

*Workshop on Inclusive Participation in Clinical Research*

# **NIDCD's Efforts to Enhance Inclusive Participation in Clinical Research**

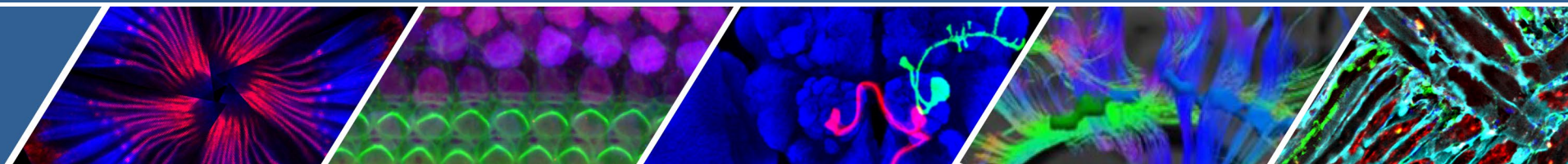
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NIDCD Director

March 30, 2023



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# 2023–2027 NIDCD STRATEGIC PLAN

Advancing the science of communication to improve lives

## Scientific Priorities



**Translate and implement scientific advances  
into standard clinical care**

Goal 3: Promote health equity and improve access to clinical care

## NIH-Wide Crosscutting Priorities



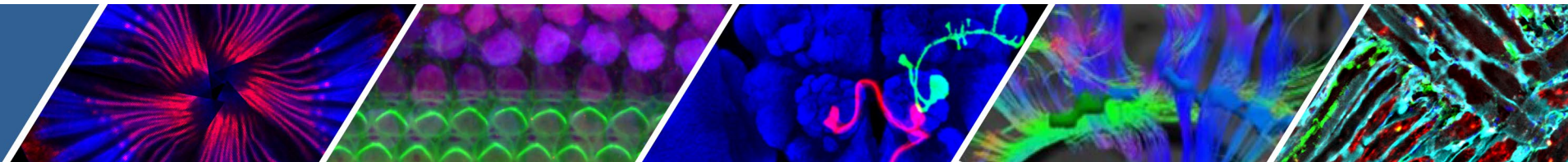
Advance research to improve women's health



Reduce health disparities



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# Promotion of Diversity in Higher Risk Clinical Trials (1)

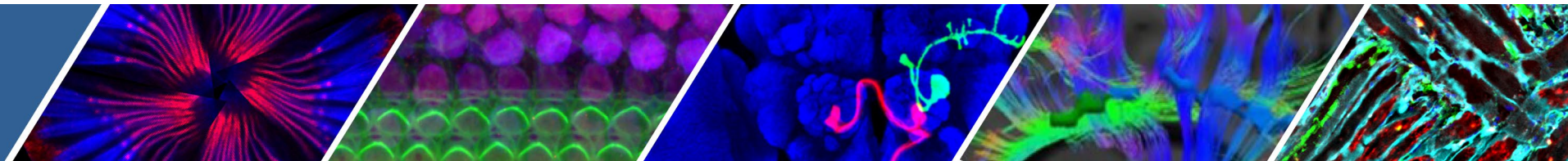
## PAR-21-064: NIDCD Cooperative Agreement for Clinical Trials in Communication Disorders (U01 - Clinical Trial Required)

Encouraged to propose innovative and proactive recruitment strategies for involving underrepresented minority participants:

- Recruitment
  - ▶ Strongly encouraged to propose innovative and proactive recruitment strategies for involving underrepresented minority participants, as applicable and justified by the scientific goals
  - ▶ NIDCD staff review plans prior to award and monitor these recruitment efforts closely.
- Monthly review of descriptions of women and minority outreach and recruitment efforts and monitoring progress by NIDCD CTP staff



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# Promotion of Diversity in Higher Risk Clinical Trials (2)

## PAR-21-064: NIDCD Cooperative Agreement for Clinical Trials in Communication Disorders (U01 - Clinical Trial Required)

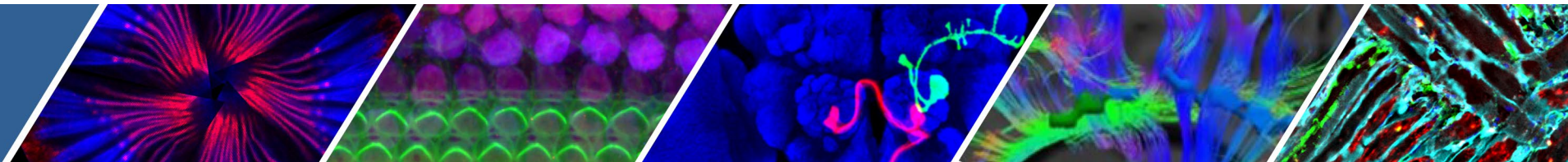
- DSMB recommendations for increased efforts to enhance diversity of participant populations.

“While total enrollment is small, the study team should provide a clear plan describing methods to increase diversity of enrollees going forward. The DSMB recommends efforts by the team to monitor this and if this trend continues prepare for measures to mitigate this and improve diversity of the study population.”

“In order for us to provide meaningful direction on how to address the low enrollment in this important demographic group, we would like to ask you to undertake an examination of the recruitment and enrollment process. Specifically, please examine each step in the process from outreach to enrollment with respect to the distribution of race and ethnicity of participants to assess where in the process African Americans seem to be impacted.”



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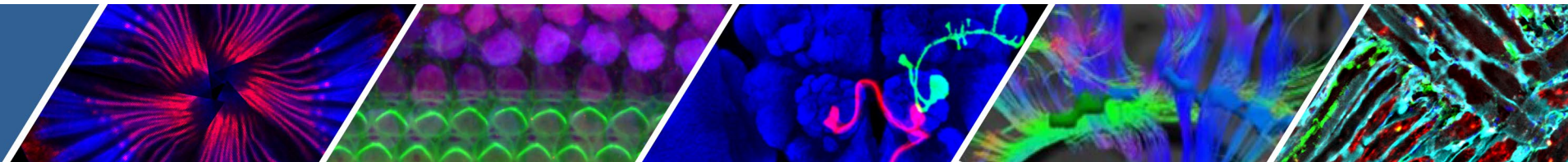
# Reducing enrollment barriers enrollment of children with Spanish-speaking parents

Effects of Hypoglossal Nerve Stimulation on Cognition & Language in Down Syndrome, U01DC019279  
PI: Hartnick, Christopher and Skotko, Brian (Massachusetts Eye and Ear Infirmary)

- Children and parents/guardians
- Removing barriers to Spanish-speaking parents:
  - Providing Spanish as an option for 24-hour technical support for device used in the study
  - Spanish-language consent forms



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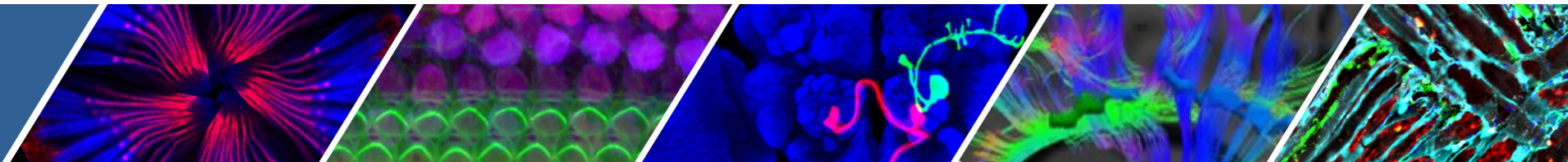
# NIDCD Research Opportunities for New Investigators to Promote Workforce Diversity (R01 Clinical Trial Optional) **RFA-DC-23-001**



- Released April 2022
- Scored Review Criteria: Applications must propose innovative and proactive recruitment strategies for involving underrepresented minority participants, as applicable and justified by the scientific goals.



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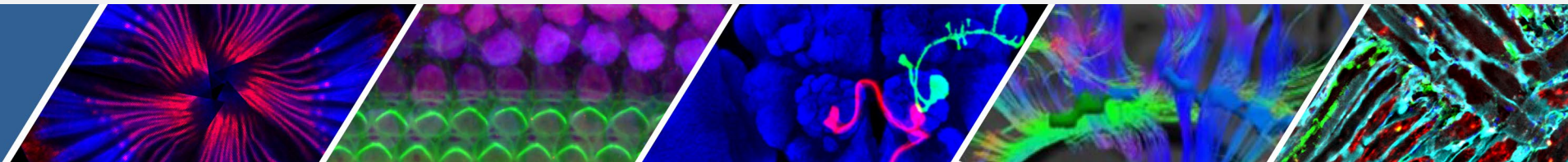
# Decentralized Clinical Trials: Unexpected Outcome from the COVID-19 Response

Decentralized Clinical Trials  
hold promise to reduce patient and sponsor burden  
and increase accrual and retention of a more  
diverse trial population.

<https://www.fda.gov/about-fda/oncology-center-excellence/advancing-oncology-decentralized-trials>



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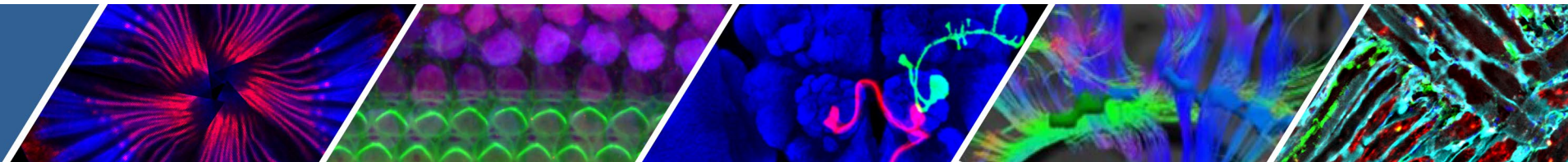
# Inclusion of Special Populations

Sign Here: How to Conduct Informed Consent with Deaf Individuals  
(5R21DC019216, PI: Melissa Lee Anderson, Univ Of Massachusetts Med Sch Worcester)

- Goal: To begin to rectify mistrust and underrepresentation in clinical research.
- Development was inclusive of Deaf researchers, filmmakers, and laypeople.
- Prototype intervention:  
*Sign Here: How to Conduct Informed Consent with Deaf Research Participants*



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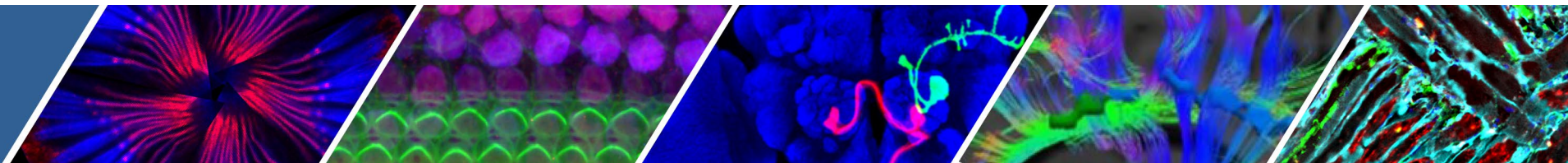




# Diverse Research Teams Facilitate Connections to Diverse Communities



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# Thank You

## 2023-2027 **NIDCD** Strategic Plan



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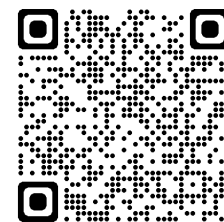


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See the  
2023-2027 NIDCD Strategic Plan  
at:

<https://www.nidcd.nih.gov/about/strategic-plans>



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