Institutional Best Practices for Facilitating Engagement of Diverse Populations in Clinical Trials

This document was created to support the HB 1745 community engagement workgroup and provides a summary of best practices that research institutions can implement to help achieve the goal of diverse participation in clinical trials. These best practices have been complied by the Integrating Special Populations Program of the Institute of Translational Health Sciences (ITHS), based on critical input from the Health Equity Research Community Advisory Council, which advises ITHS and Seattle Children's Research Institute.

INSTITUTIONAL BEST PRACTICES

Building, supporting, and training a diverse research workforce

An important strategy for increasing the diversity of clinical trial participants is to increase the diversity of the research workforce by building pathways for people of color, lower income populations, rural populations, LGBTQIA+, and those otherwise underrepresented in biomedical and health research fields. A more diverse research workforce is essential for conducting the best science, and when individuals are asked to participate in research, it is critical that they can see themselves reflected in the research team.

- Implement programs (e.g., paid summer internships, career developmental awards, mentorship programs) that offer individuals underrepresented in biomedical and health research, opportunities to gain exposure to or enter the field at multiple points in their education and career. (See Seattle Children's Research Institute Summer Scholars Program, as an example.)

Equity, diversity, and inclusion (EDI) in research will only increase through changes in both intra- and inter-personal attitudes and behaviors among research teams and changes within institutional structures, policies, and opportunities that enable equitable research practices.

- Provide research-focused EDI training and education for research teams. EDI trainings are becoming more common in academic and research institutions, yet most organizations do not offer EDI training that is specific to researchers or research teams. *EDI excellence in research training* has been developed by the Integrating Special Populations Program at the Institute of Translational Health Sciences (ITHS) and has been offered by Seattle Children's Research Institute.

Establish language access for participants who speak a language other than English

- Include translation (written) and interpreter service (spoken) costs in budgeting and negotiations for all clinical trials
- Provide translation and interpreter services to research teams regardless of budget
- Hire bilingual and multilingual research staff

- Provide language certification consistent with the needs of the research environment for bilingual and multilingual research staff
- Offer a library of templates for IRB consent and other documentation available in multiple languages
- Provide a process to enable rapid translation and approval for research materials (e.g., consent forms) in multiple languages
- Consider utilizing alternatives to written materials (e.g., videos for IRB consent, audio and voice communication for web-based surveys on smartphones), and make these available in multiple languages

Offer flexible research processes for participation

- Allow the research team to select the participant incentive method(s) that best serves their research population; these may include electronic gift cards, payment cards, and cash.
- Ensure policies exist and are utilized that provide guidance about and require fair compensation for participants
- Provide needed supports for participating in research such as transportation to study visits or childcare
- Offer remote methods of participation (e.g., telehealth study visits), as well as the supports needed to access them (e.g., wifi hotspots, devices)

Engage community stakeholders

- Ensure community voices from diverse populations are included in research policy discussions and decision making at the institutional level
- Include, train, and appropriately compensate community members on IRB committees, and other councils, taskforces, or committees that inform research policies and practices or research studies.
- Provide needed supports such as transportation, interpreters, child care, and fair compensation to reduce barriers to participation for community members.
- Create opportunities for research participants and community members who are not already engaged in research to share their research priorities, concerns, and feedback
- Integrate community/patient/participant leaders from diverse communities into research administration and leadership

Eliminate barriers to effectively partner with communities in research

- Ensure that policies exist and are utilized that allow research teams to easily partner with and compensate community organizations for their partnership in research. Examples of this include the "community collaborator" policy at Seattle Children's, which gives research teams a mechanism to pay community members for their expertise.
- Enable use of participant-centered strategies for study visits and data collection (e.g., photo-enhanced translated instructions to help with parking kiosks, building names, and locations, clearly marked Uber/Lyft drop off location near building, Zoom/phone options for completing forms, evening/weekend study visits, escort to/from parking/bus and clinic).

Strengthen IRB and other review to ensure that trials have a clear plan to use equitable practices for participants

- English-only studies should be discouraged, and only approved when researchers have clearly exhausted all possibilities to expand language access.
- Studies should demonstrate a plan and ability to recruit a diverse patient population—when this is not clearly stated, the IRB can refer researchers to an institution-provided consultation service for EDI in research planning.
- Establish institution-supported consultation services regarding EDI in research planning, implementation, and dissemination
- Require plain language on all participant-facing content