ECHO PROGRAM OFFICE

Strategic Plan
2020 – 2024

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I. Opening

The Environmental influences on Child Health Outcomes (ECHO) Program is an extramurally funded program maintained within the Office of the Director at the National Institutes of Health (NIH). The ECHO Program is currently in its fifth year of funding. The NIH ECHO Program Office developed a strategic plan to assess the program's overall direction and focus its priorities. This strategic plan articulates the mission and vision of the Program Office and will be its roadmap for success.

The purpose of this strategic plan is to guide the ECHO Program Office to implement a strategic direction for the next phase of its work, which allows for: opportunities to assess staff roles and re-prioritize activities; a process for information gathering and analysis; landscape assessment and analysis; development of program office strategic goals, objectives, and key measures of success.

The strategic planning process consisted of a series of three main steps: 1) information gathering and analysis—defining the planning process, gathering data on external environment and internal performance, and refining strategic issues; 2) landscape assessment and analysis—gathering input from ECHO component representatives and collating strategic analysis and input on goals, etc.; 3) development of the strategic plan—performing interviews with Program Office staff to define key measures of success, preparing an initial draft of the strategic plan, gathering feedback, and refining the strategic plan.

Through this process of developing the strategic plan, the ECHO Program Office clarified its mission and roles, strategic goals and objectives, and key measures of success. We also identified staff tasks and responsibilities that align with the strategic goals and objectives. Additionally, the Program Office developed a process for monitoring and adapting strategy over time to achieve desired program outcomes.

II. ECHO Program Overview

Following the closure of the National Children's Study in December 2014, Dr. Francis Collins, the NIH Director, emphasized the importance of and need for research addressing the links between the environment and child health and development. Early in 2015, NIH created a working group to develop a plan to address research at the intersection of pediatric and environmental health. This working group comprised representatives from 16 Institutes, Centers, and Offices within the NIH. To gather feedback from external communities on the direction of the plan, the working group coordinated numerous outreach activities including Stakeholder Roundtables in mid-July 2015; three webinars in late July 2015; and Requests for Information (RFI) on the ECHO Program in July and August 2015.

In September 2016, NIH launched an initiative, the ECHO Program, whose mission is to enhance the health of children for generations to come. The Program has two major components, the ECHO Cohorts – for observational research, and the ECHO IDeA States Pediatric Clinical Trials Network (ISPCTN)– for interventional research.

ECHO fulfills two congressional mandates: 1) that NIH continue a large-scale, long-term research study to investigate a broad array of early environmental factors influencing child health and 2) that NIH has a network dedicated to pediatric diseases as dictated in the CURES Act of 2016. With the ECHO Cohorts, NIH complies with the Child Health Act of 2000 through the incorporation of longitudinal cohort studies with a recruitment goal of 50,000 participants. As of March 2020, the Cohorts have enrolled an estimated 34,000 mothers and 50,000 children. The IDeA States Pediatric Clinical Trials Network (ISPCTN) helps to fulfill the original intention of the National Pediatric Research Network Act of 2013, which the 21st Century Cures Act made mandatory in 2016.

NIH funded the observational component—the ECHO Cohorts, along with supportive Cores, Centers, and Resources—for seven years. While the goals of the ECHO Cohorts are consistent with those of the former National Children's Study, the approach is different. The ingenuity of ECHO is to capitalize on existing participant populations that include more than 50,000 children from diverse background across the United States, and support approaches that can evolve with the science and take advantage of technological advances.

ECHO supports multiple, synergistic, longitudinal studies to investigate how environmental exposures—including physical, chemical, social, behavioral, biological, and natural and built environments—influence child health and development. The studies focus on five key pediatric outcomes that have a high public health impact 1) pre-, peri-, and postnatal outcomes, 2) upper and lower airway, 3) obesity, 4) neurodevelopment, and 5) positive health (added in 2017).

In addition to supporting individual cohort science, the main aim of the ECHO Cohorts is to bring separate cohorts together into one large ECHO-wide Cohort so that ECHO investigators and the wider community of scientists can address research questions about effects of a broad

range of early environmental exposures on child health and development, questions that no single cohort, or even a few, can answer alone. The cohorts consist of children and their mothers (and some fathers). In most cases, cohorts recruited participants prenatally; all cohorts are following children long term.

In its first four years, ECHO created a sophisticated ECHO-wide Cohort data collection protocol; activated the majority of cohort sites to implement the ECHO-wide Cohort Data Collection Protocol; is beginning to populate extant data and new data on ECHO-wide Cohort data platform and share previously and newly collected biospecimens; developed ECHO-wide Cohort organizational functions and policies regarding many activities, including consortium publications and data/specimen sharing; performed collective analyses that address determinants of preterm birth, incidence of asthma, and prevalence of childhood obesity; and published review articles about salient scientific issues in ECHO. In total, ECHO funds have supported ~600 publications, mostly from individual cohorts, that address many ECHO-related aspects including maternal diet during pregnancy and epigenetics, sophisticated study designs to address both genes and environment, and aspects of placental development.

The aim of ISPCTN—initially funded for four years and renewed in 2020—is to provide access to state-of-the-art clinical trials to rural or medically underserved populations and build national pediatric research capacity to conduct clinical trials and compete for future funding. While continuing to build research capacity at its 18 clinical sites and Data Coordinating and Operations Center, ISPCTN is conducting multi-site clinical trials as well as feasibility studies to underpin future trials. Pediatric clinical trials are rare, especially in rural or underserved populations, so there is limited evidence for preventing, diagnosing, or treating pediatric conditions. ISPCTN helps address this disparity in pediatric research on rural or underserved children in clinical trials, by focusing on health issues that affect these children and their families, and by building pediatric research capacity in states with historically low NIH funding. The network provides a broad scope of research not limited to a single population, specialty, condition, or age group.

During the first cycle of the ISPCTN, the ISPCTN clinical sites participated in the NICHD Pediatric Trials Network study of pharmacokinetics of medications routinely used in, but not FDA-approved for, pediatrics. ISPCTN is currently enrolling children in a pharmacokinetic trial of vitamin D supplementation in children with obesity-related asthma and is recruiting participants for a pilot study of a mobile-health healthy weight intervention in children from rural or underserved populations. In addition, as a part of the NIH Helping to End Addiction Long-term (HEAL) Initiative, ISPCTN completed a cross-sectional study of over 1800 mother-infant dyads, from 30 hospitals across the nation, of Neonatal Opioid Withdrawal Syndrome (NOWS), which showed large variation across sites. ISPCTN is currently activating sites for two trials to improve care for infants with NOWS.

Both the ECHO Cohorts and the ISPCTN have responded to the 2020 COVID-19 pandemic with new ideas for scientific advancement related to the coronavirus as well as plans for innovative ways to conduct research remotely.

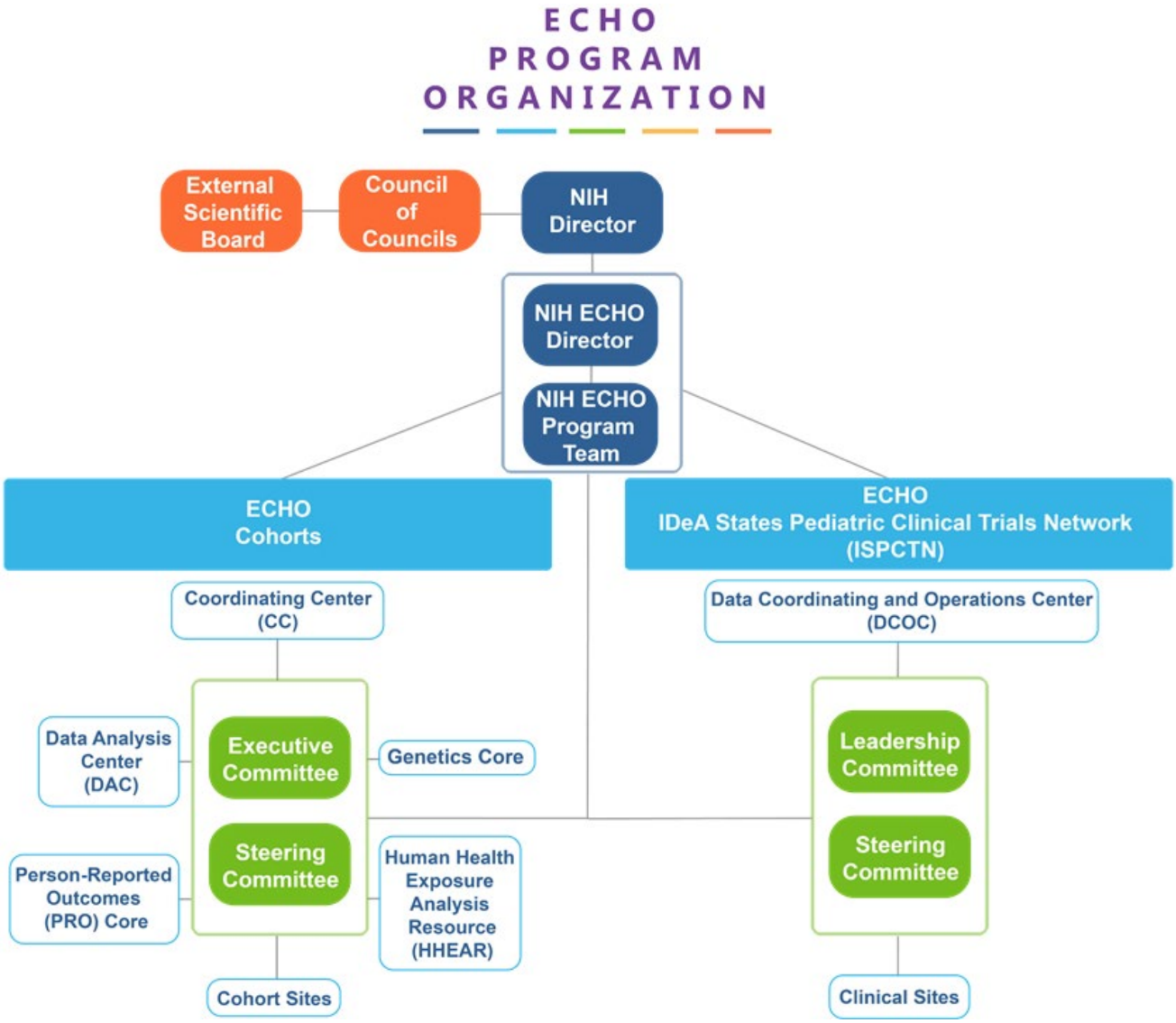
III. ECHO Program Governance

Under cooperative agreements, ECHO Cohort leadership began as a triad, consisting of the ECHO NIH Program, Data Analysis Center, and Coordinating Center. Leadership of the program then evolved to including an Executive Committee, composed of two members from Cohort awards and one member from each of ECHO's other six components, including ISPCTN. Now, as presented in the ECHO Program Organization chart in Figure 1, ECHO Cohorts kept the Executive Committee, to address issues related to strategy and resource use, and added a Steering Committee composed of one member from each award, including 31 from the cohorts and one from each other component. The Steering Committee is empowered to provide the authority in scientific issues, thus empowering investigators to drive the science. ISPCTN is also moving to a similar governance approach that invests authority for strategy and resource use in the Leadership Committee and scientific leadership in the Steering Committee.

The NIH ECHO Program Office sets scientific and collaborative vision, ensures that components adhere to NIH policies, and provides funding, including incentives for working together so that the ECHO whole is more than the sum of the parts. Given its role in ensuring maximum return on taxpayer investment, the NIH reserves the right to make final decisions on any ECHO matter.

This Strategic Plan is explicitly for the Program Office, rather than the Program itself. Nevertheless, it inextricably ties to the Office's goals for the entire Program.

Figure 1: ECHO Program Organization

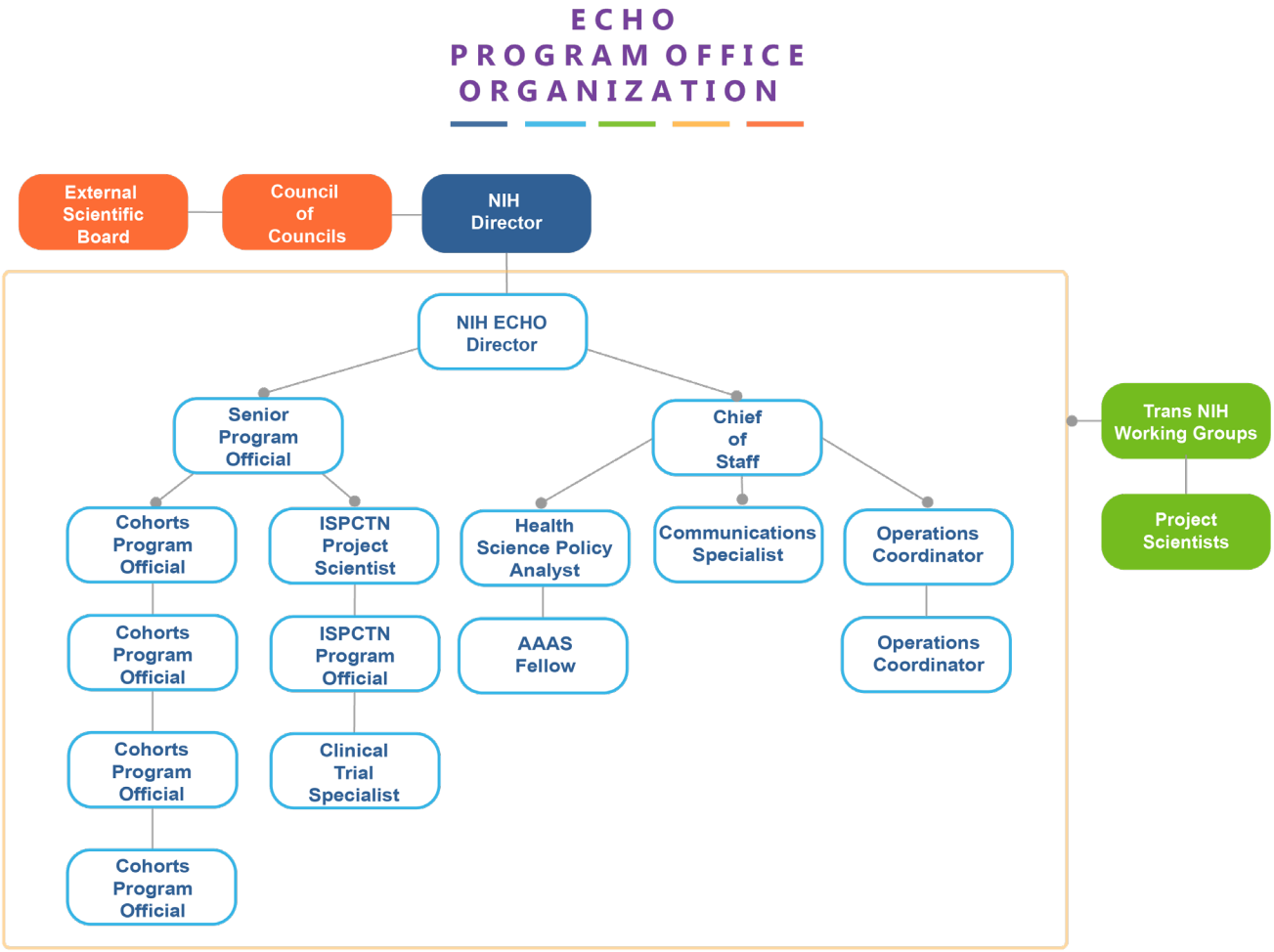


IV. ECHO Program Office Organizational Function

The ECHO Director leads the Program Office and reports to the NIH Director. In addition to the Director, the Program Office consists of 14 staff with a range of expertise who comprise program officers, project scientist, clinical trials specialist, AAAS Science & Technology Policy Fellow, and administrative roles (Figure 2). Functionally, the Director, Senior Program Officer, and Chief of Staff together set the direction of the Office. An External Scientific Board, whose role it is to consider how to overcome challenges to the ECHO Program and to provide feedback that is useful for the NIH ECHO Program Office, meets twice yearly, and reports to the Council of Councils, who advises the NIH Director on ECHO progress.

A range of subject matter experts from across the NIH provide additional counsel to the ECHO Program Office. For specific activities, ECHO has collaborated with numerous NIH Institutes, Centers, Offices, and Programs, including NCI, NHGRI, NHLBI, NIBIB, NICHD, NIDA, NIDCR, NIEHS, NIGMS, NIMH, NIMHD, OBSSR, ORWH, and *All of Us*. More generally, ECHO benefits from expertise represented on two trans-NIH Working Groups, one for the ECHO Cohorts and one for the ISPCTN. The purpose of these Working Groups is, through bi-directional collaboration, to promote the ECHO guiding principles, serve as a resource for NIH priorities and rules, and contribute expertise related to ECHO science and cross-cutting topics, such as ECHO policy development and stakeholder engagement. Some subject matter experts from NIH's Institutes, Centers, and Offices serve as project scientists for specific areas of emphasis in ECHO.

Figure 2: ECHO Program Office Organization



V. ECHO Program Office Mission and Roles

The mission of the ECHO Program Office is to promote scientific vision and mobilize nationwide capacity to catalyze observational and intervention research that will enhance the health of children for generations to come. The primary roles of the ECHO Program Office are to provide programmatic oversight, scientific guidance, organizational infrastructure, and resources to grantees, and to work with grantees to implement innovative paradigms for collaborative research.

Through a set of cooperative agreements with its grantees, the ECHO Program Office uses innovative strategies to promote collaborative research that aims to enhance the health of children, to provide high return on taxpayer investment.

The ECHO Program Office, in the NIH Office of the Director, directly oversees the work of the following grantees: cohort awardees, Coordinating Center, Data Analysis Center, Person-Reported Outcomes (PRO) Core, IDeA States Pediatric Clinical Trials Network (ISPCTN) Awardees, clinical sites, and Data Coordinating and Operations Center.

With the National Institute of Environmental Health Sciences (NIEHS), the ECHO Program Office co-oversees the ECHO-funded work of the Human Health Exposure Analysis Resource (HHEAR, formerly CHEAR). Additionally, the Program Office oversees the work of a service core, the Genetics Core.

The ECHO Program Office and grantees interact with many other individuals and organizations who have a stake in the success of the program, including: 1) ECHO participants—children and families; 2) the American public; 3) Congress; 4) stakeholder organizations—professional societies and advocacy groups; 5) NIH Institutes, Centers, Offices and Programs; 6) other federal agencies; and 7) scientists—national and international.

VI. ECHO Program Office Guiding Principles

The ECHO Program Office established four guiding principles under which to operate. These principles form a set of distinct yet related ideals that move the program closer to achieving its vision. These principles are *Impact*, *Teamwork*, *Responsibility*, and *Value*. Change is inevitable and the ECHO Program Office looks to employ these principles in every process, interaction, and task as a means of maintaining quality and attaining excellence.

Impact

The ECHO Program Office characterizes *Impact* as measurable enhancements in child health in the five ECHO health outcome domains. The Program Office's vision is that ECHO contributes to these enhancements by providing research results that inform changes in programs, policies, or practices. This programmatic vision fits with the objective of the Program Office to catalyze solution-oriented observational and intervention research. Thus, a key to ECHO Program Office success is consistent messaging to ECHO investigators and the wider scientific community that enhancing child health is the overarching goal of all ECHO research. The ECHO Program Office can facilitate ECHO Program *Impact* by actively engaging ECHO investigators to promote an atmosphere of trust; to foster a culture in which ECHO investigators share their scientific ideas with each other and their data with the broader research community; to advocate for innovative, transdisciplinary research practices; and to support strategic solution-oriented research initiatives that engage end-user stakeholders both during research question development and dissemination of results.

Teamwork

The ECHO Program Office classifies *Teamwork* as a group of individuals working well together, promoting inclusivity, and incorporating the expertise and viewpoints of all involved. The intent of this principle is to allow the ECHO Program Office, and all involved in ECHO, to reach beyond additive or sequential approaches to problem-solving. Rather, it seeks to achieve collaborative integration that transcends the professional or disciplinary boundaries between ECHO Program staff and grantees so that the whole becomes greater than the sum of its parts. The ECHO Program Office can facilitate *Teamwork* among staff and grantees by providing vision for shared scientific goals; promoting innovative approaches to collaboration; introducing active engagement strategies that enhance trust; fostering a culture that prizes the sharing of ideas and information with each other; and reminding all ECHO components to work well together as we build capacity, design and conduct clinical trials; and leverage the resources of the ECHO-wide Cohort to generate high impact research that informs the enhancement of child health.

Responsibility

The ECHO Program Office considers *Responsibility* to include ensuring that ECHO grantees conduct transparent and unbiased scientific research. The ECHO Program Office fosters responsibility by identifying primary roles and responsibilities of ECHO staff members. ECHO does this by creating an environment in which staff can both act independently and know when to engage other ECHO team members in program evaluation and oversight. The ECHO Program Office additionally ensures staff have the ability and resources needed, while also fostering accountability among staff.

The ECHO Program Office additionally ensures *Responsibility* by establishing expectations of grantees to conduct research in an ethical manner—recognizing the potential sensitivities since ECHO participants include pregnant women and children, producing and disseminating valid and reliable scientific findings, and delivering findings on appropriate timelines.

Value

The ECHO Program Office defines *Value* as the return on public investment in terms of enhancements in child health or intermediate outcomes such as changes in programs, policies, or practices. The ECHO Program Office maximizes value through a series of mechanisms, including but not limited to communicating expectations, allocating funding, and providing guidance so that investigators focus on key processes and deliverables; aligning staff capabilities with leadership roles and responsibilities to enhance benefit to the ECHO Program Office and awardees; coordinating grant resources to keep ECHO awardees within scope, on schedule, and within costs; identifying risks to scientific output, and helping to mitigate them, through implementation and evaluation of protocols, policies, and research results; fostering a culture in which ECHO investigators share their data with the broader research community; and facilitating dissemination of research findings so that they are maximally translatable into enhancing the health of children.

VII. ECHO Program Office Strategic Goals and Objectives

To achieve its mission in a manner consonant with its guiding principles, the ECHO Program Office has set three strategic goals to drive its operational activities over the next five years. During that time, the intent of our strategic goals and objectives is to capitalize on NIH, financial, and human resources so that the Program Office can effectively oversee the large ECHO Program with over 1000 investigators and key personnel, guide them to deliver on the promise of ECHO, and communicate our collective successes to ECHO's various stakeholder groups. Ultimately, the promise of ECHO is to provide high impact science and a national resource for supporting pediatric research that together serve to enhance the health of children for generations to come.

Strategic Goals

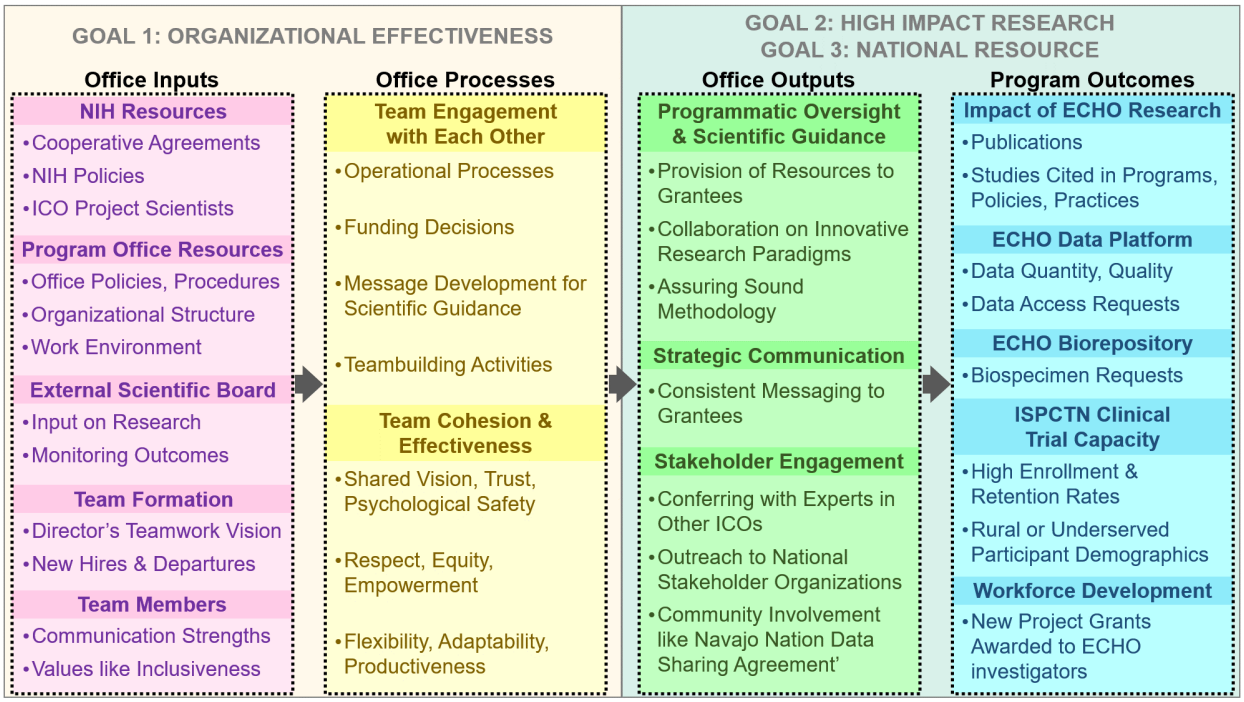
The strategic goals of the ECHO Program Office are to:

1) Enhance Program Office Organizational Effectiveness
2) Enable High Impact Research
3) Facilitate Establishment of ECHO as a National Resource

Each goal comprises multiple objectives to enhance attainability and measurability of success. Guided by the Team-based Program Office Model in Figure 3, staff implement these objectives using an annual *plan, do, study, act* approach, which involves documenting indicator data and planning expected progress at the start of each fiscal year (October). At the end of each fiscal year (September), the Program Office assesses indicator data to facilitate strategy adaptation for the subsequent fiscal year.

In Figure 3, Goal 1 emphasizes how the Program Office incorporates inputs and processes to enhance organizational effectiveness. The inputs include broader NIH resources, ECHO Program Office resources, guidance from the External Scientific Board, how the team forms and changes, and the strengths and values of our team members. The processes reflect the activities staff use to engage with each other, as well as the extent to which the team becomes an effective, cohesive unit. Goals 2 and 3 highlight the Program Office outputs that lead ECHO toward the desired program outcomes. These outputs are the outward facing services the Program Office offers its grantees and key stakeholders to enable high impact research and facilitate establishment of ECHO as a national resource.

Figure 3: Team-Based Program Office Model



The ECHO Program Office uses this team-based model to guide implementation and evaluation of its strategic goals and objectives. Doing so yields data that point to actions for enhancing ECHO Program Office processes and outputs. This Evaluation Model draws from this strategic plan, the Science of Team Science, and aspects of Continuous Quality Improvement. The entries under Office Inputs are examples of assets and resources; entries under Office Processes are examples of internal activities, as well as indicators of cohesion and effectiveness; entries under Office Outputs are examples of outward facing services provided to grantees and various stakeholder groups; and the entries under Program Outcomes are example indicators of success for ECHO.

STRATEGIC OBJECTIVES FOR GOAL 1: ENHANCE PROGRAM OFFICE ORGANIZATIONAL EFFECTIVENESS

The first strategic goal, to *Enhance Program Office Organizational Effectiveness*, describes how the Program Office strives to enhance use of its inputs and processes to shape its outputs and guide the ECHO Program to achieve the outcomes in Figure 3. Our inputs include NIH resources, Program Office resources, guidance from the External Scientific Board, how the team forms and changes, and the strengths and values of our team members. The office processes are the activities staff use to engage with each other and the extent to which the team becomes an effective, cohesive unit. To enhance Program Office organizational effectiveness, the office is taking actions that fall under three strategic objectives:

A. Optimize ECHO Program Office Organizational Structure

The objective to optimize the ECHO Program Office's organizational structure is based on the recognition that our team members are our most valuable input. The purpose of this objective is to connect staff with ECHO leadership and each other in a manner that enhances collaboration, workflow, and productivity. This structure begins with Programmatic and NIH policies that help set the boundaries for our collective work environment, *e.g.*, policies about telework, travel, publications, and diversity and inclusion. Our organizational structure (Figure 2) facilitates interpersonal connections between supervisors and staff rooted in values of inclusiveness and openness. Supervisors encourage all team members to communicate their strengths, request professional development support, serve as mentors to one another, and exhibit leadership in all their ECHO activities.

To better understand its inputs related to team member strengths, the office administers an annual staff questionnaire that allows team members to share their expertise and behavioral strengths in addition to identifying skill areas where they would like more experience. The office catalogs the results in a skills matrix to help supervisors assign collaborative tasks to staff with the most expertise and to those who desire more experience. These tasks can range from developing funding opportunities, collaborating on working groups with ECHO grantees, contributing to NIH committees, and shaping strategic messages to national stakeholder organizations interested in ECHO research. By using the annual staff questionnaire and skills matrix as indicators of team member strengths, the Program Office can continually improve its approaches for professional development and hiring when needs arise. Together, the Program Office organizational structure and approach to optimizing it, empowers the entire team to be leaders, collaborators, and mentors in their activities in the office, with our grantees, and with key stakeholders at NIH and beyond.

B. Refine ECHO Program Office Operational Processes

The objective to refine ECHO Program Office operational processes promotes a focus on how we leverage our inputs and office activities to shape our outputs. The purpose of this objective is to continually improve how our team operationalizes Program Office inputs, *i.e.*, resources and information, to make decisions and develop messages in our oversight of the ECHO Program. These operational processes fall under three categories: purchasing; travel; and communication and information management. Our purchasing processes ensure we have the material and technological inputs needed to be effective. When staff can travel, they can collect information at national meetings and disseminate messages to our grantees and stakeholder organizations in person. The ECHO Operations team periodically provides staff with refresher trainings on the Program Office's purchasing and travel procedures. The Program Office's communication and information management processes allow information to enter and leave the office in a consistent manner. For example, the Communications team continually develops and updates resources for staff to keep their presentations at conferences consistent with ECHO Program Office messaging. Weekly staff meetings provide a venue for communicating incoming information, and then using that information for decision-making and shaping outgoing messages.

Team members review the Program Office's operational processes annually to ensure they function efficiently. In addition, the office's annual staff questionnaire has sections that allow staff to critique our team communication and decision-making abilities. Pairing our operational reviews with these results from the staff questionnaire provides indicators of Program Office operational processes. By continually refining how the Program Office operationalizes its inputs and activities, we can ensure they translate into effective outputs for guiding ECHO to achieve expected outcomes (Figure 3).

C. Strengthen ECHO Program Office Interpersonal Cohesion

The ECHO Program Office takes an active approach to strengthening its interpersonal cohesion. The ECHO Director's vision of teamwork–that by working collaboratively and inclusively, we can achieve innovative solutions such that the whole is greater than the sum of its parts–drives the overarching culture and dynamics of the office. Developing cohesion primarily happens during day-to-day work activities. These activities start with staff agreeing to cooperate within the terms of our programmatic and institutional policies. Next, achieving cohesion entails actively making space for raising, managing, and resolving disagreements, which is dependent on staff creating a safe environment that welcomes differing opinions. A process of weighing alternative perspectives gives the Program Office options to compare when it comes to decision-making. To reinforce unity and team morale, office leadership includes team members in decisions related to funding choices, oversight priorities, scientific guidance, and communication strategies, and provides as much transparency as possible to staff about supervisor-level decisions.

The team assesses its progress toward cohesiveness using the part of its annual staff questionnaire that focuses on team functioning. The results inform the Program Office's approach to team building and orientation training. Some of our team-building activities aim to increase our collective awareness of each team member's individual strengths, which is an important part of developing cohesion and fostering trust among staff. For example, after our annual staff questionnaire, the office meets to share results that highlight team member skills and behavioral strengths, as well as our group responses to questions that examine our collective trust and ability to work as a team.

STRATEGIC OBJECTIVES FOR GOAL 2: ENABLE HIGH IMPACT RESEARCH

The second strategic goal, to *Enable High Impact Research*, requires offering grantees the means necessary to produce transdisciplinary science that can inform programs, policies, and practices. This goal represents a major aim of Program Office outputs, *i.e.*, the outward facing services we provide to our grantees and key stakeholders. These outputs include programmatic oversight, scientific guidance, strategic communication, and stakeholder engagement (Figure 3). The ECHO Program Office has organized Goal 2 under six strategic objectives:

A. Provide Adequate Resources to Grantees

The first part of programmatic oversight to enable high impact research is providing adequate resources to grantees. The ECHO Program Office uses an annual budgeting process that allocates funds to sites based on their documented costs, effort, and productivity. Program Officers monitor unexpended balances routinely so awardees can reallocate them to support the program's most urgent needs. The process for assessing productivity, described in the next section below, assures that ECHO grantees use their resources as NIH expects and that those funds translate to meaningful research products.

B. Monitor Grantee Progress

Another part of programmatic oversight is monitoring grantee progress. Program Officers monitor grantee progress through one-on-one meetings and standardized reporting, like Milestone Accrual Plans and Research Performance Progress Reports. The Program Office also assesses ECHO's collective performance, within the Cohorts and the ISPCTN, to ensure all grantees contribute to achieving ECHO's desired outcomes (Figure 3). For example, with its grantees, the Program Office monitors indicators like protocol implementation, study participant retention rates, data and biospecimen transfer, data quality, and publications. In cases in which a grantee needs substantial help achieving progress, their ECHO Program Officer coordinates with the grantee to develop an action plan for recovery, which includes learning strategies for success from high-achieving peer grantees.

C. Establish Multi-Team Approach to Science Governance

Offering scientific guidance is another Program Office output related to enabling high impact research. One approach the Program Office takes is promoting collaboration on innovative research paradigms like establishing a multi-team approach to science governance. This approach entails designing a system of cooperating teams to manage scientific decision-making, infrastructure, and workflows. Well-designed multi-team systems are essential to overcoming inefficiencies and enhancing collaboration in large consortia like ECHO. Multi-team systems can also help integrate many disciplinary, career-stage, and cultural perspectives into consortium products.

The Program Office has empowered ECHO's multi-team approach to science governance by gradually shifting more authority for scientific decisions from NIH to ECHO's steering committees (Figure 1). Steering committee members, along with other ECHO investigators, have established a system of teams to carry out the numerous tasks needed to operate the ECHO consortium, from protocol design and implementation to publication review. The Program Office encourages these teams to continually refine ECHO's infrastructure and research prioritization procedures to ensure that ISPCTN and Cohort investigators produce timely, rigorous, and high-impact research. Guided by indicators described in the following sections, Program Office staff participate in ECHO's scientific governance to offer scientific vision, boundary setting, and strategic course correction.

D. Assure Sound Scientific Methodology

Scientific guidance from the ECHO Program Office to grantees includes assuring sound scientific methodology. The ECHO Program Office pursues this objective by offering direction consistent with ECHO's guiding principles and research goals. For example, while the Program Office values all ECHO Cohorts research, we emphasize the need for analyses that are solution-oriented, *i.e.*, inform programs, policies, and practices. ECHO's Publications Committee scores analysis proposals as to how solution-oriented they are, and those with better scores receive added support from the Coordinating Center (CC) and Data Analysis Center (DAC). The Program Office monitors these scores. In addition, the Program Office's ISPCTN team works closely with ISPCTN site teams and the Data Coordinating and Operations Center (DCOC) to ensure its pediatric clinical trials meet rigorous standards for study design and conduct. Staff use indicators like protocol development time and clinical trial enrollment and retention rates as measures of success.

Part of this objective is focused on soliciting scientific input from across NIH. For example, the Program Office coordinates trans-NIH working groups for the ECHO-wide Cohort and ISPCTN to allow experts from across NIH Institutes, Centers, and Offices to offer input on ECHO's research methodologies. We also engage ECHO's External Scientific Board twice a year to request their

feedback on ECHO's challenges. The feedback the Program Office receives from the External Scientific Board is pivotal toward ensuring programmatic success.

E. Support Research Publication & Dissemination

The Program Office offers scientific guidance that supports research publication and dissemination. The Program Office pursues this objective, in part, by encouraging NIH Project Scientists to serve as coauthors on ECHO manuscripts. Also, Program Office staff actively participates in collaborative activities to guide investigators toward development of solution-oriented research publications. The ECHO Program Office Communications team implements a Communications Plan intended, in part, to distribute ECHO's findings and publications to national stakeholder organizations and federal agencies well-suited to enact solutions to enhance child health. The Program Office also created an internal Publications Policy to encourage NIH staff to publish papers about their own professional efforts.

Indicators to inform Program Office oversight of ECHO's publication of research findings include proxy markers of expected publication impact. For example, in the short-term, staff examine journal impact factors and the proportion of publications accompanied by editorials and commentaries. In the medium-term, staff examine the relative citation ratios of publications. In the long-term, the Program Office can review the number of ECHO publications cited in clinical trials, programs, policies, and practices.

The Program Office also engages experts in national stakeholder organizations and federal partners to better understand what evidence needs ECHO can address to better inform programs, policies, and practices that enhance children's health. Once findings are available, we engage our partners to help disseminate them to a wide audience. The Program Office pursues an active engagement strategy informed by participation of national stakeholder organizations, with a particular focus on a small number of organizations whose missions strongly overlap with ECHO's goals.

F. Enhance Diversity in Research and in Workforce Development

As a vital part of enabling high impact research, the Program Office emphasizes the importance of enhancing diversity of research participants and in the scientific workforce. To reach these related objectives, staff continually examine the proportion ECHO study participants from under-represented populations. For ISPCTN study participants, the Program Office focuses on improving participation in clinical trials among children from rural or medically underserved communities.

The Program Office also recognizes a need to provide access to ECHO's research activities as a training environment to under-represented persons in the scientific workforce. As such, the Program Office has prioritized using available funds to support Diversity Supplements. We also

promote diversity in recipients of awards from the Opportunities and Infrastructure Fund to support early-career stage investigators working in ECHO Cohorts. In ISPCTN, the Program Office encourages its Data Coordinating and Operations Center (DCOC) to implement clinical trials training activities for investigators at all career stages, including those from under-represented backgrounds. To assess ECHO's overall contributions to developing the research workforce, Program Office staff examine indicators like the number of new project grants awarded to ECHO investigators at all career stages.

STRATEGIC OBJECTIVES FOR GOAL 3: FACILITATE ESTABLISHMENT OF ECHO AS A NATIONAL RESOURCE

The third strategic goal, to *Facilitate Establishment of ECHO as a National Resource*, derives from ECHO's need to supply ample return on the investment for the United States public. This goal is another major focus of the Program Office's outputs like programmatic oversight and stakeholder engagement (Figure 3). The Program Office views ECHO as a national resource in two ways. First, ECHO is establishing robust data and biospecimen collections from the ECHO-wide Cohort to serve as a resource for pediatric research for the greater scientific community. Second, ECHO is developing ISPCTN capacity to provide children in rural or underserved communities with access to cutting-edge multi-center clinical trials. As such, ISPCTN can publish clinical trial datasets for the broader scientific community to use, thereby expanding the representation of children in rural or underserved populations in biomedical research.

The Program Office supports ECHO to establish its data and biospecimen repositories to be consonant with the principles of Findable, Accessible, Interoperable, and Reusable (FAIR), which are recommended by NIH's Office of Data Science Strategy.

The ECHO Program Office oversees achievement of this goal through three strategic objectives:

A. Broaden ECHO's Visibility as a National Resource

This objective, to broaden ECHO's visibility as a national resource aligns with the "F" in the FAIR principles, *i.e.*, Findable. As such, the Program Office oversees the inclusion of ample indexing and metadata to enhance searchability of ECHO data and biospecimen collections. Staff can examine findability of the ECHO national resource using web traffic indicators like number of page views and link clicks. The Program Office also implements a communication strategy aimed at broadening ECHO's visibility as a national resource to key end-user stakeholders, like medical professionals and child health advocacy organizations. This strategy includes establishing active points of communication with these national-level stakeholder organizations, and other federal partners, to facilitate outreach and bilateral communication. The Program Office leverages these organizations to help increase awareness of ECHO's data and biospecimen repositories to as wide an audience as possible.

B. Ensure ECHO's Accessibility as a National Resource

For the ECHO-wide Cohort to be a national resource, its data and biospecimens must be accessible to a wide scientific community, which is "A" of the FAIR principles. The Program Office assesses this objective by measuring indicators like the number of user requests for data and biospecimens. The Program Office also views accessibility through the lens of inclusion by monitoring the proportion of ECHO's data and biospecimens from under-represented populations. Staff examine indicators like the demographics of study participants contributing data onto ECHO's public-use datasets to help ensure we achieve this objective.

C. Promote ECHO's Capability as a National Resource

A major focus the Program Office's outputs is to promote ECHO's capability as a national resource. This objective aligns with the "I and R" of the FAIR principles, *i.e.*, interoperable and reusable. These principles emphasize the need for data stored in forms that are a) compatible with other datasets and b) suitable for use in multiple analyses. With these principles in mind, the Program Office oversees the development of an ECHO data and biospecimen repository with a flexible data platform that enables a broad range of analyses from the larger scientific community. Most of these data and biospecimens originate from the ECHO-wide Cohort study. ISPCTN also makes their clinical trial data available to the broader scientific community, consistent with the FAIR principles.

The Program Office uses indicators about the amount and quality of data and biospecimens to help inform strategies for enhancing the capability of these ECHO resources. Staff also monitor study participant demographics to emphasize the extent to which the scientific community can address research questions among children in under-represented populations. Ultimately, the Program Office can examine the national resource's ability to meet the scientific communities' needs by examining publications from the broader scientific community that use ECHO data or biospecimens in secondary analyses.

VIII. ECHO Program Office Key Measures of Success

ECHO Program Office success relies on the program as a whole to meet many of the outcomes in the strategic plan. As in Figure 3 in Section VII, outcomes to measure success include publication of high-impact ECHO-wide Cohort and ISPCTN research, establishment of the ECHO-wide Cohort central data platform and biorepository, building ISPCTN clinical trial capacity, and development of the pediatric research workforce. The ECHO Program Office examines the following indicators to determine the extent of ECHO's short-, medium-, and long-term success.

Table 1. Program Office Key Measures of Success

Program Outcome	Short-Term Indicator	Med- to Long-Term Indicator
Impact of ECHO Research	Number of ECHO-wide Cohort & ISPCTN publications Distribution of journal impact factors for ECHO-wide Cohort & ISPCTN publications Number of ECHO-wide Cohort & ISPCTN publications accompanied by editorial or commentary	Distribution of relative citation ratios of ECHO-wide Cohort & ISPCTN publications Number of citations of ECHO-wide Cohort & ISPCTN publications in clinical trials, programs, policies, and practices
Establishment of ECHO-wide Cohort Data Platform	Number of participants who contributed extant data to ECHO data repository	Number of active participants contributing new data to the ECHO data repository Number of user requests for ECHO-wide Cohort data
Establishment of ECHO-wide Cohort Biorepository	Number of biospecimens in the biorepository Number of participants who contributed biospecimens to the biorepository	Number of user requests for ECHO-wide Cohort biospecimens

Outcome	Short-Term Indicator	Med- to Long-Term Indicator
Building ISPCTN Clinical Trial Capacity	Enrollment rates, retention rates Proportion of clinical trial sites activated on schedule	Time from start of protocol development to implementation Number of clinical trials completed Number of new clinical trial project grants awarded to ISPCTN investigators
Development of Research Workforce	Number of investigators that participated in ISPCTN training activities Number of publications by Opportunities & Infrastructure Fund and Diversity Supplement Award recipients	Number of new project grants awarded to ECHO investigators Number of new project grants awarded to Opportunities & Infrastructure Fund & Diversity Supplement Award alumni