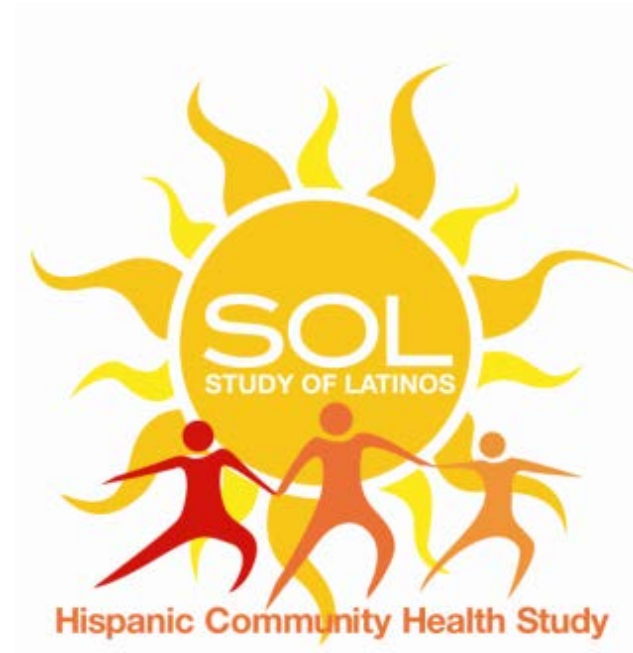


HCHS/SOL: Ancillary Studies Policy and Process




Daniela Sotres-Alvarez, DrPH and Robert Kaplan, Ph.D.
HCHS/SOL Ancillary Studies Committee Co-Chairs

Contact:

dsotres@unc.edu; robert.kaplan@einsteinmed.edu; hchsadmini@unc.edu;
HCHSAncillary@unc.edu;



Outline

- What is an Ancillary Study and Types
 - HCHS/SOL Ancillary Studies
 - Process
 - Timeline for Ancillary Studies alignment with V4
 - Resources to prepare a proposal
- 

What is an Ancillary Study (AS)?

Participant burden

- Participant contact
- NEW biospecimen collection

Stored biospecimens

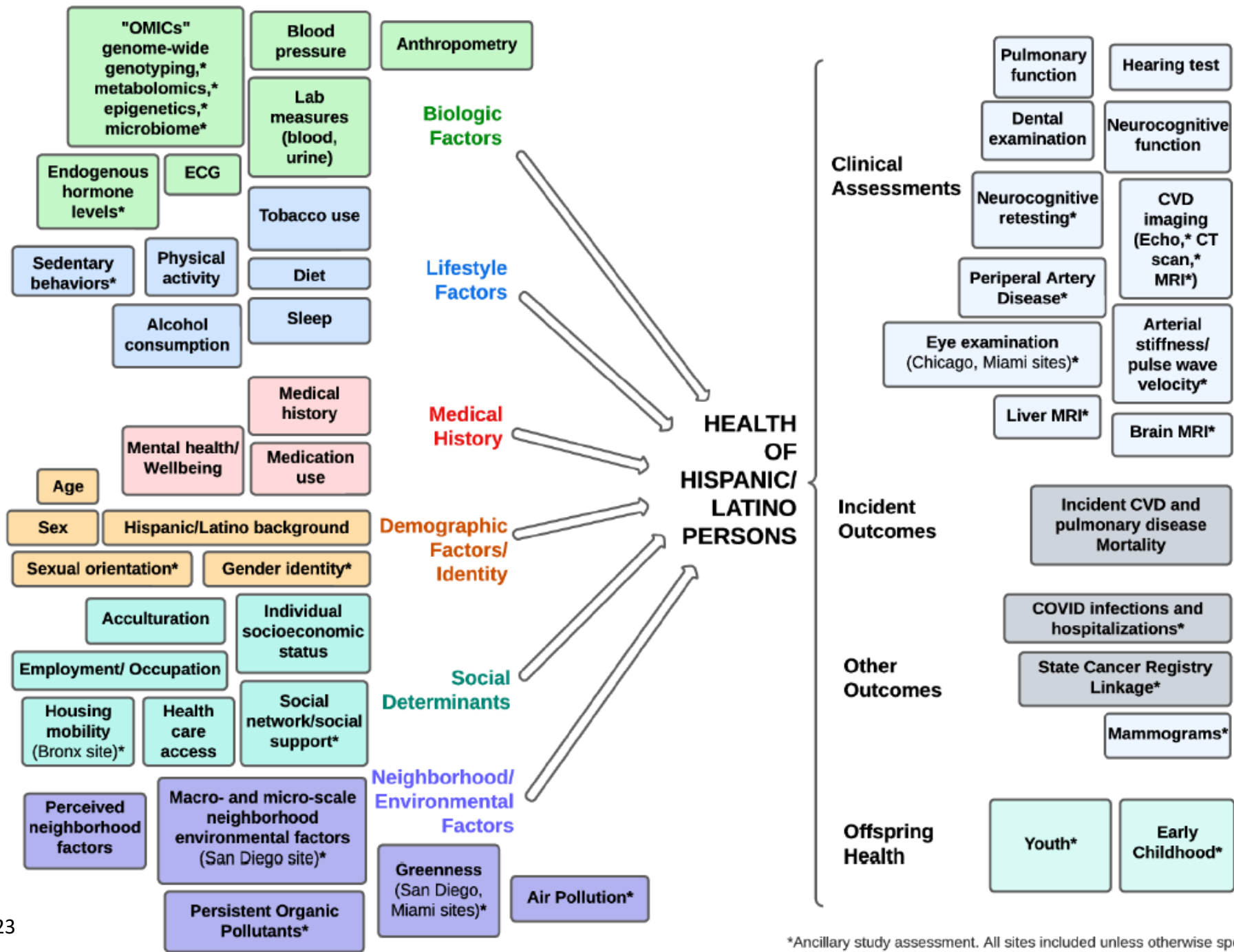
Secondary Data Analysis (SDA)

- Obtains and generates NEW data (e.g., Cancer Registry, public data from census or databases)
- Only analyses

OTHER

- Requests images
- Requests raw data

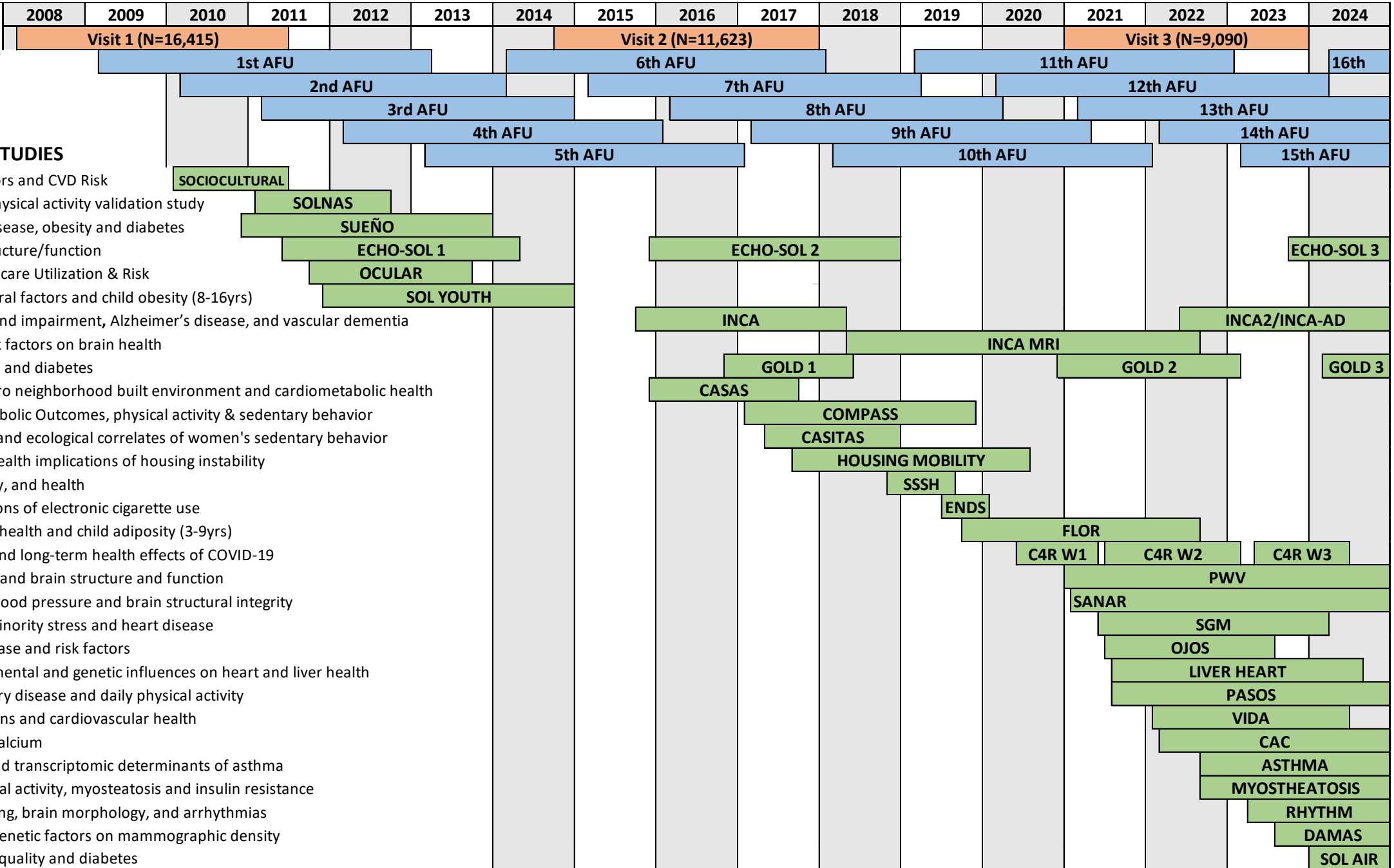
Central Illustration. HCHS/SOL Assessments and Measures: Evolving Science on Hispanic/Latino Health





ANCILLARY STUDIES

- SOCIOCULTURAL:** Factors and CVD Risk
- SOLNAS:** Nutrition & physical activity validation study
- SUEÑO:** Sleep, heart disease, obesity and diabetes
- ECHO-SOL:** Cardiac structure/function
- OCULAR:** Ocular Healthcare Utilization & Risk
- SOL YOUTH:** Sociocultural factors and child obesity (8-16yrs)
- INCA:** Cognitive aging and impairment, Alzheimer's disease, and vascular dementia
- INCA MRI:** Vascular risk factors on brain health
- GOLD:** Gut microbiome and diabetes
- CASAS:** Micro and macro neighborhood built environment and cardiometabolic health
- COMPASS:** Cardiometabolic Outcomes, physical activity & sedentary behavior
- CASITAS:** Psychosocial and ecological correlates of women's sedentary behavior
- HOUSING MOBILITY:** Health implications of housing instability
- SSSH:** Stress, spirituality, and health
- ENDS:** Health associations of electronic cigarette use
- FLOR:** Preconceptional health and child adiposity (3-9yrs)
- C4R:** Disease severity and long-term health effects of COVID-19
- PWV:** Arterial stiffness and brain structure and function
- SANAR:** Sleep apnea, blood pressure and brain structural integrity
- SGM:** Sexual/gender minority stress and heart disease
- OJOS:** Chronic eye disease and risk factors
- LIVER HEART:** Environmental and genetic influences on heart and liver health
- PASOS:** Peripheral artery disease and daily physical activity
- VIDA:** Sedentary patterns and cardiovascular health
- CAC:** Coronary artery calcium
- ASTHMA:** Epigenetic and transcriptomic determinants of asthma
- MYOSTEATOSIS:** Physical activity, myosteatosiis and insulin resistance
- RHYTHM:** Cognitive aging, brain morphology, and arrhythmias
- DAMAS:** Lifestyle and genetic factors on mammographic density
- AIR:** Neighborhood air quality and diabetes





50+ NON-PARTICIPANT CONTACT

AS# RESEARCH AREA	PI AND FUNDING
2018.16 Neighborhood Greenness and Cardiometabolic Health	Brown and Szapocznik, R01HL148880
2015.15 Genetics of kidney disease in diverse populations	Franceschini, R01DK117445
2016.04 Dietary Patterns and Risk of Cardiovascular Disease	Hu and Qi, R01HL060712
2019.02 Early and life course socioeconomic adversity and dementia risk in Hispanics/Latinos	Isasi, DeCarli and Gonzalez, RF1AG077639
2024.22 Statistical Methods for Network-based Integrative Analysis of Microbiome Data	Ma, R01GM145772
2023.26 Language acculturation, hearing loss and cognitive function	Martinez Amezcua, R21AG089091
2015.14 Fibroblast Growth Factor 23 and Sleep Disordered Breathing	Mehta, AHA funding
2022.05 Genomic contributions to FVIII and VWF levels, and identify new genomic loci	Morrison, De Vries and Smith, R01HL139553
2012.02 Genetic Epidemiology of Causal Variants across the Life Course Phase II (CALiCo I)	North, U01HG007416
2021.12 Associations between body fat and incidence of 13 obesity-related cancers	Parada, SDSU internal funding
2023.12 Tobacco-related biomarkers, nicotine metabolism, and genetic ancestry associations	Pérez-Stable, NIMHD intramural funding
2013.06 Persistent organic pollutants, endogenous hormones and diabetes	Persky, R01ES025159
2019.12 Lipids, Apolipoproteins and Lp(a) and CVD	Rodriguez and Joshi, funded by Amgen Inc/Make Well Known Foundation
2021.05 Leveraging omics data to understand sleep health and its consequences among diverse Hispanics/Latinos	Sofer, R01HL161012
2018.2 Social Stress, Epigenetics and Cardiometabolic Health of Youth	Suglia and Isasi, R01MD015204
2009.06 Genetic predictors of insulin resistance, insulin clearance, beta cell function, and T2DM	Wagenknecht and Watanabe, R01DK085175
2021.06 Perfluoroalkyl Substances (PFASs) and Liver Cancer Risk	Zhang, U01CA259208



Ancillary Studies Committee Members

Bronx



Carmen Isasi



Robert Kaplan, co-Chair



Qibin Qi

San Diego



Linda Gallo



Humberto Parada



Greg Talavera

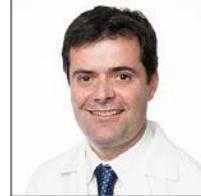
Chicago



Martha Daviglus



Amber Pirzada



Fernando Testai

Miami



Frank Penedo

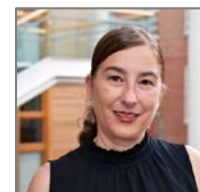


David Lee

Coordinating Center



Kari North



Daniela Sotres, co-Chair



Haibo Zhou

Central Lab



Bharat Thyagarajan

NHLBI



John Kunz

Field Center's Clinic Manager

(for participant-facing ancillaries)



What do we look for in an Ancillary Study

- Scientific value and innovation
- Potential for contributing to the health of Hispanic/Latino persons
- Ability to draw on unique characteristics of the HCHS-SOL
- Degree to which it complements the current portfolio of studies
- No undue burden on HCHS/SOL participants
- No undue burden on an HCHS/SOL Centers
- AS must be culturally sensitive to the Hispanic/Latino community
- Commitment to HCHS/SOL policies and collaboration



Ancillary Studies **MUST** be sponsored by an HCHS/SOL PI or co-PI

BRONX: Robert Kaplan, Sylvia Smoller & Carmen Isasi

CHICAGO: Martha Daviglius, Jim Lash & Amber Pirzada

MIAMI: Frank Penedo, Maria Llabre and Christina Cordero

SAN DIEGO: Greg Talavera & Linda Gallo

COORDINATING CENTER: Jianwen Cai & Daniela Sotres-Alvarez

CENTRAL LAB: Bharat Thyagarajan & Stefani Thomas

NHLBI Project Officer: John Kunz

Ancillary Studies Requesting Stored Biospecimens



- Types of specimens and amounts available to AS:
 - Serum, EDTA plasma, citrated plasma: 250 μ L
 - DNA/RNA (solution): 0.5 μ g
 - Urine: 500 μ L
- Larger amounts of specimens may be requested with scientifically compelling justification
- Biospecimens are stored in aliquots larger than the amounts released to AS. HCHS/SOL SC reserves the right to negotiate an optimal timing for the release.

Process by Type of Ancillary Study

Secondary Data Analyses (SDA)

1. Write **Manuscript** proposal
2. Submit to **Publications Committee** for Review → APPROVAL
3. Submit **SDA Ancillary Study proposal to ASC** including related APPROVED manuscript number
4. Approval by Ancillary Studies Committee
5. Establish DUA* and request analytic file to Sponsoring PI

Participant Burden or Stored Biospecimens

1. Write **Concept** proposal
2. Submit **concept proposal to ASC** for Review → Invitation to submit FULL proposal
3. Submit **FULL proposal to ASC** for Review → APPROVAL
4. Approval by Steering Committee
5. OSMB and NHLBI Approval [participant burden only]

*DUA between AS PI institution and UNC



CONCEPT Proposal Form

Ancillary Study to the HCHS/SOL

WARNING: This Form is Only Needed for Ancillary Studies Involving Participant Contact, Stored Materials or Biospecimens, or Consortia.

To select a square , please double left click, select "Checked"

ADMINISTRATIVE SECTION

Date of Submission:

Title of Ancillary Study Proposal:

Short Title of Ancillary Study Proposal (25 characters):

Lead Principal Investigator (name, institution, address, phone, e-mail address)

Name

Institution

Address

Phone

E-mail address

Early Career/Stage Investigator:

Racial or ethnic group historically underrepresented in science and healthcare:

Hispanic/Latino background:

Other Principal investigator(s) (name, institution, address, phone, e-mail address):

Administrative Supplement

To Parent Study:

To Ancillary Study: Tracking Number:

Consortium: Tracking Number:

Grant Renewal: Original Ancillary Tracking Number:

With this letter my colleagues and I indicate our intent to submit a proposal for an ancillary study to the HCHS/SOL that will involve participant contact, stored biospecimens, materials (e.g., images) and/or Secondary Data Analyses as part of a Consortium, with the aims outlined below.

1. I am familiar with the HCHS/SOL ancillary study policy (accessed on the HCHS/SOL website on) , the ancillary study review process and its timeline.
2. The funding mechanism, application due date, and award project period are: [If funding is being requested, provide source and length. If funding is NOT being requested, explain how this ancillary will be completed].
3. Brief synopsis of proposed ancillary study (should not exceed 100 words):
4. The specific aims of the proposed study are (should not exceed 300 words):
5. The study design, study size and study timeline are (should not exceed 500 words):
6. Members of the HCHS/SOL cohort [will/will not] be contacted by proposed study.
7. We will need the following existing HCHS/SOL data, materials and/or stored biospecimens for the aims of our ancillary study:
8. The new data we propose to collect are:



Key information to include

- Other ancillary studies involved
- Sample size and population of interest (women, older adults...)
- Study design
- Protocol and time
- Clinical findings
- Involve AS investigators if using their data



The FULL proposal

Administrative Section

Part A. Basic Study Information and Projected Impact on HCHS/SOL

Part B. Involvement of Centers, IRB and Laboratories

- Participant Involvement: sample size, protocol & time, benefits, risks & protections, reimbursements
- Stored Specimens: type, volume, visit, sample size, proposed Lab, analytes to be assayed

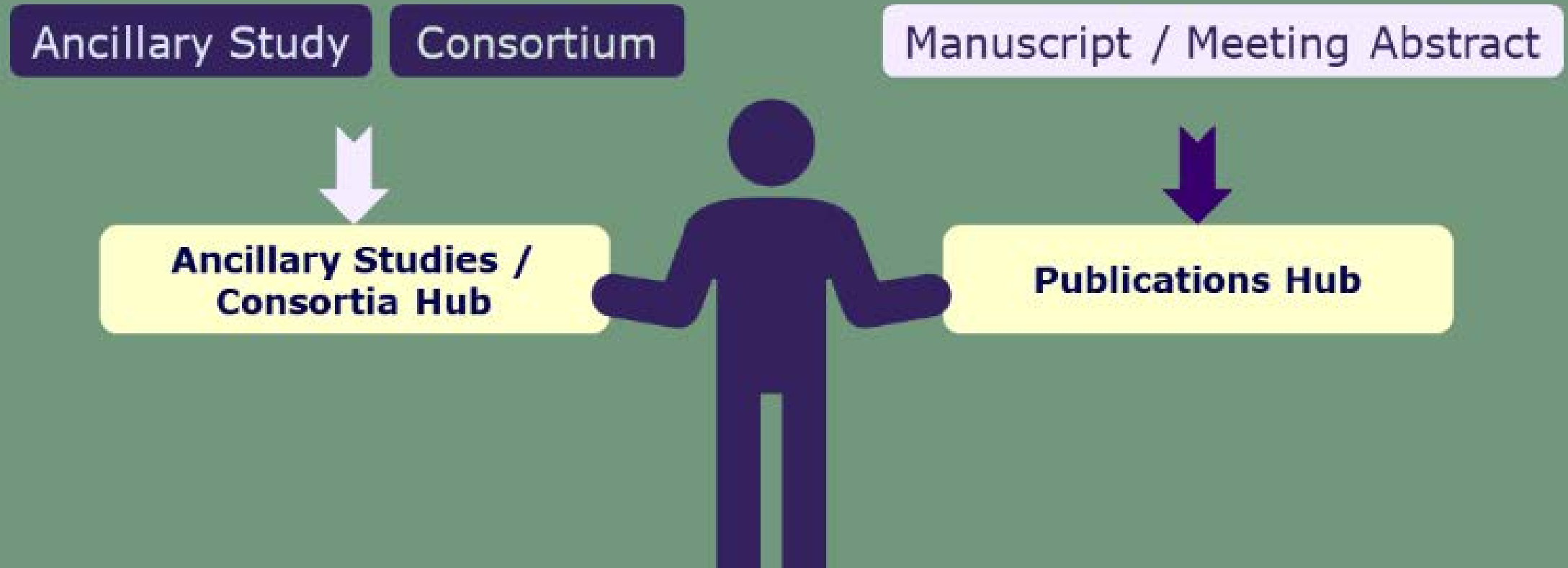
Part C. Timeline, costs, funding, data, confidentiality, data sharing

- Advantage of conducting the study within the HCHS/SOL cohort versus another population
- Impact on ongoing HCHS/SOL studies (main study or other Ancillary Studies)

Part D. Scientific description of the Ancillary

- Purpose/Aims
- Background
- Hypotheses
- Experimental Design (include sample size justification)
- Participant involvement
- Data to be collected by the ancillary study
- Analysis Methods

Submit ALL PROPOSALS through portal



Ready to submit an Ancillary Study Proposal?

Hispanic Community Health Study / Study of Latinos

Hispanic Community Health Study

My account My HCHS/SOL Work Log out

HCHS - Front Page News

Recently Published HCHS/SOL Research Findings
improving knowledge and impacting health

Ancillary & Consortium Studies

- Completed Ancillary Studies
- Bronx Asthma AS #2019.06
- C4R AS #2020.03
- CAC AS #2017.32
- DAMAS AS #2019.13
- ECHO / ECHO 2 / ECHO 3
- GOLD / GOLD 2 / GOLD 3 AS #2013.08
- Myosteatosi AS #2019.10
- NAFLD AS #2017.30
- Pulse Wave Velocity AS #2017.21
- SANAR AS #2018.08
- SOL-AIR AS #2018.21
- SGM-SOL AS #2018.22

Submissions

- Tracking
- Training
- SC Reviewed Proposals

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Clear history

Search


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dy / Study of Latinos (HCHS/SOL)

... Interest Group with HCHS/SOL Investigators. Clic
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c Community Health Study/Study o

Ready to
submit an
Ancillary
Study
Proposal?



Hispanic Community Health Study

[My account](#) [My HCHS/SOL Work](#) [Log out](#)

- [About the Study](#)
- [Collaborating with HCHS/SOL](#)
- [Publications](#)
- [Ancillary Studies / Consortia Hub](#)
- [Calendar](#)
- [Directory](#)
- [Documents](#)
- [Links](#)
- [Publications Hub](#)
- [Steering Committee](#)
- [Website Help](#)

[Download Acrobat Reader® here](#)

Hispanic Community Health Study / Study of Latinos

Ancillary Studies / Consortia Proposal Submission

Navigating this page:

This page is for submitting forms for Ancillary Concept Proposals, Ancillary Full Proposals, Consortium Proposals, and Approved Ancillary Study Amendment Requests.

The buttons below will open your email client and prepopulate a message that will be sent to HCHSAncillary@unc.edu. You must attach appropriate material, found at [Collaborating with HCHS/SOL webpages](#). All submissions require use of one of these forms; please complete the appropriate one.

If you would like to submit a letter of intent for ancillary study or consortium use button below.

[Submit a Concept Proposal Memo](#)

If you have received a decision email inviting submission of a full ancillary study proposal use button below.

[Submit an Ancillary Study Full Proposal](#)

If you have a previously approved ancillary study (with tracking number) and would like to propose amendments to this approved ancillary study use button below. Clicking the button below will open your email client and prepopulate a message where you will need to attach appropriate material.

[Submit an Approved Ancillary Study Amendment Request](#)

Submit all forms by email to HCHSAncillary@unc.edu. Contact HCHSAdministration@unc.edu if you have a question regarding the approval process or status of your submission.



Help us harmonizing file names

Please send form to "HCHS/SOL Ancillary Committee" HCHSAncillary@unc.edu

Subject line: use 'HCHS/SOL Ancillary FULL or CONCEPT proposal by LASTNAME'

FILE NAME CONVENTION:

LASTNAME_FULL/CONCEPT_BriefTitle_YYYY-MM-DD.docx (submission date)

LASTNAME_FULL /CONCEPT _BriefTitle_BIOREPOSITORY.docx (if applicable)

- Last name: use contact investigator's last name
- Brief title: use 2 to 4 key words
- Date: use date of submission
- Make file Read Only
- **Example: ISASI_FULL_SOLYouthCellCommunities_2023-07-13.docx**



Biorepository Impact Statement

Contact Central Lab:

- Bharat Thyagarajan (thya0003@umn.edu), PI
- Stefani Thomas (stefanit@umn.edu), PI
- Sharon Minnerath (minne002@umn.edu), Coordinator

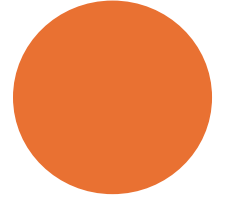
Statement includes:

- Samples requested, volume and number by visit
- Percentage of samples left
- Expiration Date



Field Center Costs

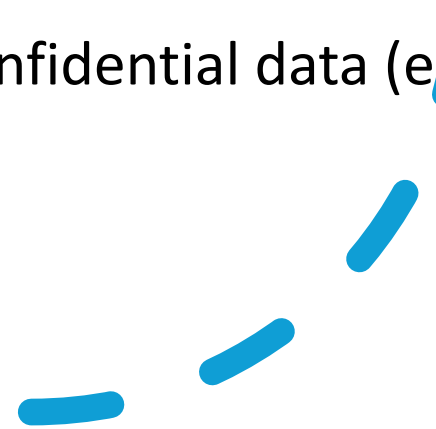
- Contacting and recruiting participants
- Conducting procedures
- Coordination of additional data collection, data transfer, and archiving
- Participant incentives, transportation, and meals
- Explaining results and alerts to participants; medical referrals
- Obtaining appropriate IRB or other approvals
- Lease of clinic space or infrastructure





Coordinating Center Costs

- Eligibility or biosample lists
- Data management system (forms and feedback reports)
 - Alerts and adverse events
- Coordinating Field Centers, Central Lab, and Reading Centers
- Data transfers and QC reports
- Management Reports
- Datasets for AS conducting only secondary data analyses
- Secure Research Workspace to use confidential data (e.g., geocodes, immigration status)





Central Lab

- Pulling samples
- Shipping samples
- Performing lab tests if requested

Single IRB



RESEARCH + HUMAN SUBJECTS = MUST ASK IRB FIRST BEFORE YOU DO ANYTHING





Amendment & Expired AS Extension Form



Amendment: adding new procedures or questionnaires, requesting additional stored biospecimens, increasing sample size.



Extension: Approval remains effective for 24 months from the date of approval by the Steering Committee.



ASC Review Timeline

- **ASC meets the 1st Tuesday of the month.** Proposals received 10 days before will be distributed for review
- Concept Proposal approval: 4-8 weeks
- Full Proposal review: 4-8 weeks
- NHLBI and HCHS/SOL OSMB review: up to 8 weeks following SC review.
- Participant burden: 3 reviewers (Field Center PI, clinic manager, ASC member)
- Biospecimens only: 2 reviewers
- SDA, amendments, extensions: 1 reviewer

PLEASE SUBMIT AT LEAST 3 MONTHS BEFORE YOUR GRANT SUBMISSION DEADLINE



Checklist

- I. **Required Application Information:** *Your proposal cannot be reviewed by the Ancillary Studies (AS) Committee without the following elements:*
 - Approval from sponsoring field center or Coordinating Center PI** (Bronx: Kaplan, Isasi; Chicago: Daviglius, Pirzada; Miami: Penedo, Llabre, Cordero; San Diego: Talavera, Gallo; Coordinating Center: Cai, Sotres-Alvarez)
 - Approval from PI of an existing Ancillary Study**, if the project will use their data or materials [if applicable]
 - Biorepository Impact Statement** [to be included when submitting Full proposal or Amendments for Ancillary Studies requesting biospecimens]
 - Response to Reviewers** [if applicable, revised proposals]
 - For Ancillary Studies involving a Consortium: The Consortium Proposal must be approved by the Steering Committee first. A Consortium number must be provided in the Ancillary Full Proposal form.
 - For Ancillary Studies doing Secondary Data Analyses: NIH aims page (including references); Secondary Data Analyses Ancillary Study form which cites the number of an approved manuscript proposal

Data



Data and Materials Distribution Agreement (DMDA)

Data integrity and security

Non-transferability

Compliance with HCHS/SOL policies

Requirement to send the AS data and documentation to CC



NIH Data Sharing Policy

AS data incorporated to HCHS/SOL database & submitted to NIH yearly

- data used in any AS publications published within the prior 12 months;
- final AS data at the end of the AS study.



Timeline for ancillary studies alignment with V4

	2024	2025	2026	2027	2028	2029	2030	2031	2032
AFU - 4th contract									
V4 Exam (9/1 2027-8/31/30)									
AS submitted Oct 2024		Start date 7/25							
AS submitted Feb 2025		Start date 9/25							
AS submitted June 2025			Start date 4/26						
AS submitted Oct 2025			Start Date 7/26						
AS submitted Feb 2026			Start date 9/26						
AS submitted June 2026				Start date 4/27					
AS submitted Oct 2026				Start Date 7/27					

Allows time for resubmissions





V4 proposed content (details and final instruments to be finalized in 2026-2027)

Component	
Blood draw (serum/plasma)	Cholesterol, HDL-C, Triglycerides, LDL-C (calculated), Creatinine; Hemoglobin A1c; Fasting Glucose
Spot Urine	Urine Albumin/Creatinine Ratio
Physical exam	Blood pressure, anthropometry
Medical history and medications	
Health Behaviors	Smoking; Diet (likely some brief FFQ), GPAQ; self-reported sleep duration/quality
Socio-demographics	Marital status, Language preference, racial identity
SDoH	Income, employment, occupation, housing and food security, and general financial security, caregiving
Psychosocial factors	Anxiety; depression, chronic stress, social support

Where do I find HCHS/SOL Ancillary Studies Documents?

The screenshot shows the website for the Hispanic Community Health Study / Study of Latinos (HCHS/SOL). At the top left is the logo featuring a sun and three stylized figures, with the text 'SOL Study of Latinos' and 'Hispanic Community Health Study'. To the right of the logo is the text 'Hispanic Community Health Study / Study of Latinos'. Below the logo are buttons for 'My account', 'My HCHS/SOL Work', and 'Log out'. A main navigation menu on the left lists: 'About the Study', 'Collaborating with HCHS/SOL' (highlighted in orange), 'Publications', 'Ancillary Studies / Consortia Hub', 'Calendar', 'Directory', 'Documents', 'Links', 'Publications Hub', 'Steering Committee', and 'Website Help'. A secondary menu titled 'HCHS - Front Page News' is open, listing 'Opportunities for New Investigators', 'Scientific Interest Groups', 'Ancillary Studies' (highlighted in orange), and 'Consortia'. At the bottom left, there is a link to 'Download Acrobat Reader® here' and a search bar with a 'Search' button. On the right side, there is a banner with the text 'Are you a potential collaborator?' and 'Join a Scientific Interest Group with HCHS/SOL Investigators' over a background image of people in a meeting.

<https://sites.csc.unc.edu/hchs/ancillary-studies-pub>

Information Available on Website

<https://sites.csc.unc.edu/hchs/ancillary-studies-pub>

Table with overlap for participant-facing AS

List of ALL Funded Ancillary Studies

HCHS/SOL Ancillary Study Timeline

Genetics-Omics Inventory Summary

Ancillary Study Committee - Membership & Reviewer

Checklist and **Word FORM TEMPLATES**

Frequently Asked Questions

For SDA proposals, can I submit to the PC and the ASC at the same time? No

When do I contact/involve Field Centers?
After Concept Proposal. If high burden, engage them early.

When do I submit the Biorepository Impact Statement? With full proposal

Where are approved AS proposals?

<https://sites.csc.unc.edu/hchs/ancillary-studies-tracking> (list only)

SEE NEXT SLIDE FOR INSTRUCTIONS ON HOW TO FIND THE CONTENT OF APPROVED CONCEPT AND FULL PROPOSALS



Where can I find each Ancillary proposal submitted? 1/2

- Go to Ancillary Studies / Consortia Hub
- Go to Ancillary & Consortium Studies
- Click SC Reviewed Proposals
- Select –Any- in the “Subcommittee filter”
- Click “Apply” button
- FOCUS on Table “Ancillary Studies”

Hispanic Community Health Study
My account My HCHS/SOL Work Log out

HCHS - Front Page News

Scientific Interest Groups

- About the Study
- Collaborating with HCHS/SOL
- Publications
- Ancillary Studies / Consortia Hub**
- Calendar
- Directory
- Documents

- Ancillary & Consortium Studies
 - Submissions
 - Tracking
 - Training
 - SC Reviewed Proposals**
- Completed Ancillary Studies
 - Bronx Asthma AS #2019.06
 - C4R AS #2020.03
 - CAC AS #2017.32

Hispanic Community Health Study
My account My HCHS/SOL Work Log out

- About the Study
- Collaborating with HCHS/SOL
- Publications
- Ancillary Studies / Consortia Hub
- Calendar
- Directory
- Documents
- Links
- Publications Hub
- Steering Committee
- Website Help

Subcommittees by Name

Navigating this page:
Sortable table(s) of meeting agendas, minutes, and notes from committee meetings filterable by date. The documents can be viewed by clicking on PDF under the view column.
For archival purposes all ancillary study concepts, proposals, and approvals are organized in alphabetical order by Submitter's last name.

Subcommittee filter
- Any -

[Download Acrobat Reader® here](#)



Where can I find each Ancillary proposal submitted? 2/2

Ancillary Studies		
Title	Date	View
A Glenn - Metabolomic signature of a cholesterol-lowering plant-based diet and cardiometabolic disease risk in HCHS/SOL - Secondary Data Analysis 12Feb2025 SC Approved #2025.07	02/14/2025	PDF
Luo - Metabolomic estimation of type 2 diabetes-associated dysbiosis and risk of cardiovascular and chronic kidney diseases - Secondary Data Analysis 12Feb2025 SC Approved #2025.08	02/12/2025	PDF
R Isasi - Understanding Return of Value in a Cohort of HCHS/SOL Participants And Investigators Full Proposal (biosample request) 12Feb2025 SC approved #2025.09	02/12/2025	PDF
Sofer - COSMIC Consortium 12Feb2025 SC Approved # C2025.01	02/12/2025	PDF
N Makarem - Interplay of Diurnal Blood Pressure, Glycemic, and Health Behavior Profiles in Cardiovascular Risk among US Hispanic/Latino Adults - Concept Proposal SC approved 12Feb2025	02/12/2025	PDF
J Lima - Coronary Atherosclerosis, Microvascular Disease and Myocardial Fibrosis as Substrates for Atrial Fibrillation and Heart Failure among Hispanic Women and Men - Full Proposal 12Feb2025 SC approved #2025.05	02/12/2025	PDF, PDF, PDF
Q Sun / E Rimm - The human gut microbiome, fecal and plasma metabolome, and coronary heart disease Concept Proposal (biosample request) SC approved 12Feb2025	02/12/2025	PDF
X Qui - A Metabolomics Approach to Investigate Neighborhood Environment, Positive Lifestyles and Mental Well-being - Secondary Data Analysis 12Feb2025 SC Approved #2025.06	02/12/2025	PDF
S Suglia - Reproductive events, menopause and biological aging among Latina women - FULL PROPOSAL SC OSMB approved - 22January2025 - #2025.02	01/22/2025	PDF
Lima - Coronary Atherosclerosis, Microvascular Disease and Myocardial Fibrosis as Substrates for Atrial Fibrillation and Heart Failure among Hispanic Women and Men - Concept Proposal SC approved 22Jan2025	01/22/2025	PDF

- Ancillary Study Concept proposals
- Ancillary Study FULL proposals
Approved include the ancillary identifier number (#YYYY.01, 02, etc.)

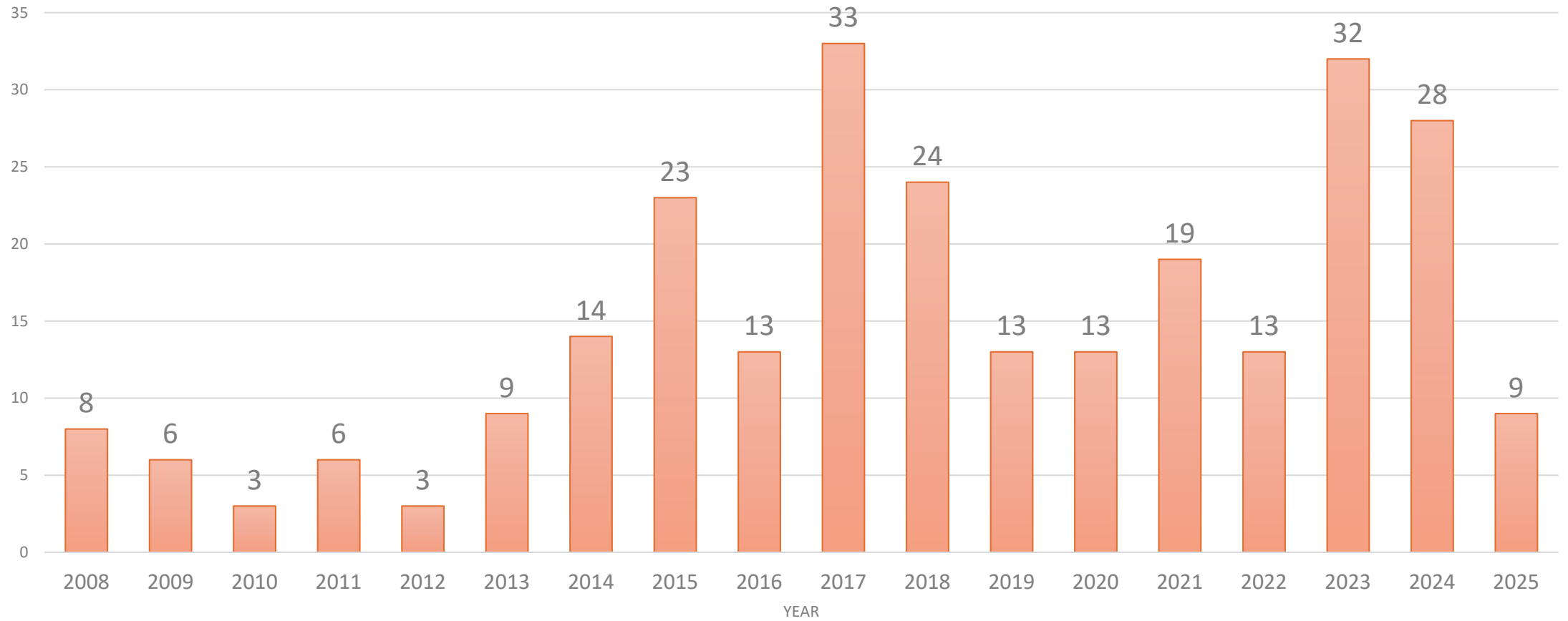
→ You can sort by Title or Date

Forms needed (see section 5.5 [AS Policy](#))

AS Type	Concept	Full	Other Form	Additional Documentation
(1) Career Development or Diversity Supplement (only doctoral, postdoctoral, ESI/ECI)			Secondary Analyses Form	1+ manuscript proposal approved
(2) Secondary data analyses only			Secondary Analyses Form	1+ manuscript proposal approved
(3) Consortium seeking funding*	Y	Y		
(4) Stored biospecimens or Material only	Y	Y		Biorepository Impact Statement
(5) Participant burden only	Y	Y		
(6) Participant burden and stored biospecimen	Y	Y		Biorepository Impact Statement
(7) Administrative Supplement	Y	Y		
(7) Competitive Renewal	Y	Y		
(7) Amendment			Amendment Form	
(7) AS time extension			Amendment Form	

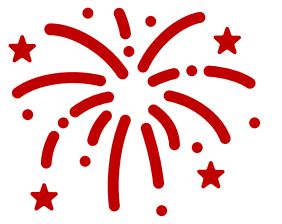
*Consortia must be approved by HCHS/SOL SC first and will have an assigned tracking #.

Approved Ancillary Studies (2008 - 2/2025)





HCHS/SOL in Numbers



19th anniversary

Publications & Ancillary Studies

- 550+ Publications in print (2014-25)
- 1082+ Manuscripts in progress
 - ~200 under peer review
- 100+ Funded Ancillary Studies
 - 32 Participant contact
 - ~60 No participant contact
 - 28 Consortia

Visits, AFU and Endpoints

- 3 clinic visits
- 16 AFU years (>82% response rate)
- 15K hospitalizations or ED visits
- 969 deaths (12/31/2021)

Investigators

- 200+ Investigators
- 20 Career Development Awards
- 18 Diversity Supplements



Thanks!



U.S. Department of Health and Human Services
National Institutes of Health



Dedicated to participants and staff of HCHS/SOL

The National Heart, Lung and Blood Institute (NHLBI) and six other Institutes and Centers from the National Institutes of Health:

National Institute of Diabetes and Digestive and Kidney Diseases
National Institute of Neurological Disorders and Stroke
National Institute of Deafness and Other Communication Disorders
National Institute of Dental and Craniofacial Research
National Institute of Minority Health and Health Disparities
National Institute of Health-Office of Dietary Supplements

