

Expanding Access to ECHO Cohort Data and Biospecimens through X01

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Concept Clearance

Concept: Issue PAR for access to ECHO data and biospecimen resources

Title: Expanding Access to ECHO Cohort Data and Biospecimens through X01

Objective/Purpose: To enhance ECHO's impact and value while fostering collaboration and equity of opportunity through expanded access to ECHO data and biospecimens

Funds Available & Number of Awards: The X01 requires no funding from ECHO. We anticipate up to 20 awards per year

Award Project Period: 1-3 years

Council Action: Council motion and vote to provide concept clearance to issue the PAR



Presentation Outline

- Opportunity to use our ECHO Cohort resource
 - ECHO Cohort as national resource
 - Opportunity: A rapidly expanding resource
- Today's Concept: PAR for resource access via X01
 - Facilitating resource access through X01
 - Plans for X01 applications
- How the PAR fits in ECHO's approach to ancillary studies
 - ECHO definition of ancillary studies
 - Overall approach to ECHO ancillary studies
 - Simultaneous applications for funding and (this PAR) resource access
- Requested Council action



Overview of ECHO Resource Access



ECHO Program

- **Who:** ECHO investigators
- **What:** Contribute and access identifiable data and biospecimens
- **Where:** ECHO Data Platforms + ECHO Cohort Biorepository

UG3/UH3



Ancillary Studies

- **Who:** ECHO and non-ECHO investigators
- **What:** Can access identifiable data and biospecimens
- **Where:** ECHO Data Platforms + ECHO Cohort Biorepository

X01



NOFOs

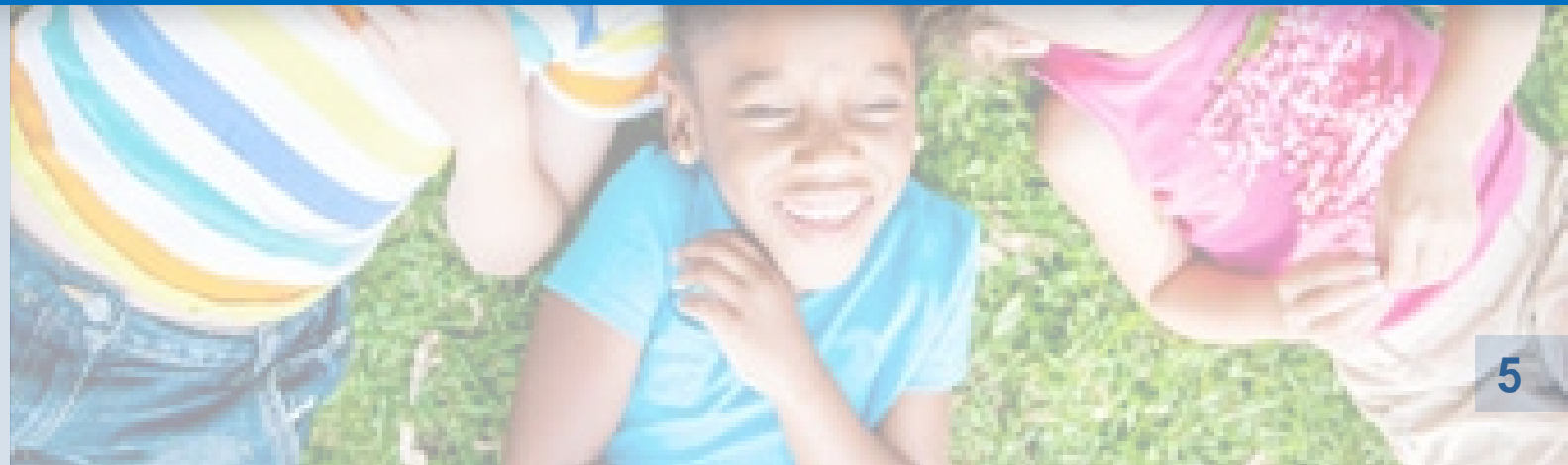
- **Who:** Non-ECHO pre- & post doctoral trainees
- **What:** Can access de-identified ECHO data
- **Where:** NICHD Data and Specimen Hub (DASH)

R36/F32





Opportunity to Use Our ECHO Cohort Resource



ECHO Program

Mission

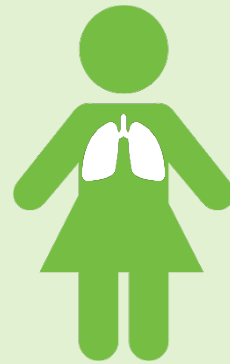
To enhance
the health of
children for
generations
to come

5 Key Areas with High Public Health Impact

PRE-, PERI-
AND POSTNATAL



UPPER AND
LOWER AIRWAY



OBESITY



NEURO-
DEVELOPMENT

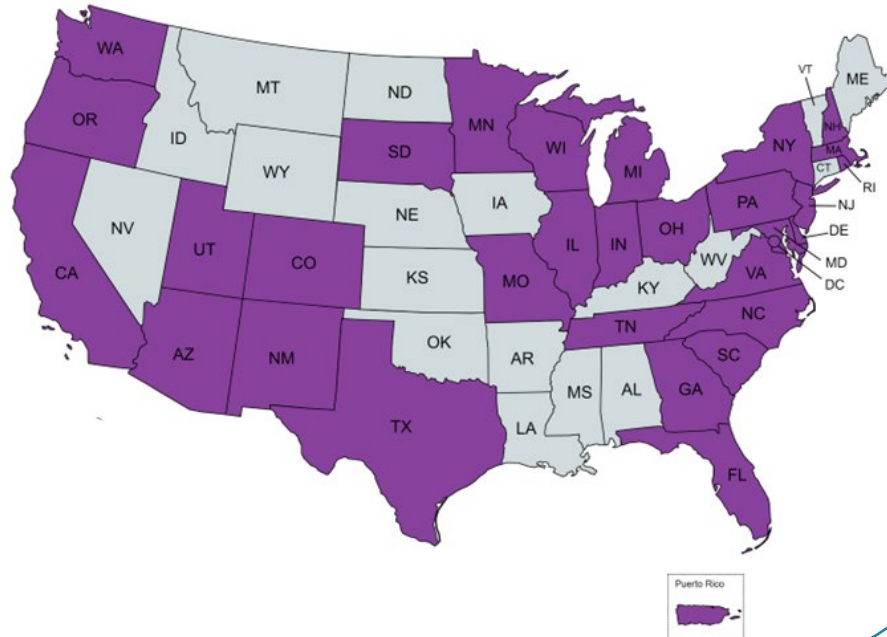


POSITIVE HEALTH

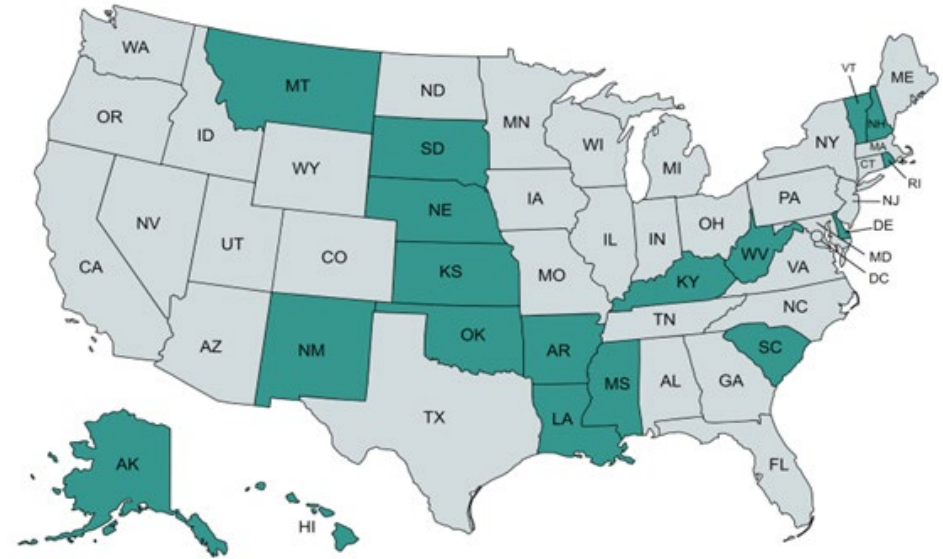


Observational & Intervention Research

ECHO Cohort



ECHO IDeA States Pediatric Clinical Trials Network



Research Sites in 42 states, DC, PR
180+ health research institutions
1200+ researchers



ECHO Cohort as a National Resource To Date

By making ECHO Cohort data and biospecimens
available to the broader scientific community

Good use so far...

Deidentified,
controlled-access
data

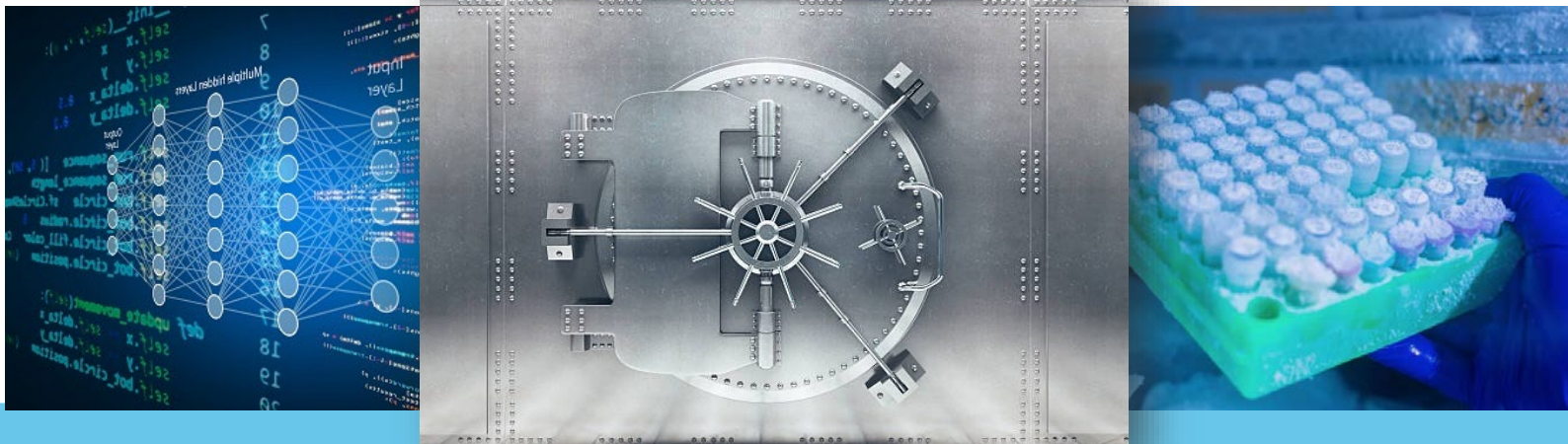


ECHO Cohort as a National Resource

Future

By making ECHO Cohort data and biospecimens available to the broader scientific community

Expanding access to identifiable data and biospecimens via *ancillary studies*



ECHO Cohort Resource After Eight Years

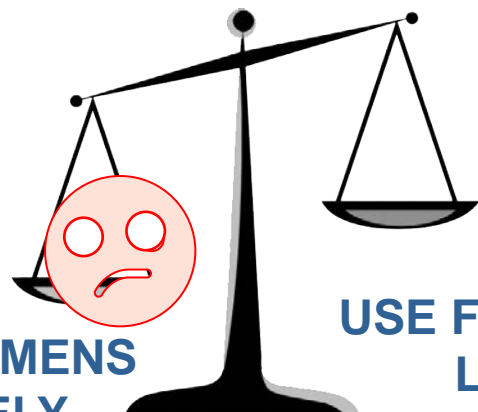


- September 2016 – August 2023
 - Harmonized data from 107,000+ participants from ~70 pre-existing, ongoing longitudinal maternal-child studies
 - ~65,000 children
 - Extant assay data
 - >100,000 biospecimens in biorepository
- September 2023 – May 2030
 - Following up >30,000 kids
 - Recruiting >30,000 new pregnancies
 - Postpartum = preconception
 - Including partners when possible
 - Rapidly expanding data platform and biorepository
 - New biospecimen assays



Exceptional Opportunity with Biospecimens

Long-term storage vs. Prompt use

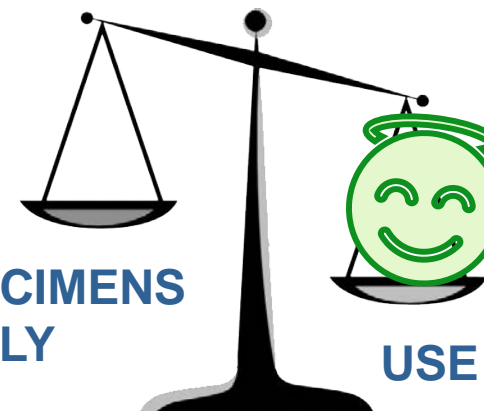


**STORE SPECIMENS
INDEFINITELY**

**USE FOR ASSAYS
LATER?**



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**STORE SPECIMENS
BRIEFLY**

**USE FOR ASSAYS
NOW**



Assays funded by
ECHO



Access for
Ancillary Studies





Today's Concept: PAR for Resources Access via X01



About X01

- ECHO proposes to issue a PAR for an X01, an NIH resource access mechanism that would allow...
 - Investigators from in and outside of ECHO to ask important research questions that require
 - Personally identifiable information on ECHO Data Platform, or
 - Assays of biospecimens in ECHO Biorepository
 - ECHO Program Office to
 - Oversee project, resource access
 - Protect interests of ECHO Sites, Cores, Centers
 - Protect interests of ancillary study investigators
 - Monitor investigator development in future years
- Other institutes, centers, offices, agencies to supply funding



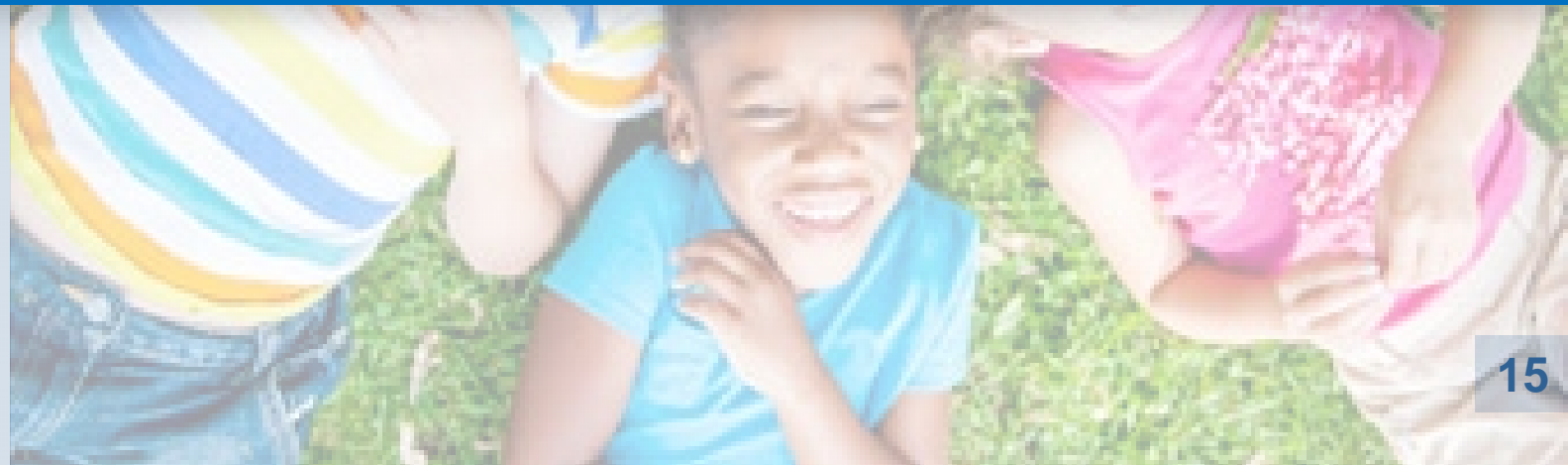
Plans for PAR to Support X01 Applications

- **Standard due dates:** February, May, October
- **Review:** Federal review panel
 - Scientific & technical merit





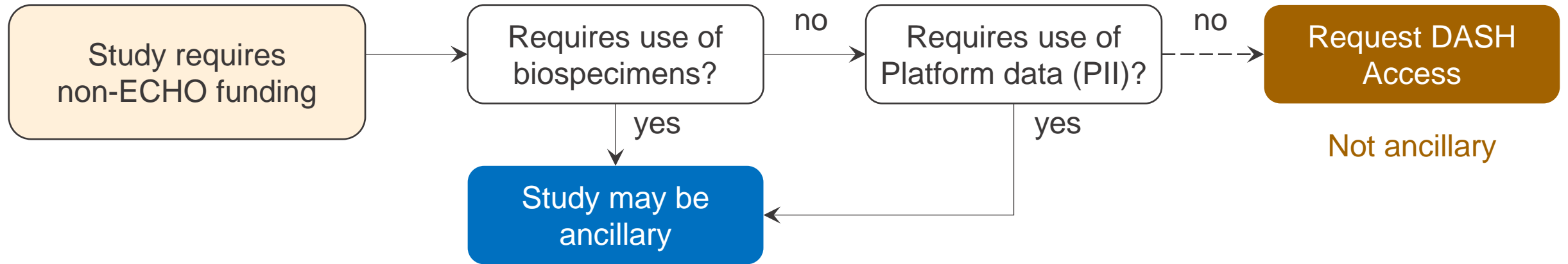
How the PAR Fits in ECHO's Approach to Ancillary Studies



ECHO's Definition of *Ancillary Study*

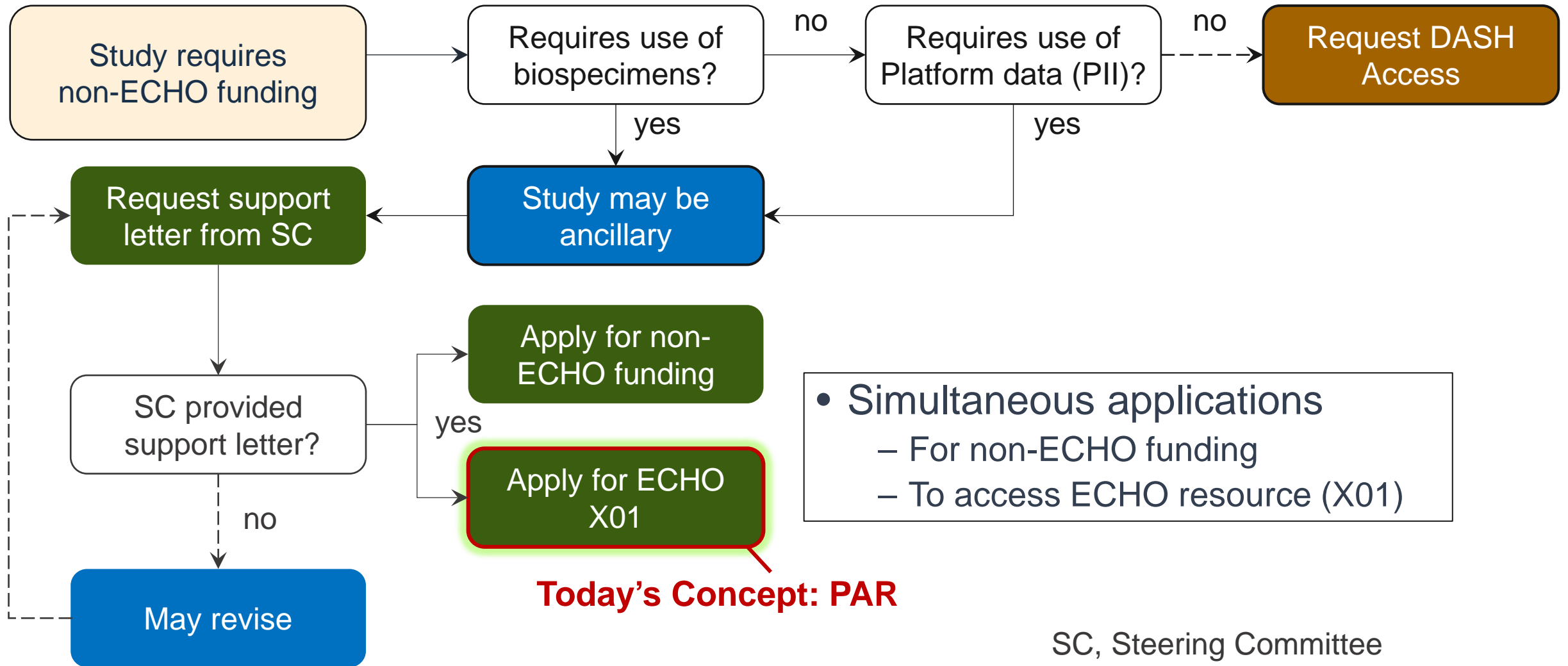
A study that derives funding from a non-ECHO source and uses non-publicly available data or biospecimens

Overall Approach to ECHO Ancillary Studies (1)



SC, Steering Committee
PII, Personally Identifiable Information
[DASH, Data and Specimen Hub](#)

Overall Approach to ECHO Ancillary Studies (2)

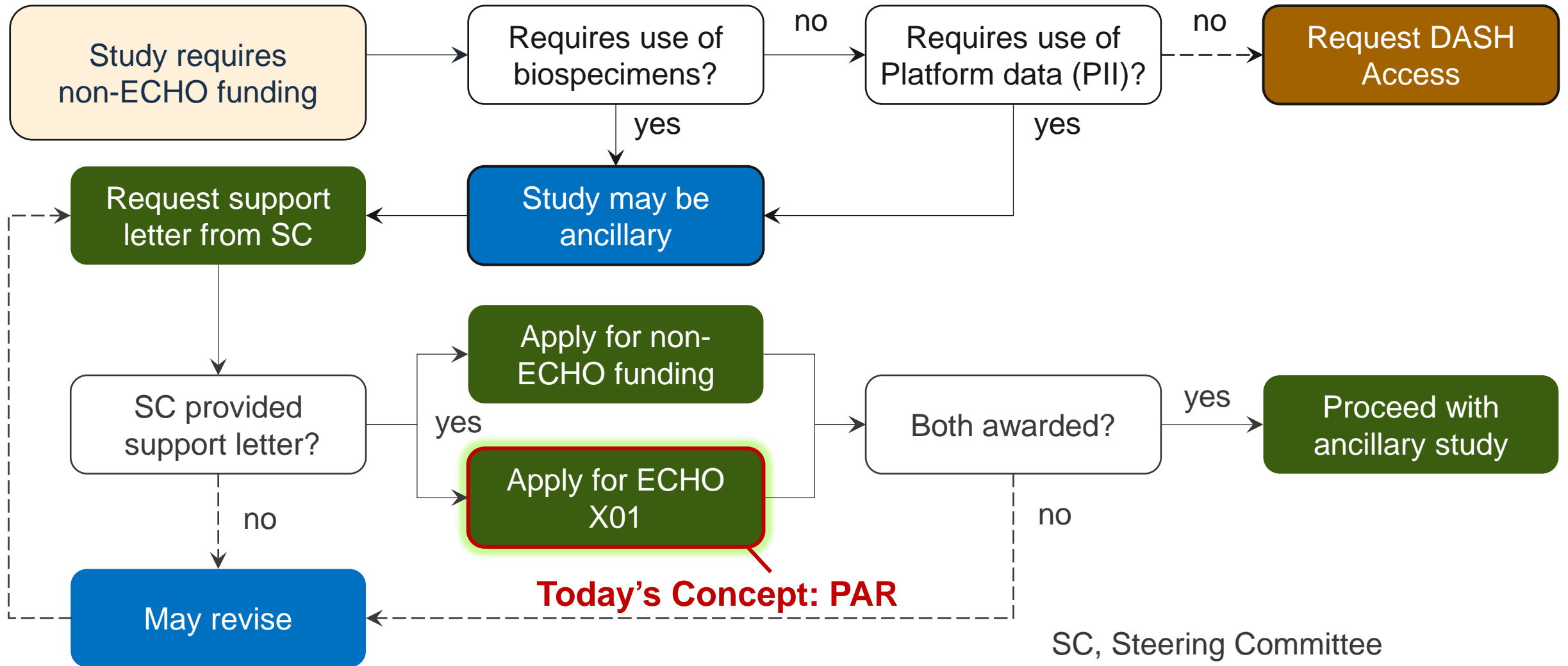


Today's Concept: PAR

- Simultaneous applications
 - For non-ECHO funding
 - To access ECHO resource (X01)

SC, Steering Committee
PII, Personally Identifiable Information
[DASH, Data and Specimen Hub](#)

Overall Approach to ECHO Ancillary Studies (3)



Today's Concept: PAR

SC, Steering Committee
PII, Personally Identifiable Information
[DASH, Data and Specimen Hub](#)

Summary

- ECHO Cohort
 - Has already made de-identifiable data available to the broad scientific community
 - Intends to follow suit with identifiable data and biospecimens, via ancillary studies process
 - Expects to use X01 mechanism to oversee conduct of ancillary studies
 - Requests Council to approve PAR concept to request X01 applications



Requested Council Action

Motion and vote to provide concept clearance for ECHO to issue the PAR