# National Institute of Diabetes and Digestive and Kidney Diseases

# 2018 Triennial Advisory Council Report on Inclusion of Women and Minorities in Clinical Research

## I. Overview and Background

### Mission

The mission of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) is to conduct and support medical research and research training and to disseminate science-based information on diabetes and other endocrine and metabolic diseases; digestive diseases, nutritional disorders, and obesity; and kidney, urologic, and hematologic diseases, to improve people's health and quality of life.

To guide his leadership of NIDDK's mission focused activities Griffin P. Rodgers, M.D., M.A.C.P., Director, NIDDK established several overarching principles, which have become known colloquially as "core values" (see https://www.niddk.nih.gov/about-niddk/meet-director/mission-vision). Among the five principles set out in the Director's vision statement is "*Support Pivotal Clinical Studies and Trials*." An indication that NIDDK has maintained focus on this principle is NIDDK's prioritization and continued high level of support of clinical research (see Figure 14 on NIDDK's "Funding Trends and Support of Core Values" webpage https://www.niddk.nih.gov/research-funding/funded-grants-grant-history/funding-trends-support-core-values).

While funding prioritization is one indication of "support" another indication is appropriate attention to the scientific requirements and also the statutory and policy obligations to ensure the appropriate inclusion of women and minorities in NIH supported clinical research.

### History

In 1986 NIH established a policy for the inclusion of women in clinical research. This policy stemmed largely from a report of the Public Health Service Task Force on Women's Health in 1985. The policy was initially published in the NIH Guide to Grants and Contracts in 1987 and then later that year the policy was revised to include language encouraging the inclusion of minorities in clinical studies as well.

To ensure that NIH rigorously implement and enforce the inclusion policy, Congress included in The NIH Revitalization Act of 1993 (Public Law 103-43) a section entitled *Women and Minorities as Subjects in Clinical Research.* In 1994, NIH revised its policies to harmonize with the statutory language.

The revisions essentially reinforced NIH's existing policies, but included four additional requirements:

1. That NIH ensure that women and minorities and their subpopulations be included in all clinical research;
2. That women and minorities and their subpopulations be included in Phase III clinical trials in numbers adequate to follow for valid analyses of differences in intervention effect;
3. That cost is not allowed as an acceptable reason for excluding these groups; and,
4. That NIH initiate programs and support for outreach efforts to recruit and retain women and minorities and their subpopulations as participants in clinical studies.

The 21st Century Cures Act of 2016 amended the NIH required reporting on the inclusion of women and minorities in clinical research from biennial reporting to triennial reporting. This report is the first such Triennial Inclusion Report.

# II. Strategies for Ensuring Compliance

## A. Peer Review

The implementation of inclusion guidelines involves the participation of review, program, policy, and grants management staff. Inclusion is first addressed by peer review. Reviewers on NIH peer review panels are given specific guidance on reviewing inclusion on the basis of sex/gender, race, ethnicity, and age when considering clinical research applications. Reviewers evaluate applications for the appropriateness of the proposed plan for inclusion by sex/gender, race and ethnicity. For Phase III studies, enrollment goals are further assessed for plans to conduct analyses of intervention effects among sex/gender, racial, and ethnic groups. Unacceptable inclusion plans must be reflected in the priority score of the application and documented in the minutes of the review session. Initial review groups make recommendations as to the acceptability of the proposed study population with respect to the inclusion policies. If issues are raised in review, program staff notify principal investigators, who are required to address these issues prior to funding. Applications with unacceptable inclusion plans receive a bar to funding; an award is not issued until an acceptable resolution is received.

### Extramural Research Awards: Bars-to-Funding and Resolutions

In cases where the study section determines that a study is not in compliance or the applicant has not addressed the requirements in the application, a code is placed in the IMPAC II system that bars funding. In order for the application to be funded, the bar must be lifted and documentation of the grounds for lifting the bar must be included in the official grant file.

Responsibility for review and approval of finalized human subjects' research protocols resides with the Institutional Review Board (IRB) of record. NIH must receive certification of IRB approval before NIH funds can be used for human subject research. If certification of IRB approval cannot be provided prior to award, NIDDK may make restricted awards to allow the non-human subject research to go forward while human subjects concerns are addressed by the IRB. In general, once IRB approval is received,

the Grants Management Specialist will request review by the Program Officer before funding for human subjects research can be made.

**NIDDK Scientific Review Procedures for Inclusion**

Scientific Review Officers (SRO) read all applications and proposals and note if clinical research is being proposed and if the application is in compliance with NIH policy on the Inclusion of Women and Minorities.

SROs send "*NIH Instructions to Reviewers for Evaluating Research Involving Human Subjects in Grant and Cooperative Agreement Applications*" to scientists/clinicians that serve as peer reviewers on Scientific Review Panels to ensure they are up to date on all human subject policy issues when evaluating applications.

The study section evaluates each application during the initial review to determine if it is in compliance with the Inclusion Policy. The evaluation results are noted on the summary statement. In addition, reviewers are instructed to include compliance with the inclusion policy as a factor when assigning a priority score to an application.

Using specific codes, SROs document in the IMPAC II system any concerns regarding inclusion of women and minorities. Codes are also used to indicate and track studies that are Phase III clinical trials. If the study proposed is a clinical trial then the type of trial (i.e., Phase I, Phase II or Phase III) is noted in the summary statement.

## B. Program Monitoring and Grants Management Oversight

Prior to award, program officials/-directors are responsible for reviewing the inclusion information in the application and indicating whether the plans are scientifically appropriate. Program staff monitor actual enrollment progress in annual progress reports and provide consultation when necessary. For Phase III clinical trials, program officials monitor the requirement for sex/gender and race/ethnicity analyses in applications and annual progress reports. Grants management staff ensure appropriate terms and conditions of award are included in the Notice of Award, and that information is appropriately documented in the official grant file.

For multi-center clinical trials managed through a cooperative agreement or research contract there is typically a steering committee on which the responsible NIDDK program staff member serves. This committee monitors recruitment to make sure the ongoing study is on target with the initial study design approved through peer review. The committee will take corrective actions to ensure recruitment stays on target by employing appropriate enrollment strategies. These studies have, in addition, an outside advisory Data and Safety Monitoring Board (DSMB) that also monitors recruitment. The proceedings of the DSMB meetings are reported to the Institutional Review Boards (IRB) at all participating sites.

## C. Intramural

All intramural clinical research 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 NIH protocol reviews. Intramural IRBs review intramural research protocols for

compliance with inclusion guidelines and conduct annual monitoring. 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. The Clinical Center's Office of Protocol Services (OPS) coordinates annual reporting of demographic participant data to the Office of Extramural Research and the Office of Research on Women's Health.

## D. NIDDK Training Approaches

NIH and NIDDK provide staff training on inclusion requirements. For example, NIDDK Program Officials/Program Directors and Scientific Review Officers attended a May 11, 2018 training "*Ensuring Inclusion in NIH Clinical Research: Policies and Procedures for Grants and Contracts*". Staff are able to access the archived training on the NIH staff intranet.

A section on inclusion guidelines is part of orientation training for all newly hired review and program staff members. In addition, the "NIDDK Extramural Program: Standard Operating Procedures (SOPs)," which are available on NIDDK's internal SharePoint site, include specific guidance to staff regarding inclusion. Some of the SOPs most focused on inclusion include:

- **SOP #8** - Preparing for Review Meetings At NIDDK: Administrative Review by the Scientific Review Officer
- **SOP #19** - Recording the Results of Review Meetings: Preparing and Releasing Summary Statements
- **SOP #27** - Staff Review of Applications Prior to Award: Resolving Concerns About the Inclusion of Women, Members of Minority Groups, and Children

NIDDK has a regularly updated section of its public website devoted to policies associated with conducting clinical trials that includes specific policies and implementation procedures for inclusion of women and minorities in clinical research (see https://www.niddk.nih.gov/research-funding/human-subjects-research/policies-clinical-researchers).

The NIDDK Division of Extramural Activities (DEA) recurrently schedules inclusion refresher training at the NIDDK Extramural Program (EP) Staff meeting (includes review, program and grants management staff) to ensure that staff members are familiar with the materials and to address any questions that may arise. This refresher training was last presented at the November 08, 2017 EP Staff Meeting by the NIH Inclusion Policy Officer, Ms. Dawn Corbett MPH. Regular updates on inclusion policy are presented at the monthly EP Staff Meeting throughout the year.

## E. Additional NIDDK Actions to Ensure Compliance with the Inclusion Policy

The NIDDK DEA conducts annual review of ongoing efforts associated with inclusion policy compliance and provides data to the NIH Office of Research on Women's Health. As Director, DEA, Dr. Karl Malik oversees the process and provides leadership to all NIDDK Extramural Divisions. Dr. Jennie Larkin, as Director of the Office of Research Evaluation and Operations (OREO) within DEA, is point person responsible for most reporting activities, including the coordination of the triennial report. Ms. Lauren

Meskill, a program analyst, is point person for inclusion data entry and tracking at the division level. All NIDDK Program Officers are responsible for monitoring the clinical trials within their respective programs. Ms. Theresa Smith within OREO works closely with Ms. Meskill to monitor reporting progress and reports any problems to Dr. Larkin.

## III. Analysis and Interpretation of Data

In June 2018, NIH transitioned from the previous Inclusion Management System (IMS) to the Human Subject System (HSS). In HSS, the Principal Investigator (PI) directly uploads their inclusion data, which is then reviewed and approved by the program officer. Training and support by the NIH Inclusion Policy Officer in conjunction with the NIDDK Inclusion Monitoring staff has been important in managing this transition and identifying/correcting some FY 2018 data issues that arose because of the change. As training, support, and monitoring continue and investigators and NIH staff become more familiar with the new system, we expect that errors will continue to decline. NIDDK will continue to provide training and support for staff and closely monitor inclusion data for any issues.

NIDDK staff members have continued their efforts to ensure that persons of both genders and all ethnic and racial backgrounds are included in studies involving human subjects (see data in Appendix I, Tables 1-7).

**All NIDDK Clinical Research (Intramural and Extramural)**

The total number of prospective Inclusion Enrollment Records (IERs) with enrollment reported by NIDDK rose from 703 in FY 2016 to 848 in FY 2017, then remained at 891 in FY 2018 (Table 1). Each year there were between 70 to 82 single sex (either female-only or male-only) IERs.

NIDDK minority enrollment across all clinical studies remains at about 40%, ranging from 39.6% in FY 2017 to 42.4% in FY2018 (Table 2). There was an increase in number of individuals enrolled in FY 2017 to 664,854 participants, though the percentage of these that were minority remained consistent. In FY 2018, the numbers of individuals enrolled in NIDDK clinical research studies dropped back down to 367,199: in part this reported decline was due to rigorous cross-checking of data in the new HSS system. The increased numbers of enrollees in FY 2017 were associated with several large studies on pre-existing datasets being included in the inclusion records. These records were removed from the NIDDK inclusion records in FY 2018, and we expect such errors will continue to decrease as the new HSS becomes more familiar and NIDDK implements additional quality check procedures.

NIDDK enrollment data for FY 2016-2018 are subdivided by gender, race, and ethnicity in Table 3. Females comprise ~ 53% of all NIDDK clinical research participants, while males make up ~ 45%, and those of unknown sex/gender are ~ 2% each year. Inclusion in racial categories remained consistent across FY 2016 – 2018. American Indian/Alaska Natives were ~ 5%, Asian were ~ 4%, Black/African Americans were ~ 20%, Native Hawaiian/Pacific Islander were ~ 0.8%, White were ~ 59%, and more than one race were ~ 2%. About 7% of individuals had unknown/not reported race. Report of unknown ethnicity increased from ~ 4% in FY 2016 to ~ 25% in FY 2017 and 2018. The increase in unknown ethnicity resulted from 4 large extramural studies in each FY 2017 and 2018 that did not report

ethnicity. These studies were responsible for 150,926 participants of unknown ethnicity in FY 2017 and 90,733 participants of unknown ethnicity in FY 2018. NIDDK is establishing updated data validation checks to ensure that studies report ethnicity or have a valid reason for not doing so.

**NIDDK Phase III Clinical Trials (Intramural and Extramural)**

Between FY 2016 – FY 2018, NIDDK report between 10 and 20 Phase III Clinical Trial inclusion records, including both Intramural and Extramural research (Table 4), with a peak in FY 2017. Most NIDDK Phase III trials each year were US sites, and virtually all enrolled both male and female subjects. These Phase III trials enrolled 6971 participants in FY 2016, 11,716 participants in FY 2017, and 7199 in FY 2018. Despite the larger number of trials and enrollees in FY 2017, the proportion of participants that were male and female remained consistent in FY 2016 and FY 2017 (Table 5). In FY 2018, there was a rise in the fraction of male enrollees, rising from 49% in FY 2016-2017 to 59% in FY2018. Such variability is not unexpected considering the small number of Phase III Clinical Trial IERs (N = 10 in FY 2018) and enrollees (N = 7,199 in FY 2018), when compared to overall NIDDK Clinical Research in FY 2018 (1,026 IERs and 367,199 enrollees).

NIDDK Phase III trial enrollment by race ranged from 65% minority in FY 2016 to 82% minority in FY 2017 (Table 6). In FY 2018, the numbers of Phase III trial IERs, number of participants, and the fraction of participants that were minorities returned to values similar to FY 2016. In FY2018, the number of Black/African American participants in Phase III trials dropped sharply from ~43% in FY 2016 and FY 2017 to ~17% in FY 2018. As the Phase III Clinical Trial enrollment data has small sample sizes, such variability is not unexpected, however NIDDK will be closely monitoring Phase III inclusion data to ensure diverse, sex, racial, and ethnic diversity continues to be represented.

Since FY 2016, the representation of Hispanic/Latino ethnicity in NIDDK Phase III Trials has increased (Table 7), from 1,077 participants in FY2016, to 4,831 participants in FY 2017, and 4,544 participants in FY 2018. The recent increase in Hispanics and Latinos in NIDDK Phase III Clinical Trials is a result of successful recruitment by the Glycemia Reduction Approaches in Diabetes: A Comparative Effectiveness (GRADE) Trial (NCT01794143).

The inclusion data summarized in this report can be further explored within the RCDC category reports, https://report.nih.gov/RISR/.

During the last three years, the NIDDK has funded research that has resulted in significant data and subsequent publications focused on and highlighting differences in gender, ethnic, and race within the conditions and diseases relevant to the mission of NIDDK. Appendix II lists a selection of publications supported by NIDDK that highlight race, ethnicity and/or gender.

NIDDK has been diligent in adhering to the requirements of the NIH Revitalization Act of 1993 and he NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research. NIDDK clinical studies have significant minority recruitment and appropriate representation of women.

NIDDK staff will continue to encourage participation of all minority groups in clinical research, to maintain diversity and scientific integrity of the Institute's funded clinical research. In addition, the NIDDK will continue to seek out and fund clinical research in areas of high relevance to either a specific gender or racial group.

# IV. APPENDIX I

## Table 1: Metrics Based on Inclusion Enrollment Records (IERs) - NIDDK

**Total Inclusion Enrollment Records (IERs) for NIH-Defined Extramural and Intramural Clinical Research Reported Between FY2016 and FY2018**

| Fiscal Year | Total IERs | IERs Without Enrollment | IERs With Enrollment | US Site IERs | Non-US Site IERs | Female Only IERs | Male Only IERs | IERs Excluding Male-only and Female-only* |
|---|---|---|---|---|---|---|---|---|
| 2016 | 770 | 67 | 703 | 688 | 15 | 45 | 25 | 633 |
| 2017 | 936 | 88 | 848 | 820 | 28 | 54 | 28 | 766 |
| 2018 | 1,026 | 135 | 891 | 856 | 35 | 54 | 26 | 811 |

*Inclusion Enrollment Records (IERs) excluding male-only and female-only include unknown sex/gender, and combination of unknown and any sex/gender(s).

## Table 2: Enrollment by Race

**Total Enrollment of All NIH-Defined Clinical Research**

| Fiscal Year | Total Enrollment | No. Inclusion Data Records | Minority Enrollment | % Minority Enrollment |
|---|---|---|---|---|
| 2016 | 447,227 | 770 | 179,640 | 40.2% |
| 2017 | 664,854 | 936 | 263,208 | 39.6% |
| 2018 | 367,199 | 1,026 | 155,697 | 42.4% |

# Table 3: Total Enrollment: All NIH-Defined Clinical Research - NIDDK

## NIDDK Enrollment for All NIH-Defined Clinical Research, Sex/Gender by Race and Ethnicity

| Year | Sex Gender | Minority | % Minority | Total Enrollment | % Total | Not Hispanic | % Not Hispanic | Hispanic Latino | % Hispanic Latino | Unknown Not Reported | % Unknown Not Reported |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 2016 | Female | 101,056 | 41.8 | 241,541 | 54.0 | 203,583 | 84.3 | 29,221 | 12.1 | 8,737 | 3.6 |
| 2016 | Male | 77,767 | 40.5 | 191,947 | 42.9 | 160,658 | 83.7 | 23,142 | 12.1 | 8,147 | 4.2 |
| 2016 | Unknown | 817 | 5.9 | 13,739 | 3.1 | 1,910 | 13.9 | 344 | 2.5 | 11,485 | 83.6 |
| 2017 | Female | 141,936 | 41.8 | 339,917 | 51.1 | 235,955 | 69.4 | 37,816 | 11.1 | 66,146 | 19.5 |
| 2017 | Male | 120,409 | 38.4 | 313,898 | 47.2 | 182,168 | 58.0 | 30,154 | 9.6 | 101,576 | 32.4 |
| 2017 | Unknown | 863 | 7.8 | 11,039 | 1.7 | 1,678 | 15.2 | 314 | 2.8 | 9,047 | 82.0 |
| 2018 | Female | 85,868 | 44.6 | 192,338 | 52.4 | 124,319 | 64.6 | 21,683 | 11.3 | 46,336 | 24.1 |
| 2018 | Male | 69,144 | 41.2 | 167,745 | 45.7 | 100,580 | 60.0 | 16,790 | 10.0 | 50,375 | 30.0 |
| 2018 | Unknown | 685 | 9.6 | 7,116 | 1.9 | 2,058 | 28.9 | 130 | 1.8 | 4,928 | 69.3 |

| Year | Sex Gender | American Indian Alaska Native | % American Indian Alaska Native | Asian | % Asian | Black African American | % Black African American | Native Hawaiian Pacific Islander | % Native Hawaiian Pacific Islander | White | % White | More Than One Race | % More Than One Race | Unknown Not Reported | % Unknown Not Reported |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 2016 | Female | 12,513 | 5.2 | 10,088 | 4.2 | 48,390 | 20.0 | 1,786 | 0.7 | 142,547 | 59.0 | 4,946 | 2.0 | 21,271 | 8.8 |
| 2016 | Male | 10,460 | 5.4 | 8,820 | 4.6 | 35,922 | 18.7 | 1,511 | 0.8 | 113,879 | 59.3 | 4,169 | 2.2 | 17,186 | 9.0 |
| 2016 | Unknown | 11 | 0.1 | 194 | 1.4 | 279 | 2.0 | 3 | 0.0 | 1,091 | 7.9 | 39 | 0.3 | 12,122 | 88.2 |
| 2017 | Female | 13,311 | 3.9 | 12,390 | 3.6 | 76,952 | 22.6 | 1,903 | 0.6 | 203,621 | 59.9 | 7,402 | 2.2 | 24,338 | 7.2 |
| 2017 | Male | 10,946 | 3.5 | 11,184 | 3.6 | 68,478 | 21.8 | 1,500 | 0.5 | 192,219 | 61.2 | 6,357 | 2.0 | 23,214 | 7.4 |
| 2017 | Unknown | 4 | 0.0 | 189 | 1.7 | 332 | 3.0 | 1 | 0.0 | 1,241 | 11.2 | 70 | 0.6 | 9,202 | 83.4 |
| 2018 | Female | 13,897 | 7.2 | 9,713 | 5.0 | 38,242 | 19.9 | 1,798 | 0.9 | 109,895 | 57.1 | 5,066 | 2.6 | 13,727 | 7.1 |
| 2018 | Male | 11,764 | 7.0 | 10,109 | 6.0 | 28,290 | 16.9 | 1,445 | 0.9 | 99,918 | 59.6 | 4,166 | 2.5 | 12,053 | 7.2 |
| 2018 | Unknown | 7 | 0.1 | 50 | 0.7 | 249 | 3.5 | 0 | 0.0 | 1,005 | 14.1 | 287 | 4.0 | 5,518 | 77.5 |

The data presented in this report show only inclusion records labeled as prospective data. Inclusion records labeled as existing data are excluded.

## Table 4: Total Inclusion Enrollment Records (IERs): All NIH-Defined Phase III Trials - NIDDK

**Total Inclusion Enrollment Records (IERs) for NIH-Defined Extramural and Intramural Phase III Trials Reported Between FY2016 and FY2018**

| Fiscal Year | Total IERs | IERs Without Enrollment | IERs With Enrollment | US Site IERs | Non-US Site IERs | Female Only IERs | Male Only IERs | IERs Excluding Male-only and Female-only* |
|---|---|---|---|---|---|---|---|---|
| 2016 | 17 | 1 | 16 | 16 | 0 | 1 | 0 | 15 |
| 2017 | 20 | 1 | 19 | 16 | 3 | 1 | 0 | 18 |
| 2018 | 10 | 1 | 9 | 8 | 1 | 0 | 0 | 9 |

*Inclusion Enrollment Records (IERs) excluding male-only and female-only include unknown sex/gender, and combination of unknown and any sex/gender(s).
The data presented in this report show only inclusion records labeled as prospective data. Inclusion records labeled as existing data are excluded.

## Table 5: Total Enrollment: All NIH-Defined Phase III Trials - NIDDK

**Total Enrollment for All NIH-Defined Phase III Trials Reporting Between FY2016 and FY2018**

| Fiscal Year | Total Enrollment | Total Females | % Females | Total Males | % Males | Total Unknown | % Unknown |
|---|---|---|---|---|---|---|---|
| 2016 | 6,971 | 3,544 | 50.8 | 3,424 | 49.1 | 3 | 0.0 |
| 2017 | 11,716 | 5,910 | 50.4 | 5,806 | 49.6 | 0 | 0.0 |
| 2018 | 7,199 | 2,926 | 40.6 | 4,256 | 59.1 | 17 | 0.2 |

| Fiscal Year | Total Enrollment | Enrollment in Female-only | % Female-only | Enrollment in Male-only | % Male-only | Females, Excluding Female-only | % Females, Excluding Female-only | Males, Excluding Male-only | % Males, Excluding Male-only |
|---|---|---|---|---|---|---|---|---|---|
| 2016 | 6,971 | 123 | 1.8 | 0 | 0.0 | 3,421 | 49.1 | 3,424 | 49.1 |
| 2017 | 11,716 | 123 | 1.0 | 0 | 0.0 | 5,787 | 49.4 | 5,806 | 49.6 |
| 2018 | 7,199 | 0 | 0.0 | 0 | 0.0 | 2,926 | 40.6 | 4,256 | 59.1 |

The data presented in this report show only inclusion records labeled as prospective data. Inclusion records labeled as existing data are excluded.

## Table 6: Total Phase III Trials Enrollment by Race - NIDDK

**Total Enrollment of All NIH-Defined Phase III Trials**

| Fiscal Year | Total Enrollment | No. Inclusion Records | Minority Enrollment | % Minority Enrollment | American Indian Alaska Native | % American Indian Alaska Native | Asian | % Asian |
|---|---|---|---|---|---|---|---|---|
| 2016 | 6,971 | 17 | 4,569 | 65.5 | 385 | 5.5 | 144 | 2.1 |
| 2017 | 11,716 | 20 | 9,636 | 82.2 | 505 | 4.3 | 238 | 2.0 |
| 2018 | 7,199 | 10 | 5,349 | 74.3 | 412 | 5.7 | 239 | 3.3 |

| Fiscal Year | Total Enrollment | No. Inclusion Records | Black African American | % Black African American | Native Hawaiian Pacific Islander | % Native Hawaiian Pacific Islander | White | % White | More Than One Race | % More Than One Race | Unknown Not Reported | % Unknown Not Reported |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 2016 | 6,971 | 17 | 2,940 | 42.2 | 14 | 0.2 | 2,852 | 40.9 | 258 | 3.7 | 378 | 5.4 |
| 2017 | 11,716 | 20 | 5,177 | 44.2 | 35 | 0.3 | 4,846 | 41.4 | 364 | 3.1 | 551 | 4.7 |
| 2018 | 7,199 | 10 | 1,212 | 16.8 | 40 | 0.6 | 4,672 | 64.9 | 365 | 5.1 | 259 | 3.6 |

The data presented in this report show only inclusion records labeled as prospective data. Inclusion records labeled as existing data are excluded.

## Table 7: Total Phase III Trials Enrollment by Ethnicity - NIDDK

### Total Enrollment of All NIH-Defined Phase III Trials

| Fiscal Year | Not Hispanic | % Not Hispanic | Hispanic Latino | % Hispanic Latino | Unknown Not Reported | % Unknown Not Reported |
|---|---|---|---|---|---|---|
| 2016 | 5,829 | 83.6 | 1,077 | 15.4 | 65 | 0.9 |
| 2017 | 6,800 | 58.0 | 4,831 | 41.2 | 85 | 0.7 |
| 2018 | 2,587 | 35.9 | 4,544 | 63.1 | 68 | 0.9 |

The data presented in this report show only IERs labeled as prospective data. IERs labeled as existing data are excluded.

# V. APPENDIX II:

## Representative NIDDK Publications Highlighting Gender, Race, and Ethnicity

## *FY 2016*

**P01DK056492.** Razzak CS; Workeneh, BT; *et al.* Trends in the outcomes of end-stage renal disease secondary to human immunodeficiency virus-associated nephropathy. 2015. Nephrology, Dialysis, Transplantation. 30(10): 1734-40. doi/10.1093/ndt/gfv207

**R01DK076683.** Osafo, C; Raji, YR; *et al.* Human Heredity and Health (H3) in Africa Kidney Disease Research Network: A Focus on Methods in Sub-Saharan Africa. 2015. Clinical Journal of the American Society of Nephrology. 10 (12):2279-87. doi/10.2215/CJN.11951214

**P50DK096418.** Cooper, DS; Claes, D; *et al.*. Follow-Up Renal Assessment of Injury Long-Term After Acute Kidney Injury (FRAIL-AKI). 2016. Clinical Journal of the American Society of Nephrology. 11(1):21-9. doi/10.2215/CJN.04240415

**P01DK056492; ZIADK043411; & ZIADK043308**. Atta, MG; Estrella, MM; *et al.* Association of APOL1 Genotype with Renal Histology among Black HIV-Positive Patients Undergoing Kidney Biopsy. 2016. Clinical Journal of the American Society of Nephrology. 11(2): 262-70. doi/10.2215/CJN.07490715

**R01DK104718; R21DK09743**. Thomas-White, KJ;Hilt, EE; *et al.* Incontinence medication response relates to the female urinary microbiota. 2016. International Urogynecology Journal. 27(5): 723-33. doi/10.1007/s00192-015-2847-x

**R01DK093770.** Parikh, CR; Hall, IE; *et al.* Associations of Perfusate Biomarkers and Pump Parameters With Delayed Graft Function and Deceased Donor Kidney Allograft Function. 2016. American Journal of Transplantation. 16(5): 1526-39. doi/10.1111/ajt.13655

**R01DK07223; U01DK060990; U01DK060980; U01DK060984; U01DK061022; U01DK061028; U01DK060902; U01DK061021; & U01DK060963**. Porter, AC; Lash, JP; *et al.* Predictors and Outcomes of Health-Related Quality of Life in Adults with CKD. 2016. Clinical Journal of the American Society of Nephrology. 11(7): 1154-62. doi/10.2215/CJN.09990915

**P30DK092950.** Nicklett, EJ; Taylor, RJ; *et.al*. Mediators and Moderators of the Effectiveness of a Community Health Worker Intervention That Improved Dietary Outcomes in Pregnant Latino Women. 2015. *Health Educ Behav.* 42(5):593-603. doi/10.1177/1090198114568307

**P30DK026687.** Widen, EM; Whyatt, RM; *et.al*. Excessive gestational weight gain is associated with long-term body fat and weight retention at 7 y postpartum in African American and Dominican mothers with underweight, normal, and overweight prepregnancy BMI. 2015. *The American Journal of Clinical Nutrition*. 102(6)1460-7. doi/10.3945/ajcn.115.116939

**R01DK049587.** Lydecker, JA; Grilo, CM. Different yet similar: Examining race and ethnicity in treatment-seeking adults with binge eating disorder. 2016. *Journal of Consulting and Clinical Psychology*. 84(1):88-94. doi/10.1037/ccp0000048

**P30DK040561 & P30DK072476.** Myers, CA; Slack, T; *et.al*. Change in Obesity Prevalence across the United States Is Influenced by Recreational and Healthcare Contexts, Food Environments, and Hispanic Populations. 2016. *PloS One*. 11(2):e0148394. doi/10.1371/journal.pone.0148394

**P30DK026687.** Luchsinger, JA; Ma, Y; *et.al*. Medication Adherence Does Not Explain Black-White Differences in Cardiometabolic Risk Factor Control among Insured Patients with Diabetes. 2016. *J Gen Intern Med.31(2):188-95*. doi/10.1007/s11606-015-3486-0

**P30DK046204.** Marquez, B; Anderson, A; *et.al*. The relationship of social support with treatment adherence and weight loss in Latinos with type 2 diabetes. 2016. *Obesity (Silver Spring)*. (24)3: 568-75. doi/10.1002/oby.21382

**P30DK092949.** Effoe, VS; Carnethon, MR; *et.al*. Multiple Healthful Dietary Patterns and Type 2 Diabetes in the Women's Health Initiative. 2016. *Am J Epidemiol.183(7):622-33*. doi/10.1093/aje/kwv241

**P30DK079626; P60DK079626; P30DK056336; & R01DK051684**. Sweatt, SK; Roy, J; *et.al*. Ethnic differences in the consistency and accuracy of perceived exertion. 2016. *American Journal of Human*. 28(3):398-404. doi/10.1002/ajhb.22801

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