2015 Biennial Advisory Council Report Certifying Compliance with Inclusion Guidelines NIDCD

I. Background/Overview

A. NIDCD mission

The National Institute on Deafness and Other Communication Disorders (NIDCD) is one of the Institutes that comprise the National Institutes of Health (NIH). Part of the U.S. Department of Health and Human Services, the NIH is the primary federal agency for leading, conducting, and supporting biomedical and behavioral research. NIH's mission is to seek fundamental knowledge about the nature and behavior of living systems and to apply that knowledge to enhance health, lengthen life, and reduce the burdens of illness and disability. Research and educational programs supported by the NIH continue to have a major positive impact on our lives by improving human health, fueling the U.S. economy, and creating jobs in our communities.

Approximately one in six Americans will experience a communication disorder in his or her lifetime. For millions of individuals, families, and communities, these conditions contribute significantly to diminished quality of life, unfulfilled potential, and economic challenges. To address these public health needs, the NIDCD was established in 1988 to conduct and support biomedical and behavioral research and research training in the normal and disordered processes of seven areas in human communication: hearing, balance, taste, smell, voice, speech, and language.

The Institute also conducts and supports research and research training related to disease prevention and health promotion; addresses special biomedical and behavioral problems associated with communication disorders; and supports efforts to create devices that substitute for lost and impaired sensory and communication function. In addition, the NIDCD translates and disseminates science-based health information about its seven mission areas and serves as a trusted resource for researchers, health professionals, policymakers, and the public.

Over the course of the past 25 years, NIDCD-supported scientists have made astonishing discoveries that are advancing scientists' understanding of mechanisms involved in communication and chemical senses. These findings lay the foundation for clinical and translational research studies in the NIDCD mission areas. As profound biomedical accomplishments are being realized, millions of people are benefiting. Vast opportunities for clinical advances in the communications and chemosensory sciences remain. The NIDCD has made clinical research a priority and in the past decade the institute has significantly expanded its clinical trials program.

More than half of the NIDCD-supported clinical trials address hearing and balance disorders, areas that are especially likely to have growing public health significance as the population continues to age and live longer. Slightly less than one-half of NIDCD-funded clinical trials address voice, speech, and language problems including interventions for assessing these conditions and for helping those with these disorders communicate.

One of the greatest contributions to public health by NIDCD-supported research has been evidence to support and enable newborn screenings for hearing loss. In 1993, only about one in 10 newborns was screened for hearing loss. Today, nearly all newborns are screened before they leave the hospital. Research has led to hundreds of thousands of children who have profound hearing loss or deafness benefitting from early interventions, such as cochlear implants -- one of the most groundbreaking biomedical achievements of the past 30 years, which was developed as the result of NIDCD funding. Scientists have reported that early use of cochlear implants not only improves the ability to hear or sense sounds, but when eligible children receive a cochlear implant followed by intensive therapy before 18 months of age, they can develop language skills at rates comparable to children with normal hearing.

The NIDCD also supports epidemiological and population-based research studies in all seven mission areas of the Institute: hearing, balance, taste, smell, voice, speech, and language. Studies assess hearing loss and other communication disorders across the lifespan, including risks associated with other health conditions as well as behavioral, demographic, environmental, and genetic factors. Longitudinal cohort studies, population-based health interview or examination cross-sectional surveys, and case-control studies provide important insights into the prevalence and determinants of communication disorders.

B. Institute portfolio

As a whole, the Institute supports and conducts approximately 1,300 research grants, training awards, and Research &Development contracts. These programs take place within the research laboratories and clinic at the NIH campus in Bethesda, Maryland (intramural research), or in public and private institutions and organizations across the country and around the world (extramural research).

Research in the *Division of Intramural Research* includes basic and clinical research in several areas, with a primary interest in hearing and balance. The identification and characterization of genes linked to hereditary hearing impairment, stuttering, head-and-neck cancers and other conditions that affect human communication, and treatment of voice disorders, are also studied.

Extramural research and training programs are administered through the *Division of Extramural Activities* (DEA) and the *Division of Scientific Programs* (DSP). DEA staff provides grant management and processing for all of the Institute's extramural research projects and conduct initial scientific merit review of a large array of grant mechanisms. In DSP, program staff plan and direct NIDCD's extramural research grants, career development awards, individual and institutional research training awards, center grants, and contracts to public and private research institutions and organizations.

Both intramural and extramural research and training programs include the full spectrum of scientific activities including basic, clinical, and translational research. These studies answer fundamental scientific questions to prevent, screen, diagnose, and treat disorders of human communication.

Hearing and Balance

Hearing and balance disorders decrease quality of life, cross all ethnic and socioeconomic lines, and impose significant social and economic burdens upon individuals, their families, and the communities in which they live. Millions of Americans experience a hearing or balance disorder at some point in their life, especially as young children or older adults. Common examples

include otitis media (middle ear infections), noise-induced hearing loss, tinnitus (ringing or buzzing in the ear), age-related hearing loss, dizziness, and vertigo. Nearly 25 percent of Americans age 65 to 74, and 50 percent of those who are 75 and older, have disabling hearing loss. In addition, two to three out of 1,000 babies born in the U.S. each year have a detectable hearing loss that can affect their speech, language, social, and cognitive development. Nearly 15 percent of adults in the U.S. report experiencing a problem with dizziness or balance during the past 12 months. The NIDCD Hearing and Balance Program comprises over half of NIDCD's portfolio. To study normal and disordered functions of the auditory and vestibular systems, the NIDCD employs a wide range of research approaches such as molecular genetics, cellular biology, animal models, biomedical imaging, nanotechnology, psychoacoustics, and structural and functional biology.

Improving hearing health for all ages has been an ongoing priority for the NIDCD. The NIDCD continues to support research to develop new approaches, assessment methods, and small business technologies to improve access to hearing health care. Clinical trials include developing or enhancing devices to improve hearing or enable the sense of sound, such as hearing aids, cochlear implants, and auditory brainstem implants (ABI); methods to prevent hearing loss and otitis media; and treatments and techniques for hearing loss and tinnitus.

Fewer than one in three U.S. adults who could benefit from hearing aids has ever used them. To improve access to hearing health care, scientists are studying ways to advance how well hearing-aid users can detect and interpret spoken sounds in noisy environments, low-cost hearing aids and service-delivery models, and community-based kiosks for hearing screening of potential candidates for hearing aids.

Balance disorders can be caused by certain health conditions, medications, or a problem in the inner ear or the brain. They disproportionately affect the elderly, and they can have a profound negative effect on the individual. The NIDCD is supporting clinical studies on tests of balance and vestibular function as well as potential treatments for balance disorders. For example, researchers are studying the use of a novel device, based upon the technology used in cochlear implants, to normalize balance in people with severe to profound bilateral vestibular deficiency, a condition that affects more than 150,000 people in the U.S. The device, developed with NIDCD funding, could also help individuals with disabling episodes of vestibular dysfunction from conditions such as Ménière's disease.

Taste and Smell

Each year, more than 200,000 people visit a physician for chemosensory problems, such as taste or smell disorders. Prevalence increases with age, affecting more than one in ten women and one in four men over the age of 60. These disorders can have a major impact on quality of life, food preferences, diet, and overall health. For example, taste and smell problems are often associated with major health risks, such as poor nutrition, diabetes, obesity, and cardiovascular disease, as well as safety concerns. In addition, a decline in the sense of smell may serve as an indicator of future cognitive problems such as Alzheimer's disease or Parkinson's disease.

The NIDCD Taste and Smell Program supports research to enhance our understanding of taste and smell mechanisms and how chemosensory disorders can be identified and treated. NIDCD-supported studies on molecular and cellular biology, animal models, biophysics, and biochemistry of the gustatory (taste) and olfactory (smell) systems are paving the way for improved diagnosis, prevention, and treatment of chemosensory disorders. Scientists are pursuing how the brain interprets sensory data, as well as mapping the functional organization of the neural circuits that

mediate these senses. The NIDCD also supports research to study the prevalence of taste and smell dysfunction and associated health risks.

Voice, Speech, and Language

Disorders involving voice, speech, or language can have an overwhelming effect on an individual's health and quality of life. These disorders affect millions of Americans of all ages. For example, six to eight million people have a language impairment, including children with autism and adults with aphasia (loss of the ability to understand or express speech). Another 7.5 million people have trouble using their voice.

Studies in the NIDCD Voice and Speech Program focus on determining the nature, causes, treatment, and prevention of disorders of motor speech production throughout the lifespan. The Language Program explores the genetic bases of child speech and language disorders, and characterizes the linguistic and cognitive deficits in children and adults with language disorders. Both programs use a wide range of research approaches, including animal models of communication, to develop effective diagnostic and intervention strategies for people with voice, speech, or language impairments.

Advances in understanding the areas of the brain involved in dyslexia, aphasia, stuttering, and autism spectrum disorder, for example, are growing. The NIDCD is supporting research on disorders such as stuttering, speech-sound acquisition disorders, childhood apraxia of speech, voice disorders, and swallowing disorders. Other studies are exploring ways to prevent and treat voice problems in teachers; novel voice therapy in children with vocal nodules; and telemedicine for language development in cochlear implant recipients.

A growing number of clinical studies are focusing on effective interventions for voice, speech, and language impairments. For example, innovative therapies are being tested to help people with aphasia, a potentially debilitating condition that may occur suddenly from stroke or traumatic brain injury, or from brain tumors, infections, Alzheimer's disease, and other neurologic or neurodevelopmental disorders.

Substantial progress has been made in the development of augmentative communication devices to facilitate the expressive communication of persons with severe communication disabilities. For example, NIDCD-supported researchers have developed a brain-computer interface communication prosthesis, which enables individuals with locked-in syndrome to immediately use personal computer software programs and speech synthesizers to translate thought into synthesized speech.

Researchers are developing effective diagnostic and intervention strategies for children with autism, or who have specific language impairment. NIDCD researchers are providing critical information regarding ways to predict useful speech development in children with autism, as well as to assess language, social, and behavior functioning in nonverbal school-aged children with autism. Such information will provide much-needed guidance in selecting among existing communication treatments and guide the development of new communication treatments for children with autism.

II. Strategies of ensuring compliance

A. Peer Review

Extramural:

As the initial review groups of the NIDCD and the Center for Scientific Review evaluate the scientific and technical merit of applications proposing clinical research, they examine the proposed plan for the appropriate inclusion of women and minorities and any justification that is provided when representation is limited or absent. This evaluation also considers the proposed plans for recruitment and outreach or retention of study participants. The reviewers include this assessment as one of the criteria when assigning an impact score to the application. If the reviewers find that the plans for either gender or minority representation are unacceptable, their determination is noted in the summary statement. Applications with such a determination are coded in the IMPACII database and must be addressed with institute staff.

At this time all NIDCD Phase I, II, and III clinical trial and clinical trial planning grant applications are reviewed by the NIDCD's *Scientific Review Branch* (SRB). In-house review facilitates policy compliance during the peer review phase. The NIH's Population Track Database identifies the number of applications that are determined during peer review as having acceptable inclusion plans. Appendix 1 and 2 contain the data from FY13 and FY14, respectively. In general, only a small percent of research applications are identified to have problems with their proposed plans for gender/minority/ethnicity inclusion. The most frequently cited problem has been that insufficient information was provided.

The second level of review is performed by the National Deafness and Other Communication Disorders (NDCD) Advisory Council. All applications (irrespective of their impact score rating) in which representation is designated unacceptable by the initial review group are specifically brought to the Council's attention. Any question about appropriate inclusion of women or minorities with which Council concurs requires action by the program staff of NIDCD.

Program staff communicates these concerns about appropriate inclusion to the applicant. Only when the applicant has responded to these concerns to the satisfaction of institute staff, may the funded research proceed. The NIH's Population Track Database tracks the number of applications that must address inclusion concerns prior to award. Appendix 3 and 4 contain the data from FY13 and FY14, respectively. Depending on the particular Council round, the number of such applications is most frequently zero, but has ranged as high as four.

Intramural:

All intramural clinical studies require investigators to provide plans for the appropriate inclusion of women and minorities, and/or a justification whenever representation is limited or absent, as part of their NIDCD and NIH protocol reviews. The protocols and plans are reviewed and approved by NIDCD's Protocol Review and Monitoring Committee, and central NIH Combined Neuroscience (CNS) Institutional Review Board (IRB). NIDCD protocols that are oncology protocols, are reviewed by the NIH National Cancer Institute's (NCI) Scientific Review Board and the NCI IRB. These protocol evaluations also consider the proposed plans for recruitment/outreach or retention of study participants. If plans for representation of gender or minority are unacceptable, the investigators must fully address all issues prior to approval.

This review is continued through the life of the protocol's active accrual stage and is conducted annually by the NIH CNS IRB or the NCI IRB. With each annual review and renewal, the investigator documents the number, gender, and ethnicity of those who were accrued during the past year; any issues with accrual are addressed at the annual review by the investigator and reviewed by the pertinent IRB.

B. Institute training approaches

Extramural:

All staff is appropriately sensitized to the need for broad inclusion in all NIH-sponsored clinical research. This awareness and implementation of inclusion practices are accomplished in a variety of ways.

Castilla F. McNamara, Ph.D., M.P.A., C.I.P., Population Tracking Officer, is responsible for assuring that the appropriate policy and policy updates are implemented by the NIDCD and that staff are trained.

Gordon B. Hughes, M.D., Program Director, Clinical Trials, works closely with program and review staff to ensure that research proposals classified as NIH-defined clinical trials are properly monitored and documented.

Scientific Review Officers of NIDCD's SRB implement the applicable policies and document outcomes of the initial peer review of applications.

NIDCD extramural staff has participated in the required NIH-wide training sessions to inform program, grants management, and review staff on the NIH inclusion policy, focusing on NIH-defined human subject research, U.S. Office of Management and Budget defined minority and ethnic group categories, NIH-defined Phase III clinical trials, and reporting requirements. New staff members who join the NIDCD extramural divisions after the annual NIH training are provided the required training utilizing archived resources.

The NIH-wide training session on the NIH Inclusion policy and new Inclusion Management System (IMS) was held in January 2014. This training introduced the new management system, demonstrated the system's value, and reinforced NIH inclusion management principles. The archived training videocast remains a resource for staff who are involved in implementation of the NIH inclusion policy. Because the IMS changed internal grant award processes, the NIDCD Grants Management Branch and Division of Scientific Programs have standard operating procedures that clarify policy requirements and system requirements. Additionally, other training resources are available, supplemented by one-on-one discussions with Dr. McNamara concerning various research projects that have issues of population inclusion and tracking. Updates and reminders are regularly provided to staff.

Intramural:

The NIDCD intramural Clinical Director and Protocol Coordinator are responsible for maintaining, updating and assuring compliance with NIH policies for inclusion for all NIDCD protocols. The NIDCD Protocol Coordinator attends CNS IRB training and Human Subjects Research Advisory Committee, IRB Professional Administrators' Committee, CNS Staff and Protocol Tracking Management System Steering Committee meetings, and provides information

to the Clinical Director and investigators during protocol development and continuing reviews. All NIDCD and other intramural members of the CNS IRB must take orientation and refresher training, which includes the NIH Inclusion Policy.

All NIDCD clinical investigators are required to take Introduction to Clinical Research, which describes the rationale and requirements for inclusion plans in protocols, and any other NIH clinical research training as required and described by the NIH Office of Human Subjects Research. This training must be completed prior to being an investigator on any NIDCD protocol and certificates of training are kept by the NIDCD Protocol Coordinator and the investigators.

III. Analysis and Interpretation of Data

A. All clinical research

This section combines summary data from grants/cooperative agreements/contracts and reflects human subjects from NIDCD extramural and intramural projects. Detailed descriptions are found under III C. and D. where extramural and intramural data are presented separately. NIDCD data will be combined with data from all other NIH components as part of a comprehensive report. The Annual Comprehensive Report - *Monitoring Adherence to the NIH Policy on the Inclusion of Women and Minorities as Subjects in Clinical Research* (Comprehensive Report: Inclusion in Clinical Research), which presents aggregate data regarding inclusion and tracking for all the NIH Institutes and Centers (ICs) can be accessed by the following link: http://orwh.od.nih.gov/research/inclusion/reports.asp. The NIH Office of Research on Women's Health will post the Comprehensive Report for Fiscal Years 2013 & 2014 Tracking Data when it is available.

All collected data in this report are based on self-reporting by study participants. Some participants do not disclose their race, ethnicity, or sex and/or do not understand the racial and ethnic categories defined by the U.S. Office of Management and Budget. Data for grants that are in no-cost-extension are not included in the eRA Population Tracking system.

FY 2013: NIDCD total subjects being tracked: 114,558 (100%)

White: 67,076 (58.55%)
Minority: 37,056 (32.35%)
Race Unknown/Not Reported: 10,426 (9.10%)

Female: 55,412 (48.37%)
Male: 57,872 (50.52%)
Gender Unknown/Not Reported: 1,274 (1.11%)

Hispanic: 6,990 (06.10%)
Not Hispanic: 102,107 (89.13%)
Ethnicity Unknown/Not Reported: 5,461 (4.77%)

FY 2014: NIDCD total subjects being tracked: 280,994 (100%)

White: 171,186 (60.92%)
Minority: 90,127 (32.07%)
Race Unknown/Not Reported: 19,681 (7.01%)

Female: 133,287 (47.43%)
Male: 145,799 (51.89%)
Gender Unknown/Not Reported: 1,908 (0.68%)

Hispanic: 40,135 (14.28%)
Not Hispanic: 235,037 (83.64%)
Ethnicity Unknown/Not Reported: 5,822 (2.08%)

B. NIH-defined Phase III clinical trials

The NIDCD intramural program does not currently conduct any Phase III trials. Consequently, the following data reflect only extramural protocols. Detailed descriptions are found in the extramural section, III. C.

FY 2013: NIDCD Phase III Clinical Trial total subjects being tracked: 98 (100%)

White: 74 (75.51%)
Minority: 22 (22.49%)
Race Unknown/Not Reported: 2 (2%)

Female: 26 (26.53%)
Male: 72 (73.47%)
Gender Unknown/Not Reported: 0 (0%)

Hispanic: 13 (13.27%)
Not Hispanic: 79 (80.61%)
Ethnicity Unknown/Not Reported: 6 (6.12%)

FY 2014: Phase III Clinical Trial

There were no reported Phase III data for extramural protocols in FY 2014 because data for grants that are in no-cost-extension are not included in the eRA Population Tracking system.

C. Extramural

In FY 2014, approximately 41% of NIDCD's portfolio of extramural research grants included human subjects. That percentage has been fairly stable over recent years. Appendix 5 contains a demographic breakdown (gender, race, and ethnicity) of all study participants enrolled in active research grants during FY 2013 and FY 2014. Summary information from those tables is reflected in the following discussion.

Study participants are fairly evenly distributed between males and females. Minority

representation has been at about the same level in FY 2013 and FY 2014.

The large difference between the FY 2013 total and the FY 2014 total is due to DC 900005, "Natural History of CMV-related Hearing Loss and Feasibility of CMV Screening as Adjunct to Hearing Screening in the Newborn" with an existing dataset of 100,605 subjects. This contract had a break in FY 2013 and started again in FY 2014. Furthermore, DC 12207 "Audiological and Genetic Resource for Pediatric Hearing Research" made significant progress: 37,273 subjects in FY 2013 rose to 84,194 subjects in FY 2014, reaching toward the target of 100,000 subjects.

FY 2013: Total extramural subjects being tracked: 94,758 (100%)

White: 63,271 (66.77%)
Minority: 21,546 (22.74%)
Race Unknown/Not Reported: 9,941 (10.49%)

Female: 45,766 (48.30%)
Male: 47,927 (50.58%)
Gender Unknown/Not Reported: 1,065 (1.12%)

Hispanic: 6,839 (7.22%)
Not Hispanic: 82,458 (87.02%)
Ethnicity Unknown/Not Reported: 5,461 (5.76%)

FY 2014: Total extramural subjects being tracked: 259,598 (100%)

White: 167,250 (64.43%)
Minority: 73,160 (28.18%)
Race Unknown/Not Reported: 19,188 (7.39%)

Female: 122,929 (47.35%)
Male: 134,972 (51.99%)
Gender Unknown/Not Reported: 1,697 (0.65%)

Hispanic: 39,972 (15.40%)
Not Hispanic: 213,806 (82.36%)
Ethnicity Unknown/Not Reported: 5,820 (2.24%)

NIDCD extramural tracking data for a Phase III clinical trial are shown below. In FY 2013, Trial 7411 (Tinnitus Retraining Therapy) has achieved approximately 43% accrual and is demonstrating good progress in reaching targets for Hispanic (13% vs. 7% targeted), Asian (5% vs. 10% targeted), Hawaiian/Pacific Islander (2% vs. 0 % targeted), African American (12% vs. 5% targeted), and female (27% vs. 26% targeted) populations. Additional minorities are captured in the category of "more than one race" (3%). This Phase III clinical trial continues to recruit subjects during its no-cost-extension period. The prevalence of noise-induced tinnitus may be higher in the military than in the general population. In so far as the clinical sites in the trial are all military, we might expect to see higher numbers of military males with noise-induced tinnitus, in addition to expected gender differences reflected by local demographics. Since this issue has not really been well studied in Phase III trials, this project proposes to conduct valid analyses of the treatment effect by sex/gender as well as by racial or ethnic subgroups in the trial.

FY 2013: Phase III Clinical Trial

Tinnitus Retraining Therapy (Trial 7411)

Target Enrollment (100%)

Sex/Gender:	Male/Female	74%/26%
Ethnicity:	Hispanic	7%
	Non-Hispanic	93%
Race:	American Indian/Alaskan Native	0%
	Asian	10%
	Hawaiian/Pacific Islander	0%
	Black/African-American	5%
	White	85%

Actual Enrollment (43% of the planned total)

Sex/Gender:	Male/Female	73%/27%
Ethnicity:	Hispanic	13%
	Non-Hispanic	81%
	Unknown	6%
Race:	American Indian/Alaskan Native	0%
	Asian	5%
	Hawaiian/Pacific Islander	2%
	Black/African-American	12%
	White	75%
	More than one race	3%
	Unknown	3%

FY 2014: Phase III Clinical Trial

There was no reported Phase III data for extramural grants in FY 2014 because data for grants that are in no-cost-extension are not included in the eRA Population Tracking system.

D. Intramural

Subjects accrued for FY 2013 and FY 2014 both have an almost equal distribution of female to male ratio and a low number of unknown genders (most of these are from the older active NIDCD protocols). The ethnicity collected was almost entirely Non-Hispanic/Latino, but considering where the majority of the subjects have been accrued as can be seen under the Race section, it is acceptable. Several of our protocols (OH93-DC-016, 01-DC-0230 and 97-DC-0057) have accrued or still accrue subjects from Pakistan and India, who fall under the Non-Hispanic/Latino for Ethnicity and under Asian for Race. This means that the vast majority of the study participants seen under active NIDCD intramural protocols will show as Asian. The racial percentages shown are then followed by White, Black, American Indian/Alaska Native and More

than One Race, respectively. Those subjects whose race is Unknown or Not Reported have been less than 2.6% for both years.

FY 2013: Total intramural subjects being tracked: 19,800 (100%)

White: 3,805 (19.22%)
Minority: 15,510 (78.33%)
Race Unknown/Not Reported: 485 (2.45%)

Female: 9,646 (48.70%)
Male: 9,945 (50.20%)
Gender Unknown/Not Reported: 209 (1.10%)

Hispanic: 151 (00.76%)
Not Hispanic: 19,649 (99.24%)
Ethnicity Unknown/Not Reported: 0 (0%)

FY 2014: Total intramural subjects being tracked: 21,396 (100%)

White: 3,936 (18.39%)
Minority: 16,967 (79.31%)
Race Unknown/Not Reported: 493 (2.30%)

Female: 10,358 (48.40%)
Male: 10,827 (50.60%)
Gender Unknown/Not Reported: 211 (0.09%)

Hispanic: 163 (0.76%)
Not Hispanic: 21,231 (99.23%)
Ethnicity Unknown/Not Reported: 2 (0.01%)

IV. Additional Information

A. Bibliography of projects or publications with analysis(es) on sex/gender, race, and/or ethnicity

This list includes publications by NIDCD intramural staff, NIDCD extramural staff, and federally funded investigators. The listing is limited to publications since the 2013 Biennial Advisory Council Report.

Hearing

Aarhus L, Tambs K, Kvestad E, Engdahl B. Childhood otitis media: a cohort study with 30-year follow-up of hearing (The HUNT Study). *Ear Hear*. 2014 Nov 14. [Epub ahead of print]

Aarhus L, Engdahl B, Tambs K, Kvestad E, Hoffman HJ. The association between childhood hearing disorders and tinnitus in adulthood: Results from a cohort study (HUNT). *JAMA Otolaryngol Head Neck Surg.* In press.

Bainbridge KE, Ramachandran V. Hearing aid use among older U.S. adults: the National Health and Nutrition Examination Survey, 2005–2006 and 2009–2010. *Ear Hear*. 2014 May-Jun; 35(3): 289–294.

Bainbridge KE, Wallhagen MI. Hearing loss in an aging American population: extent, impact, and management. *Annu Rev Public Health*. 2014; 35: 139–152.

Chen DS, Genther DJ, Betz J, Lin FR. Association between hearing impairment and self-reported difficulty in physical functioning. *J Am Geriatr Soc*. 2014 May; 62(5): 850-856.

Cruickshanks KJ, Dhar S, Dinces E, Fifer RC, Gonzalez F II, Heiss G, Hoffman HJ, Lee DJ, Newhoff M, Tocci L, Torre P III, Tweed TS. Hearing impairment prevalence and associated risk factors in the Hispanic Community Health Study/Study of Latinos (HCHS/SOL). *JAMA Otolaryngol Head Neck Surg*. In press.

Curhan SG, Eavey R, Wang M, Stampfer MJ, Curhan GC. Body mass index, waist circumference, physical activity, and risk of hearing loss in women. *Am J Med*. 2013 Dec; 126(12): 1142.e1–8. doi: 10.1016/j.amjmed.2013.04.026.

Dawes P, Cruickshanks KJ, Moore DR, Edmondson-Jones M, McCormack A, Fortnum H, Munro KJ. Cigarette smoking, passive smoking, alcohol consumption, and hearing loss. *J Assoc Res Otolaryngol*. 2014 Aug; 15(4): 663–674.

Dreher AM, Arora N, Fowler KB, Novak Z, Britt WJ, Boppana SB, Ross SA. Spectrum of disease and outcome in children with symptomatic congenital cytomegalovirus infection. *J Pediatr*. 2014 Apr; 164(4): 855–859.

Dukes KA, Burd L, Elliott AJ, Fifer WP, Folkerth RD, Hankins GD, Hereld D, Hoffman HJ, Myers MM, Odendaal HJ, Signore C, Sullivan LM, Willinger M, Wright C, Kinney HC; PASS Research Network. The Safe Passage Study: Design, methods, recruitment, and follow-up approach. *Pediatr Perinatal Epidemiol*. 2014 Sep; 28(5): 455–465.

Engdahl B, Tambs K, Hoffman HJ. Otoacoustic emissions, pure-tone audiometry, and self-reported hearing. *Int J Audiol*. 2013 Feb; 52(2): 74–82.

Fischer ME, Cruickshanks KJ, Pinto A, Klein BE, Klein R, Dalton DS. Hearing impairment and retirement. *J Am Acad Audiol*. 2014 Feb; 25(2): 164–170.

Fischer ME, Schubert CR, Nondahl DM, Dalton DS, Huang G, Keating BJ, Klein BE, Klein R, Tweed TS, Cruickshanks KJ. Subclinical atherosclerosis and increased risk of hearing impairment. *Atherosclerosis*. 2014 Dec 20; 238(2): 344–349.

Fisher D, Li CM, Chiu MS, Themann CL, Petersen H, Jónasson F, Jónsson PV, Sverrisdottir JE, Garcia M, Harris TB, Launer LJ, Eiriksdottir G, Gudnason V, Hoffman HJ, Cotch MF. Impairments in hearing and vision impact on mortality in older people: the AGES–Reykjavik Study. *Age Aging*. 2014 Jan; 43(1): 69–76.

Genther DJ, Frick KD, Chen D, Betz J, Lin FR. Association of hearing loss with hospital-ization and burden of disease in older adults. Letter. *JAMA*. 2013 Jun 12; 309(22): 2322–2324.

Genther DJ, Betz J, Pratt S, Kritchevsky SB, Martin KR, Harris TB, Helzner E, Satterfield S, Xue QL, Yaffe K, Simonsick EM, Lin FR; Health ABC Study. Association of hearing impairment and mortality in older adults. *J Gerontol A Biol Sci Med Sci.* 2015 Jan; 70(1): 85–90.

Gispen FE, Chen DS, Genther DJ, Lin FR. Association between hearing impairment and lower levels of physical activity in older adults. *J Am Geriatr Soc*. 2014 Aug; 62(8): 1427–1433.

Helvik AS, Krokstad S, Tambs K. Hearing loss and risk of early retirement. The HUNT Study. *Eur J Public Health*. 2013 Aug; 23(4): 617–622.

Hoffman HJ, Daly KA, Bainbridge KE, Casselbrant ML, Homøe P, Kvestad EK, Kvaerner KJ, Vernacchio L. Panel 1: Epidemiology, natural history, and risk factors. Report from the Tenth International Research Conference on Otitis Media. *Otolaryngol Head Neck Surg*. 2013 April; 148 (4 Suppl): E1–25. doi: 10.1177/0194599812460984. Review.

Hoffman HJ, Chiu MS, Losonczy KG, Themann CL. Hearing loss in adolescents with abnormal tympanograms, history of frequent ear infections, and loud noise exposure: The National Health and Nutrition Examination Survey (NHANES), 2005–2008. In: *Proceedings of the 10th International Symposium on Recent Advances in Otitis Media.* New Orleans, LA: June 5–9, 2011.

Kamil RJ, Genther DJ, Lin FR. Factors associated with the accuracy of subjective assessments of hearing impairment. *Ear Hear*. 2015 Jan; 36(1): 164–167.

Li CM, Zhang X, Hoffman HJ, Cotch MF, Themann CL, Wilson MR. Hearing impairment associated with depression in US adults, National Health and Nutrition Examination Survey 2005-2010. *JAMA Otolaryngol Head Neck Surg.* 2014 Apr 1; 140(4): 293–302.

Li R, Dee D, Li CM, Hoffman HJ, Grummer-Strawn LM. Breastfeeding and risk of infections at 6 years. *Pediatrics*. 2014 Sep; 134 Suppl 1: S13–20.

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B. Gap areas/projects specifically addressing inclusion of women and/or minority populations

- *The NIH Fogarty International Center highlighted NIDCD research as one of their top feature stories in 2014: Global research is vital for deafness, speech disorders (May / June 2014 | Volume 13, Issue 3)*

A Pakistani baby never hears her mother sing and a Cameroon teen who stutters is teased by peers. They both struggle with communication conditions that can undermine their health and quality of life. By studying these disorders in populations outside as well as within the U.S., NIH scientists and funded researchers are working to discover new causes and improve interventions. These conditions can bring substantial costs throughout the lifespan. Untreated hearing impairment in the very young can hold back language development and education, and in adults can hurt professional and social lives. Over time, these types of health burdens are likely to increase as more premature infants and victims of traumatic injury survive. Also, as the aging population grows, so will the numbers of individuals with hearing loss, speech difficulty after stroke and other communication hurdles.

Many NIDCD-supported scientists have some global health research involvement. By studying large families that have a particular communication disorder, NIDCD scientists have discovered a number of genes associated with deafness and stuttering. These findings are steadily increasing scientific knowledge and moving science closer to more effective tools to diagnose and treat people with these communication disorders.

- *Prenatal Alcohol and SIDS and Stillbirth (PASS) Network: The Safe Passage Study [Auditory Component]*

  The Safe Passage Study, which is being conducted by the Prenatal Alcohol and SIDS and Stillbirth (PASS) Research Network, includes American Indian populations. This study includes auditory tests of brainstem function, including auditory brainstem response (ABR) and otoacoustic emissions (OAE). While not a true hearing assessment program, these tests may reveal deficits in auditory conduction and neural processing as well as their association with maternal alcohol intake prenatally and other possible risk factors. The study will also help to develop better prevention and intervention strategies that can enhance the future health or lives of these high-risk newborns in American Indian populations and increase knowledge about the importance of hearing screening and follow-through for underrepresented groups to ensure improved communication, occupational, and financial outcomes for these children.

  As of September 2014, the Northern Plains study had obtained almost 1,500 ABR and 2,800 OAE exams on newborns or neonates at one month of age and the Cape Town, South Africa site had collected over 2,000 ABR and 3,000 OAE exams from a highly genetically diverse population. The PASS Research Network study is still collecting data and will not publish findings until after completion of subject enrollments at the end of 2015.

- *Cytomegalovirus*

  Cytomegalovirus (CMV) is the leading cause of nonhereditary deafness. Maternal transmission of CMV is well recognized as the most common cause of sensorineural hearing loss (SNHL). CMV is also recognized as the most common cause of human congenital infection, occurring in up to 2.5 percent of all live births. It is estimated that the sequelae of congenital CMV infection may account for as many as 40,000 new cases of SNHL per year. NIDCD-sponsored scientists continue to make significant progress to fully characterize the effects of CMV on SNHL as well as the mechanisms and epidemiology of CMV maternal transmission. Recent results demonstrate a highly significant effect of CMV infection on the development of late onset SNHL.

  NIDCD-supported investigators conducted a preclinical animal trial of delivering antiviral drugs to the inner ear via an intratympanic route. Drawing upon the vast otologic experience with intratympanic administration of drugs (such as corticosteroids or aminoglycosides) to treat the cochlea and inner ear, the investigators proposed that the intratympanic delivery of antiviral agents (ganciclovir and cidofovir) can be used to effectively treat CMV-related hearing loss while avoiding the numerous and significant potential side effects of these antiviral drugs. They tested this hypothesis using their well-developed guinea pig model of CMV infection and hearing loss.

  CMV-related hearing loss was first induced by directly inoculating the cochleas of guinea pig pups with guinea pig CMV (GPCMV) or newly generated chimeric GPCMV. Experimental antiviral treatment groups then received intratympanic doses of drug, and the effects of therapy monitored by performing auditory brainstem response (ABR) testing and histopathologic examination of the cochleas. By executing this proposed research plan, the investigators

generated novel data that will serve as the foundation for early clinical trials administering antiviral drugs to the middle ear space in order to treat CMV-related inner ear disease. The potential benefits of delivering antivirals intratympanically include advantages in efficacy as well as reduced toxicities.

- *Voice Disorders*

  Voice production and its quality influence the communicative exchange throughout the lifespan with some voices being perceived as pleasing and facilitating to reception of the message and others being perceived as unpleasant and not communication-enhancing. Voice disorders are not trivial, although they are overwhelmingly under-recognized. Occupational voice disorders are estimated to affect 28 million Americans (www.ohsonline.com) and have a significant impact on the livelihood of teachers/professors, TV and radio journalists, lawyers, and singers. The NIDCD supports basic and clinical research studies that focus on normal voice production and the prevention and treatment of voice disorders.

  Spasmodic dysphonia (SD) is a voice disorder caused by involuntary movements of one or more muscles of the larynx (voice box) and can affect anyone. When a person with SD attempts to speak, the muscles in the larynx spasm involuntarily and cause the voice to break up and sound strained or whispery. The disorder is estimated to affect 50,000 people in North America (www.dysphonia.org). The first signs of this disorder are found most often in individuals between 30 and 50 years old. More women than men are affected. There is no cure for SD, and the most common treatment is the injection of very small amounts of botulinum toxin directly into the affected muscles of the larynx. Repeat injections are necessary because the effects last only a few months.

  The NIDCD currently funds research to determine the causes and pathophysiology of SD in order to develop new diagnostic and better treatment options. NIDCD-supported scientists are using multi-modal imaging and next-generation DNA sequencing to identify brain abnormalities and genetic risk factors for SD. The identification of genes responsible for this voice disorder directly addresses the need for better, more accurate detection and diagnosis in this clinical population. Locating specific brain areas involved in regulating laryngeal muscles and understanding the neural mechanisms by which they exert their control opens avenues for new pharmacological therapies and surgical interventions.

- *Stuttering*

  Stuttering is a speech disorder in which sounds, syllables, or words are repeated or prolonged, disrupting the flow of speech. These disruptions may be accompanied by struggling behaviors, such as rapid eye blinks or tremors of the lips. Stuttering can make it difficult to communicate with other people. Boys are twice as likely to stutter as girls. Whereas stuttering is not a condition that is life-threatening, it is a disorder that is life-altering. NIDCD intramural and extramural researchers continue to study stuttering and increase our understanding of this condition.

  There is a fundamental gap in understanding the neural bases for childhood developmental stuttering, particularly with respect to why certain children recover naturally whereas others continue to stutter throughout life and why there is a greater probability of recovery among girls than boys. One NIDCD-supported project aims to identify neural markers for stuttering and to develop interventions that lead to behavioral and neurophysiological normalization in speech. The

overall objective is to identify structural and functional neural markers of stuttering close to symptom onset and determine gender-specific brain developmental trajectory markers that serve to differentiate those children who do or do not recover from stuttering.

- *Translating Discovery into Health – Global Health and Reducing Health Disparities among Minority and Underserved Children:*

  The NIDCD invests in research to help disadvantaged children with hearing impairment or language disorders, who can experience various barriers to health care, including proper identification/diagnosis, limited access to follow-up care, lack of provider knowledge, challenges to families in obtaining services, and information gaps. To reduce health disparities, the NIDCD is participating in two initiatives to encourage the development and testing of interventions targeted toward ethnic and racial minorities and populations of underserved children. The NIDCD also supports research in foreign countries, which has led to the identification of genes involved in deafness and other communication disorders. This international research provides the potential to develop new treatments for hearing impairments, stuttering, and other conditions for underserved children in the U.S.

- *Training*

  NIDCD supports the Ruth L. Kirschstein National Research Service Award (NRSA) Pre-doctoral and Post-doctoral Training Programs and Supplements to Promote Diversity in Health Related Research to assist students from racial and ethnic groups that have been shown to be underrepresented in health-related research to prepare for scientific careers. The long-term goal of the NRSA programs and Supplements are to maintain the number of qualified research trainees and individuals in career development programs to enable the research community to be in a position to meet the future health needs of individuals with communication disorders. The NRSA programs and Supplements ensure that communication research is supported by a diverse pool of highly-trained scientists. In addition, projects have been supported by multiple federal agencies, enhancing collaboration between these entities in training and communication science.

Appendix 1: Table A - FY13

Table A. Level of Compliance with Inclusion Policy in New Extramural Grant Applications as Assessed During Scientific Peer Review

NATIONAL INSTITUTE ON DEAFNESS AND OTHER COMMUNICATION DISORDERS

Council Dates		Jan-12	May-12	Aug-12	Oct-12	Jan-13	May-13	Aug-13	Oct-13
Total Number of Applications Reviewed	(#)	375	358	57	391	368	381	57	363
Number of Applications with Human Subjects	(#)	182	163	1	186	168	163	0	188
Number (percent) of Applications approved by IRG as submitted	(#)	175	161	1	176	162	159	0	184
	(%)	96.15%	98.77%	100%	94.62%	96.43%	97.55%	0%	97.87%
Number (percent) of Applications with unacceptable *minority-only* inclusion	(#)	6	1	0	5	3	4	0	2
	(%)	3.3%	0.61%	0%	2.69%	1.79%	2.45%	0%	1.06%
Number (percent) of Applications with unacceptable *sex/gender-only* inclusion	(#)	0	0	0	2	1	0	0	1
	(%)	0%	0%	0%	1.08%	0.6%	0%	0%	0.53%
Number (percent) of Applications with both unacceptable minority AND sex/gender inclusion	(#)	1	1	0	3	2	0	0	1
	(%)	0.55%	0.61%	0%	1.61%	1.19%	0%	0%	0.53%
Total Number (percent) of Applications with unacceptable minority inclusion	(#)	7	2	0	8	5	4	0	3
	(%)	3.85%	1.23%	0%	4.3%	2.98%	2.45%	0%	1.6%
Total Number (percent) of Applications with unacceptable sex/gender inclusion	(#)	1	1	0	5	3	0	0	2
	(%)	0.55%	0.61%	0%	2.69%	1.79%	0%	0%	1.06%
Total Number (percent) of unacceptable Applications as submitted	(#)	7	2	0	10	6	4	0	4
	(%)	3.85%	1.23%	0%	5.38%	3.57%	2.45%	0%	2.13%

Appendix 2: Table A - FY14

Table A. Level of Compliance with Inclusion Policy in New Extramural Grant Applications as Assessed During Scientific Peer Review

NATIONAL INSTITUTE ON DEAFNESS AND OTHER COMMUNICATION DISORDERS

Council Dates		Jan-13	May-13	Aug-13	Oct-13	Jan-14	May-14	Aug-14	Oct-14
Total Number of Applications Reviewed	(#)	368	381	57	363	363	348	44	330
Number of Applications with Human Subjects	(#)	168	163	0	188	165	177	1	165
Number (percent) of Applications approved by IRG as submitted	(#)	162	159	0	184	143	174	0	161
	(%)	96.43%	97.55%	0%	97.87%	86.67%	98.31%	0%	97.58%
Number (percent) of Applications with unacceptable *minority-only* inclusion	(#)	3	4	0	2	18	2	1	4
	(%)	1.79%	2.45%	0%	1.06%	10.91%	1.13%	100%	2.42%
Number (percent) of Applications with unacceptable *sex/gender-only* inclusion	(#)	1	0	0	1	1	0	0	0
	(%)	0.6%	0%	0%	0.53%	0.61%	0%	0%	0%
Number (percent) of Applications with both unacceptable minority AND sex/gender inclusion	(#)	2	0	0	1	3	1	0	0
	(%)	1.19%	0%	0%	0.53%	1.82%	0.56%	0%	0%
Total Number (percent) of Applications with unacceptable minority inclusion	(#)	5	4	0	3	21	3	1	4
	(%)	2.98%	2.45%	0%	1.6%	12.73%	1.7%	100%	2.42%
Total Number (percent) of Applications with unacceptable sex/gender inclusion	(#)	3	0	0	2	4	1	0	0
	(%)	1.79%	0%	0%	1.06%	2.42%	0.56%	0%	0%
Total Number (percent) of unacceptable Applications as submitted	(#)	6	4	0	4	22	3	1	4
	(%)	3.57%	2.45%	0%	2.13%	13.33%	1.69%	100%	2.42%

Appendix 3: Table B - FY13

Table B. Extramural Research Awards: Bars-To-Funding and Resolutions

NATIONAL INSTITUTE ON DEAFNESS AND OTHER COMMUNICATION DISORDERS

Council Dates		Jan-12	May-12	Aug-12	Oct-12	Jan-13	May-13	Aug-13	Oct-13
Total number of awards	(#)	104	98	21	84	87	99	14	87
Number of awards involving Human Subjects	(#)	45	38	0	44	41	35	0	41
Number (percent) of awards involving Human Subjects that met the inclusion requirements as submitted	(#)	41	37	0	41	38	35	0	41
	(%)	91%	97%	0%	93%	93%	100%	0%	100%
Number (percent) of awards where *minority-only* bar-to-funding was removed by program staff (M_U)	(#)	3	1	0	2	3	0	0	0
	(%)	7%	3%	0%	5%	7%	0%	0%	0%
Number (percent) of awards where *sex/gender-only* bar-to-funding was removed by program staff (G_U)	(#)	0	0	0	1	0	0	0	0
	(%)	0%	0%	0%	2%	0%	0%	0%	0%
Number (percent) of awards where both minority AND sex/gender bar-to-funding were removed by program staff	(#)	1	0	0	0	0	0	0	0
	(%)	2%	0%	0%	0%	0%	0%	0%	0%
Total Number (percent) of awards where minority bar-to-funding was removed by program staff	(#)	4	1	0	2	3	0	0	0
	(%)	9%	3%	0%	5%	7%	0%	0%	0%
Total Number (percent) of awards where sex/gender bar-to-funding was removed by program staff	(#)	1	0	0	1	0	0	0	0
	(%)	2%	0%	0%	2%	0%	0%	0%	0%
Total Number (percent) of awards where bar-to-funding was removed	(#)	4	1	0	3	3	0	0	0
	(%)	9%	3%	0%	7%	7%	0%	0%	0%

Appendix 4: Table B - FY14

Table B. Extramural Research Awards: Bars-To-Funding and Resolutions

NATIONAL INSTITUTE ON DEAFNESS AND OTHER COMMUNICATION DISORDERS

Council Dates		Jan-13	May-13	Aug-13	Oct-13	Jan-14	May-14	Aug-14	Oct-14
Total number of awards	(#)	87	99	14	87	102	93	20	75
Number of awards involving Human Subjects	(#)	41	35	0	41	36	47	0	32
Number (percent) of awards involving Human Subjects that met the inclusion requirements as submitted	(#)	38	35	0	41	33	44	0	32
	(%)	93%	100%	0%	100%	92%	94%	0%	100%
Number (percent) of awards where *minority-only* bar-to-funding was removed by program staff (M_U)	(#)	3	0	0	0	3	3	0	0
	(%)	7%	0%	0%	0%	8%	6%	0%	0%
Number (percent) of awards where *sex/gender-only* bar-to-funding was removed by program staff (G_U)	(#)	0	0	0	0	0	0	0	0
	(%)	0%	0%	0%	0%	0%	0%	0%	0%
Number (percent) of awards where both minority AND sex/gender bar-to-funding were removed by program staff	(#)	0	0	0	0	0	0	0	0
	(%)	0%	0%	0%	0%	0%	0%	0%	0%
Total Number (percent) of awards where minority bar-to-funding was removed by program staff	(#)	3	0	0	0	3	3	0	0
	(%)	7%	0%	0%	0%	8%	6%	0%	0%
Total Number (percent) of awards where sex/gender bar-to-funding was removed by program staff	(#)	0	0	0	0	0	0	0	0
	(%)	0%	0%	0%	0%	0%	0%	0%	0%
Total Number (percent) of awards where bar-to-funding was removed	(#)	3	0	0	0	3	3	0	0
	(%)	7%	0%	0%	0%	8%	6%	0%	0%

Appendix 5: FY13 Table 1: FY 2013 Aggregate Enrollment Data for All Extramural Research Protocols

NATIONAL INSTITUTE ON DEAFNESS AND OTHER COMMUNICATION DISORDERS

Old Form: Total of All Subjects Reported Using the 1977 OMB Standards

Number of Protocols with Enrollment Data: 0

	American Indian/ Alaska Native	Asian	Black or African American	* Hawaiian/ Pacific Islander	Hispanic	White	* More Than One Race	Unknown/ Other	Total
Female									
Male									
Unknown									
Total									

* Categories not in use in Old Forms, but are provided here for consistency with the 1997 OMB Standard.

New Form: Total of All Subjects Reported Using the 1997 OMB Standards

Number of Protocols with Enrollment Data: 232

	Total of All Subjects by Race								Total of All Subjects by Ethnicities			
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Not Reported	Total	Not Hispanic	Hispanic or Latino	Unknown/ Not Reported	Total
Female	115	3,938	5,286	74	30,827	1,258	4,268	45,766	39,914	3,406	2,446	45,766
	0.25%	8.6%	11.55%	0.16%	67.36%	2.75%	9.33%	48.3%	87.21%	7.44%	5.34%	48.3%
Male	98	3,606	5,732	68	32,364	1,055	5,004	47,927	42,149	3,421	2,357	47,927
	0.2%	7.52%	11.96%	0.14%	67.53%	2.2%	10.44%	50.58%	87.94%	7.14%	4.92%	50.58%
Unknown	1	306	6	0	80	3	669	1,065	395	12	658	1,065
	0.09%	28.73%	0.56%	0%	7.51%	0.28%	62.82%	1.12%	37.09%	1.13%	61.78%	1.12%
Total	214	7,850	11,024	142	63,271	2,316	9,941	94,758	82,458	6,839	5,461	94,758
	0.23%	8.28%	11.63%	0.15%	66.77%	2.44%	10.49%	100%	87.02%	7.22%	5.76%	100%

Appendix 5: FY14

Table 2: FY 2014 Aggregate Enrollment Data for All Extramural Research Protocols

NATIONAL INSTITUTE ON DEAFNESS AND OTHER COMMUNICATION DISORDERS

Old Form: Total of All Subjects Reported Using the 1977 OMB Standards

Number of Protocols with Enrollment Data: 0

	American Indian/ Alaska Native	Asian	Black or African American	* Hawaiian/ Pacific Islander	Hispanic	White	* More Than One Race	Unknown/ Other	Total
Female									
Male									
Unknown									
Total									

* Categories not in use in Old Forms, but are provided here for consistency with the 1997 OMB Standard.

New Form: Total of All Subjects Reported Using the 1997 OMB Standards

Number of Protocols with Enrollment Data: 215

	Total of All Subjects by Race								Total of All Subjects by Ethnicities			
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Not Reported	Total	Not Hispanic	Hispanic or Latino	Unknown/ Not Reported	Total
Female	634	10,266	21,068	164	79,988	2,703	8,106	122,929	100,444	19,936	2,549	122,929
	0.52%	8.35%	17.14%	0.13%	65.07%	2.2%	6.59%	47.35%	81.71%	16.22%	2.07%	47.35%
Male	599	11,179	23,052	130	87,204	2,468	10,340	134,972	112,409	20,028	2,535	134,972
	0.44%	8.28%	17.08%	0.1%	64.61%	1.83%	7.66%	51.99%	83.28%	14.84%	1.88%	51.99%
Unknown	2	888	5	1	58	1	742	1,697	953	8	736	1,697
	0.12%	52.33%	0.29%	0.06%	3.42%	0.06%	43.72%	0.65%	56.16%	0.47%	43.37%	0.65%
Total	1,235	22,333	44,125	295	167,250	5,172	19,188	259,598	213,806	39,972	5,820	259,598
	0.48%	8.6%	17%	0.11%	64.43%	1.99%	7.39%	100%	82.36%	15.4%	2.24%	100%

Appendix 6: Intramural FY13

FY 2013 Gender/Race/Ethnicity Report for Active Intramural Protocols

Gender:	Number	Percentage
Females	9,646	48.7%
Males	9,945	50.2%
Unknown	209	1.1%
Total	*19,800*	*100.0%*

Ethnicity:	Number	Percentage
Non-Hispanic	19,649	99.2%
Hispanic/Latino	151	0.8%
Unknown/Not Reported	0	0.0%
Total	*19,800*	*100.0%*

Race:	Number	Percentage
American Indian/Alaska Native	29	0.2%
Asian	14,882	75.2%
Hawaiian/Pacific Islander	0	0.0%
Black/African American	580	2.9%
White	3,805	19.2%
More than 1 Race	19	0.1%
Unknown/Not Reported	485	2.5%
Total	*19,800*	*100.0%*

FY 2014 Gender/Race/Ethnicity Report for Active Intramural Protocols

Gender:	Number	Percentage
Females	10,358	48.4%
Males	10,827	50.6%
Unknown	211	1.0%
Total	*21,396*	*100.0%*

Ethnicity:	Number	Percentage
Non-Hispanic	21,231	99.2%
Hispanic/Latino	163	0.8%
Unknown/Not Reported	2	<0.01%
Total	*21,396*	*100.0%*

Race:	Number	Percentage
American Indian/Alaska Native	29	0.1%
Asian	16,295	76.2%
Hawaiian/Pacific Islander	1	<0.01%
Black/African American	619	2.9%
White	3,936	18.4%
More than 1 Race	23	0.1%
Unknown/Not Reported	493	2.3%
Total	*21,396*	*100.0%*