrie Moffitt suggested that the proposal include the collection of a wide range of individuals with the same level of cognitive reserve in earlier life, then follow those who develop into non-super-agers as well as those who become super-agers. This would provide a comparator group for subsequent studies. Dr. Reisa Sperling emphasized the importance of examining the brains of both cognitive super-agers and non-super-agers to assess underlying pathology and to study resilience to such pathology.

A motion was forwarded and seconded to defer the concept for additional information. The motion passed, with 10 votes for, 2 votes against, and 2 abstentions.

In Vivo Synaptic Function in AD and ADRD

Synapses form a fundamental part of the neural architecture, and loss of synapses is an early characteristic of AD. This concept proposes two linked FOAs. One will support the replication and validation of positron emission tomography using carbon-11 ($^{11}$C-PET) to follow the presynaptic protein SV2A. The second will support the development of novel tools to study synaptic function in vivo in humans. In proposing this concept, NIA acknowledges that the FOAs will support high-risk, high-reward research.

Working Group reviewers supported the concept. However, they cautioned NIA to temper its expectations with respect to what such research will yield. The use of $^{11}$C as a tracer will have limited uptake, and it is not yet clear whether measuring synaptic function in vivo is possible in humans. The reviewers expressed concern, for example, that a focus on biomarkers will not yield tools specific to AD, because markers of synaptic dysfunction would underlie any type of neurodegeneration. Program staff agreed with this assessment and will revise the concept accordingly.

A motion to approve this concept was forwarded and seconded. The motion passed unanimously.

Clinical Trial on Effects of Statins in Older Adults without Clinical Cardiovascular Disease

Statins have proven effective in preventing cardiovascular events in individuals with cardiovascular disease (CVD) and in individuals aged up to 75 years with no CVD. However, the risks and benefits of statins in adults older than 75 years without CVD are not clear. CVD prevention trials have enrolled few individuals older than 70 years, and none has assessed the impact of statins on cognitive function or addressed concerns about the adverse muscular effects associated with statins. This concept proposes to support a major clinical trial in this population. The proposed design for the clinical trial was developed at a workshop in August 2017 and approved by the Clinical Trials Advisory Panel. The trial will be structured as a primary
prevention trial, but its primary endpoint will be a composite of disability- and dementia-free survival. The proposed clinical trial will be as pragmatic as possible.

Reviewers expressed concern that data about the primary endpoint cannot be found in the electronic health record. They also questioned whether this question could be assessed in a smaller trial with well-defined measures of cognitive and physical performance. They also asked whether there is a biologic and mechanistic basis for differences in cardiovascular events in individuals older than 75 years. Prior to today’s meeting, Dr. Evan Hadley responded that primary data will be collected from individuals in person, that evidence suggests that associations between lipids and CVD and thus the effects of statins change with age, and that the proposed trial will include cardiovascular outcomes as secondary endpoints.

A motion to approve this concept was forwarded and seconded. The motion passed unanimously.

De-prescribing Strategies for Older Adults with Multiple Chronic Conditions

De-prescribing, or the discontinuation of some drugs, has been proposed as a strategy to manage polypharmacy in older adults with multiple chronic conditions (MCC). This concept, based on recommendations from a U13 workshop on CVD, proposes to establish a research network to define scientific priorities and develop a pilot to study de-prescribing. Individuals who are at an advanced age and/or exhibit cognitive decline will be included in the study population.

Working group reviewers questioned the use of a network approach to increase research on de-prescribing. It was not clear whether applicants would focus on a limited range of multimorbidities or be expected to focus on a wider range. Reviewers also expressed concern that participation in the proposed network would gather all the experts in this field, leaving none to review applications and creating a highly exclusive network. One reviewer also suggested that NIA encourage the inclusion of individuals with expertise in analytics and comparative effectiveness research.

Program staff noted successful examples of a network approach, such as a delirium-focused network that has recently launched. To address the problem gathering reviewers from a limited pool of experts, NIA could look to international reviewers. For example, de-prescribing is the focus of robust research activity in Canada. Program staff also suggested that the proposed network would focus on conditions that are common in older age and driving medication use and polypharmacy. However, NIA would allow applicants to specify the group of conditions they would want to study. Because of this response, Working Group reviewers supported the concept, with the suggestion that expertise in analytics and comparative effectiveness research be included.

A motion to approve the concept was forwarded and seconded. The motion passed unanimously.

B. Division of Neuroscience (DN) Review

Dr. Eliezer Masliah, DN Director, reported that the program has established internal timelines and invited potential reviewers. Review meetings will likely begin in March. A preliminary report will be given at the September Council meeting, and the final report will be given at the January 2019 Council meeting.
C. Statement of Understanding

Dr. Barr reminded the Council that the Statement of Understanding outlines housekeeping rules and smaller activities that NIA can undertake without clearance from NACA. The Council must approve the Statement of Understanding each year.

This year, NIA is requesting to increase the threshold for approving administrative supplements from $100,000 to $250,000. This increase will allow NIA to approve administrative supplements, without Council clearance, for investigators who are rebuilding their laboratories following a natural disaster or to allow rapid AD-related funding in anticipation of large increases in funds set aside for AD research. Council members agreed on the need to increase the threshold for these specific reasons. However, one member expressed concern that this increase would extend to other purposes for which Council-approved grants would be a better approach.

A motion to approve an amendment to the Statement of Understanding, with the threshold for administrative supplements increased from $100,000 to $250,000, was forwarded and seconded. The motion passed unanimously.

IV. ADJOURNMENT

The open session of the 133rd meeting of the National Advisory Council on Aging adjourned at 6:10 p.m. on January 19, 2018. The next meeting is scheduled for May 22–23, 2018.

V. INTRAMURAL PROGRAM REVIEW

This portion of the meeting was closed to the public in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S. Code and Section 10(d) of the Federal Advisory Committee Act as amended (5 U.S.C. Appendix 2).

VI. CERTIFICATION

I hereby certify that, to the best of my knowledge, the foregoing minutes and attachments are accurate and complete.\(^5\)

Richard J. Hodes, M.D.
Chairman, National Advisory Council on Aging
Director, National Institute on Aging

Prepared by Robin Barr, D. Phil
With assistance by Rose Li and Associates, Inc.

\(^5\)These minutes will be approved formally by Council at the next meeting on May 22–23, 2018, and corrections or notations will be stated in the minutes of that meeting.
COMMITTEE ROSTER
National Advisory Council on Aging

NATIONAL INSTITUTE ON AGING

May 22-23, 2018

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