



# NACC Flow and Subaward Setup

**Presented by: NACC**

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**Feb 28, 2024**

# Agenda

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- CLARiTI updates
- Overview of subaward setup process
- Overview of site payments process
- Who to contact at NACC
- Questions?



# CLARiTI

# ADRC Consortium for CLARiTi

## (CLarity in ADRD Research Through Imaging)



Johnson, Mormino, Foroud, Rabinovici, Okonkwo, Rivera-Mindt, Dickerson, Wolk, Kukull

### Vision

Empower individuals from all communities to prevent or effectively treat the multiple intersecting causes of cognitive impairment within ADRD

### COMPONENT LEAD INVESTIGATORS (partial list of 47 investigators)

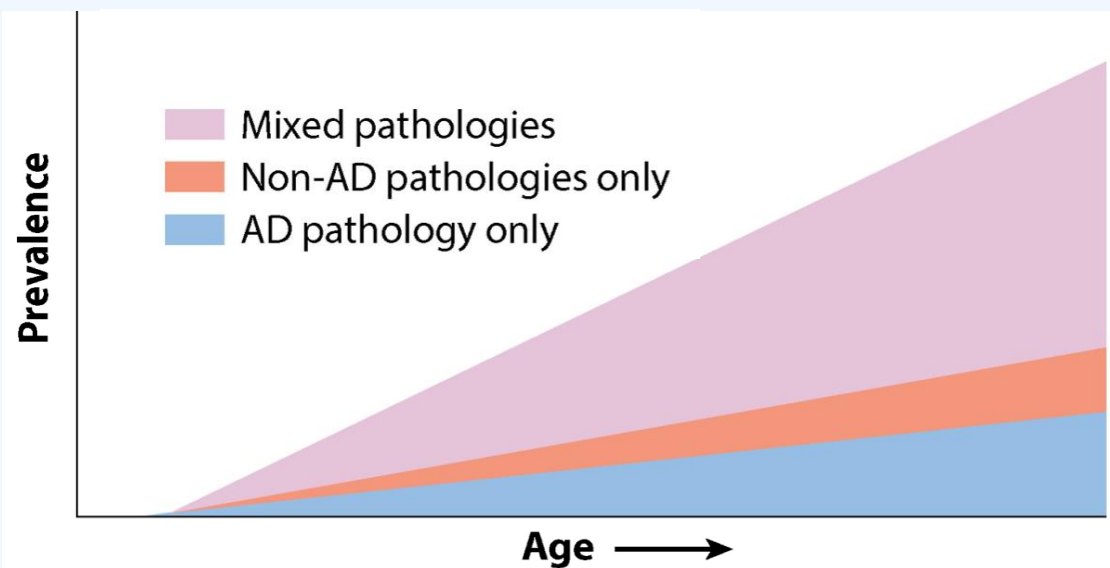
- **Johnson/Mormino/NACC:** Admin
- **Rivera-Mindt/Okonkwo:** Inclusion
- **Biber/Kukull/Toga:** Image-Data informatics
- **Keene:** Neuropath
- **Rabinovici:** PET image reads
- **Shibata:** MRI scoring
- **Rahman-Filipiak/Clark/Chin:** Disclosure
- **Rosen:** neuropath MRI templates
- **Jagust/Jack:** SCAN
- **Villemagne:** PET harmonization
- **Detre:** Advanced MRI methods
- **Dage/Foroud:** Biofluid mgmnt, assays
- **Donohue:** Stats
- **Betthausen:** Biomarker time
- **Jones:** FDG analysis
- **Hohman:** Data harmonization integration
- **Kantarci:** LBD image analysis

### Industry collaborators

- LMI
- Lantheus/Cerveau
- Enigma
- Lilly
- Flywheel
- Alzpath
- Amprion
- Merck
- GE
- Siemens
- Phillips

# CLARiTI

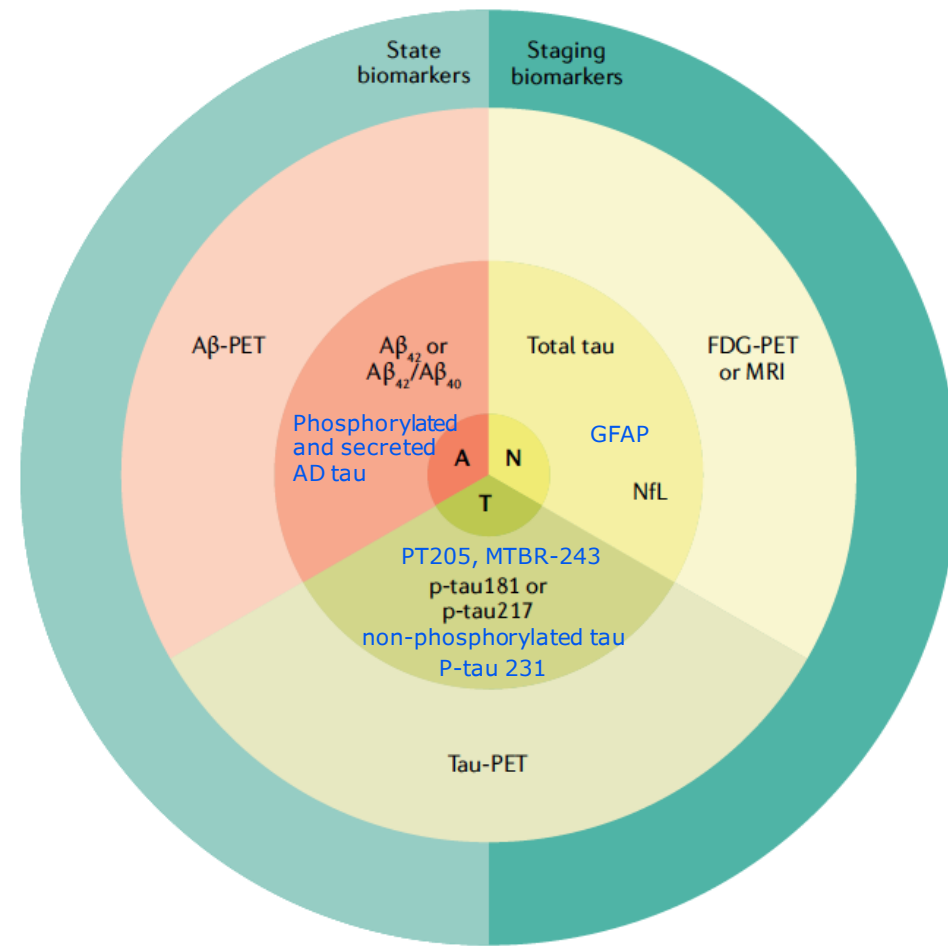
## Mixed Etiology Dementia is Common



### Common co-occurring pathologies

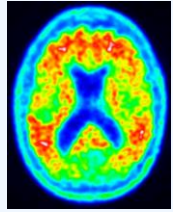
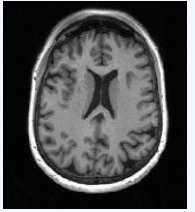
- Lewy body (LBD)
- Frontotemporal lobar degeneration (FTLD)
- Cerebrovascular disease
- LATE (TDP-43)

## ATN Biomarker

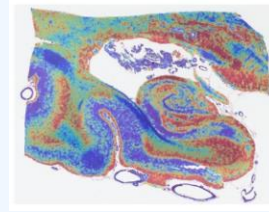


# CLARiTI Goals

## 1. Create individual etiologic profiles using imaging, plasma, and antemortem biomarkers



	Initial Visit (IV)	Follow-up Visit (FV)	Tel. Initial Visit (TIP)	Tel. Follow-up (TFP)
A1: Subject Demographics				
A2: Co-participant Demographics				
A3: Subject Family History				
A4: Subject Medications				



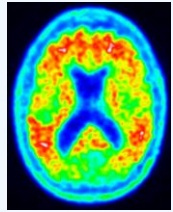
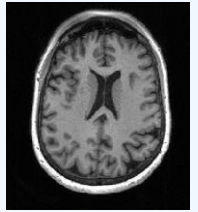
ATN Imaging and Plasma

Longitudinal UDS

Digital Neuropath

# CLARiTI Goals

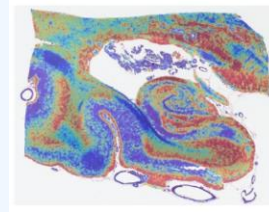
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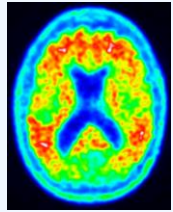
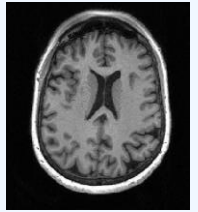


Digital Neuropath

## 2. Provide resources to implement standard biomarker methods across the ADRC Program

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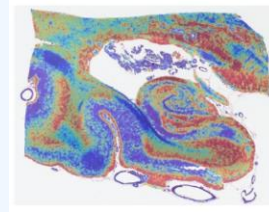
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Longitudinal UDS



Digital Neuropath

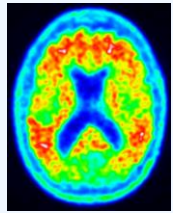
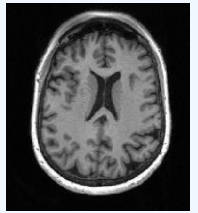
## 2. Provide resources to implement standard biomarker methods across the ADRC Program

## 3. Diverse representation for generalizable discoveries



# CLARiTI Goals

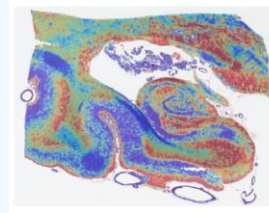
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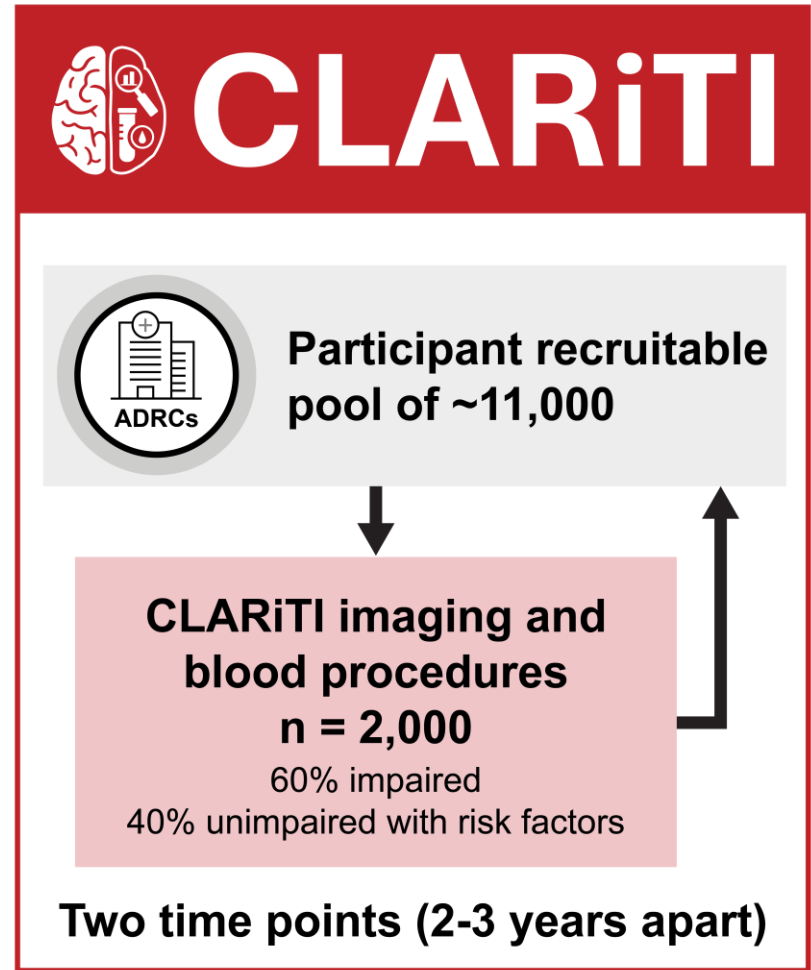
Longitudinal UDS



Digital Neuropath

2. Provide resources to implement standard biomarker methods across the ADRC Program

3. Diverse representation for generalizable discoveries



# CLARiTI updates

- **Site survey – please complete ASAP!**

- Arizona, Nevada, New Mexico, NYU, UAB, UC Davis, UCSD, University of Washington, USC, Vanderbilt, Yale

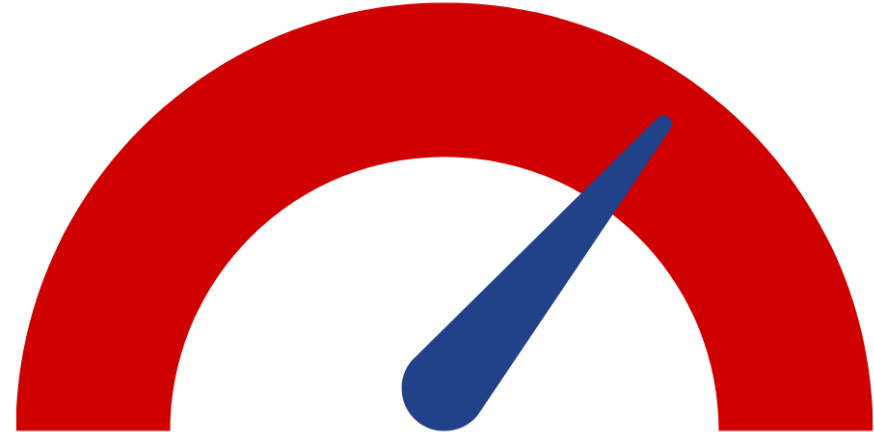
ADRC	Completed
Boston University	✓
Columbia University	✓
Emory University	✓
Massachusetts	✓
Indiana University	✓
Johns Hopkins	✓
Mayo Clinic	✓
Mount Sinai	✓
Northwestern	✓
OHSU	✓
Rush University	✓
University of Kentucky	✓
PENN	✓

ADRC	Completed
University of Pittsburgh	✓
Washington University	✓
UC Irvine	✓
UCSF	✓
Wisconsin	✓
University of Kansas	✓
Stanford	✓
1Florida	✓
Wake Forest University	✓
University of Michigan	✓
Duke/UNC	✓
Cleveland	✓
South Texas	✓

# CLARiTI updates

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- CLARiTI breakout session at NACC spring meeting
  - May 6th, 11:35-1:05pm CT
- IRB approval
  - Consent templates available
  - Change of protocol coming soon
- Single IND has been submitted
- Biweekly CLARiTI newsletter
- CLARiTI Concierge
- Site handbook
- Site initiation meetings

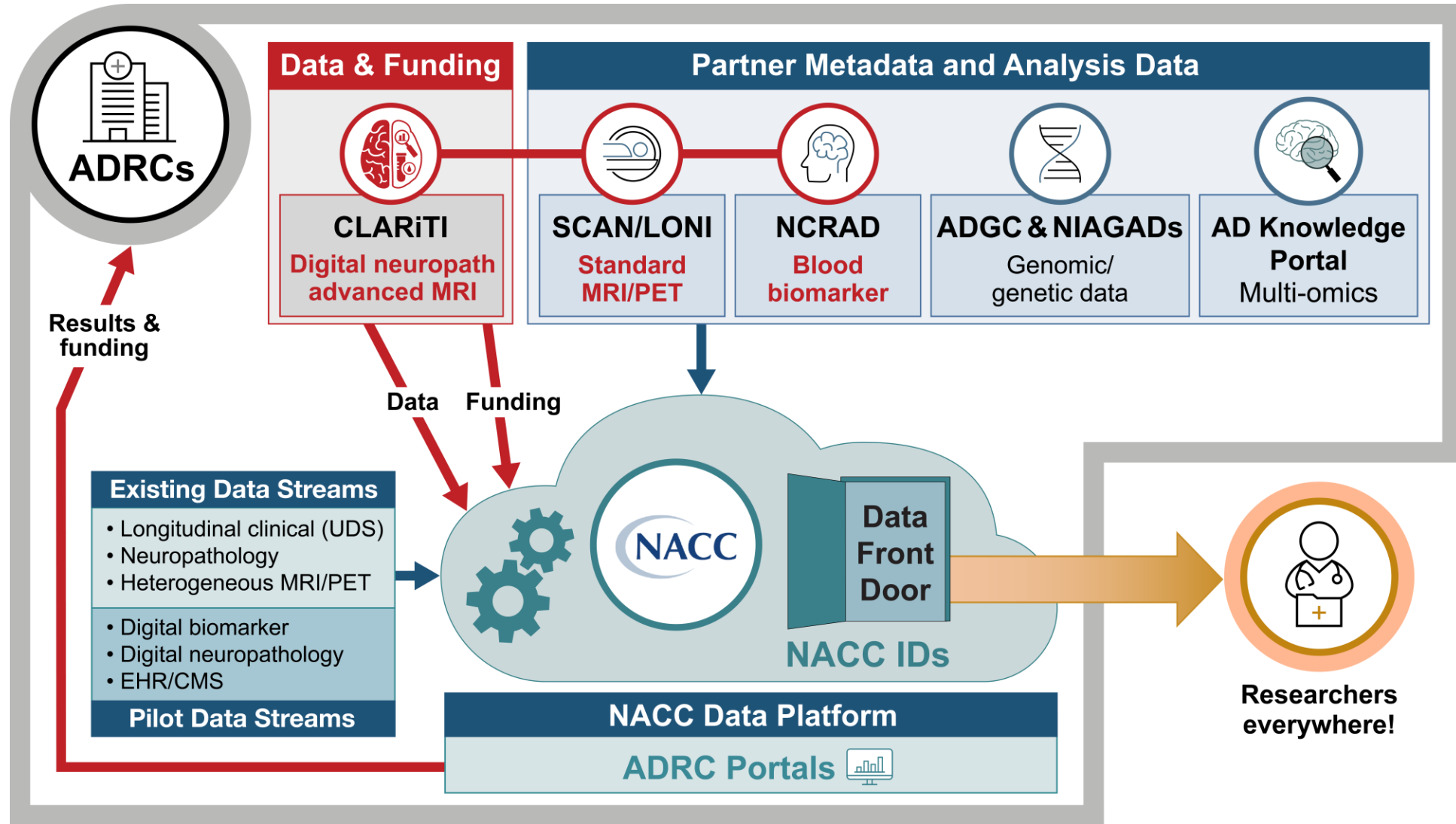


# Site Readiness Checklist

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- Site survey completed
- Ceding local IRB review to WCG
- WCG approval of local consent forms
- Adding your site to the SOWs for tracers (if applicable)
- Training with radioligand companies (if applicable)
- 1572 form on file under single IND (if applicable)
- Site initiation training with U Wisc Central Monitoring Service
- Training on case report forms
- Imaging upload training
- See full list: <https://go.wisc.edu/478880>

# CLARiTI Summary





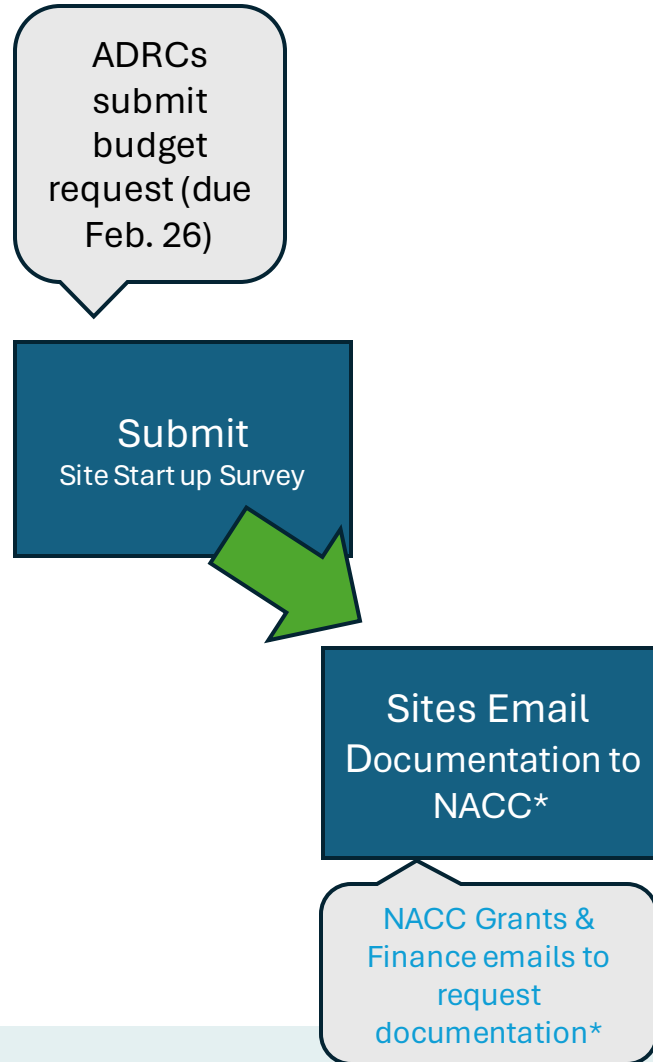
# Subaward Process & Payments

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# Subaward Agreement Set up Process Timeline & Roles

Role	Process	Timeline
ADRCs	Submit site start-up survey via REDCap	Due February 26, 2024
CLARiTI Leadership	Identify 1st wave of sites to activate	Early March 2024
NACC	Contact ADRCs to collect startup documentation	Mid-March 2024
ADRCs	Submit required startup documentation to NACC	TBD by ADRCs (~3 weeks)
ADRCs and NACC	Execute Subaward Agreement	5-7 weeks
NACC	Process payments to ADRCs	4-8 weeks

# Subaward Agreement Process



*\*see next slide for required documentation*

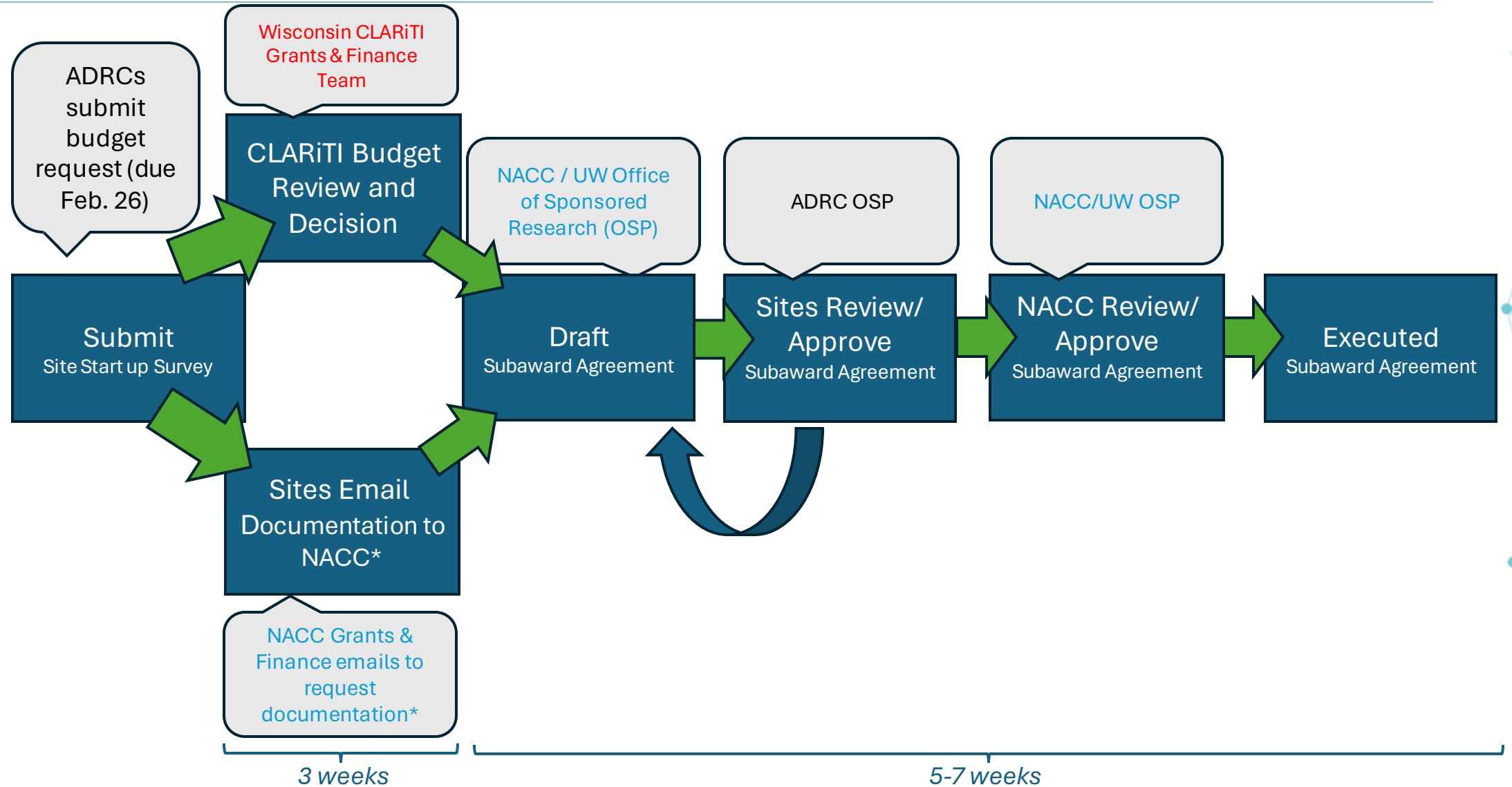


# Subaward Required Documentation

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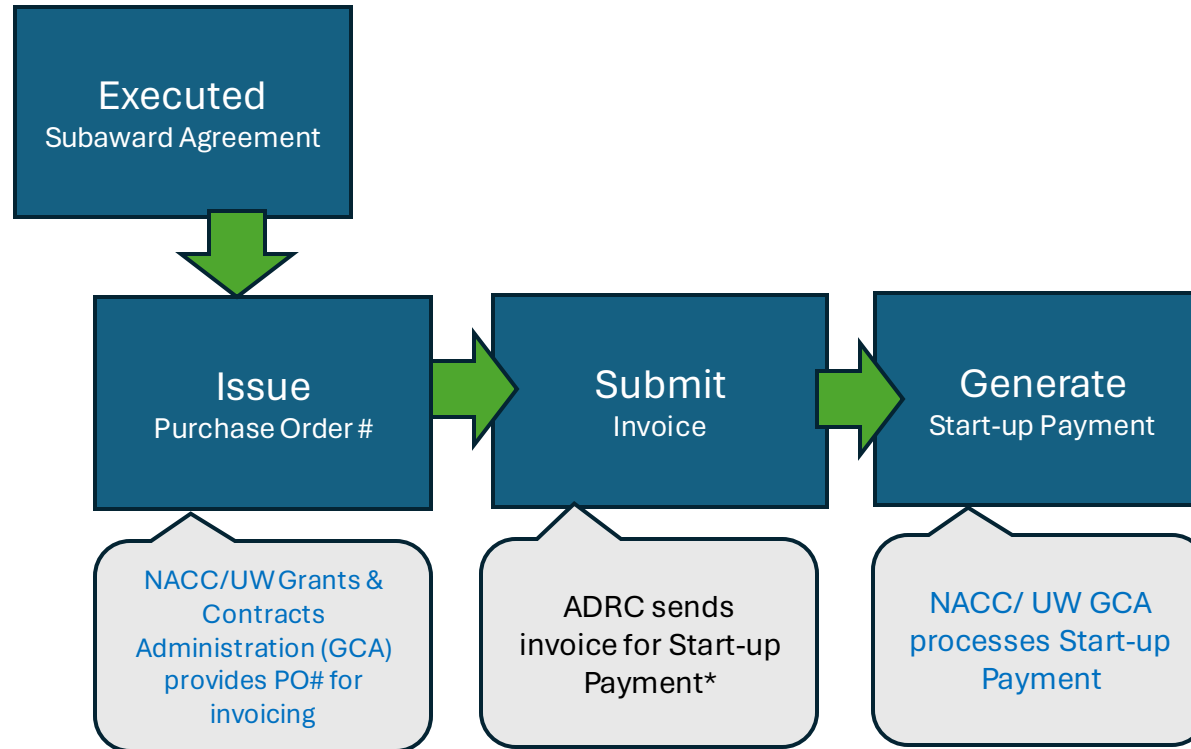
- F&A agreement
- Site PI & key personnel bio sketches
- Senior and Key person profile form
- Site UEI # and performing site addresses
- Institutional Letter of Intent signed by Authorized Organization Representative *(includes final, reviewed budget and letter is addressed to University of Washington)*

# Subaward Agreement Set-up Process



\*see next slide for required documentation

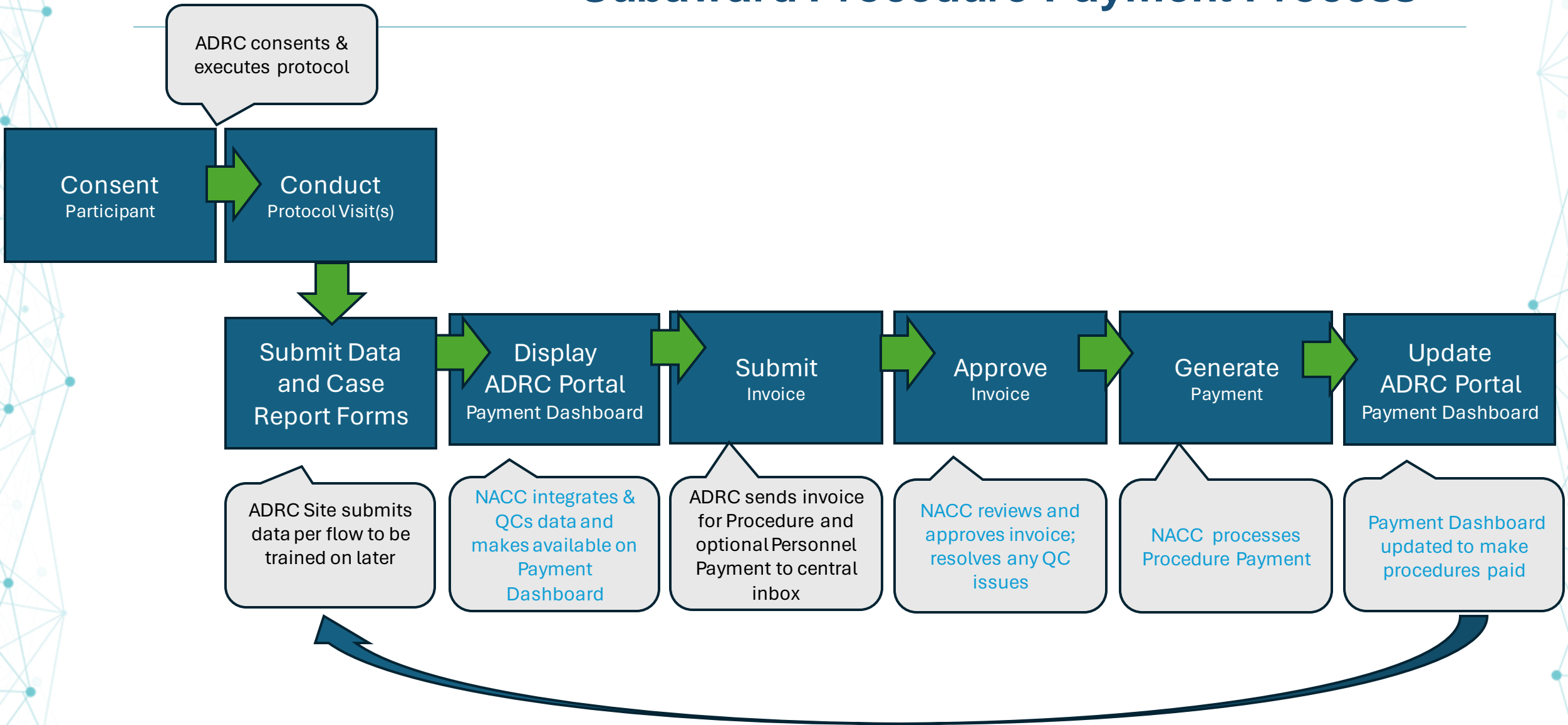
# Subaward Start-up Payment Process



\*Start-up payment includes:

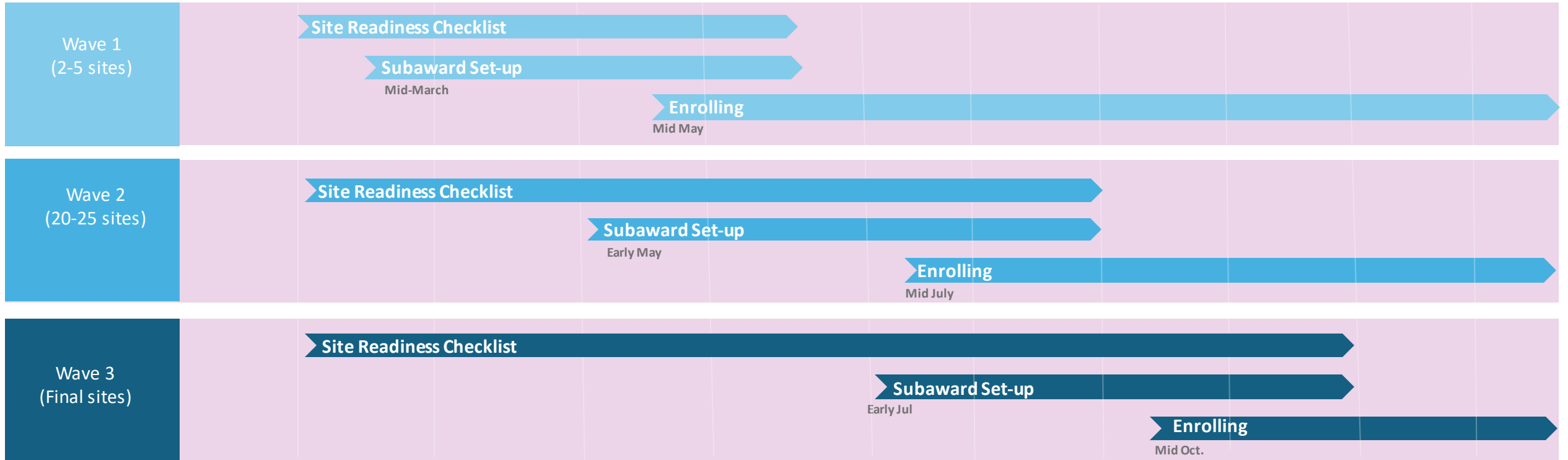
- Start-up costs: \$10k
- Outreach costs: \$10k
- Personnel fixed costs

# Subaward Procedure Payment Process



Site Start-up Survey Due  
Feb 26

First Enrollment



# NACC Contacts

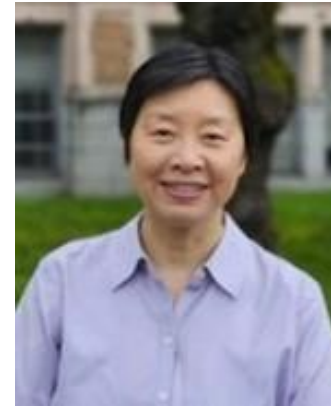
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Jingyan (Jane) Xia  
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Finance Manager  
[naccgrants@uw.edu](mailto:naccgrants@uw.edu)

# Upcoming Webinar



## Study Startup & Inclusion Processes

Wednesday, March 27, 2024  
2:30 - 3:30pm ET



Register now using QR  
Code

or via email that will be sent  
following this meeting

### Speakers

- **Sterling Johnson, PhD**  
CLARiTI MPI & Administration Co-Lead,  
Wisconsin ADRC
- **Elizabeth Mormino, PhD**  
CLARiTI MPI & Administration Co-Lead,  
Stanford ADRC
- **Erin Chin**  
CLARiTI Program Administrator,  
Wisconsin ADRC
- **Monica Rivera-Mindt, PhD**  
CLARiTI mPI & Inclusion Co-Lead  
Associate Scientist and Professor of  
Psychology & Latin American and Latino  
Studies Institute, Fordham University
- **Ozioma Okonkwo, PhD**  
CLARiTI mPI & Inclusion Co-Lead  
Professor, Department of Medicine  
Division of Geriatrics and Gerontology,  
University of Wisconsin, Madison



# Thank you!

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# Questions?

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# EXTRA SLIDES

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