Welcome and Introductions

Ming Lei, Ph.D.
National Institute of General Medical Sciences
## Webinar Outline

<table>
<thead>
<tr>
<th>Topic</th>
<th>Presenter</th>
<th>Time</th>
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<tbody>
<tr>
<td>Welcome &amp; Introductions</td>
<td>Ming Lei Ph.D.</td>
<td>1:00-1:05pm</td>
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<tr>
<td>Overview of RADx</td>
<td>Ming Lei Ph.D.</td>
<td>1:05-1:15pm</td>
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<tr>
<td>Testing and Vaccination &amp; CR</td>
<td>Monica Webb Hooper Ph.D.</td>
<td>1:15-1:35pm</td>
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<tr>
<td>RFA-OD-21-008 &amp; NOT-OD-21-103</td>
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<tr>
<td>SEBI</td>
<td>Dave Kaufman Ph.D.</td>
<td>1:35-1:50pm</td>
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<td>RFA-OD-21-009</td>
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<tr>
<td>CDCC and Data Sharing</td>
<td>Dottie Castille Ph.D.; Beda Jean-Francois Ph.D.</td>
<td>1:50-2:05pm</td>
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</tbody>
</table>
Presenters and Panelists

Presenters:

**Dr. Ming Lei** (Director of the Division for Research Capacity Building, NIGMS, RADx-UP Working Group Co-Chair)

**Dr. Monica Webb Hooper** (Deputy Director, NIMHD, RADx-UP Working Group Co-Chair)

**Dr. Dave Kaufman** (Program Director, NHGRI, Division of Genomics and Society)

**Dr. Beda Jean-Francois** (Health Scientist Administrator, NIMDH, RADx-UP Coordination and Data Collection Center Program Officer)

**Dr. Dorothy Castille** (NIMDH, RADx-UP Coordination and Data Collection Center Program Officer)

Additional Panelists:

• **Grants Management**
  - Brian Albertini (NINR)

• **Testing-Vaccination FOA/Notice**
  - Dr. Wilson Compton (NIDA)
  - Dr. Lindsey Martin (NIEHS)
  - Dr. Tiffani Lash (NIBIB)
  - Dr. Judith Arroyo (NIMHD)

• **SEBI**
  - Dr. Nancy Jones (NIMHD)

• **Return to School**
  - Dr. Alison Cernich (NICHD)
  - Dr. Sonia Lee (NICHD)
Housekeeping

• All participants except speakers and panelists will be muted.

• Please place questions in the Questions and Answers module; they will be answered either in the chat box or during the Q&A sessions.

• Immediately after each presentation, the speaker will answer a few questions; the extended Q&A session after all presentations will cover all questions.

• All questions and answers will be captured in an FAQ.

• The webinar will be recorded.

• The FAQ, the video, and the slides for today’s webinar will all be posted on the NIH RADx website: https://www.nih.gov/research-training/medical-research-initiatives/radx/events
Rapid Acceleration of Diagnostics (RADx) Overview

Ming Lei, Ph.D.
National Institute of General Medical Sciences
Rapid Acceleration of Diagnostics (RADx) Overview

<table>
<thead>
<tr>
<th>Project</th>
<th>Description</th>
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<tbody>
<tr>
<td>RADx Tech</td>
<td>Highly competitive, rapid three-phase challenge to identify the best candidates for at-home or point-of-care tests for COVID-19.</td>
</tr>
<tr>
<td>RADx-Advanced Technology Platforms (RADx-ATP)</td>
<td>Rapid scale-up of advanced POC technologies and laboratories to accelerate, enhance and validate utility of ultra-high throughput machines and facilities.</td>
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<tr>
<td>RADx-Radical (RADx-rad)</td>
<td>Develop and advance novel, non-traditional approaches or new applications of existing approaches for testing.</td>
</tr>
<tr>
<td>RADx-Underserved Populations (RADx-UP)</td>
<td>Interlinked community-engaged projects focused on implementation strategies to enable and enhance testing of COVID-19 in underserved and/or vulnerable populations.</td>
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</tbody>
</table>
RADx awards contributed a cumulative 6.1M tests per day to the National Testing capacity as of February 2021.
RADx-UP focuses on people who are experiencing a disproportionate burden of COVID-19

- **Underserved**: NIH-designated health disparity populations and other groups known to experience barriers to accessing needed health care services or have inadequate health care coverage. A full description can be found at [https://www.nimhd.nih.gov/about/overview/](https://www.nimhd.nih.gov/about/overview/)

- **COVID-19 medically and/or socially vulnerable populations**: Specific populations included in this program thought to be specifically vulnerable to the impact of COVID-19 due to specific medical conditions, social determinants, or living situations. A detailed list is provided in the FOA.
RADx-UP Strategies

• **Expand capacity to test broadly** for SARS-CoV-2 in highly affected populations, including asymptomatic persons.

• **Deploy validated point of care tests** as available, including self-test and saliva-based methods.

• **Inform implementation of mitigation strategies** based on isolation and contact tracing to limit community transmission.

• **Understand social, ethical and behavioral factors** that contribute to COVID-19 disparities and **implement interventions** to reduce these disparities.

• **Establish infrastructure** that could facilitate evaluation and distribution of vaccines and therapeutics.
RADx-Underserved Populations (RADx-UP)

Overarching Goals

Enhance COVID-19 testing among **underserved** and **vulnerable populations** across the US

Develop/create a consortium of community-engaged research projects designed to rapidly improve and implement testing interventions

**Strengthen the available data on disparities** in infection rates, disease progression and outcomes, and identify strategies and interventions to **reduce these disparities in COVID-19 diagnostics**

---

**September – November 2020**

**Phase I**

- **Build infrastructure**
- **Rapidly implement testing, other capabilities**

**Early 2021 – Summer/Fall 2021**

**Phase II**

- **Integrate new advances**
- **Expand studies/populations**
RADx-UP Phase I

Awarded September & November 2020

• **Competitive revisions** to current NIH grantees to leverage **established research infrastructures and partnerships**

• Projects to **understand COVID-19 testing access/uptake patterns** and implement strategies or interventions to identify and address disparities

• Projects to **assess and address social, ethical, and behavioral factors** influencing acceptability and uptake

• **Coordination and Data Collection Center** New award to provide overarching support and guidance for 1) Operations and Logistics, 2) COVID-19 Testing Technology, 3) Community Engagement, and 4) Data Collection, Integration and Sharing
RADx-UP Phase I Snapshot: 69 Funded Research Projects and Coordination and Data Collection Center

**NOT-OD-20-121, NOT-OD-20-120, NOT-OD-20-119**

Funded sites and research projects span a total of **31 states** in addition to DC and Puerto Rico and include **55 institutions**.

Projects include diverse health disparity population affected by COVID-19.

<table>
<thead>
<tr>
<th>Populations with Health Disparities</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hispanics/Latinos/as</td>
<td>41</td>
</tr>
<tr>
<td>Blacks/African Americans</td>
<td>33</td>
</tr>
<tr>
<td>Asian Americans</td>
<td>25</td>
</tr>
<tr>
<td>American Indians/Alaska Natives</td>
<td>24</td>
</tr>
<tr>
<td>Sexual and Gender Minorities</td>
<td>19</td>
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<tr>
<td>Socioeconomically disadvantaged...</td>
<td>15</td>
</tr>
<tr>
<td>Underserved Rural Populations</td>
<td>5</td>
</tr>
<tr>
<td>Native Hawaiians and other Pacific Islanders</td>
<td>3</td>
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<tr>
<td>---------------</td>
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<tr>
<td>Testing / Vaccination</td>
<td>Testing/Vaccination</td>
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<tr>
<td>Competitive Revisions</td>
<td>U01</td>
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<tr>
<td>$750,000</td>
<td>$750K-$1.5M</td>
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<tr>
<td>May 24</td>
<td>July 07</td>
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<tr>
<td>NIH grantees</td>
<td>Open</td>
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<tr>
<td>Testing interventions in environment of vaccine availability</td>
<td>Testing interventions in environment of vaccine availability</td>
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</table>
COVID-19 Testing and Vaccination

RFA-OD-21-008 & NOT-OD-21-103

Monica Webb Hooper, Ph.D.
National Institute on Minority Health and Health Disparities
What's new in Phase II?

What are the main differences between the Phase I and Phase II Awards?

1. Interventions to reduce COVID-19 disparities

2. Increasing SARS-CoV-2/COVID-19 testing access and uptake given the availability of vaccines
Emergency Awards: Community-Engaged COVID-19 Testing Interventions among Underserved and Vulnerable Populations – RADx-UP Phase II (U01 Clinical Trial Optional)

**RFA-OD-21-008**

- New U01 awards

Notice of Special Interest (NOSI): Emergency Competitive Revisions for Community-Engaged COVID-19 Testing Interventions among Underserved and Vulnerable Populations – RADx-UP Phase II (Emergency Supplement - Clinical Trial Optional)

**NOT-OD-21-103**

- Competitive revisions to existing awards

**Scientific objectives are the same**
Community-Engaged COVID-19 Testing Interventions among Underserved and Vulnerable Populations – RADx-UP Phase II (Clinical Trial Optional)

RFA-OD-21-008 and NOT-OD-21-103

Purposes

1. To expand the scope and reach of testing interventions to reduce COVID-19 disparities among underserved and vulnerable populations

2. Address questions on interventions to increase access to and uptake of COVID-19 testing given the increasing availability of SARS-CoV-2 vaccines.

**CASES**
- 148M cases worldwide
- 32.1M cases in U.S.

**DEATHS**
- 3.1M deaths worldwide
- 572.7K deaths in U.S.

**VACCINES**
- 230.7M doses administered in U.S.
- 87.9M people fully vaccinated in U.S.

- U.S. cases represent 9.7% of U.S. population
- U.S. deaths represent 18.4% of deaths worldwide
- 26.8% of people are fully vaccinated in U.S.
Demographic Characteristics of People Receiving COVID-19 Vaccinations in the U.S., April 25, 2021 (6:00 AM)

Race/Ethnicity of People with 1+ Doses Administered

- White, Non-Hispanic
- Asian, Non-Hispanic
- American Indian/Alaska Native, Non-Hispanic
- Hispanic/Latino
- Black, Non-Hispanic
- Native Hawaiian/Other Pacific Islander, Non-Hispanic
- Multiple/Other, Non-Hispanic

Grey denotes percentage of the US Population in the Demographic Category

Race/Ethnicity of People with 2 Doses Administered

- White, Non-Hispanic
- Asian, Non-Hispanic
- American Indian/Alaska Native, Non-Hispanic
- Hispanic/Latino
- Black, Non-Hispanic
- Native Hawaiian/Other Pacific Islander, Non-Hispanic
- Multiple/Other, Non-Hispanic

Demographic Characteristics of People Receiving COVID-19 Vaccinations in the United States from CDC's COVID Data Tracker
Background and Goals

Apply scientific knowledge gained thus far to:

• Develop and evaluate interventions with the goal of decreasing disparities
• Address disparities in testing and the effects of testing combined with other mitigation strategies (e.g., public health guidance) on infection rates, transmission, and outcomes
• Propose innovative science to fill gaps and address new challenges
Research Topic Examples

The following list of possible research topics is not exhaustive

• Examine and address disparities in the availability, ease of use, and/or accessibility of at-home COVID-19 testing options
• Rapid cycle designs to examine testing technologies to improve uptake of testing, vaccination, and repeat testing
• Testing implementation strategies to increase the reach, access, uptake, and sustainability of testing in community-, workplace-, school-, or family-based settings (e.g., technology-based approaches, mobile health units)
• Modeling and/or simulation studies to understand drivers of COVID-19 disparities followed by interventions to reduce them
Key Considerations

Below are some key components of the study design, community engagement, and testing specifications in the FOAs

- Focus must be on underserved and vulnerable populations
- Primary outcomes must focus on testing, however secondary aims can include vaccination
- Leverage, expand, or strengthen community partnerships
- Testing capacities used must be FDA-authorized and results must be CLIA certified
- Consistency and reproducibility by planning to collect NIH RADx-UP Common Data Elements (CDEs)
- Mixed methods research OK; qualitative only not accepted
Requirements

Work with the **Coordinating and Data Collection Center (CDCC)**

Ability to **demonstrate impact** within 6 months of award

**Milestones and timelines**

Utilize research strategies that reflect the **evolving landscape of the pandemic**

**Sustainability** description including partnerships

**Letters of support** from and inclusion of community partners

Collaborate with RADx-UP consortium members where appropriate

NIH RADx-UP CDE/Data **Sharing**

(https://radx-up.org/learning-resources/cdes/)
Non-Responsive Factors (see NOSI for full list)

The following are examples that would be considered non-responsive:

- Populations that are not underserved and COVID-19 vulnerable
- Project focusing exclusively on vaccination; primary outcome vaccine-related
- Lack of demonstrated community engagement with populations of interest
- Study populations or sites outside of the U.S. or its territories
- Exclusively qualitative research (mixed methods are acceptable)
- Lack of structure and planning to coordinate with CDCC and other RADx-UP sites to align and share data
  - Must be able to collect NIH RADx-UP Common Data Elements and aligned Informed Consent Forms with the appropriate Data Use Agreements
- No testing plan/strategies or use of FDA-authorized or approved test
Review Considerations

**NOT-OD-21-103 (Competitive revisions to existing awards)**

Internal NIH staff review panel using standard criteria with additional criteria of:

1. Urgency and significance of research
2. Research feasibility and design
3. Investigators
4. Community partners
5. Data sharing plan
6. Coordination plans
7. Outcomes
8. Sustainability
9. Testing
10. Post-vaccination testing studies
11. Evaluation plan
Review Considerations

RFA-OD-21-008 (*New U01 awards*)

1. Overall Impact
2. Significance
3. Innovation
4. Investigators
5. Approach
6. Study Timeline
7. Environment
8. Protection of Human Subjects
9. Inclusion

Please see [RFA Announcement](#) for additional detail.
Respondents can request a budget option that exceeds $750K in direct costs per year

**Conditions**

**Collaboration with 1 or more PIs from institutions that received specified maximum of NIH funding**
FOA details partner institutions that have received no more than $6M average in NIH RPG funding per year from 2018-2020 are eligible to be multi-PIs or key collaborators

**Collaborator Institution(s) will receive no less than 40% of award**
A list of possible eligible applicants is available in the FOA, but range from American Indian Tribal governments to Public Institutions of Higher Education

**Process**

**Higher Budget Requires Prior Approval**
Submit a request for a budget exceeding $750,000 and up to $1.5M in direct costs per year no later than 6 weeks prior to application receipt date, or **May 26, 2021**

**Applicants will be informed of the decision prior to application receipt date**
An Institute Program Official will review the higher budget request and ensure they meet the two conditions and provide a decision no later than **June 16, 2021**
### Key Dates

**RFA-OD-21-008 & NOT-OD-21-103**

<table>
<thead>
<tr>
<th></th>
<th>Application Receipt</th>
<th>Scientific Merit Review</th>
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<tbody>
<tr>
<td>RFA-OD-21-008 (New U01s)</td>
<td>July 7, 2021 5pm</td>
<td>July-October 2021</td>
<td>October 2021</td>
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<td><em>Select Institute or Center based on relevance to scientific aims of your research</em></td>
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<tr>
<td>NOT-OD-21-103 (Competitive Revisions)*</td>
<td>May 24, 2021 5pm</td>
<td>May-August 2021</td>
<td>August 2021</td>
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<td>* Electronic submission to Institute or Center of existing NIH grant*</td>
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*No higher budget option; $.75M/ year direct costs

Late applications will not be accepted for any of these funding opportunities
Questions?
Social Ethical Behavioral Implications
RFA-OD-21-009

Dave Kaufman, Ph.D.
National Human Genome Research Institute
Phase II Social Ethical and Behavioral Implications (SEBI)

RFA-OD-21-009

RADx-UP - Social, Ethical, and Behavioral Implications (SEBI)
Research on Disparities in COVID-19 Testing among Underserved and Vulnerable Populations

Purpose:
To address actionable **social, ethical, behavioral, structural, environmental, historical and policy factors** that are sources of COVID-19 disparities, including inequities in testing access.
SEBI Overview

- Plan to fund 16 awards
- 2 years
- $400,000/year direct costs
- Community/stakeholder partnerships
- Emphasis on actionable findings
- One receipt date (July 7, 2021)
- U01 Mechanism – cooperative agreement
Requirements

Address **social, ethical, and behavioral factors** associated with COVID-19 testing disparities

Describe **sustainability**

Flexible response to a **rapidly changing** pandemic environment

Inclusion of **community partners and stakeholders**; letters of support

Include milestones and timelines

Work with **RADx-UP, CCDC, consortium members**

Collect **personal identifiers** where permitted & possible

NIH RADx-UP CDE/Data Sharing
https://radx-up.org/learning-resources/cdes/-resources
Research Topic Examples for RFA-OD-21-009

The following list is not exhaustive

• Develop culturally competent communication about COVID-19 testing and vaccination
• Assess how the presence and prevalence of COVID-19 vaccination will affect societal views, roles, and uptake of SARS CoV-2 testing
• Assess testing and vaccination programs’ resource allocation plans and determine characteristics that perpetuate or mitigate disparities
Scientific Emphases

The following are examples of important considerations for SEBI projects

• Looking ahead to future roles of/with testing
• Testing in groups and areas where vaccines have/have not reached
• Vaccination effects on adherence to other prevention behaviors
• Effects of structural racism
• Impact and sequelae of COVID-19 diagnostic tests and results
• Effective collection of testing data and use in decision-making
• Impact on communities of stacking COVID-19 research on top of testing/vaccination services
Key Study Design Components

- Examine SEBI implications of testing among underserved and vulnerable populations
- Projects can conduct COVID-19 testing, but not the primary goal
- Projects can examine SEBI of vaccination, but a major focus must be COVID-19 testing disparities
- Projects without quantitative components are acceptable
- Plan to collect Common Data Elements (CDEs) where appropriate
- Community engagement and collaboration
- Multi-level analysis (individual, interpersonal, institutional, community, policy)
Non-Responsive Factors

The following types of projects would generally not be appropriate

- Administer COVID-19 testing or vaccination as the primary activity (see RFA-OD-21-008)
- Do not have a primary focus on SEBI issues
- Do not focus on underserved and COVID-19 vulnerable populations
- Focus exclusively on vaccination
- Offer COVID-19 testing, or work with COVID-19 testing or vaccination programs that are not FDA authorized/approved, and not using CLIA certified labs
- Do not discuss generalizability and public health impact
- Do not demonstrate equitable relationships with populations and stakeholders
- Study populations or COVID-19 testing outside the United States
- Lack of structure and planning to coordinate with CDCC and other RADx-UP sites to align and share data

- Applications must discuss consent for and collection of NIH RADx-UP Common Data Elements
## Key Dates

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<td>Late applications will not be accepted</td>
<td>October 2021</td>
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Questions?
RADx-UP Coordination and Data Collection Center (CDCC) and Data Sharing

Dottie Castille, Ph.D.
Beda Jean-Francois, Ph.D.
Program Officials for CDCC
National Institute of Minority Health and Health Disparities
The RADx-UP CDCC

RADx-UP Coordination and Data Collection Center (CDCC)

- Serves as a hub for all RADx-UP funded projects
- Provides steadfast assistance to RADx-UP projects to optimize engagement, outreach, testing strategies, data collection and integration, and co-learning opportunities between and among projects and to the communities that we serve
- Is led by the Duke Clinical Research Institute (DCRI), the Center for Health Equity Research at UNC-Chapel Hill with support from a key partner, Community-Campus Partnerships for Health
RADx-UP

CDCC Goals

**Accelerate** COVID-19 community implementation science via an agile, flexible, participatory, transparent and sustainable CDCC.

**Amplify** and disseminate community best practices for successful implementation of COVID-19 testing strategies and vaccines.

**Support** data collection, integration, and sharing while preserving necessary data protections.

**Utilize** RADx-UP infrastructure to support COVID-19 research.
RADx-UP CDCC

Principal Investigator Leadership: Michael Cohen-Wolkowiez, MD, PhD, Giselle Corbie-Smith, MD, MSc, Warren Kibbe, PhD, FACMI
Operations Director: Renee Pridgen
Program Director: Susan Knox

ADMINISTRATION AND COORDINATION CORE
Operational Lead: Donna Parker

RADx-UP Awardees
SERVICES: Project Leadership, Communications, Evaluation

COVID-19 TESTING CORE
Core Leadership: Chris Woods, MD, Thomas Denny, MSc, MPhil
Program Lead: Tim Veldman, PhD
Operational Lead: Barrie Harper
NIH Project Scientist: Fabienne Santel, MD, MPH

COMMUNITY ENGAGEMENT CORE
Core Leadership: Al Richmond, Krista Perreira, PhD
Program Lead: Renee Leverty
Operational Lead: Crystal Cannon
NIH Project Scientist: Nadra Tyus, Dr.PH, MPH

DATA SCIENCE AND BIOSTATISTICAL CORE
Core Leadership: Keith Marsolo, PhD, Lisa Wruck, PhD
Program Lead: Bhargav Adagarla
Operational Lead: Laura Johnson
NIH Project Scientist: Partha Bhattacharyya, PhD

ENGAGEMENT IMPACT TEAMS

NIH Program Officers: Dottie Castille, PhD
Beda Jean-Francois, PhD
NIH Vision for RADx-UP Data

- Largest single NIH investment to understand the factors that protect or harm underserved communities
- NIH RADx-UP Common Data Elements (CDEs) to help capture consistent data for comparison across studies
- Alignment with requirements to make data findable, accessible, interoperable and reusable (FAIR)
- Resource for NIH, communities, and researchers to understand the impact of COVID-19 on the well-being, risk, resilience, and disparities in underserved and vulnerable communities
Data collected under RADx-UP will be anonymized and shared through the RADx-UP CDCC, and ultimately deposited into the COVID RADx Data Hub.

CDCC will coordinate across the consortium to ensure:

- Collection and reporting of NIH RADx-UP CDEs
- Consistent language in consent
  - General Research Use
  - Ability to re-contact participants for future research
  - Hash (Hash is usually a string of characters and are generated by a formula)
- Return of Results
- CDCC work with program staff to resolve special considerations for SEBI projects (NIH RADx-UP CDEs, Data Deposit)
NIH RADx-UP CDE Requirements

Projects funded under the RADx-UP Initiative are **required** to collect the **NIH RADx-UP Tier 1 CDEs**

Permission to collect and share NIH RADx-UP CDEs will be solicited through specific language in the Informed Consent Form (ICF) on the following points:

1. Depositing de-identified data in the CDCC and NIH RADx Data Hub
2. Sharing de-identified data with the CDCC and NIH for future scientific research
3. Sharing identifiable data to permit re-contact for future follow-up and participation in future research
4. Sharing identifiable data to perform linkages with external data sets, such as the Centers for Medicare & Medicaid Services (CMS), electronic health records (EHR), or other identifiable datasets, to understand health outcomes of the COVID-19 pandemic among underserved and vulnerable populations

**NIH RADx-UP CDEs should be viewed in conjunction with the Informed Consent language. Refer to the Informed Consent Data Sharing Template Language found [here](#) in English and [Spanish](#) for guidance.**
Data

Data Sharing and Standards

• Data acquisition, collection, and curation strategies of Phase II projects shall be coordinated with:
  • CDCC guidance for annotation and benchmarking of data
  • Collection of standardized NIH Tier 1 Common Data Elements (CDEs)
  • Obtaining appropriate consent for data sharing
  • Linkage of data to external data sets, and recontact for future follow-up research
• If a clinical trial is proposed, data and safety monitoring plans, and, if needed, plans for a Data Safety Monitoring Board (DSMB)
Question and Answer

Ming Lei, Ph.D.
National Institute of General Medical Sciences
Question & Answer

Please submit all questions in the Q&A box

• If you have questions today, please place them in the Questions and Answers module; the moderator will facilitate a discussion of them at the conclusion of the presentation or in the chat box.

• All questions and answers will be captured in an FAQ that will be distributed after the webinar to all parties who received the solicitation.

• This meeting will be recorded and will be made available via a link that will be distributed after the webinar.