National Institute of Diabetes and Digestive and Kidney Diseases
2015 Biennial 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 has established several overarching principles, which have become known somewhat colloquially as "core values" (see http://www.niddk.nih.gov/about-niddk/meet-the-director/mission-vision/Pages/mission-vision.aspx). 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 13 on NIDDK's "Funding Trends and Support of Core Values" webpage http://www.niddk.nih.gov/research-funding/funded-grants-grant-history/funding-trends-support-core-values/Pages/funding-trends-core-values.aspx).

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.

Purpose of this Report

The NIH Revitalization Act of 1993, PL 103-43, signed into law on June 10, 1993, directed the NIH to establish guidelines for inclusion of women and minorities in clinical research. ***The law also requires that the advisory council of each national research institute prepare biennial reports describing the manner in which the institute has complied with those inclusion guidelines established under the law.*** Guidelines for the inclusion of women and minorities in clinical research were updated in October 2001. Current policy, implementation, and reference documents regarding inclusion of women and minorities in NIH-supported clinical research are available at http://grants.nih.gov/grants/funding/women_min/women_min.htm.

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,

That NIH initiate programs and support for outreach efforts to recruit and retain women and minorities and their subpopulations as participants in clinical studies.

NIH Policy and Implementation Summary

As outlined in "*NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research—Amended, October, 2001":*

> It is the policy of NIH that women and members of minority groups and their subpopulations must be included in all NIH-funded clinical research, unless a clear and compelling rationale and justification establishes to the satisfaction of the relevant Institute/Center Director that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. Exclusion under other circumstances may be made by the Director, NIH, upon the recommendation of an Institute/Center Director based on a compelling rationale and justification. Cost is not an acceptable reason for exclusion except when the study would duplicate data from other sources. Women of childbearing potential should not be routinely excluded from participation in clinical research. This policy applies to research subjects of all ages in all NIH-supported clinical research studies.
>
> The inclusion of women and members of minority groups and their subpopulations must be addressed in developing a research design or contract proposal appropriate to the scientific objectives of the study/contract. The research plan/proposal should describe the composition of the proposed study population in terms of sex/gender and racial/ethnic group, and provide a

> rationale for selection of such subjects. Such a plan/proposal should contain a description of the proposed outreach programs for recruiting women and minorities as participants.

In addition:

> When an NIH-defined Phase III clinical trial is proposed, evidence must be reviewed to show whether or not clinically important sex/gender and race/ethnicity differences in the intervention effect are to be expected. This evidence may include, but is not limited to, data derived from prior animal studies, clinical observations, metabolic studies, genetic studies, pharmacology studies, and observational, natural history, epidemiology and other relevant studies.

Ethnicity and Race Data

To allow comparisons to other federal databases, NIH is required by Office of Management and Budget (OMB) Directive No. 15 (see http://www.whitehouse.gov/omb/fedreg_1997standards) to use the following ethnic and racial categories for tracking and reporting purposes:

> Ethnic Categories
>
> - Hispanic or Latino
> - Not Hispanic or Latino
>
> Racial Categories
>
> - American Indian or Alaska Native
> - Asian
> - Black or African American
> - Native Hawaiian or Other Pacific Islander
> - White

Using respondent self-reported or self-identification to collect an individual's data on ethnicity and race, investigators should use two separate questions with ethnicity information collected first followed by the option to select more than one racial designation.

Roles and Responsibilities

NIH inclusion policy specifies roles and responsibilities for a number of groups associated with the conduct of clinical research supported by NIH (see link to policy at the beginning of this section). In general, responsibility for compliance with this policy is crosscutting and requires participation of principal investigators developing research proposals, subjects and patients participating in clinical research, NIH staff (including review, program and grants management), and members of the public including peer reviewers and advisory council members. Some specific roles are outlined below.

Principal Investigators

Instructions in application forms SF 424 and PHS 398 require that clinical research proposals address inclusion of women and minorities. The forms require principal investigators to address:

- Targeted/Planned Enrollment Table—Establishes the targeted/planned distribution of study subjects by sex/gender and racial/ethnic groups
- Subject selection criteria and rationale
- Compelling rationale for any exclusions
- Description of outreach programs for study recruitment

To help principal investigators develop their clinical research proposals in accordance with the requirements of the NIH inclusion policy, NIH has developed a number of resources including a series of Frequently Asked Questions, Pod casts, narrated slide decks, links to NIH forms and applications, and other resources including links to policy documents (see http://grants.nih.gov/grants/funding/women_min/women_min.htm).

Peer Reviewers

Reviewers on NIH peer review panels are given specific instructions when considering clinical research applications (see NIH Instructions to Reviewers for Evaluating Research Involving Human Subjects in Grants and Cooperative Agreement Applications http://grants.nih.gov/grants/peer/hs_review_inst.pdf). In addition to instructions for evaluating plans for protecting human subjects from research risks, reviewers are given specific instructions for evaluating plans for inclusion of women and minorities, and are also given instructions for evaluating Phase III clinical trials (Phase III clinical trial applications must include a plan to perform a valid analysis of significant differences in intervention effect based on sex/gender and race/ethnicity). Unacceptable inclusion plans must be reflected in the priority score of the application and must also be documented in the minutes of the review session.

NIH Staff and Advisory Councils

It is the responsibility of both NIH staff members (including review, program, and grants management) and Advisory Councils to ensure that applications that have unacceptable inclusion plans are not funded.

II. NIDDK Strategies Ensuring Policy Compliance with Inclusion Guidelines

NIDDK uses a number of strategies to ensure full compliance with inclusion guidelines.

Training

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 intranet, 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; ***and***
- ***SOP #27*** - Staff Review Of Applications Prior To Award: Resolving Concerns About The Inclusion Of Women, Members Of Minority Groups, And Children.

NIDDK also 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 http://www.niddk.nih.gov/research-funding/process/human-subjects-research/policies-for-clinical-researchers/Pages/default.aspx). Furthermore, the 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 13, 2013 EP Staff Meeting by the NIH Inclusion Officer, Dr. Meredith Temple-O'Conner and regular updates on inclusion policy are presented at the monthly EP Staff Meeting throughout the year.

Oversight and Data Monitoring

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 of the DEA, Dr. Brent Stanfield oversees the process and provides leadership to all of the Divisions within NIDDK. Dr. Karl Malik, as Deputy Director of DEA, as well 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 biennial report. Ms. Lauren Meskill, a program analyst, is responsible for analysis and entry of all data at the division level. Weekly updates on the progress of entering data into the Population Tracking system are generated by NIH and shared with the division representatives.

All NIDDK Program Officers are responsible for monitoring the clinical trials within their respective programs. Ms. Meskill has the lead role in monitoring the input of Population Tracking data and works very closely with Program Officers to ensure that any missing data or any apparent discrepancies are addressed in a timely fashion.

Ms. Christine Salaita within OREO was responsible for conducting regular audits of inclusion tracking progress throughout the year. Prior to her departure in the in the spring of 2014 Ms. Salaita worked closely with Ms. Meskill to monitor reporting progress and reports any problems to Dr. Malik. Ms. Salaita's duties have now been taken over by Ms. Theresa Smith.

Grants Process Procedures

NIDDK has put procedures in place throughout the grants process to ensure compliance with inclusion guidelines.

NIDDK Scientific Review Officers (SROs) implement the following procedures:

- SROs 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.

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. In general the Grants Management Specialist will note the bar and refer the issue to the Program Officer. The Program Officer must then justify lifting the bar. This may include obtaining additional information from the investigator or asking for a change in the design. Once appropriate justification is obtained for lifting the bar, the Program Officer must prepare a memo explaining the situation and justifying removal of the bar. The memo and appropriate documentation are then sent to the Office of Extramural Programs (OEP) within the NIH OD for concurrence. Once approval is obtained from OEP, then the Grants Management Specialist is authorized to remove the bar to funding.

At the time of renewal of non-competing awards, the program officers must stipulate on the renewal worksheet that data on the inclusion of gender and minorities are included and appropriate. No new or continuing awards are made without information on either proposed "target for enrollment" or data on enrollment.

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.

III. Information Regarding Aggregate Tracking and Inclusion Data

NIDDK staff members have continued their efforts to ensure that persons of both genders and all ethnic and racial backgrounds are included in all studies involving human subjects (see data in Appendix I, Tables 1-6):

NIDDK Extramural Research

There were a total of 482 NIDDK extramural research protocols with enrollment data in fiscal year (FY) 2013 and 405 NIDDK extramural research protocols with enrollment data in FY 2014 (see Tables 1 and 2 in Appendix I).

- Higher numbers of female subjects than male subjects were enrolled in NIDDK clinical studies in both FY 2013 and 2014. In FY 2013 approximately 54% of participants enrolled in NIDDK extramural research protocols were female and in FY 2014 approximately 55% of the participants enrolled in NIDDK extramural research protocols were female.

- Approximately 20% of subjects enrolled in NIDDK clinical studies in FY 2013 and 21% in FY 2014 indicated that they belonged to a minority racial group. Approximately 1% of subjects in both fiscal years reported belonging to more than one racial group.

- Approximately 8% of subjects enrolled in NIDDK clinical studies in FY 2013 and 10% in FY 2014 indicated their ethnicity is Hispanic.

NIDDK Intramural Research (Division of Intramural Research)

There were a total of 113 NIDDK intramural research protocols with enrollment data in fiscal year (FY) 2013 and 119 NIDDK intramural research protocols with enrollment data in FY 2014 (see Tables 3 and 4 in Appendix I).

- Higher numbers of female subjects than male subjects were enrolled in NIDDK Intramural Research Program clinical studies in both FY 2013 and 2014. In both FYs 2013 and 2014 approximately 52% participants enrolled in NIDDK intramural research protocols were female.

- Approximately 64% of subjects enrolled in NIDDK intramural program clinical studies in FY 2013 and 65% FY 2014 indicated that they belonged to a minority racial group. It should be noted that within the Division of Intramural Research the Phoenix Epidemiology and Clinical Research Branch focuses on Pima Indians of Arizona who have the highest reported prevalence of type 2 diabetes of any population worldwide, and also have a high prevalence of obesity. Approximately 45% of the subjects enrolled in intramural program clinical studies in both FY 2013 and 2014 were American Indian/Alaska Native.

- Approximately 5% of subjects enrolled in NIDDK intramural program clinical studies in FY 2013 and 6% in FY 2014 indicated their ethnicity is Hispanic. However, as noted above, many intramural program clinical studies target specific populations for valid scientific reasons.

NIDDK NIH-defined Phase III Clinical Trials

There were 11 Phase III research protocols with enrollment data in FY 2013 and 8 Phase III research protocols with enrollment data in FY 2014 (see Appendix I, Tables 5 and 6).

- The percentage of women enrolled in NIDDK supported Phase III clinical trials (67% and 68% respectively for FY 2013 and 2014) was higher than the percentage of men. These data, in part, reflect the challenge of engaging men, particularly racial and ethnic minority men, in behavioral or lifestyle interventions. To address this challenge, NIDDK is active in supporting research to identify methods to engage racial and ethnic minority men from low income communities in lifestyle interventions (e.g., R18 DK102080 Translating the Diabetes Prevention Program to Engage Men in Disadvantaged Areas).

- The percentage of subjects enrolled in NIDDK supported Phase III clinical trials indicating that they belonged to a minority racial group was approximately 35% and 63% respectively for FY 2013 and 2014. Slightly more than 1% reported belonging to more than one racial group in both fiscal years.

- Approximately 13% of subjects enrolled in NIDDK supported Phase III clinical trials for FY 2013 and 11% for FY 2014 indicated their ethnicity to be Hispanic.

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.

During the past two years the NIDDK has funded research that has resulted in significant data and subsequent publications targeting 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 recent publications supported by NIDDK that highlight race, ethnicity and/or gender.

IV. Conclusions

NIDDK has been diligent in adhering to the requirements of NIH Revitalization Act of 1993 and the NIH Policy and Guidelines on The Inclusion of Women and Minorities as Subjects in Clinical Research. NIDDK has established appropriate resources on a programmatic division basis (i.e., professional staff members from each division are appointed as subject matter leaders and senior program analysts provide expert-level support). NIDDK clinical studies have significant minority recruitment and appropriate representation of women.

APPENDIX I

NIDDK Enrollment Data Tables

Table 1: FY 2013 Aggregate Enrollment Data for All Extramural Research Protocols --NIDDK

Categories	Count	Percentage
Female	175,502	53.72%
Male	149,466	45.75%
American Indian/Alaska Native	1,745	0.53%
Asian	25,190	7.71%
Hawaiian/Pacific Islander	480	0.15%
Black	37,388	11.44%
Hispanic	27,506	8.42%
White	233,717	71.54%
More Than One Race	2,815	0.86%
Unknown/Not Reported (Race)	25,374	7.77%
Unknown/Not Reported (Ethnicity)	43,271	13.24%
Unknown/Not Reported (Gender)	1,741	0.53%
Total Participants	326,709	
Total Protocol Records	482	

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

Categories	Count	Percentage
Female	132,258	55.33%
Male	104,681	43.79%
American Indian/Alaska Native	1,679	0.70%
Asian	6,201	2.59%
Hawaiian/Pacific Islander	473	0.20%
Black	41,468	17.35%
Hispanic	23,158	9.69%
White	159,491	66.72%
More Than One Race	2,849	1.19%
Unknown/Not Reported (Race)	26,884	11.25%
Unknown/Not Reported (Ethnicity)	26,173	10.95%
Unknown/Not Reported (Gender)	2,106	0.88%
Total Participants	239,045	
Total Protocol Records	405	

Table 3: FY 2013 Aggregate Enrollment Data for All Intramural Research Protocols --NIDDK

Categories	Count	Percentage
Female	20,993	51.66%
Male	18,171	44.71%
American Indian/Alaska Native	18,469	45.45%
Asian	1,187	2.92%
Hawaiian/Pacific Islander	2,351	5.79%
Black	4,181	10.29%
Hispanic	1,951	4.80%
White	10,246	25.21%
More Than One Race	202	0.50%
Unknown/Not Reported (Race)	4,003	9.85%
Unknown/Not Reported (Ethnicity)	2,904	7.15%
Unknown/Not Reported (Gender)	1,475	3.63%
Total Participants	40,639	
Total Protocol Records	113	

Table 4: FY 2014 Aggregate Enrollment Data for All Intramural Research Protocols --NIDDK

Categories	Count	Percentage
Female	22,336	51.96%
Male	19,176	44.61%
American Indian/Alaska Native	19,642	45.69%
Asian	1,333	3.10%
Hawaiian/Pacific Islander	2,355	5.48%
Black	4,437	10.32%
Hispanic	2,403	5.59%
White	11,225	26.11%
More Than One Race	255	0.59%
Unknown/Not Reported (Race)	3,739	8.70%
Unknown/Not Reported (Ethnicity)	3,220	7.49%
Unknown/Not Reported (Gender)	1,474	3.43%
Total Participants	42,986	
Total Protocol Records	119	

Table 5: FY 2013 Aggregate Enrollment Data for Extramural Phase III Research Protocols --NIDDK

Categories	Count	Percentage
Female	5,022	67.19%
Male	2,334	31.23%
American Indian/Alaska Native	78	1.04%
Asian	323	4.32%
Hawaiian/Pacific Islander	25	0.33%
Black	2,185	29.23%
Hispanic	939	12.56%
White	3,199	42.80%
More Than One Race	129	1.73%
Unknown/Not Reported (Race)	1,535	20.54%
Unknown/Not Reported (Ethnicity)	1,129	15.11%
Unknown/Not Reported (Gender)	118	1.58%
Total Participants	7,474	
Total Protocol Records	11	

Table 6: FY 2014 Aggregate Enrollment Data for Extramural Phase III Research Protocols --NIDDK

Categories	Count	Percentage
Female	4,014	67.84%
Male	1,877	31.72%
American Indian/Alaska Native	27	0.46%
Asian	211	3.57%
Hawaiian/Pacific Islander	10	0.17%
Black	3,488	58.95%
Hispanic	668	11.29%
White	1,379	23.31%
More Than One Race	69	1.17%
Unknown/Not Reported (Race)	733	12.39%
Unknown/Not Reported (Ethnicity)	778	13.15%
Unknown/Not Reported (Gender)	26	0.44%
Total Participants	5,917	
Total Protocol Records	8	

APPENDIX II

Representative NIDDK Publications Highlighting Gender, Race and Ethnicity

2013

R01DK059211 Type 2 Diabetes in Hispanic Adolescents

Alderete TL, Toledo-Corral CM, Desai P, et al. Liver Fat Has a Stronger Association with Risk Factors for Type 2 Diabetes in African-American Compared with Hispanic Adolescents. *J Clin Endocrinol Metab*. 2013;98(9):3748-54.

R01DK59211 Type 2 Diabetes in Hispanic Adolescents

Kim JY, Goran MI, Toledo-Corral CM, et al. One-hour glucose during an oral glucose challenge prospectively predicts β-cell deterioration and prediabetes in obese Hispanic youth. *Diabetes Care*. 2013;36(6):1681-6.doi: 10.2337/dc12-1861.

U01DK61230 Studies to Treat or Prevent Pediatric Type 2 Diabetes--STOPP-T2D

Buse JB, Kaufman FR, Linder B, et al. Diabetes screening with hemoglobin A(1c) versus fasting plasma glucose in a multiethnic middle-school cohort. *Diabetes Care*. 2013;36(2):429-35.doi: 10.2337/dc12-0295.

P01DK053369 Pathogenic Mechanisms in Urinary Tract Infection

P50DK064540 Molecular and Epidemiologic Basis of UTI in Women

Hooton TM, Roberts PL, Cox ME, Stapleton AE. Voided Midstream Urine Culture and Acute Cystitis in Premenopausal Women. *N Engl J Med*. 2013; 369(20):1883-91. doi: 10.1056/NEJMoa1302186.

R01DK062249 Effects of Anorexia Nervosa on Peak Bone Mass

Faje AT1, Karim L, Taylor A, et al. Adolescent girls with anorexia nervosa have impaired cortical and trabecular microarchitecture and lower estimated bone strength at the distal radius. *Clin Endocrinol Metab*. 2013;98(5):1923-9. doi: 10.1210/jc.2012-4153.

R01DK062249 Effects of Anorexia Nervosa on Peak Bone Mass

Misra M, Katzman DK, Clarke H, et al. Hip structural analysis in adolescent boys with anorexia nervosa and controls. *J Clin Endocrinol Metab*. 2013;98(7):2952-8. doi: 10.1210/jc.2013-1457.

R21DK078352 Telehealth for Weight Maintenance of African-American Women

Gerber BS, Schiffer L, Brown AA, et al. Video telehealth for weight maintenance of African-American women. *J Telemed Telecare*.2013;19(5):266-72. doi: 10.1177/1357633X13490901.

R01DK072932 Targeted Obesity Prevention Program for Adolescent Females

Stice E, Rohde P, Shaw H, Marti CN. Efficacy trial of a selective prevention program targeting both eating disorders and obesity among female college students: 1- and 2-year follow-up effects. *J Consult Clin Psychol.* 2013 Feb;81(1):183-9. doi: 10.1037/a0031235.

R15DK088949 Biopsychosocial Determinants of Weight Gain in Black First-Year College Women

Webb JB, Butler-Ajibade P, Robinson SA, Lee SJ. Weight-gain misperceptions and the third-person effect in Black and White college-bound females: potential implications for healthy weight management. *Eat Behav.* 2013 Aug;14(3):245-8. doi: 10.1016/j.eatbeh.2013.03.002.

R01DK073006 Ethnic Dance & Screen Time Reduction to Prevent Weight Gain in Latina Girls

Azevedo KJ, Mendoza S, Fernández M,et al. Turn off the TV and dance! Participation in culturally tailored health interventions: implications for obesity prevention among Mexican American girls. *Ethn Dis*. 2013 Autumn;23(4):452-61.

P30DK61981 Diet, Physical Activity, and Body Composition in Human Populations Core

Ferrari RM, Siega-Riz AM, Evenson KR, Moos MK, Carrier KS. A qualitative study of women's perceptions of provider advice about diet and physical activity during pregnancy. *Patient Educ Couns*. 2013 Jun;91(3):372-7. doi: 10.1016/j.pec.2013.01.011.

U01DK060990 Continuation of the Chronic Renal Insufficiency Cohort (CRIC) Study

Parsa A, Kao WH, Xie D, et al. APOL1 risk variants, race, and progression of chronic kidney disease. *N Engl J Med*. 2013;369(23):2183-96.

U01DK082315 Washington University MAPP Network Discovery Site

Sutcliffe S, Colditz GA, Pakpahan R, Bradley CS, et al. Changes in symptoms during urologic chronic pelvic pain syndrome symptom flares: Findings from one site of the MAPP Research Network. *Neurourol Urodyn*. 2013. doi: 10.1002/nau.22701.

R01DK078798 Community Based Obesity Prevention Among Black Women

Bennett GG, Foley P, Levine E, et al. Behavioral treatment for weight gain prevention among black women in primary care practice: a randomized clinical trial. *JAMA Intern Med.* 2013; 173(19):1770-7.

IA DK056009-08 Chemoprevention and Therapeutic Treatment of BRCA1 Associated Mammary Tumors

Laronda MM, Unno K, Ishi K, Serna VA, Butler LM, Mills AA, Orvis GD, Behringer RR, Deng C, Sinha S, Kurita T (2013) Diethylstilbestrol induces vaginal adenosis by disrupting SMAD/RUNX1-mediated cell fate decision in the Mllerian duct epithelium. *Dev Biol* 381:5-16

ZIA DK069071-18 Structural Analysis Of Candidate Genes For Type 2 Diabetes and Obesity

Hanson RL, Guo T, Muller YL, Fleming J, Knowler WC, Kobes S, Bogardus C, Baier LJ (2013) Strong Parent-of-Origin Effects in the Association of KCNQ1 Variants With Type 2 Diabetes in American Indians. *Diabetes* 62:2984-91

ZIA DK069000-49 Epidemiology of Type 2 Diabetes Mellitus in the Gila River Indian Community

Kim NH, Mason CC, Nelson RG, Afton SE, Essader AS, Medlin JE, Levine KE, Hoppin JA, Lin C, Knowler WC, Sandler DP. Arsenic exposure and incidence of type 2 diabetes in Southwestern American Indians. *Am J Epidemiol*. 2013 May 1;177(9):962-9.

2014

R01DK071891 Subclinical CVD in African American Type 2 Diabetics

Freedman BI, Langefeld CD, Lu L, Palmer ND, et al. APOL1 associations with nephropathy, atherosclerosis, and all-cause mortality in African Americans with type 2 diabetes. *Kidney Int*. 2014. doi: 10.1038/ki.2014.255.

U01DK048489 Diabetes Prevention Program Outcomes Study

Sullivan SD, Jablonski KA, Florez JC, et al. Genetic risk of progression to type 2 diabetes and response to intensive lifestyle or metformin in prediabetic women with and without a history of gestational diabetes mellitus. *Diabetes Care*. 2014;37(4):909-11. doi: 10.2337/dc13-0700.

U01DK061230 Treatment Options for Type 2 Diabetes in Adolescents and Youth (TODAY) Study

TODAY Study Group. Alterations in left ventricular, left atrial, and right ventricular structure and function to cardiovascular risk factors in adolescents with type 2 diabetes participating in the TODAY clinical trial. *Pediatr Diabetes*. 2014. doi: 10.1111/pedi.12119.

U01DP000250 SEARCH for Diabetes in Youth

Pettitt DJ, Talton J, Dabelea D, et al. Prevalence of diabetes in U.S. youth in 2009: the SEARCH for diabetes in youth study. *Diabetes Care*. 2014 Feb;37(2):402-8. doi: 10.2337/dc13-1838.

Dabelea D, Mayer-Davis EJ, Saydah S,et al. Prevalence of type 1 and type 2 diabetes among children and adolescents from 2001 to 2009. *JAMA*. 2014 May 7;311(17):1778-86. doi: 10.1001/jama.2014.3201.

U01DK094157 Epidemiology of Diabetes Interventions and Complications (EDIC)

Buschur E, Sarma AV, Pietropaolo M, et al. Self-reported autoimmune disease by sex in the diabetes control and complications trial/epidemiology of diabetes interventions and complications (DCCT/EDIC) study. Diabetes Care. 2014;37(2):e28-9. doi: 10.2337/dc13-1890

Holt SK, Lopushnyan N, Hotaling J, et al. Prevalence of Low Testosterone and Predisposing Risk Factors in Men With Type 1 Diabetes Mellitus: Findings From the DCCT/EDIC. J Clin Endocrinol Metab. 2014 Sep;99(9):E1655-60. doi: 10.1210/jc.2014-1317.

Kim C, Cleary PA, Cowie CC, et al. Effect of glycemic treatment and microvascular complications on menopause in women with type 1 diabetes in the Diabetes Control and Complications Trial/Epidemiology of Diabetes Interventions and Complications (DCCT/EDIC) cohort. Diabetes Care. 2014;37(3):701-8.doi: 10.2337/dc13-1746.

U01DK074059 Randomized Intervention for Vesicoureteral Reflux (RIVUR)

Hoberman A, Greenfield SP, Mattoo TK, et al. Antimicrobial prophylaxis for children with vesicoureteral reflux. *N Engl J Med.* 2014; 370(25):2367-76.

R01 DK082753 Elucidating IgA Nephropathy through Genetic Studies of IgA1 Glycosylation

R01 DK095510 Discovery and Fine Mapping of Susceptibility loci for IgA Nephropathy

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