

**NATIONAL ADVISORY COUNCIL FOR HUMAN GENOME RESEARCH  
MEETING SUMMARY**  
February 9-10, 2015

The Open Session of the 73<sup>rd</sup> meeting of the National Advisory Council for Human Genome Research (NACHGR) was convened at 10:00 AM on February 9, 2015, at the Fishers Lane Terrace Level Conference Center in Rockville, MD. Dr. Eric Green, Director of the National Human Genome Research Institute (NHGRI), called the meeting to order.

The meeting was open to the public from 10:00 AM until 5:45 PM on February 9, 2015. In accordance with the provisions of Public Law 92-463, the meeting was closed to the public from 8:00 AM to 10:00 AM and 6:00 PM to 6:30 PM on February 9, 2015 and from 8:30 AM until adjournment on February 10, 2015, for the review, discussion, and evaluation of grant applications.

Council members present:

Carlos Bustamante  
Lon Cardon  
Joseph Ecker  
James Evans  
Howard Jacob  
Amy McGuire  
Anthony Monaco  
Robert Nussbaum  
Lucila Ohno-Machado  
Arti Rai  
Eric Boerwinkle, ad hoc  
Carol Bult, ad hoc  
Chanita Hughes-Halbert, ad hoc  
David Page, ad hoc  
Dan Roden, ad hoc  
Val Sheffield, ad hoc  
Jay Shendure, ad hoc

Council members absent:

Martin Kreitman

Staff from the National Human Genome Research Institute

|                           |                             |
|---------------------------|-----------------------------|
| Ronit Abramson, DPCE      | Deborah Colantuoni, ERP     |
| Alice Bailey, DPCE        | Catherine Crawford, ERP     |
| Shannon Biello, ERP       | Camilla Day, ERP            |
| Vence Bonham, IOD and DIR | Edith DeHaut, ERP           |
| Joy Boyer, ERP            | Valentina Di Francesco, ERP |
| Larry Brody, ERP          | Carla Easter, DPCE          |
| Comfort Browne, ERP       | Elise Feingold, ERP         |
| Monika Christman, ERP     | Adam Felsenfeld, ERP        |

Leigh Finnegan, ERP  
Ann Fitzpatrick, DM  
Elyse Galloway, DPCE  
Tina Gatlin, ERP  
Daniel Gilchrist, ERP  
Bettie Graham, ERP  
Mark Guyer, IOD  
Linda Hall, ERP  
Lucia Hindorff, ERP  
Sara Hull, DIR  
Carolyn Hutter, ERP  
Heather Junkins, ERP  
Alexander Lee, ERP  
Rongling Li, ERP  
Nicole Lockhart, ERP  
Ebony Madden, ERP  
Allison Mandich, IOD  
Casey Martin, ERP  
Jean McEwan, ERP  
Ken Nakamura, ERP  
Hannah Naughton, ERP  
Vivian Ota Wang, ERP  
Bianca Patel, ERP

Diane Patterson, ERP  
Michael Pazin, ERP  
Ajay Pillai, ERP  
Lita Proctor, ERP  
Erin Ramos, ERP  
Laura Rodriguez, DPCE  
Ellen Rolfes, DM  
Jeff Schloss, ERP  
Mike Smith, ERP  
Heidi Sofia, ERP  
Tasha Stewart, ERP  
Jeff Struewing, ERP  
Michelle Tallman, DEP  
Adrienne Tracy, DM  
David Trantin, ERP  
Elizabeth Tuck, DPCE  
Yekaterina Vaydylevich, ERP  
Simona Volpi, ERP  
Chris Wellington, ERP  
Kris Wetterstrand, IOD  
Bob Wildin, DPCE  
Ken Wiley, ERP

Others present for all or a portion of the meeting:

Adam Berger, IOM  
Katherine Donigan, FDA  
Adam Fagen, Genetics Society of America  
Ellen Giarelli, International Society of  
Nurses in Genetics (ISONG)  
Joseph McInerney, ASHG

Marilyn Miller, NIA  
William Mobley, Univ. of CA, San Diego  
James O'Leary, Genetic Alliance  
Jerry Schellenberg, Univ. of Pennsylvania  
Rhonda Schonberg, NSGC  
Charles Zellers, LCG, Inc.

**INTRODUCTION OF NEW NHGRI COUNCIL MEMBERS, STAFF, LIAISONS, AND GUESTS**

**APPROVAL OF MINUTES FOR THE SEPTEMBER, 2014 MEETING**

**DIRECTOR'S REPORT**

Dr. Eric Green presented the Director's Report to Council.

Council noted that the Million Veteran Program (MVP) was not mentioned in the discussion about the Precision Medicine Initiative and the plans for the one-million-person cohort study. Dr. Green reassured Council that the MVP will be included in the NIH discussions and plans about available cohorts. In fact, Dr. Michael Gaziano will present on the MVP as an example of a large cohort in the United States at the NIH workshop on "Building a Large US Cohort for Precision Medicine Research" scheduled to take place February 11-12, 2015. Council member Dr. Robert Nussbaum is an advisor for the MVP and offered to serve as a liaison in the future.

Council asked if NHGRI has any plans to collaborate with (or learn from) the UK Biobank, or use this study as a model for future endeavors. Dr. Teri Manolio noted that Dr. Rory Collins will be in attendance at the aforementioned NIH workshop on building a large US cohort. NHGRI agreed that maximizing the cross-fertilization of NHGRI efforts and other similar efforts like the UK Biobank will be critical in the future.

Council wanted to know who will lead this cohort effort. Governance details will be fleshed out at a later date; however, it will be shaped in a trans-NIH manner using relevant expertise from all NIH institutes.

NHGRI was encouraged to identify cohorts that are diverse, representative, and properly powered. One challenge in gathering diverse cohorts is that minority groups sometimes have smaller sample sizes that tend to prohibit discovery. More detailed discussions on how to approach available cohorts will begin at the NIH workshop on Wednesday.

### **Update on the Genomic Medicine Working Group by Teri Manolio**

Dr. Teri Manolio presented an update for the Genomic Medicine Working Group.

Council noted that many of the components of the genomic medicine research program will be important to the Precision Medicine Initiative. One of the tasks for the Genomic Medicine Working Group will be to consider how the scope of these projects could be expanded by an order of magnitude or more given the scope of the proposed initiative

Council commented there is a perception that the field of genomic medicine is on the verge of an explosion of activity. NHGRI has been working at the interface of clinical practice and research and the Council wondered what the genomics community should be doing to prepare for this expansion. Understanding the current barriers and impediments that each research program confronts is one way NHGRI can prepare for anticipated changes. Finding ways to facilitate the implementation of genomic technologies in clinical settings that are not part of research-intensive institutions is another challenge NHGRI would like to push forward. Council noted the one-million-person cohort associated with the Precision Medicine Initiative represents a tremendous opportunity for genomics to push the interface between research and clinical practice much further than the current position.

Council went on to note the genomics community is working towards greater consensus regarding how to define a “causal” variant and what functional information is necessary to interpret variants. It will be important to leverage data across sites and, in doing so, to establish firm boundaries about what are secondary reportable variants for clinical purposes.

The American College of Medical Genetics and Genomics (ACMG) published a list of secondary findings, which demonstrate the tremendous variability in how the community uses these guidelines. This was noted as a good discussion point, but far removed from how physicians will use this data in the practice of medicine. ClinGen, an NHGRI genomic medicine program, is an example of a current NIH effort aimed at curating a list of variants most relevant for patient care.

As the Genomic Medicine Working Group moves forward, incentives to share data should be made more explicit. A flawed incentive structure would be one of the biggest bottlenecks for the effective aggregation of genomic data. Council noted it may become necessary for regulatory agencies such as the Food and Drug Administration (FDA) and Centers for Medicare and

Medicaid Services (CMS) to make data sharing a requirement for providing clinical services. Arti Rai pointed to an Institute of Medicine report <http://www.iom.edu/Reports/2015/Sharing-Clinical-Trial-Data.aspx> on the sharing of clinical data, for which she was an author. Without regulatory authority like the European Medicine Agency (EMA), it may be more of a challenge for the US to implement widespread sharing of clinical data.

In the educational setting, Dr. Robert Nussbaum has worked on the implementation of human medical genetics in medical students' and residents' curricula at UCSF. The Association for Molecular Pathology (AMP) and others have been involved in discussions on including genomic medicine as part of the medical school curriculum.

### **“Alzheimer’s Disease Sequencing Project” by Eric Boerwinkle**

Dr. Eric Boerwinkle presented a summary of the Alzheimer’s Disease Sequencing Project (ADSP).

The field seems to be moving away from simple burden tests (like counting) and towards more sophisticated measures to do association studies using multiple variants within genes and gene networks and to code, annotate, and analyze structural variants.

The ADSP plans to generate a consensus variant call format (VCF) that will be released in March 2015 to the public, and will encompass all variants in common between the two sequencing center calling pipelines that pass quality control (QC) protocols. The raw data from the three sequencing centers will also be made available to the public in dbGaP.

Council asked if the ADSP has the capability to use Alzheimer’s disease (AD) endophenotypes and the genotype/phenotype relationship, particularly for drug discovery context in the future. Though the ADSP has not analyzed the data yet with these sequence variants, Dr. Boerwinkle is confident that endophenotypes will be key in identifying protective variants (PVs) and will be used as stratifying variables to identify a more homogenous set of individuals in an effort to increase power. Longitudinal measurements for individual subjects will also be important. The ADSP data are not centralized, so the ADSP representatives at Council were not sure how much data are currently available.

The National Institute on Aging (NIA) has funded the National Cell Repository for AD (NCRAD) which has samples that go back as far as thirty years. NCRAD has approximately 25,000 phenotyped samples, and NIA would like to leverage this resource. An equal number of samples are available from the Cohorts for Heart and Aging Research in Genetic Epidemiology (CHARGE). NIA has data from other similar efforts that they will attempt to harmonize with the ADSP data. It would be beneficial to also obtain post-autopsy brain samples when possible.

The AD community is laying the foundation for the proposed precision medicine initiative—which reinforces the notion that large sequencing efforts should be done in a collaborative manner.

NIA is currently involved in a large effort to identify targets through an accelerated medical partnership (AMP) initiative; in fact, NIA is looking for areas of intersection between the AMP and the ADSP. NIA released a Request For Applications (RFA) for the ADSP replication phase that requests the identification of functional components in AD. It is a Congressional mandate to find AD targets by 2020.

The ADSP documents can be found at the ADSP website: <https://www.niagads.org/adsp/content/home>). The documents provide further information on the project's specific aims for power.

The group acknowledged that the genomics community does not have an adequate pipeline to identify which variants are functional and which are not functional. Better measures will unfold as the genomics community moves from whole exome sequencing (WES) to whole genome sequencing (WGS). Functional genomics is still an open field.

## **CONCEPT CLEARANCES**

### **“Centers of Excellence in ELSI Research RFA Renewal” presented by Joy Boyer**

Ms. Boyer gave a presentation on the concept to renew the Centers of Excellence in ELSI Research (CEER).

Council concurred that moving away from a focus on one major research project and instead allowing investigators to propose multiple smaller projects would be a positive change for this program.

The four-year funding timeline, with one opportunity to renew for an additional four years appears appropriate. The benefit of the long-term investment in the P50 grants is to build the infrastructure necessary to support and sustain training activities in the P50 centers.

Regarding the question about eligibility requirements, Council expressed the view that it would be preferable to see new centers established at institutions that did not have existing or previous P50 center awards in order to promote the expansion of ELSI research training across the country, rather than concentrating it in just a few major locations. However, investigators who are currently, or previously, involved in a P50 center should be eligible to participate as collaborators on new P50 applications.

Council also expressed the view that the P20 planning grants can be a very effective mechanism to help newly forming research groups successfully transition to a P50 award. Therefore, NHGRI is encouraged to continue to include the P20 activity code in the reissued funding opportunity announcement (FOA).

It may also be useful to consider other components of NHGRI that could help in co-funding some of the activities in the CEER program.

Ms. Boyer was encouraged to document and discuss metrics of success for evaluating training within the CEER program and to ensure that these metrics are consistent with metrics employed in the other education and training activities supported by NHGRI.

The CEER program has been useful for setting up infrastructure for researchers focused on ELSI topics; however, political scientists and economists do not appear well represented in this group. These perspectives would be useful for the program.

Some Council members noted that the budget proposed for this FOA seemed low for an NHGRI ELSI flagship program. Ms. Boyer noted that the suggested set aside for this FOA was for new awards, and NHGRI hoped to maintain the current level of funding for the ELSI CEER program. Other Council members noted that ELSI research is also taking place in some of the genomic

medicine research components such as the Clinical Sequencing Exploratory Research (CSER) program.

Council encouraged Ms. Boyer to collect data on additional funding sources P50 CEER grantees are able to receive to support the research activities of their CEER program and what infrastructure remains in place after NHGRI CEER funding ends. Ultimately, the hope is that the CEER investigators will be able to successfully compete for funding that extends beyond NHGRI support to ensure the sustainability of the programs.

Council approved the Centers of Excellence in ELSI Research concept by a vote of: 12 for approval, none opposed, and none abstaining.

### **“Genome Sequencing Program Analysis Satellites” presented by Adam Felsenfeld**

Dr. Felsenfeld gave a presentation on the concept for Genome Sequencing Program (GSP) Analysis Satellites.

Council asked how NHGRI plans to ensure data can be integrated across all of the analysis centers. Ideally, all analysis centers will have access to all of the data. Some projects may function similarly to ADSP with their own arrangements for data repositories.

Some Council members expressed concern that this concept continues with the recent trend to “commoditize” science; that is, by funding separate smaller components of a truly large research endeavor we will lessen the cohesion that makes difficult genome sequencing problems tractable. Dr. Felsenfeld agreed that what is most important is ensuring that all GSP participants work together to solve problems. The intent of the analysis centers is that they will have the opportunity to be more innovative and to have a more outward looking perspective that hopefully will lead to novel computational approaches to conduct data-driven science and analyze large genomic datasets.

It was suggested that the sequencing centers also compete for funds that would be taken from the current Centers for Common Disease Genomics (CCDG) set aside to be put towards analysis efforts in an effort to generate the most innovative and effective science possible. Dr. Felsenfeld noted that NHGRI would have to consider what funding mechanisms would best serve this idea. Collaboration within the GSP program should not be impeded by the structure of the analysis satellites or by competition between the CCDG applicants and the analysis satellite investigators.

NHGRI will need to consider how best to encourage the sharing of data among the centers to an extent where the full value of data sharing is achieved.

Council suggested the NHGRI look at the Cancer Genome Atlas (TCGA) and the pan-cancer analysis structure as a possible model to consider for the analysis satellite FOA.

Council agreed with NHGRI that investigators for the CCDG and Centers for Mendelian Genomics (CMG) grants cannot be principal investigators for the satellite analysis applications. It is appropriate that the sequencing centers should not be too closely aligned with the analysis satellites. Council encouraged NHGRI to be clear about the distinction between the sequencing center and the analysis satellites from the outset of the new CCDG program.

Council noted the difficulty of making the determination that a sequencing project was complete and that all useful variants have been identified. Equally important is the challenge of getting negative results published, or at least reported in a useful and meaningful way; there is great value to the community to know about negative outcomes. It would be useful if this could be included in this FOA, or some other component of the GSP.

Council encouraged Dr. Felsenfeld to better define the role of the analysis satellites while the future GSP program is still in a preliminary stage. Ideally, NHGRI would welcome applications with creative ideas about how to include additional types of datasets, like useful functional data or expression data to make inferences about the functions of variants that are identified by the sequencing centers.

Council also asked if there was a connection, or a distinction, between what will be done by the analysis satellite groups and the Functional Variation (FunVar) project. Dr. Lisa Brooks noted that FunVar is designed to use computational methods (with some amount of experimental validation) to elucidate causality of the discovered variants. NHGRI noted it is possible that the CCDGs and their analysis satellites could propose to work in this area, and those investigators would be welcomed to participate in the FunVar consortium activities.

Council approved the GSP Analysis Satellites Concept by a vote of: 12 for approval, none opposed and none abstaining.

#### **“Genome Sequencing Program Coordinating Center” presented by Adam Felsenfeld**

Dr. Felsenfeld gave a presentation on the concept for Genome Sequencing Program Coordinating Center. He reminded the Council this concept had been presented at the September, 2014 meeting and the current concept reflects changes suggested by the Council during that discussion.

Council agreed that an administrative function is absolutely essential for the future GSP. It is a leadership role that will require specific expertise to function within a complex consortium. The GSP coordinating center may have room for some analysis capabilities, but these capabilities would be limited.

NHGRI plans to have funding for the coordinating center align with the funding of the CCDGs and CMGs, which would be early in the fiscal year 2016.

Council asked if NHGRI had considered the possibility of one of the sequencing centers functioning as the GSP coordinating center. Dr. Felsenfeld noted that a similar mechanism was employed in the previous CMG program. NHGRI deliberately did not want to make any of the funded sequencing centers eligible for this coordinating center role.

The ability of the analysis satellites to succeed and to add value to the GSP as a whole depends on the coordinating center function; therefore, Council cautioned again that this concept should extend beyond administration. Dr. Felsenfeld stressed there is no intention for the GSP coordinating center to serve in a purely administrative capacity; at the same time, the GSP coordinating center is also not meant to function as a data coordinating center because the sequencing centers will be working with outside collaborators who will have their own coordinating centers outside of the GSP. A major function of the coordinating center will be to make sure the analysis satellite groups get GSP data to work on. Since the movement, sharing, and harmonization of data will be critical, especially with a large number of analysis satellites,

NHGRI is aware that without analysis capabilities, the GSP coordinating center will not be able to lead trans-analysis satellites tasks, such as the selection of common controls.

Two current NHGRI programs—Population Architecture using Genomics and Epidemiology (PAGE) and Clinical Sequencing Exploratory Research (CSER)—have a hybrid administrative/data coordinating center. For example, the coordinating center creates harmonized data sets and imputes data from new and existing individuals as well as organizes working group calls and meetings. There are different types of tasks that will require the work of multiple centers; for example, two or more centers that plan to work on the same phenotype. The coordinating center will be the main facilitator for combining these, data and will be expected to act as a neutral party (and successful mediator) within a consortium. NHGRI staff has a wealth of experience to draw upon from other coordinating centers operating in several other research consortium settings.

Council recommended that NHGRI emphasize the requirement to work with the rest of the GSP components. NHGRI assured Council that this collaborative element will be explicitly stated in the RFA. A GSP Steering Committee will likely be formed to facilitate communications between the GSP coordinating center and GSP PIs.

Council approved the GSP Coordinating Center concept by a vote of: 12 for approval, none opposed and none abstaining.

#### **“Producing High Quality (‘Gold’) Genome Sequences” presented by Adam Felsenfeld**

Dr. Felsenfeld gave a presentation on the concept for Producing High Quality (‘Gold’) Genome Sequences.

Council cautioned against limiting this concept to groups already funded under the GSP consortium. This type of activity needs its own focus and own grant funds—independent of the GSP. This will require a focused approach and specific expertise, so it will be appropriate to separate this work from the existing consortium.

Council asked if annotation of the genome assembly would be out of the scope of this project. NHGRI could encourage computational gene predictions or use of cDNA libraries to generate better gene models. It was noted that there are a lot of data analysis methods to improve quality and annotation of genomes, but these efforts would require a greater amount of funds; therefore, experimental-based annotation efforts would be considered out of scope for this concept.

This effort would likely be proposed as a cooperative agreement for a research resource. Companies would be allowed to apply to this funding opportunity announcement. Council noted it will be critical to have racial and ethnic diversity well represented among the genomes that are produced under this FOA.

Council asked if the Genome Reference Consortium (GRC) would take stewardship of the high quality genomes once they are produced. Staff noted there will likely be an interface between this project and the GRC because the GRC will want to have access to these sequences once they are available.

Council agreed that this is a critically important initiative and will be a small investment for a significant and important product.



It is up to the applicant to propose the best means to accomplish this task, whether all genomes are independently assembled or not, to produce the best reference.

Council encouraged NHGRI to discuss this further with the “Genome in a Bottle” consortium.

Council approved of the High Quality Gold Genome Sequences concept by a vote of: 12 for approval, none opposed and none abstaining.

### **“Comparative and Evolutionary Genomics” presented by Adam Felsenfeld**

Dr. Felsenfeld gave a presentation on a proposed project titled “Comparative and Evolutionary Genomics.” The FOA announcing this project would be in the form of a specific Program Announcement (PAR). There would be no set-aside of funds to support this initiative; these would be unsolicited R01 applications from the community.

Council asked if the project could go beyond WGS, for instance capturing other types of data that would provide information on function. Dr. Felsenfeld answered that proposals could go beyond WGS data, so long as they align with the fundamental driving questions of the project.

Council also requested clarification on the anticipated quality of the products. Dr. Felsenfeld noted that data quality will be a factor but not the primary component of the project.

Grantees will not be asked for an early deposit of the data, though data deposition will be a requirement.

Council suggested that rather than planning to make two awards in this area NHGRI might benefit more from funding many groups, with smaller budgets, that focus on different organisms for different reasons, and organize this effort as a loose consortium. This approach may get more done than focusing on the research questions posed by one or two investigators. This project is an area where NHGRI made investments in the past, but has not in recent years. Council members noted that NHGRI may be surprised by the size of the response to this PAR from investigators who have been looking to other funding sources for the last several years.

## **PRESENTATIONS**

### **“Biennial Report on Inclusion of Women and Minorities in NHGRI-Supported Research” by Jacqueline Odis**

Ms. Odis provided the biennial report on the Inclusion of Women and Minorities in NHGRI-Supported Research.

Council was enthusiastic about the data trends presented in the biennial report on the Inclusion of Women and Minorities in NHGRI-Supported Research.

Council suggested NHGRI revise the graphs to present data in two ways: with 23andMe data included and without 23andMe data. The purpose of showing two sets of data is because the 23andMe dataset is much larger than all other surveyed projects, and it lacked information about sex, race and ethnicity.

Council asked if the racial and ethnic representation is evenly distributed across all surveyed research projects, or is the research participation of minorities due to a small subset of research projects that have over-sampled minority participants. Staff noted that the racial and ethnic diversity is distributed across all studies, and not just from a few specific project cohorts. There are some studies in the NHGRI intramural division that specifically recruit certain racial and ethnic populations due to the phenotypes under investigation (e.g., sickle cell disease). In future reports, Council suggested it would be beneficial to see the distribution across individual studies to be able to determine more precisely the distribution of racial and ethnic diversity across projects.

NHGRI was encouraged to make this data available for others in the community who may be interested to see where population diversity in genomic research is taking place.

Hispanic groups were presented based upon Office of Management and Budget (OMB) classifications. The report provides data on both racial groups and ethnicity

The age of participants was not collected through the survey mechanism. Dr. Bettie Graham clarified that the data collected in this report come from the actual enrollment tables presented in the applications, which do not include the ages of the participants.

NHGRI will make all appropriate changes before further circulation of the report.

Council voted to accept the Biennial Report on Inclusion of Women and Minorities in NHGRI-Supported Research by a vote of: 11 for approval, none opposed and none abstaining.

## **COUNCIL INITIATED DISCUSSION**

Council wanted to address again how NHGRI plans to aid in the implementation of critical databases for genomic data. Dr. Green stressed that this task is not just for NHGRI but for NIH as a whole. Drs. Jon Lorsch and Phil Bourne are also very interested in navigating these data resource issues. This discussion will need to take place with greater NIH leadership involved.

The BD2K program is in the midst of planning a workshop. Council will be updated on the status of this workshop at a later date. Drs. Lorsch, Bourne, and Green are communicating regularly about how to present this issue to the other ICs and NIH Directors.

Database initiatives are operating at two different levels: within NHGRI where the institute is attempting to determine how best to prioritize and promote database resources and relevancy, and at the NIH level with the BD2K office. The BD2K Sustainability Working Group is evaluating a number of initiatives. NIH will also query the community for alternative funding models for database resources. Many database activities are exploratory at this point. Currently, the BD2K program is in a “discovery mode.”

In the coming months, it will be important for database initiatives to strike a balance between deliverables that are needed and innovations to improve these deliverables. The need for sustainable database initiatives is an international issue that will have to be managed on a global scale. These initiatives will be defined somewhat by international funders.

Council noted that all NIH ICs should mandate data sharing to all grantees as NHGRI has done.

The community is enthusiastic for more data, but the current database infrastructures lack the capacity, curators, and annotators to handle more data. Hopefully, the database problems pinpointed by programs like BD2K will prompt new expertise to be brought in.

Council hopes that NHGRI will be involved in the precision medicine process. Precision medicine will likely be a topic at future Council meetings, but NHGRI will engage Council members between Council meetings if needed.

Two workshops will be held in March. Workshop reports will be distributed to Council members as they become available.

## **ANNOUNCEMENTS AND ITEMS OF INTEREST**

Quarterly reports were provided by the National Society of Genetic Counselors and by the American Society of Human Genetics.

## **REVIEW OF THE STATEMENT OF UNDERSTANDING**

The Statement of Understanding (SOU) is a description of how the Council and NHGRI will interact. This document also provides the limits of NHGRI's administrative authority. No substantive changes have been made to the SOU since it was last presented at the February, 2012 Council meeting.

Dr. Rudy Pozzatti reviewed the Statement of Understanding with the Council members. The Council voted to accept the SOU by a vote of: 11 for approval, none opposed and none abstaining.

## **CONFIDENTIALITY AND CONFLICT OF INTEREST**

Dr. Pozzatti read the Confidentiality and Conflict of Interest policy to Council and asked the members to sign the forms provided to them.

## **REVIEW OF APPLICATIONS<sup>1,2</sup>**

In the closed session, the Council reviewed 216 applications, requesting \$107,567,038 (total cost). The applications included: 72 research project applications, 70 cooperative agreement (U01) applications, 9 ELSI research program applications, 2 research center applications, 25

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<sup>1</sup> For the record, it is noted that to avoid a conflict of interest, Council members absent themselves from the meeting when the Council discusses applications from their respective institutions or in which a conflict of interest may occur. Members are asked to sign a statement to this effect. This does not apply to "en bloc" votes.

<sup>2</sup> A subset of the T32 applications were submitted in response to BD2K initiatives and were temporarily assigned to NHGRI.

institutional training applications, 2 conference applications, 5 career transition award applications, 1 research scientist development award applications, 19 SBIR Phase I applications, 8 SBIR Phase II applications, and 3 STTR Phase 1 applications. A total of 124 applications totaling \$53,224,564 were recommended.

5/18/2015  
Date

Rudy O. Pozzatti  
Rudy Pozzatti, Ph.D.  
Executive Secretary  
National Advisory Council for Human Genome Research

5/18/2015  
Date

Eric D. Green  
Eric Green, M.D, Ph.D.  
Chairman  
National Advisory Council for Human Genome Research