

INvestigation of Co-occurring conditions across the Lifespan to Understand Down syndrome (INCLUDE)

Building a Diverse Community for Down Syndrome Research

Listening Session #2—Researchers

May 17, 2022

Welcome and Overview

- *Sujata Bardhan, Ph.D., Program Director at NIH/NICHD Intellectual and Developmental Disabilities Branch (IDDB)/INCLUDE Leadership Team*
- *Linda Garcia, B.A., Communications and Outreach Coordinator for INCLUDE/INCLUDE Leadership Team*
- *Aruna Natarajan, M.D., Ph.D., F.A.A.P., Program Officer NIH/NHLBI and NIH Down syndrome Working Group*

Dr. Bardhan welcomed the attendees. Ms. Garcia reviewed the agenda and the meeting objectives:

- *Provide an overview of the [INvestigation of Co-occurring conditions across the Lifespan to Understand Down syndrome \(INCLUDE\)](#) Project's purpose and objectives.*
- *Encourage inclusion and engagement by listening to community stakeholders.*
- *Understand the needs of the research community to facilitate diverse participation in research studies.*

Dr. Natarajan discussed the importance of research for the Down syndrome community and reviewed the goals of the INCLUDE initiative and the DS-Connect® registry. Key points included the following:

- *The life expectancy of people with Down syndrome has increased from 9 years in 1959 to more than 50 years in 2007, largely due to improved medical treatments.*
- *Launched in 2018, INCLUDE will investigate conditions that affect individuals with Down syndrome and the general population, including Alzheimer's disease/dementia, autism, cataracts, celiac disease, congenital heart disease, and diabetes.*
- *INCLUDE plans to increase participation from diverse backgrounds in Down syndrome research and increase the number of investigators and trainees studying Down syndrome.*
- *In fiscal year (FY) 2021, INCLUDE funded \$65 million of research and 53 new awards.*
- *[DS-Connect®](#): The Down syndrome registry is an online survey tool to collect basic health information about people with Down syndrome. The registry aims to assemble a large study population of individuals with Down syndrome to follow the natural history of the condition. Launched in 2013, the registry currently has about 5,480 registrants.*

- *The DS-Connect® demographics show a predominance of White participants, with very limited representation from [health disparity populations](#), whose unique health problems are often not addressed in global universal research.*
- *The INCLUDE team is beginning to engage communities, listen and learn about positive experiences, and identify barriers and challenges in order to develop actions and initiatives to increase diverse participation.*
- *A workshop, Building a Diverse Community for Down Syndrome Research, is planned for September 20–21, 2022.*

Listening Session Discussion

Erika Tarver, M.S.M., NIH/NIA and INCLUDE Leadership Team

After brief introductions by the attendees, Ms. Tarver moderated responses to five questions.

Share any positive experiences you have had when recruiting a diverse cohort in your research study.

Researchers reported positive experiences with recruiting diverse cohorts when the researchers focused on building trust. They accomplished this by acknowledging the participants' time and effort, facilitating transportation, engaging participants early on, and listening without being defensive. They also fostered relationships with local organizations, employed diverse coordinators, and integrated community partners as equal partners in the research.

- *A researcher said that at her Federally Qualified Health Center (FQHC), the most important factors are trust in whomever is conducting the research and convenient facilitation. Successful efforts have included meeting participants where they are to facilitate recruitment and engagement, helping them complete the study (e.g., by having a video recording of the informed consent), and recognizing their time and effort (e.g., by facilitating transportation to and from visits).*
- *A researcher noted that facilitating transportation has been a game-changer for her older adult populations, along with providing one or two meals (depending on the length of the visit) to populations who are new to research. Also, engaging stakeholders from the beginning has been effective in building relationships with the community. She has worked with a community research advisory board at her institution and learned a lot from community members. Listening without being defensive created a strong bond. Her university-based group is now working on a grant with the community advisory board.*
- *A researcher expressed that, at a university, minority students and researchers have led some of the research work, including making neurotechnology more accessible to Black-haired populations. The experience has been extremely positive for both participants and the research team.*
- *A researcher said that her team has capitalized on fostering relationships with local Down syndrome groups and engaging with families in person. Attending a recent event for Spanish-speaking families was a very positive experience. Her team answered general questions about childcare. This active engagement has helped build trust and*

demonstrated to participants that, “we are here to help them just as much as they would be helping us in our research”.

- *A researcher conveyed that having a diverse group of research coordinators helps families relate to them. His team used video visits when in-person visits to the main hospital were limited during the pandemic. The timing worked for families and facilitated consent. He would like to enroll Spanish-speaking families for his research, but it has been difficult to find interviewers to conduct qualitative interviews.*
- *A researcher noted that a lesson learned from a research colleague is that research is often done in silos; the academic world is not in touch with the community where the research application is supposed to occur. The colleague is breaking down these silos by having researchers and community partners involved as equal contributors. For example, a maternal health project would involve both a representative from a community-based health program and a university-based researcher from a school of public health who would work together to determine clinical questions that make sense to the community.*
- *A researcher agreed with the idea of integrating community partners into research and having them not only as advisors but as members of the research team. Devising ways that NIH could help support these community partners within grants would be helpful.*
- *A researcher said that participants need a consistent and accessible source of expertise and care, and that it is difficult to get funding for clinical work through institutions, such as NIH, that provide only research funding. At FQHCs like hers, it is difficult to develop good research projects while trying to provide care so families can participate.*

What can help facilitate participation in clinical research by people in underserved communities?

Researchers made several suggestions for helping underserved communities participate in clinical research, such as linking the research activity to the participant’s current medical care as much as possible and providing support (e.g., transportation, day care) to keep the burden and “asks” low. They also advised following up to give participants the results, using remote online programs, explaining how the research will help the participants, and conducting focus groups to learn more about barriers.

- *A researcher suggested trying to couple the research activity with the participant’s medical care, as much as possible. It is difficult for families of diverse backgrounds to commit an entire day or morning to the research protocol. If a person is coming in for a blood test for clinical care, for example, the sample for research could be collected with the same puncture.*
- *A researcher said that researchers can remind themselves to keep the burden to the participant as low as possible and their asks reasonable. They should also aim to provide as much support as possible in terms of transportation, day care, meals, and other options to reduce the families’ burden and should be careful about the use of a placebo and the appearance of care as an experiment.*
- *A researcher said that establishing a presence and being seen as a partner before asking the community for help is critical. Also, most treatment studies exclude people who are not English speakers, excluding those individuals from the potential benefit of generating*

generalizable data. Simply having a translator is naïve. More measures for culturally appropriate behavioral phenotyping and behavioral science research are needed.

- *A researcher suggested utilizing remote online programs that can be adapted and disseminated to different communities. During the pandemic, her group adapted burdensome activities, such as completing questionnaires, to be online activities. Outside programs could be used to translate questionnaires or consent forms to other languages to get a more diverse sample of community participants as well as global population samples.*
- *A researcher said that research participants grew tired of meeting researchers and investigators without any follow-up on the outcomes and how the research would help their lives. Also, some Asian communities have some stigma against children with developmental disabilities and are often reluctant to share their experiences without having strong relationships. She noted that investigators also face challenges in investing time and effort. Family commitments and heavy teaching work make engaging with the community every day difficult.*
- *A researcher discussed addressing the broader community of individuals with developmental disabilities—not just Down syndrome. She said that resources could be provided in Spanish to avoid having a Spanish-speaking person go through an interpreter to discuss developmental disabilities.*
- *A researcher said that her team worked with organizations in Colorado to learn how the team’s skill set could benefit the organization and how to better meet the needs of the specific community. Students on the team worked with a local Down syndrome organization to develop plans to evaluate ongoing programming and do baseline and qualitative interviews. Organizations can approach their funders or the community and demonstrate the positive impact of their work. Her team is also conducting focus groups to learn more about barriers to research for families, particularly around parent-mediated early interventions.*
- *A researcher stressed the importance of returning results to families who travel and commit time but learn nothing. Receiving this information creates an incentive to come back to the study or tell others about it. Finding ways to provide information without giving medical advice is important.*

What are the barriers/challenges in recruiting diverse cohorts to take part in research studies?

Attendees were asked to state in one or two words what they saw as barriers or challenges in recruiting diverse cohorts to take part in research studies. More than one answer per attendee was allowed. The responses generated the following word cloud.



Researchers further discussed the barriers and challenges, citing the need for more flexibility in obtaining consent after work hours and alleviating the burden for families. They also noted problems with transportation, inconsistent study partners, and language barriers.

- A researcher said that his institution is rethinking the value of online registries, a passive approach that is not a good mechanism for recruiting diverse samples unless coupled with intense community outreach and targeted social media.
- A researcher expressed that one researcher provided study cell phones for Spanish-speaking participants to enable better communication without using their personal cell phones. This has been comfortable for the research staff and more engaging for families.
- A researcher said that the lack of flexibility in the research operation can be an impediment. He suggested doing remote consents after work hours or on weekends. Making clinical coordinators available after hours can go a long way in facilitating the first steps of obtaining consent.
- A researcher noted that her biggest challenge for testing or developing new interventions was to not burden Asian immigrant families further. It was difficult to encourage them to join as a family. They were fine with allowing their children in the program, but it was not feasible to involve families as caregivers, because they use that time for their own respite care.
- A researcher said that study participants often do not have a study partner who can consistently participate in visits or interviews. In some cases, the research team had to provide a study partner or clinical coordinator to arrange home visits or provide

transportation, which a participant's parent or sibling would normally do. This was expensive, so ways to relieve the need for a consistent study partner would help.

- A researcher said that bridging transportation gaps would help build a larger diverse sample. His team used DS-Connect® to recruit participants and had many responses from across the United States and one from another country. Lack of transportation was the primary barrier for not accepting these people, many of whom came from minority populations with no access to similar research in their hometowns.
- A researcher stated that his team often works with rare conditions and needs to recruit nationally. The team has partnered with advocacy groups and national organizations, but most of these groups are not diverse and provide the same pools of participants. He suggested thinking about ways that research organizations, perhaps including NIH, could help these organizations become more diverse.
- A researcher said it is important to budget for adequately compensating families and participants for their time, meals, transportation, and other expenses. With no money to do this, researchers will end up recruiting a less diverse group.

How can the scientific community build trust with diverse Down syndrome communities?

To build trust with diverse Down syndrome communities, researchers suggested that the scientific community share its knowledge and disseminate information in person as much as possible and always strive to understand and respect diverse cultures. They recommended collaborating with organizations within the community and including community advocates on the research team from the start. They also suggested including students on diverse research teams to help translate research for participants, as well as supporting staff longevity to build long-term relationships.

- A researcher said that it is important to share knowledge and disseminate information in person as much as possible. Trust is built by being present, listening, sharing, and not asking for anything.
- A researcher noted that a program's longevity and a staff who build relationships over time are critical ingredients. Her team has built relationships with families that lasted from when the children were toddlers until young adulthood and have demonstrated a commitment to working hard to answer their questions. She also said that the process for outreach and engagement is time-consuming and requires staff resources. She suggested including vocabulary in budgets and proposals that clearly delineates the percentage of staff effort needed for outreach and engagement. This would allow the team to stay true to their ideals from the earliest stages of project development and have the resources needed throughout.
- A researcher suggested intentionally including advocates from the community by putting them on the research team from the beginning and allowing them to be part of decision making and providing feedback. Collaborating with faith-based groups is also important for building trust, because faith plays a large role for many members of communities underrepresented in biomedical research and relates to their health. Collaborating with fraternities and sororities that are engaged within the community is also helpful. These

intentional collaborations have been successful in communities with children with Down syndrome, as well as in ethnic and racial minority communities.

- *A researcher suggested forming a diverse research team before going to the community. It is important to train researchers or students from underrepresented groups; they have a much better understanding of their communities and can convey the benefits of research more effectively.*
- *A researcher agreed with the importance of a diverse research team and encouraging undergraduate students from underrepresented populations to pursue further education and consider careers in research. Also, research participants are interested in finding out the results of the studies. Graduate or undergraduate students could help by translating research papers into accessible messages for the community.*
- *A researcher said that there is a need to better understand and respect the culture of Asian Americans so they can express their needs and ideas in a comfortable way. The majority are immigrants who, although living in this country for more than 10 years, are not fluent in English or are culturally reluctant to speak up during encounters with healthcare providers.*

How can NIH support your efforts to increase diversity, equity, inclusion, and accessibility in your research studies?

Researchers said that NIH could help support their efforts to recruit diverse cohorts by encouraging technological advancement to develop more accessible biomedical devices and systems. They also suggested involving more students from UBR groups in research and supporting community- and partnership-building in calls for proposals and grant supplements.

- *A researcher said that it would be nice to have an NIH initiative that explicitly focuses on encouraging technological solutions for improving inclusion, diversity, and equity. When working on his project to study headaches, every program manager encouraged him to look at the problems of individuals with textured or curly hair but said it was not something their program could support. Efforts are needed to help support data analysis and develop biomedical devices and systems that are accessible to more people.*
- *A researcher suggested including more students (both graduate and undergraduate) from underrepresented groups in research so they can remain in the pipeline and prepare for the next stage of research. He also suggested including community- and partnership-building efforts in call for proposals or using the administrative supplements to existing grants.*

Wrap-Up and Closing Thoughts

Dr. Natarajan and Dr. Bardhan

Dr. Natarajan briefly summarized the attendees' ideas and suggestions, which included helping national organizations address diversity, improving flexibility in scheduling, addressing the need for a study partner to accompany participants throughout the study, discussing compensation, and resolving logistical barriers. Major topics focused on building trust, sharing in-person experiences, having advocates in faith-based groups, and collaborating with minority students

and researchers. NIH can support efforts to increase diversity by melding clinical care with research, including community support in funding, and addressing the role of medical devices geared toward inclusion. Diversity, community-building, and technological solutions should be considered in the evaluation of every scientific study.

Attendance

23 Researchers

8 NIH

3 Unknown