I. BACKGROUND/OVERVIEW

The mission of the National Institute for Dental and Craniofacial Research (NIDCR) is to advance fundamental knowledge about dental, oral, and craniofacial (DOC) health and disease and translate these findings into prevention, early detection, and treatment strategies that improve overall health for all individuals and communities across the lifespan. We accomplish our mission through five strategic priorities:

- Advance cross-disciplinary fundamental research in the biomedical, behavioral, social, and environmental sciences and drive its translation into innovations for the early diagnosis, prevention, and treatment of DOC diseases and conditions across the lifespan.
- Develop more precise and individualized ways of managing and preventing DOC diseases.
- Accelerate the translation of research and the uptake of new discoveries into oral and general healthcare practices that reduce health inequities and disparities and improve oral health outcomes for individuals and communities worldwide.
- Nurture future generations of DOC researchers and oral health professional scholars who can address existing and emerging challenges driven by personalized and public health needs and a continually evolving landscape of science and technology advances.
- Expand already existing partnerships and create new ones to advance the NIDCR research enterprise and increase its reach and impact.

The NIDCR aspires to transform human lives through scientific discoveries and innovations that advance DOC health and overall well-being for all.

The NIH Revitalization Act of 1993 directed the NIH to establish guidelines for inclusion of women and minorities in NIH-funded clinical research. The 21st Century Cures Act, enacted December 13, 2016, included several new requirements related to inclusion of participants in clinical research. As a result, NIH updated its Policy on the Inclusion of Women and Minorities in Clinical Research on November 28, 2017, to require studies that are NIH-defined Phase III clinical trials and/or applicable clinical trials to report the results of analyses by sex/gender and/or race/ethnicity to ClinicalTrials.gov. This requirement is in effect for competing grant awards on or after December 13, 2017, as well as contract solicitations and Intramural studies initiated after this date. Additionally, NIH revised its Inclusion of Children policy on December 19, 2017. The revised policy, now called the NIH Policy and Guidelines on the Inclusion of Individuals Across the Lifespan as Participants in Research Involving Human Subjects, addresses
consideration of individuals of all ages in NIH-funded clinical research and requires reporting of participant age at enrollment in annual progress reports. The policy is in effect for applications submitted on or after January 25, 2019, and contract solicitations and Intramural studies initiated after this date.

The 21st Century Cures Act also amended the frequency from biennial to triennial for reporting inclusion activities to advisory councils and providing the Report of the NIH Director on the Inclusion of Women and Minorities. The triennial report provides information from each NIH Institute and Center (IC) on inclusion of participants in NIH-defined clinical research from Fiscal Year (FY) 2019 through FY 2022. This report of monitoring adherence to inclusion policies being presented to the National Advisory Dental and Craniofacial Research Council (NADCRC) presents the NIDCR’s activities related to fulfilling its responsibilities under these statutes.

II. STRATEGIES FOR ENSURING POLICY COMPLIANCE

The implementation of inclusion guidelines involves the participation of NIH Review, Program, Policy, and Grants Management staff. Inclusion is first addressed by peer review. Reviewers on NIH peer review panels are given specific Guidelines for the Review of Inclusion on the Basis of Sex/Gender, Race, Ethnicity and Age in Clinical Research 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 NIH-defined Phase III clinical trials, 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. Review groups make initial recommendations as to the acceptability of the proposed study population with respect to the inclusion policies. The NADCRC performs the second level of review.

Applications with unacceptable inclusion plans receive a bar to funding; an award is not issued until an acceptable resolution is received. If issues are raised in review, Program and/or Grants Management staff notify Principal Investigators, who are required to address these issues prior to funding. Prior to funding a new award, Program staff are responsible for reviewing the inclusion information in the application and indicating whether the plans are scientifically appropriate. For NIH-defined Phase III clinical trials, Program staff review applications for the requirement that sex/gender and race/ethnicity analyses are planned. Grants Management staff ensure that applications with unacceptable inclusion plans are resolved prior to issuing an award. Further, for awards that require inclusion monitoring, Program staff monitor actual enrollment progress in annual and final progress reports and provide consultation when necessary. For NIH-defined Phase III clinical trials, Program staff monitor annual and final progress reports for the requirement to conduct analyses by sex/gender and race/ethnicity. Grants Management staff ensure that appropriate terms and conditions of award are included.
in the Notice of Award, and that inclusion information is appropriately documented in the official grant file.

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. These plans are considered during the scientific review process. With the annual scientific review and IRB review renewal, the Intramural investigator documents the number, sex/gender, race, 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. Dr. Janice Lee, Clinical Director of the Intramural Program at NIDCR, is responsible for overseeing protocol recruitment efforts of NIDCR Intramural investigators and ensuring they make efforts to include appropriate representation of sex/gender, race, and ethnicity in their studies. The Clinical Center’s Office of Protocol Services (OPS) coordinates annual reporting of demographic participant data to the Office of Extramural Research (OER) and the Office of Research on Women’s Health.

The NIH Revitalization Act of 1993 and subsequent statutes have stipulated that NIH staff and Extramural investigators understand the requirement of the statues and their impact on the conduct of clinical research. Dr. Dena Fischer, Director for the Center for Clinical Research, Division of Extramural Research, NIDCR, has provided guidance to NIDCR’s Extramural Program Officials/Directors about the inclusion guidelines. Dr. Fischer is a member of the NIH Inclusion Operating Procedures Workgroup, which reviews the tracking system used by NIH to capture inclusion data and recommends changes as needed. NIDCR Extramural Program Officials/Directors provide assistance to investigators to ensure that target and current enrollment information for the inclusion of human subjects on the basis of sex/gender, race, ethnicity, and age are included in grant applications and provided in progress reports. Further, NIDCR Program Officials/Directors, Scientific Review Officers, and Grants Management staff attended the 2020 Inclusion Training for Program Staff and the 2020 Inclusion Training for Review Staff in April 2020. Staff may access the archived training on the NIH staff intranet.

III. ANALYSIS AND INTERPRETATION OF DATA

All NIDCR Extramural and Intramural Clinical Research Studies

In FY 2019, 27,594 participants were enrolled in 123 of 181 NIDCR-supported Extramural and Intramural studies that required enrollment monitoring. In FY 2020, 17,874 participants were enrolled in 128 of 212 NIDCR-supported Extramural and Intramural studies that required enrollment monitoring, and in FY 2021, 21,790 participants were enrolled in 141 of 272 NIDCR-supported clinical studies that required enrollment monitoring. The decreased enrollment with increased IERs in FY 2020 and 2021 compared to FY 2019 is likely due to COVID-related impacts upon clinical research activities.
Aggregate FY 2019 data (Table 2) revealed 54.2% of enrolled participants were female, 43.2% were male, and sex/gender was unknown for 2.6%. Similar patterns were present in the aggregate FY 2020 (Table 3) and FY 2021 (Table 4) data in that 54.9% (2020) and 54.2% (2021) of participants were female, 43.0% (2020) and 43.1% (2021) were male, and sex/gender was unknown for 2.1% in 2020 and 2.7% in 2021.

In FY 2019 through FY 2021 (Tables 2 through 4), Whites had the highest rates of participation (48.7% in FY 2019, 51.6% in FY 2020, 50.0% in FY 2021). Black / African American participation was 26.5% in FY 2019, 23.6% in FY 2020, and 23.2% in FY 2021. In FY 2019, Asian participation was 3.3%; it was 3.0% in FY 2020 and 4.3% in FY 2021. American Indian / Alaska Native participation was 1.3% in FY 2019, 2.7% in FY 2020, and 2.5% in FY 2021. Race was unknown / not reported or refused identification for 12.0% of participants in FY 2019, 14.5% FY 2020, and 10.5% in FY 2021. The racial distribution of research participants remained consistent between FY 2019 and FY 2021. Hispanics represented 20.6% of enrolled participants in FY 2019, 17.7% in FY 2020, and 16.0% in FY 2021. Ethnicity was unknown / not reported for 7.3% in FY 2019, 12.5% in FY 2020, and 9.8% in FY 2021. Hispanic participation decreased during the reporting timeframe from FY 2019 to FY 2021.

Tables 5 through 7 display the total number of participants enrolled in NIDCR-supported Phase III clinical trials between FY 2019 and FY 2021. In FY 2019, 4469 participants were enrolled in seven Phase III clinical trials (Table 5); 4486 participants were enrolled in eight Phase III trials in FY 2020 (Table 6), and 3981 participants were enrolled in eight Phase III trials in FY 2021 (Table 7). All NIDCR-supported Phase III clinical trials are required to report the results of analyses by sex/gender and/or race/ethnicity to ClinicalTrials.gov. The majority of participants enrolled in these Phase III trials were female (65.3% in FY 2019, 65.0% in FY 2020, and 69.0% in FY 2021). In FY 2019, 48.1% of Phase III clinical trial participants were White, and White participation decreased to 38.0% in FY 2020 and 32.0% in FY 2021. Black / African Americans represented 35.7% of Phase III clinical trial participants in FY 2019. In FY 2020 and FY 2021, Black / African American participation in Phase III clinical trials increased and exceeded White Phase III trial participation. In FY 2020, 40.2% of Phase III trial participants were Black / African American, and participation increased to 47.5% of Phase III trial participants in FY 2021. Race was unknown or not reported by 6.2% of Phase III clinical trial participants in FY 2019, 11.0% in FY 2020, and 9.0% in FY 2021. Black / African American participation was higher in Phase III trials than in the aggregate clinical studies in FYs 2019 through 2021. Hispanic enrollment in Phase III trials was 10.4% in FY 2019, 13.1% in FY 2020, and 16.3% in FY 2021, representing an increase over the reporting timeframe; in FY 2021, Hispanic participation in Phase III trials was similar to Hispanic enrollment for all clinical research. Ethnicity was unknown or not reported by 28.3% of Phase III clinical trial participants in FY 2019, 9.7% in FY 2020, and 4.6% in FY 2021.

Inclusion enrollment data by Research, Condition, and Disease Categorization (RCDC) categories are available at the following link: https://report.nih.gov/RISR/.
Summary

- The number of NIDCR-supported clinical studies requiring enrollment monitoring has increased substantially from FY 2019 to FY 2021 (increase from 181 to 272), while the number of cumulative participants enrolled has decreased over the reporting timeframe. This discrepancy is likely due to COVID-related impacts upon clinical research activities.
- Substantial numbers of women were enrolled in NIDCR-supported clinical research studies (>54%), and this number was consistent over the reporting timeframe.
- The number of study participants identifying as Hispanic decreased somewhat from FY 2019 to FY 2021, while the number of individuals for whom ethnicity was unknown or not reported slightly increased. It is possible that COVID-related impacts have affected participation of Hispanic individuals in clinical research activities.
- The participation of study participants identifying as White has remained relatively stable from FY 2019 to FY 2021, with an increase in White participation relative to other racial categories occurring in FY 2020. Further, participation of Blacks / African Americans and those reporting more than one race decreased in FY 2020. These aberrations may represent racial differences in COVID issues impacting clinical research study participation.
- NIDCR supported 7-8 Phase III clinical trials on a variety of topical areas, including dental caries prevention and treatment, acute post-surgical pain management, timing of cleft lip/palate primary surgery, tobacco cessation, and reduction of dental anxiety.
- The majority of NIDCR-supported Phase III clinical trial participants were women (>65%), and this number increased over the reporting timeframe.
- Hispanic participation in NIDCR-supported Phase III trials increased over the reporting timeframe from approximately 10% to greater than 16%.
- Phase III clinical trial participants identifying as White decreased from FY 2019 to FY 2021, while Black / African American participation in Phase III clinical trials increased and exceeded White Phase III trial participation (FY 2021: 32% White vs 47.5% Black / African American).

Conclusions

- The FY 2019 through FY 2022 NIDCR inclusion data shows that substantial numbers of women were enrolled in NIDCR-supported clinical studies requiring enrollment monitoring. The racial and ethnic distribution of study participants reflects the US population in certain categories, but more work needs to be done to increase enrollment in other categories.
- Phase III clinical trial participation in FY 2019 through FY 2022 shows that NIDCR-supported Phase III trials have improved the racial and ethnic distribution of trial participants over the reporting timeframe.
Table 1. Total Inclusion Enrollment Reports (IERs) for Research Studies Receiving Funding between FY 2019 and FY 2021
Extramural and Intramural NIH-Defined Clinical Research
NATIONAL INSTITUTE OF DENTAL & CRANIOFACIAL RESEARCH

<table>
<thead>
<tr>
<th></th>
<th>FY 2019</th>
<th>FY 2020</th>
<th>FY 2021</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Phase III trials*</td>
<td>Other Clinical studies**</td>
<td>Phase III trials*</td>
</tr>
<tr>
<td>Domestic site IERs</td>
<td>5</td>
<td>114</td>
<td>8</td>
</tr>
<tr>
<td>Foreign site IERs</td>
<td>2</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>IERs reporting combination of females, males, and/or unknown sex/gender</td>
<td>7</td>
<td>104</td>
<td>8</td>
</tr>
<tr>
<td>Female-only IERs</td>
<td>0</td>
<td>7</td>
<td>0</td>
</tr>
<tr>
<td>Male-only IERs</td>
<td>0</td>
<td>5</td>
<td>0</td>
</tr>
<tr>
<td>Total IERs with enrollment data</td>
<td>7</td>
<td>116</td>
<td>8</td>
</tr>
<tr>
<td>Total IERs without enrollment data</td>
<td>2</td>
<td>56</td>
<td>5</td>
</tr>
<tr>
<td>Total IERs</td>
<td>9</td>
<td>172</td>
<td>13</td>
</tr>
</tbody>
</table>

IER = Inclusion Enrollment Report, as reported by grantee institution

* An NIH-Defined Phase III Clinical Trial “usually involves several hundred or more human subjects, for the purpose of evaluating an experimental intervention in comparison with standard or control intervention or comparing two or more existing treatments.”

** Human subjects studies that are not a NIH-Defined Phase III Clinical Trial
Table 2: FY2019 Aggregate Enrollment Data for Extramural and Intramural NIH-Defined Clinical Research
NATIONAL INSTITUTE OF DENTAL AND CRANIOFACIAL RESEARCH
All Domestic and Foreign Sites, Total Reported Enrollment *

<table>
<thead>
<tr>
<th></th>
<th>Total Enrollment by Race</th>
<th>Total Enrollment by Ethnicity</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>American Indian/</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Alaska Native</td>
<td>Asian</td>
</tr>
<tr>
<td>Female</td>
<td>169</td>
<td>467</td>
</tr>
<tr>
<td></td>
<td>0.6%</td>
<td>1.7%</td>
</tr>
<tr>
<td>Male</td>
<td>195</td>
<td>333</td>
</tr>
<tr>
<td></td>
<td>0.7%</td>
<td>1.2%</td>
</tr>
<tr>
<td>Unknown</td>
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<td>113</td>
</tr>
<tr>
<td></td>
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<td>0.4%</td>
</tr>
<tr>
<td>Total</td>
<td>365</td>
<td>913</td>
</tr>
<tr>
<td></td>
<td>1.3%</td>
<td>3.3%</td>
</tr>
</tbody>
</table>

* Number of Inclusion Enrollment Reports (IERs) with Enrollment Data: 123 of 181 total IERs in FY2019
Table 3: FY2020 Aggregate Enrollment Data for Extramural and Intramural NIH-Defined Clinical Research
NATIONAL INSTITUTE OF DENTAL AND CRANIOFACIAL RESEARCH
All Domestic and Foreign Sites, Total Reported Enrollment*

<table>
<thead>
<tr>
<th></th>
<th>Total Enrollment by Race</th>
<th></th>
<th>Total Enrollment by Ethnicity</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>American Indian/Alaska Native</td>
<td>Asian</td>
<td>Black/ African American</td>
<td>Hawaiian/ Pacific Islander</td>
</tr>
<tr>
<td>Female</td>
<td>291</td>
<td>292</td>
<td>2,689</td>
<td>25</td>
</tr>
<tr>
<td></td>
<td>1.6%</td>
<td>1.6%</td>
<td>15.0%</td>
<td>0.1%</td>
</tr>
<tr>
<td>Male</td>
<td>197</td>
<td>241</td>
<td>1,518</td>
<td>12</td>
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<tr>
<td></td>
<td>1.1%</td>
<td>1.3%</td>
<td>8.5%</td>
<td>0.1%</td>
</tr>
<tr>
<td>Unknown</td>
<td>1</td>
<td>2</td>
<td>11</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>0.0%</td>
<td>0.0%</td>
<td>0.1%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Total</td>
<td>489</td>
<td>535</td>
<td>4,218</td>
<td>37</td>
</tr>
<tr>
<td></td>
<td>2.7%</td>
<td>3.0%</td>
<td>23.6%</td>
<td>0.2%</td>
</tr>
</tbody>
</table>

* Number of Inclusion Enrollment Reports (IERs) with Enrollment Data: 128 of 212 total IERs in FY2020
<table>
<thead>
<tr>
<th></th>
<th>Total Enrollment by Race</th>
<th>Total Enrollment by Ethnicity</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>American Indian/Alaska Native</td>
<td>Asian</td>
</tr>
<tr>
<td>Female</td>
<td>304</td>
<td>516</td>
</tr>
<tr>
<td></td>
<td>1.4%</td>
<td>2.4%</td>
</tr>
<tr>
<td>Male</td>
<td>219</td>
<td>406</td>
</tr>
<tr>
<td></td>
<td>1.0%</td>
<td>1.9%</td>
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<tr>
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<td>12</td>
<td>11</td>
</tr>
<tr>
<td></td>
<td>0.1%</td>
<td>0.1%</td>
</tr>
<tr>
<td>Total</td>
<td>535</td>
<td>933</td>
</tr>
<tr>
<td></td>
<td>2.5%</td>
<td>4.3%</td>
</tr>
</tbody>
</table>

* Number of Inclusion Enrollment Reports (IERs) with Enrollment Data: 141 of 272 total IERs in FY2021
Table 5: FY2019 Aggregate Enrollment Data for Extramural and Intramural NIH-Defined Phase III Clinical Trials
NATIONAL INSTITUTE OF DENTAL AND CRANIOFACIAL RESEARCH
All Domestic and Foreign Sites, Total Reported Enrollment *

<table>
<thead>
<tr>
<th></th>
<th>American Indian/Alaska Native</th>
<th>Asian</th>
<th>Black/African American</th>
<th>Hawaiian/Pacific Islander</th>
<th>White</th>
<th>More than One Race</th>
<th>Unknown/Not Reported</th>
<th>Total</th>
<th>Not Hispanic</th>
<th>Hispanic or Latino</th>
<th>Unknown/Not Reported</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female</td>
<td>5</td>
<td>49</td>
<td>1,112</td>
<td>3</td>
<td>1,354</td>
<td>222</td>
<td>172</td>
<td>2,917</td>
<td>1,895</td>
<td>281</td>
<td>741</td>
<td>2,917</td>
</tr>
<tr>
<td></td>
<td>0.1%</td>
<td>1.1%</td>
<td>24.9%</td>
<td>0.1%</td>
<td>30.3%</td>
<td>5.0%</td>
<td>3.8%</td>
<td>65.3%</td>
<td>42.4%</td>
<td>6.3%</td>
<td>16.6%</td>
<td>65.3%</td>
</tr>
<tr>
<td>Male</td>
<td>3</td>
<td>26</td>
<td>481</td>
<td>1</td>
<td>787</td>
<td>132</td>
<td>87</td>
<td>1,517</td>
<td>844</td>
<td>155</td>
<td>518</td>
<td>1,517</td>
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<tr>
<td></td>
<td>0.1%</td>
<td>0.6%</td>
<td>10.8%</td>
<td>0.0%</td>
<td>17.6%</td>
<td>3.0%</td>
<td>1.9%</td>
<td>33.9%</td>
<td>18.9%</td>
<td>3.5%</td>
<td>11.6%</td>
<td>33.9%</td>
</tr>
<tr>
<td>Unknown</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>10</td>
<td>3</td>
<td>20</td>
<td>35</td>
<td>0</td>
<td>31</td>
<td>4</td>
<td>35</td>
</tr>
<tr>
<td></td>
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<td>0.0%</td>
<td>0.0%</td>
<td>0.2%</td>
<td>0.1%</td>
<td>0.4%</td>
<td>0.8%</td>
<td>0.0%</td>
<td>0.7%</td>
<td>0.1%</td>
<td>0.8%</td>
</tr>
<tr>
<td>Total</td>
<td>9</td>
<td>75</td>
<td>1,594</td>
<td>4</td>
<td>2,151</td>
<td>357</td>
<td>279</td>
<td>4,469</td>
<td>2,739</td>
<td>467</td>
<td>1,263</td>
<td>4,469</td>
</tr>
<tr>
<td></td>
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<td>1.7%</td>
<td>35.7%</td>
<td>0.1%</td>
<td>48.1%</td>
<td>8.0%</td>
<td>6.2%</td>
<td>100.0%</td>
<td>61.3%</td>
<td>10.4%</td>
<td>28.3%</td>
<td>100.0%</td>
</tr>
</tbody>
</table>

* Number of Inclusion Enrollment Records (IERs) with Enrollment Data: 7 of 9 total IERs in FY2019
Table 6: FY2020 Aggregate Enrollment Data for Extramural and Intramural NIH-Defined Phase III Clinical Trials
NATIONAL INSTITUTE OF DENTAL AND CRANIOFACIAL RESEARCH
All Domestic and Foreign Sites, Total Reported Enrollment*

<table>
<thead>
<tr>
<th></th>
<th>Total Enrollment by Race</th>
<th>Total Enrollment by Ethnicity</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>American Indian/Alaska Native</td>
<td>Asian</td>
</tr>
<tr>
<td>Female</td>
<td></td>
<td>9</td>
</tr>
<tr>
<td></td>
<td></td>
<td>0.2%</td>
</tr>
<tr>
<td>Male</td>
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<td>5</td>
</tr>
<tr>
<td></td>
<td></td>
<td>0.1%</td>
</tr>
<tr>
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</tr>
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<td></td>
<td></td>
<td>0.0%</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>14</td>
</tr>
<tr>
<td></td>
<td></td>
<td>0.3%</td>
</tr>
</tbody>
</table>

* Number of Inclusion Enrollment Reports (IERs) with Enrollment Data: 8 of 13 total IERs in FY2020
Table 7: FY2021 Aggregate Enrollment Data for Extramural and Intramural NIH-Defined Phase III Clinical Trials
NATIONAL INSTITUTE OF DENTAL AND CRANIOFACIAL RESEARCH
All Domestic and Foreign Sites, Total Reported Enrollment*

<table>
<thead>
<tr>
<th></th>
<th>Total Enrollment by Race</th>
<th>Total Enrollment by Ethnicity</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>American Indian/Alaska Native</td>
<td>Asian</td>
</tr>
<tr>
<td>Female</td>
<td>9</td>
<td>49</td>
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<tr>
<td></td>
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<td>1.2%</td>
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<tr>
<td>Male</td>
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</tr>
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<td>0.7%</td>
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<tr>
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<td>0.0%</td>
</tr>
<tr>
<td>Total</td>
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<td>78</td>
</tr>
<tr>
<td></td>
<td>0.4%</td>
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</tr>
</tbody>
</table>

* Number of Inclusion Enrollment Reports (IERs) with Enrollment Data: 8 of 12 total IERs in FY2021
APPENDIX – ADDITIONAL TABLES

Appendix Table A: NIDCR Total Inclusion Data Records (IERs) for NIH-Defined Extramural and Intramural Clinical Research Reported Between Fiscal Years 2019 and 2021

<table>
<thead>
<tr>
<th>Fiscal Year</th>
<th>Total IERs</th>
<th>IERs Without Enrollment</th>
<th>IERs With Enrollment</th>
<th>US Site IERs</th>
<th>Non-US Site IERs</th>
<th>Female Only IERs</th>
<th>Male Only IERs</th>
<th>IERs Excluding Male only and Female only*</th>
</tr>
</thead>
<tbody>
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<td>123</td>
<td>119</td>
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<td>7</td>
<td>2</td>
<td>119</td>
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<td>8</td>
<td>3</td>
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</tbody>
</table>

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

Appendix Table B1: NIDCR Enrollment for All NIH-Defined Clinical Research, Sex/Gender by Race and Ethnicity

<table>
<thead>
<tr>
<th>Fiscal Year</th>
<th>Sex Gender</th>
<th>Minority</th>
<th>% Minority</th>
<th>Total Enrollment</th>
<th>% Total</th>
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<th>% Not Hispanic</th>
<th>Hispanic Latino</th>
<th>% Hispanic Latino</th>
<th>Unknown Not Reported</th>
<th>% Unknown Not Reported</th>
</tr>
</thead>
<tbody>
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<td>948</td>
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<td>43.2</td>
<td>8,900</td>
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<td>19.8</td>
<td>658</td>
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<td>241</td>
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<tr>
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<tr>
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<td>11,812</td>
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The data presented in this report show only inclusion data records labeled as prospective data. Inclusion data records labeled as existing data are excluded.
## Appendix Table B2: NIDCR Enrollment for All NIH-Defined Clinical Research, Sex/Gender by Race and Ethnicity (continued)

<table>
<thead>
<tr>
<th>Fiscal Year</th>
<th>Sex</th>
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<th>American Indian Alaska Native</th>
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<th>% Asian</th>
<th>Black African American</th>
<th>% Black African American</th>
<th>Native Hawaiian Pacific Islander</th>
<th>% Native Hawaiian Pacific Islander</th>
<th>White</th>
<th>% White</th>
<th>More Than One Race</th>
<th>% More Than One Race</th>
<th>Unknown Not Reported</th>
<th>% Unknown Not Reported</th>
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<td>467</td>
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<td>4,276</td>
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<td>28</td>
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<td>1,766</td>
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The data presented in this report show only inclusion data records labeled as prospective data. Inclusion data records labeled as existing data are excluded.

## Appendix Table C1: NIDCR Enrollment for All NIH-Defined Extramural and Intramural Phase III Clinical Research, Sex/Gender by Race and Ethnicity

<table>
<thead>
<tr>
<th>Fiscal Year</th>
<th>Sex</th>
<th>Minority</th>
<th>% Minority</th>
<th>Total Enrollment</th>
<th>% Total</th>
<th>Not Hispanic</th>
<th>% Not Hispanic</th>
<th>Hispanic Latino</th>
<th>% Hispanic Latino</th>
<th>Unknown Not Reported</th>
<th>% Unknown Not Reported</th>
</tr>
</thead>
<tbody>
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<td>2019 Female</td>
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</tr>
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<td>518</td>
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<td>0.0</td>
<td>4</td>
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</tbody>
</table>

The data presented in this report show only inclusion data records labeled as prospective data. Inclusion data records labeled as existing data are excluded.
Appendix Table C2: NIDCR Enrollment for All NIH-Defined Extramural and Intramural Phase III Clinical Research, Sex/Gender by Race and Ethnicity

<table>
<thead>
<tr>
<th>Fiscal Year</th>
<th>Sex Gender</th>
<th>American Indian Alaska Native</th>
<th>% American Indian Alaska Native</th>
<th>Asian</th>
<th>% Asian</th>
<th>Black African American</th>
<th>% Black African American</th>
<th>Native Hawaiian Pacific Islander</th>
<th>% Native Hawaiian Pacific Islander</th>
<th>White</th>
<th>% White</th>
<th>More Than One Race</th>
<th>% More Than One Race</th>
<th>Unknown Not Reported</th>
<th>% Unknown Not Reported</th>
</tr>
</thead>
<tbody>
<tr>
<td>2019</td>
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<tr>
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The data presented in this report show only inclusion data records labeled as prospective data. Inclusion data records labeled as existing data are excluded.