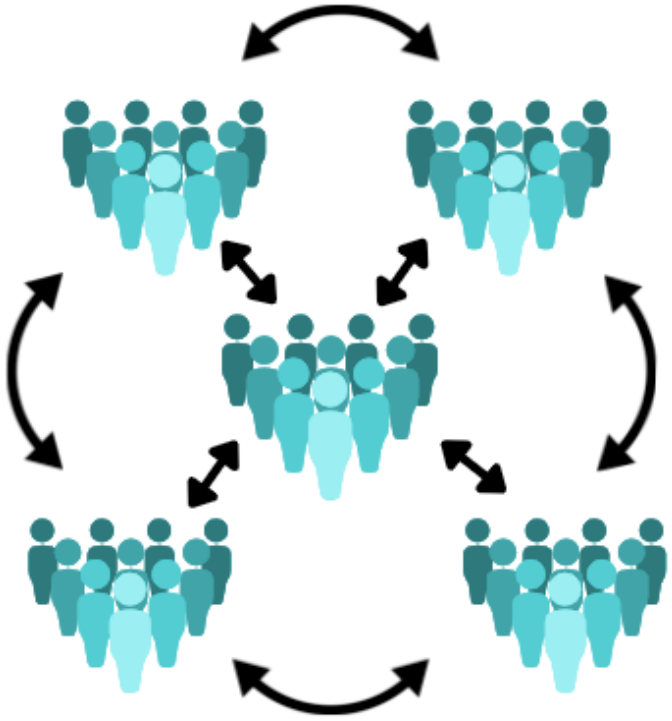
ASSERT (All StakeholderS Engaged in Research Together) Procedure Manual



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Background

This procedure manual describes the actions and processes necessary to implement a program for stakeholders interested in co-creating research focused on people with intellectual and developmental disabilities (IDD). Stakeholders include self-advocates (adults with IDD), family advocates (parents, spouses, siblings of people with IDD), clinicians who care for adults with IDD, and researchers. The goal of our program is to drive research forward that is responsive to the IDD community, with stakeholders working together, being an essential part of this mission. Objectives for patient- and family stakeholders included being equipped to develop future patient-centered outcomes research (PCOR) and research questions to address the challenges encountered during adulthood. Objectives for clinicians and researchers were to build skills in partnering with various stakeholder groups and learning ways to improve research and delivery of care to people with IDD.

This program was funded by a Patient Centered Outcomes Research Institute (PCORI) Eugene Washington PCORI Engagement Award (#EASC-IDD-00233). Program co-leads were Beth Malow, MD, MS, Professor of Neurology and Pediatrics at Vanderbilt University Medical Center (beth.malow@vumc.org), and Susan Brasher, PhD, RN, CPNP, FAAN, Assistant Professor at the Nell Hodgson Woodruff School of Nursing, Emory University (susan.n.brasher@emory.org). Drs. Malow and Brasher are appreciative to those reading this manual for your interest in wanting to continue this important work and welcome your feedback, questions, and future collaboration.

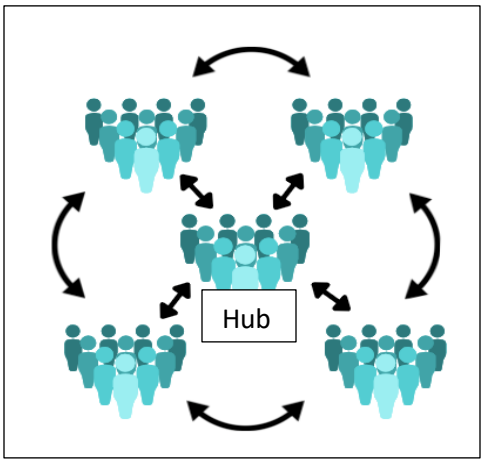
The statements presented in this manual are solely the responsibility of the authors and do not necessarily represent the views of the Patient Centered Outcomes Research Institute® (PCORI®), its Board of Governors or Methodology Committee.

Advisory Board

An advisory board consisting of self-advocates (adults with IDD), family advocates (parents, spouses, siblings of people with IDD), clinicians, researchers, payors, and advocacy group leaders met throughout the project to review and guide this process.

The ECHO Model

The ECHO Model is a learning community that is **collaborative** and **multidirectional** (all learners gain knowledge from each other). At its foundation, Project ECHO is a framework for educating groups of people (e.g., clinicians) that has been applied to hundreds of topics with partners in 40 countries and has trained more than 140,000 professionals. Project ECHO uses secure video conferencing to connect learners in local communities to a team of experts (hub) built on the principle of “all teach and all learn.”



The ASSERT ECHO Model leveraged these principles to extend the collaborative and multidirectional format to create a virtual community of people with IDD (e.g., Trisomy 21, Spina Bifida, Tourette Syndrome, Autism Spectrum Disorder), including those with a range of communication preferences (e.g., verbal, type to speak, written

communication in chat), and family advocates, clinicians and researchers. A key component of this program was the co-creation of future research that is patient centered.

Program Structure

The ASSERT ECHO program consisted of stakeholders (e.g., self-advocates, family advocates, clinicians, researchers). It is recommended that no more than 25 participants be enrolled in each cohort, to provide for ample engagement along with diverse perspectives. A subset of ASSERT ECHO participants with IDD experience served as the expert "hub" team and helped facilitate sessions (e.g., lead topics, go into breakout rooms with participants to keep discussions on track) although everyone contributed to the discussion. We found that overenrolling self-advocates (e.g., having 7-8 of the participants be self-advocates) was beneficial for ensuring diverse perspectives. The self-advocate group was also vulnerable to needing to leave the program due to employment or educational constraints and overenrolling ensured there would be an ample number of self-advocates throughout the program.

Each cohort of participants met twice a month for six months, for 90 minutes each session. The advantage of a twice monthly meeting is that it provided ample time to build relationships and sustain engagement, as well as allowed time for the organizers to prepare each session and send out materials to participants prior to the session and following the session. A 90-minute session proved to be an ideal duration for ECHO ASSERT sessions that provided time for participants time to interact and learn topics at an enjoyable pace, while not excessively long that it interfered with work or other schedules or led to people being disengaged during sessions.

Session Structure

Each session consists of the following elements:

1. Introductions (10-15 minutes). Everyone introduces themselves starting with non-hub team (referred to "spoke" participants in the ECHO model), then the "hub" team (experts with ECHO experience), and then coordinators. This is consistent with other ECHOs and helps build community.
2. Topic Introduction. Stakeholder facilitators introduce the topic for the ECHO session to all of the participants.
3. Engage in Breakout Sessions. Participants engage in breakout sessions, with facilitators helping to frame the discussions. Breakout groups discuss the ECHO session topic in more depth.
4. Group Share. Participants return to the main session all together to summarize what they discussed in their breakouts. They share their questions, concerns, and solutions to shape future research.
5. Lightbulb Moments. Participants reflect on one thing that resonated or deeply impacted each stakeholder.
6. Announcements (5 minutes). For example, mentioning the next session topic or any housekeeping items such as completing forms for reimbursement.
7. Evaluation. Participants complete a brief evaluation of the ECHO session so that we can learn what worked and what need to be improved.

Please see **Table 1** for more details of topics discussed at each session.

Preparing for the Project

IRB and the Consenting Process

Eligibility criteria to participate in ASSERT ECHO included:

1. Ability to provide informed consent.
2. Commitment to attend ECHO sessions regularly.
   Identify as a self-advocate, family advocate, clinician, or researcher with interest to contribute towards the purpose of the project.

To determine informed consent and ability of IDD self-advocates to participate in the project, one of the ASSERT ECHO co-leads met one-on-one with each self-advocate via Zoom and followed the informed consent procedures outline by Bailey (2013) that asked the following questions of participants to determine informed consent:

1. Please tell me, in your own words, what is this study about?
2. What will you be doing if you take part in this study?
3. What are the risks of being in this study?
4. When I say your taking part is completely voluntary, what does that mean to you?
5. When I say that your answers will be kept confidential, what does that mean to you?
6. What can you do if you start the study but don't want to finish it?

The questions assessed the extent to which participants understand the study information that had been presented to them. Level of understanding was used to assess appropriateness for participation in the ASSERT ECHO project, and whether they were able to provide informed consent. The terms within the questions were explained as needed. For more details, please refer to the peer-reviewed article this approach was based [Horner-Johnson W, Bailey D. Assessing Understanding and Obtaining Consent from Adults with Intellectual Disabilities for a Health Promotion Study. J Policy Pract Intellect Disabil. 2013;10(3):10. PMID: 24223054; PMCID: PMC3821759).]

Preparing for Each Session

ASSERT ECHO Email Reminders, Zoom Link, and Calendar Invites

Our study team emailed the participants two to three days prior to a session with the following: Zoom link, materials for the upcoming session, and an agenda. Additionally, our study team created a calendar invitation to increase accessibility and ease of access and reminding.

Session Summaries

After each ASSERT ECHO session, a summary was sent to all participants. These summaries helped participants recall what was discussed and perspectives shared at the sessions.

Summaries were structured to include the following:

1. Key points from the topic intro. These points summarized the information covered in the presentation’s topic intro.
2. Anonymous quotes that our team found insightful that participants shared during the breakout discussion and group share.

3. Anonymous quotes from the “lightbulb moments”.

   Summaries were concise (aiming for one page or less) and in plain language with ample spacing, so it was easy for all participants to read.

   After the summary was written, they were sent to two of the participants to review. This allowed participants the opportunity to review whether the information in the summary accurately captured what was shared at the session. It is important to remember the summaries can share sometimes vulnerable perspectives and experiences. This is why it was crucial to have participants review session summaries to ensure accuracy and approval before distribution.

Pre- and Post-Surveys

Pre- and post-surveys were distributed to participants to identify concepts that participants were expected to master by the conclusion of the project. These surveys allowed the team to determine whether the project met the established goals and whether any changes should be made for future ECHOs. The pre-survey was sent after the participant signed the consent and before they started the first session. This provided a baseline assessment of the experiences of each participant prior to engaging in the project. Pre-surveys evaluated the confidence of participants on each of the research concepts that would be presented. Confidence was rated on a six-point Likert scale (no confidence to high confidence). For example, participants rated their confidence level in “Understanding what the informed consent means in research”, “Knowing ways to share research with others”, and “Identifying types of research.” We also asked their confidence levels in talking to others about research.

Post-surveys were distributed at the conclusion of the 12 sessions. They asked the same questions as the pre-survey using the six-point Likert scale to determine changes. Additionally, post-surveys asked participants to rank their perception of organization of the project on a five-point Likert scale with “Agree” to “Disagree” to determine if the organization of the project was successful. For example, the questions included “My role was clearly defined on this project”, “I understood what was expected of me.”, and “Participating in this project benefitted me professionally.” Post surveys concluded with an optional open response section to hear more from participants on what they enjoyed about the project and if they had any further feedback. The post survey should be sent a few days after the last session.

Feedback Surveys

After each session, feedback surveys were sent to participants to identify important points of feedback. In our ECHO, we wanted to know if participants felt heard, valued, trusted, and if they felt we were building a community. These questions were asked in Yes/No format. Additionally, participants were asked if they felt the session was meaningful to them, how the variety in the group strengthened discussion, and how the ECHO format of the session strengthened the discussion. Participants were asked if the topic intro, breakout rooms, and group share were “too short”, “too long”, or “just right” amount of time. These questions helped gauge whether we were successfully achieving our goals after each session.

Table 1. Examples of ECHO Sessions

Session number	Topic	Description	Discussion Questions
Pre-Session	**Introduction to ECHO**	What is ECHO, and why are we here?	Participants engage in **mixed** breakout groups (all stakeholders represented in each group) to discuss the following question: **How can we best support each other during the ECHO sessions so that everyone can fully contribute?**
1	**Introduction to goals of the project**	What is PCORI and what is our mission?	Participants engage in mixed breakout groups to discuss the following questions: **What excites you about this project?** **What strengths do you bring to this project?**
2	**Informed Consent**	Institutional Review Board (IRB) representatives* present the elements of informed consent * An experienced hub team member may also present this information	Each stakeholder group (self-advocates, caregivers, clinicians, and researchers) engages in separate breakout groups to review and improve a "poorly written" consent form. • **Voluntary participation (family advocates)** • **Risks & Benefits (self-advocates)** • **Clarity & Relevance (researchers)** • **Confidentiality (clinicians)** Participants are also asked to discuss: **What is important in consent?** **Share your positive/negative experiences with informed consent.**
3	**Types of Research**	Explore the strengths and weaknesses of these study designs: • Case Report & Case Series • Cohort Study • Randomized Clinical Trial • Comparative Effectiveness Study	Participants engage in **mixed** breakout groups to discuss the following questions: **What are the strengths of this type of study design?** **What are the weaknesses?** **What problems do you see?**

4	**Sharing Research Results**	What is the importance and methods of dissemination of research findings? Include poll for participants to choose which of the following methods would work for them the best: • Zoom meetings • Email • Websites • Social Media • Podcast • Video/YouTube • Books/Magazines • Other	Participants engage in **mixed** breakout groups to discuss the following questions: **How have you been notified of research results?** **What worked and what didn't work for you?** **What methods of sharing information would you prefer?**
5	**Patient-Centered Outcomes**	What is meant by patient-centered outcomes?	Participants engage in **mixed** breakout groups to discuss the following questions: **What are the strengths of patient-centered outcomes?** **What are the weaknesses of patient-centered outcomes?** **What challenges do you see for our work?**
6	**What do we call ourselves?**	A variety of terms have been used to describe people on the autism spectrum, with Down syndrome, with Tourette syndrome, and with other differences. What terms should we use to describe our self-advocates and the people we care and involve in research? Articles were sent before the meeting. Participants were encouraged to read this article. Below is one example of an article, but other articles can be used. What Does It Mean to Be Neurodivergent and What Is	*In place of a breakout group, clinicians and researchers turn cameras off and observe interview, to promote focused discussion with self-advocates and family advocates.* *Project co-lead interviews Hub team self-advocate and a family advocate, and then opens the questions to other self-advocates and family advocates who are willing to speak or respond via chat.* In group discussion, self-advocates discuss this question, followed by family advocates. **What do you prefer to be called (or to have your loved one called)? Why?** Then family advocates answer the following question, followed by self-advocates.

		Neurotypical vs Neurodivergent? (shape.com)	**What terms do you not like? Why?** *Clinicians and researchers turn on cameras and answer the following questions*: **What was the most impactful thing you observed in today's session?** **What surprised you in today's session?**
7	**Stakeholder Advocacy**	How can stakeholders & researchers co-create research?	Each stakeholder group (self-advocates, caregivers, clinicians, and researchers) engages in separate breakout groups to discuss the following questions: **What does meaningful stakeholder participation look like to you?** **How do you get people engaged?** **What ways foster co-creation?**
8	**Building Trust**	How can researchers and stakeholders build trust together?	Self-advocates and family advocates engage together in breakout groups to discuss the following questions: **Can you think of a time that your trust strengthened with a clinician or researcher? What did they do? What did you do?** **Now think of a time that trust was broken with a clinician or researcher. What did they do? What did you do?** **How has building trust been affected by COVID/being on-line?** At the same time, clinicians and researchers engage together in breakout groups to discuss the following questions: **Can you think of a time that your trust strengthened with a patient/family? What did you do? What did they do?** **Now think of a time that trust was broken with a patient/family. What did they do? What did you do?**

			Has building trust been affected by COVID/being on-line?
9	**Consuming Research**	Invited experts to present on a topic related to consuming research For example, Applied Behavior Analysis* and how to navigate articles and data on this topic. *A different topic can be substituted for ABA. The purpose was to present a topic that has been viewed in two ways across consumers.	Participants engage in **mixed** breakout groups to discuss the following questions: **When you think of ABA, what comes to mind?** (a different topic can be substituted for ABA) **What have been your experiences with ABA?** (a different topic can be substituted for ABA) **How do you decide if research is credible/evidence-based?** **<u>Large Group Discussion</u>** **What have you heard today that has influenced your view of ABA?** (a different topic can be substituted for ABA) **What changes are needed, if any, that might help ABA be practiced more ethically?** (a different topic can be substituted for ABA)
10	**Creating Research Together**	Discuss how we think through a research topic as a team of clinicians, researchers, self-advocates, and family advocates	Participants engage in **mixed** breakout groups to discuss the following questions: **<u>Part 1</u>** **Brainstorm and Discuss Research Topic Ideas** <u>Self- Advocates and Family Advocates</u>: What do you think should be researched further? Think of what a meaningful research project would study. Research ideas can be influenced by the questions and topics you may have discussed with your healthcare clinician. They can also be influenced by what you heard others talk about, things that you have wondered about, or think may be important to study. <u>Clinicians</u>: You will help determine the clinical relevance of potential research questions, and any human subjects' issues. What have you seen in clinic? For a given research question, any human subjects concern to be aware of?

			Researchers: You will help identify the best way to construct a research project to address the interests raised by our advocate groups. What type of research study would be suited for the topic? What data (variables) should be collected? **Part 2** **What topics are you most excited about? (List topics you wish someone would research)** **What did you learn about research today?**
11	**Creating Research Together**	Participant discussion of an article relevant to a topic discussed during Session 10 The article along with a summary in lay language was sent by email ahead of the meeting.	Participants discuss the following questions from the article or article summary in **mixed** breakout groups to discuss the following questions: **What did you like about the study?** **What could be improved on?** **If you were designing the next phase of this study, what might your sample look like (e.g., # of people, ages, etc.)** **What type of research approach would you recommend (e.g., case study, cohort study etc.)?** **What types of methods would you recommend (e.g., qualitative, quantitative)?**
12	**Where Do We Go from Here**	Participant discussion on how to capitalize on momentum	Participants discuss the following questions together in a large group discussion (no breakout groups): **What would you like to see happen as next steps after ASSERT ECHO?** **What areas or topics would you like researchers to focus on?** **What are creative ways we can include individuals with disabilities in research?**