

RFA and Cohort Overview



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CPRIT: Purpose of RFA

- This prospective study will address priorities in cancer prevention, early detection, and etiology research, which include emerging exposures, novel biomarkers, and genomics in diverse populations.
- The Connect Study has the long-term potential to identify social, environmental, behavioral, and genetic factors that underlie cancer risk among Texans.
- CPRIT will support a recruitment site(s) in Texas to recruit a diverse cohort of 25,000-35,000 individuals to participate in the Connect study.

Study Objectives

Comprehensive research resource using new technologies and methods for the scientific community to study:

Cancer Etiology

Precursor to Tumor Progression

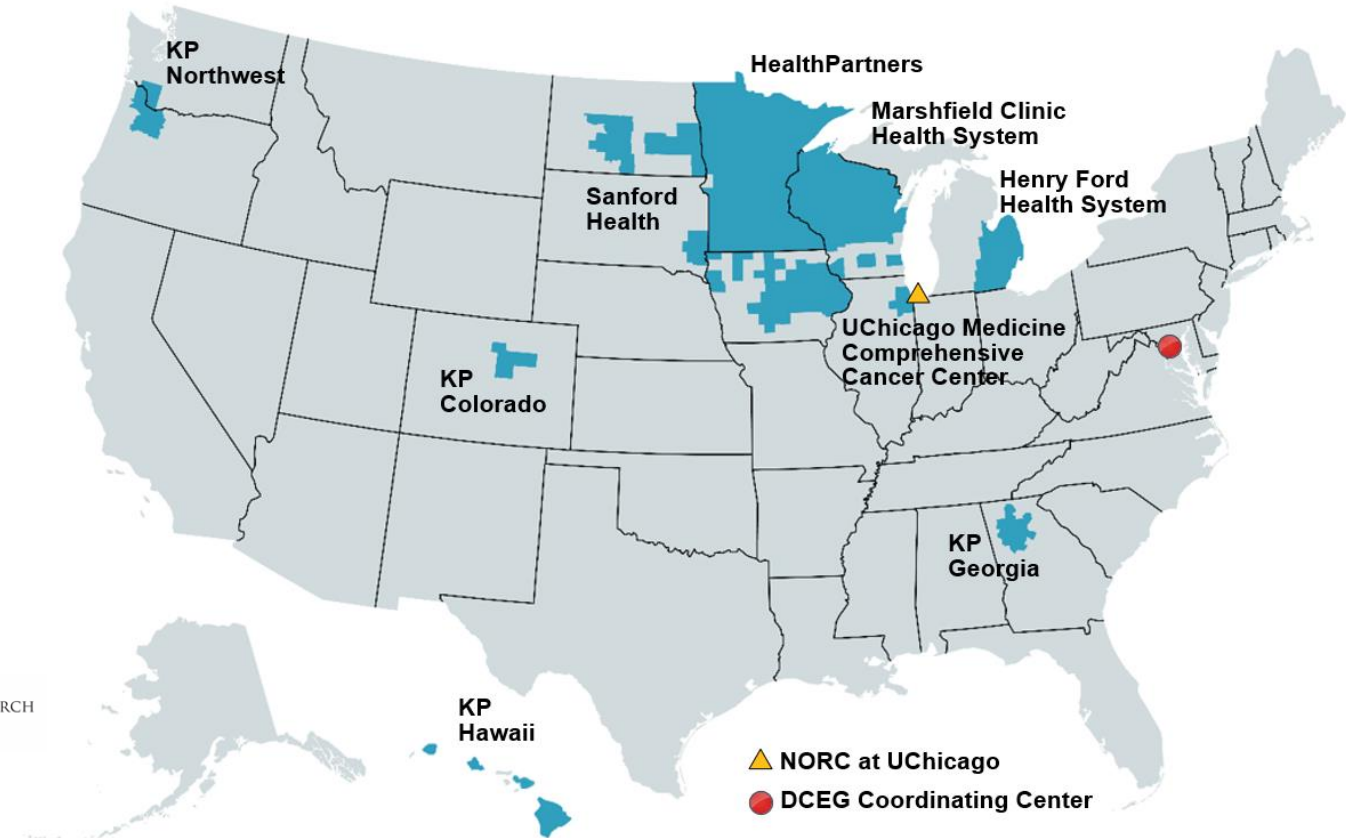
Cancer Risk Prediction

Early Detection of Cancer

Survivorship

Current Catchment Population and Study Enrollment

Current Partner Health Care Systems

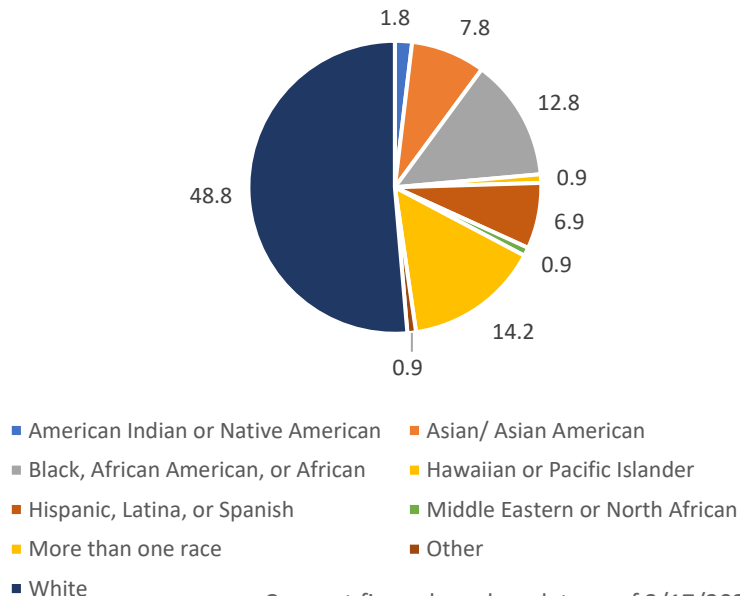


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connect
for cancer prevention study

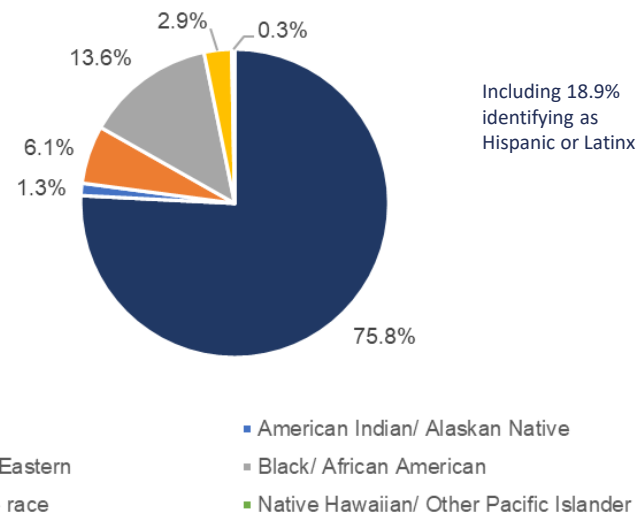
Distribution of Race and Ethnicity Among Connect Verified Participants and US Population (V2021)

Distribution (%) of Race among Enrolled Participants



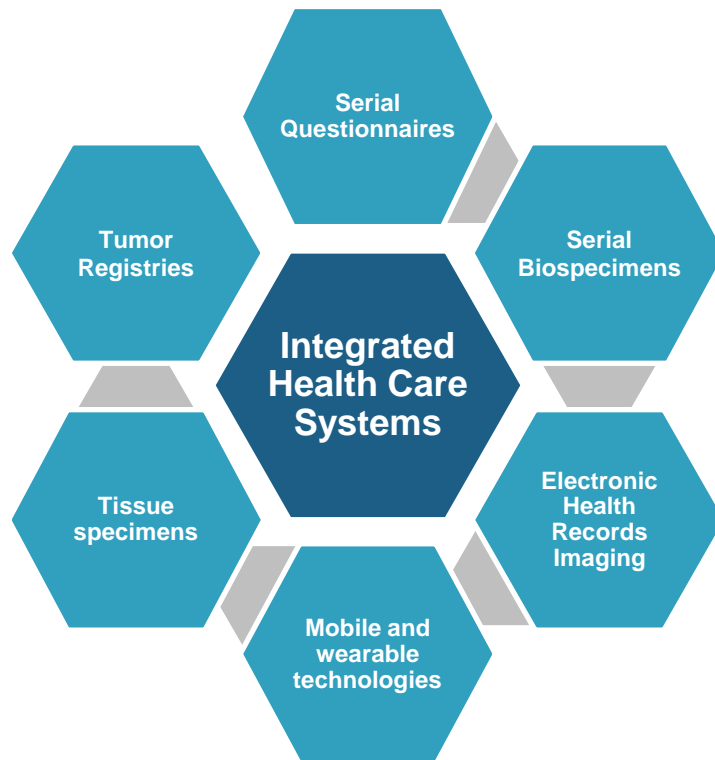
Connect figure based on data as of 3/17/2023

Distribution of Race among US Population (V2021)



Key Study Design Features of Connect

- ▶ 200,000 diverse individuals across the US
 - ✓ Aged 40-65 years
 - ✓ No history of cancer
 - ✓ Patients or members of partner health care systems
- ▶ Long-term follow-up
- ▶ Serial assessments
- ▶ Comprehensive cancer outcomes
- ▶ Flexible infrastructure for enhancement studies

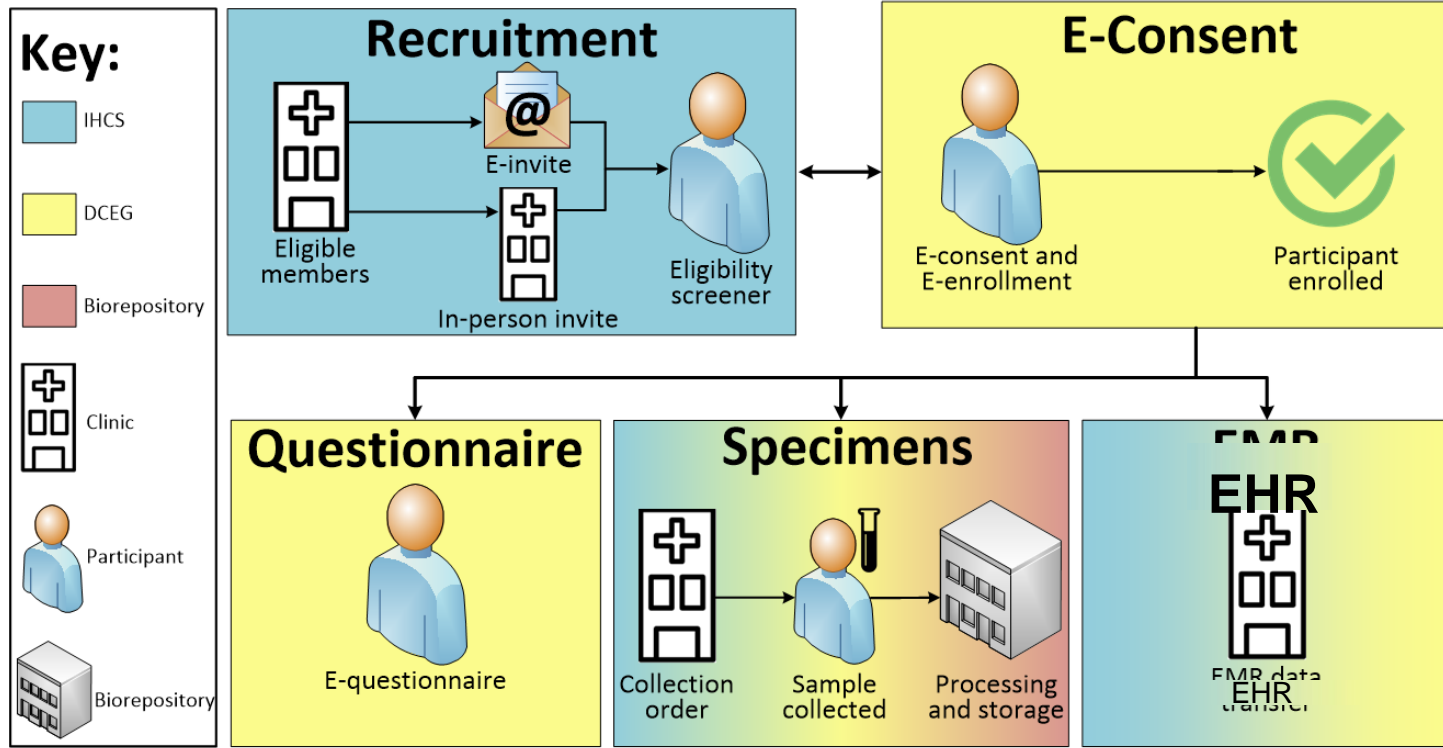


Study Activities and Infrastructure

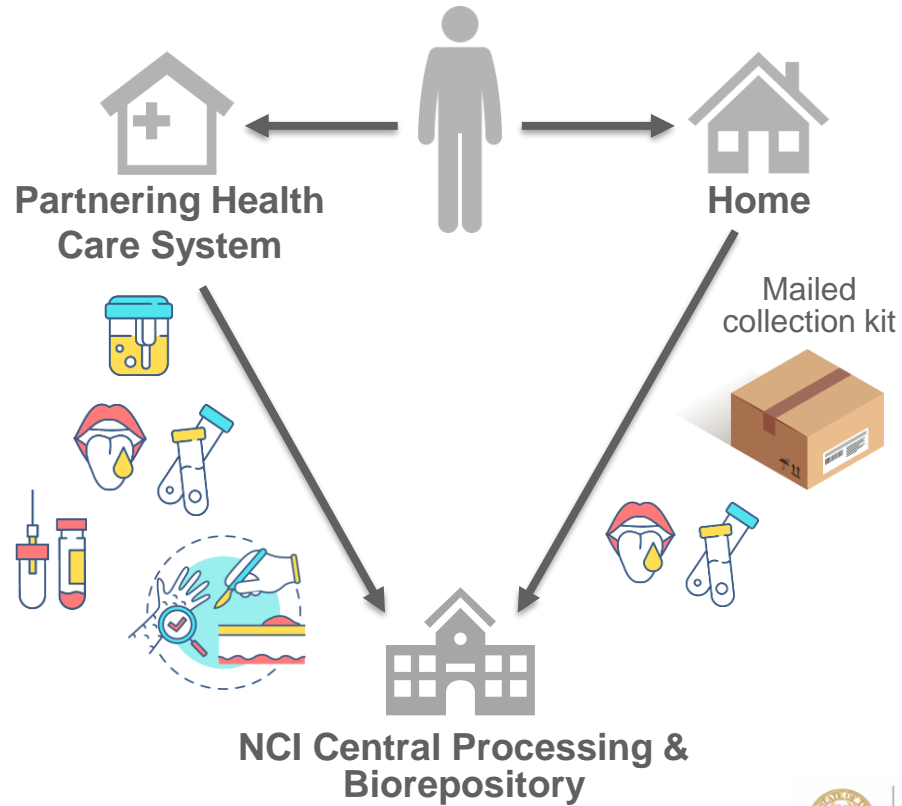
Elements of Connect Site(s)

- Integrated Healthcare System
 - ✓ Providers of comprehensive, coordinated care
 - ✓ EMR, cancer registry, archived tissue specimens
 - ✓ Biological specimen collection facilities (clinical or research setting)
- Diverse, ideally large, catchment population
- Site team of PI, study/biospecimen managers, programmers, RAs/ phlebotomists

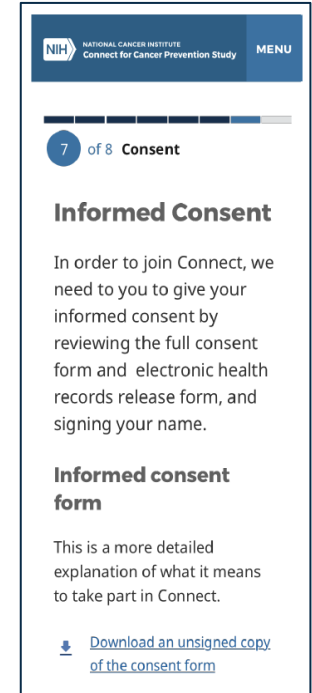
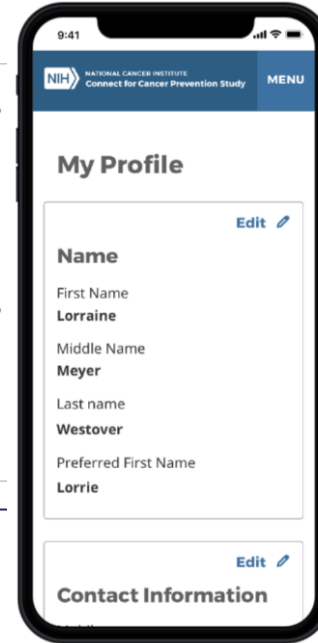
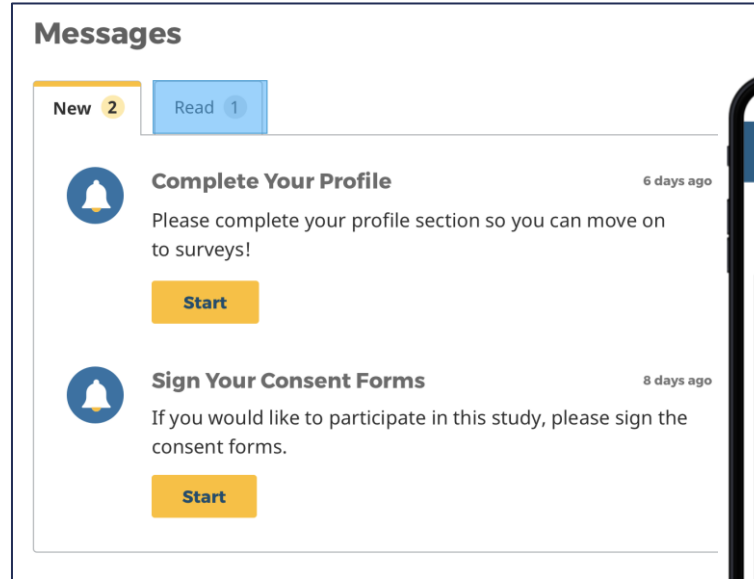
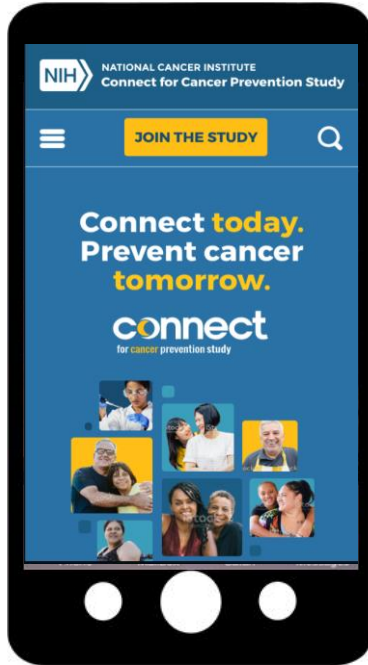
Overview of Recruitment to Baseline Study Activities



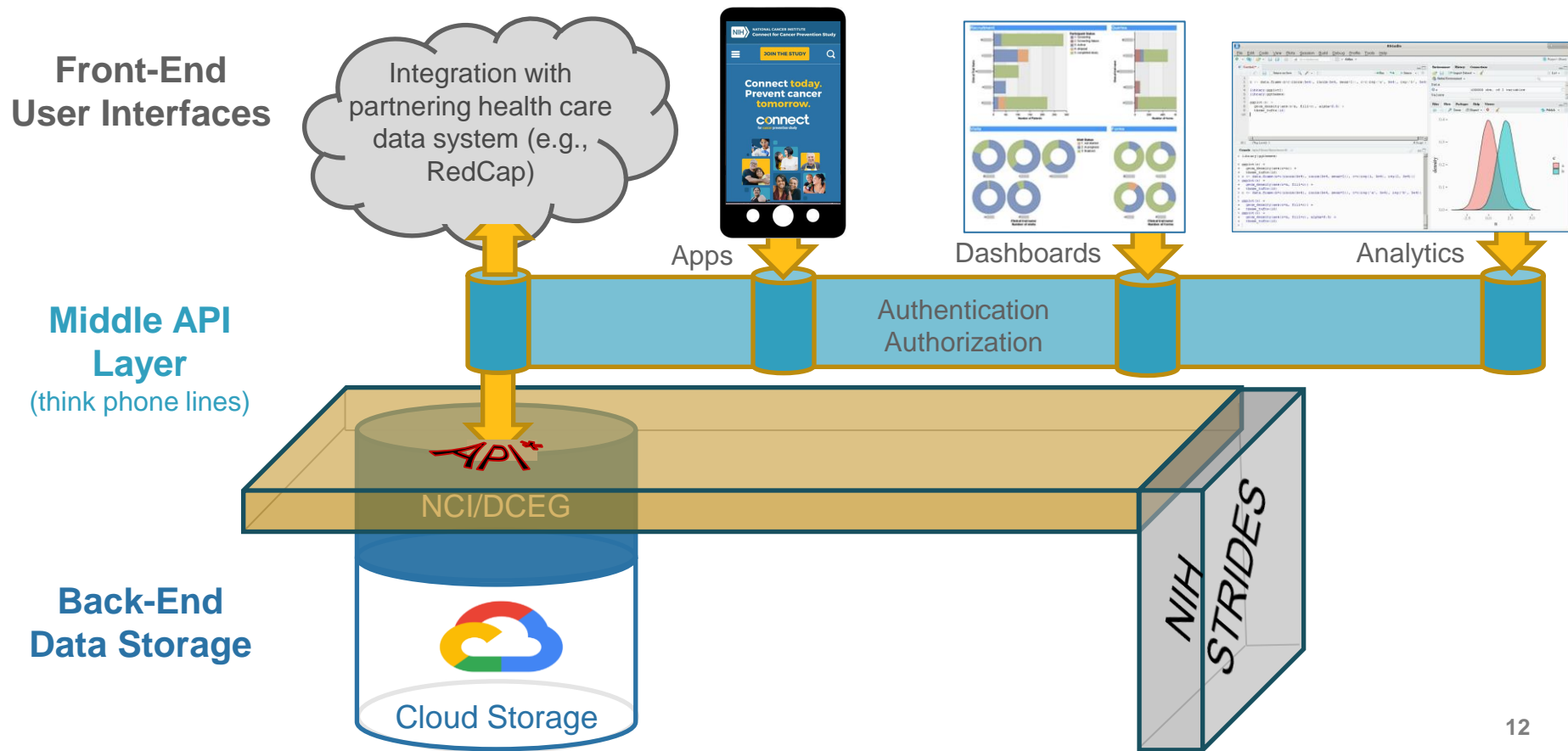
Recruitment Biospecimen Collection Options



MyConnect Participant App: Communication and Study Activity Hub



Connect Data Ecosystem provides an interoperable infrastructure



Connect Coordinating Center (at DCEG) Responsibilities

- ✓ Manage central IRB, NIH IRB
- ✓ Develop recruitment assets (e.g., emails, brochures, banners)
- ✓ Maintain and enhance MyConnect app and GCP-based data ecosystem, built in-house
- ✓ Coordinate site activities
- ✓ Manage enhancements to study activities (e.g., new questionnaires, novel biospecimens)

Partnering Site Team and Responsibilities

Team Member	Responsibilities (abbreviated list)
Site PI & other senior leadership	<ul style="list-style-type: none">✓ Identify clinical champions to promote Connect✓ Contribute to development of study enhancements
Programmers	<ul style="list-style-type: none">✓ Develop algorithms with EHR data to identify and verify eligible patients✓ Connect to existing APIs for bidirectional data transfer✓ Transfer EHR data via file transfer protocol
Study & Biospecimen Manager(s)	<ul style="list-style-type: none">✓ Customize template SOPs✓ Customize recruitment assets✓ Collaborate on enhanced recruitment strategies
Research Assistants/ Phlebotomists	<ul style="list-style-type: none">✓ Navigate participant through biospecimen collection✓ Draw blood (if creating research setting)

Governance & Organizational Structure

Connect Governance

Connect Leadership and Coordinating Center

Governing Board

Stephen Chanock (Chair)

Executive Leadership

DCEG Steering Committee

Chief Scientist (Chair), Connect PI, co-PIs,
Coordinating Center Leadership, Associate
Directors

Executive Committee

Chief Scientist (co-Chair), Rotating Site co-PI (co-
Chair), Steering Committee Members, Site PIs,
Participant Advisory Board Lead,
Support Service Contractor Leads

External Advisory and Review Groups

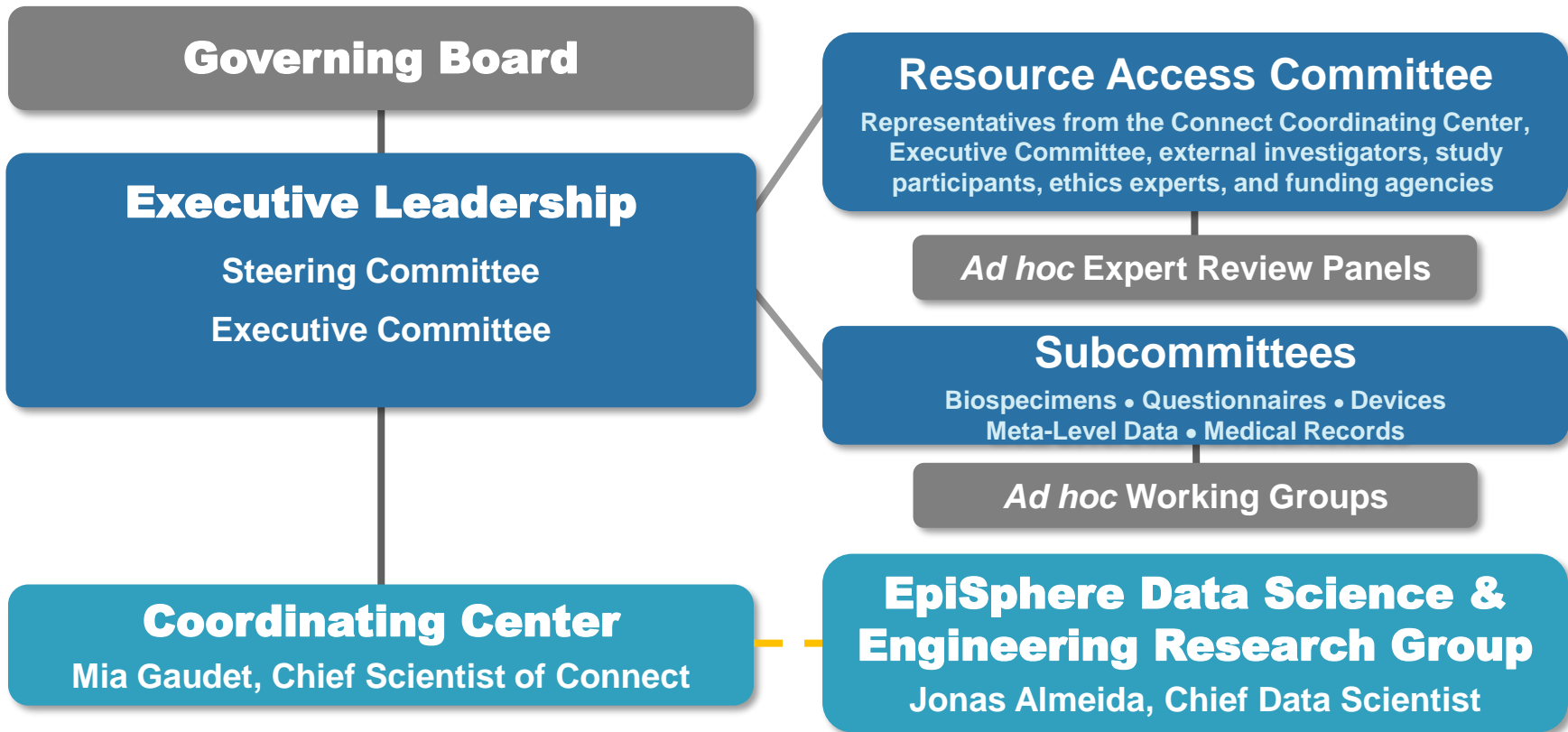
International Scientific Advisory Board

Naomi Allen, Eric Boerwinkle, Julie Buring, Carmen
Guerra, Chris Haiman, David Hunter, Roger Milne,
Lucila Ohno-Machado, Alpa Patel, Karriem Watson

National Cancer Institute (NCI) Board of Scientific Counselors (BSC) – Clinical Sciences and Epidemiology

Participant Advisory Board (PAB)

Connect Leadership and Organization



Recruitment Timeline

Full Recruitment and Retention Timeline



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