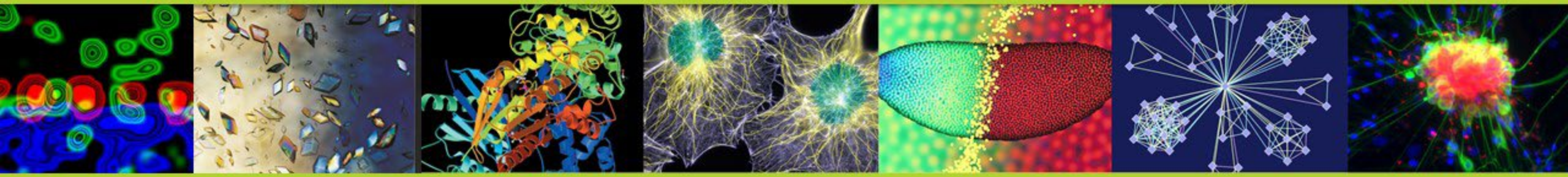
National Institute of General Medical Sciences

# IDeA Clinical Research Resource Center (I-CRRC)
## PAR-22-150

**Ming Lei, PhD**
**Director, Division for Research Capacity Building**

**May 18, 2022**



# Participating NIGMS Staff

**Michele McGuirl, PhD**
Branch Chief, Research Advancement Programs Branch

**Lisa Dunbar, PhD**
Section Chief, Scientific Review Branch

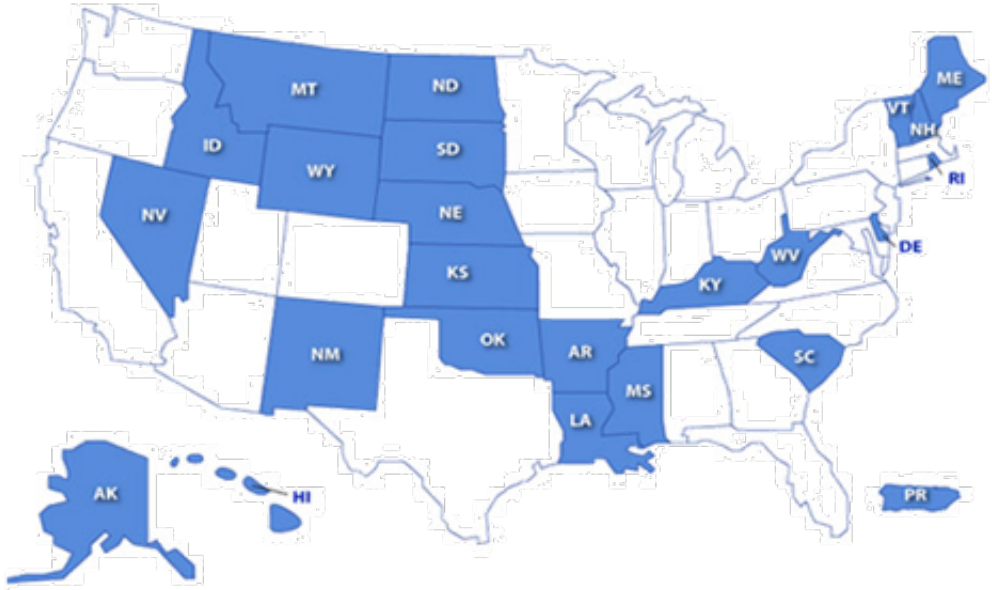
**Lumy Sawaki-Adams, MD, PhD**
Program Director, Research Advancement Programs Branch

**Christy Leake**
Team Leader, Grants Administration Branch

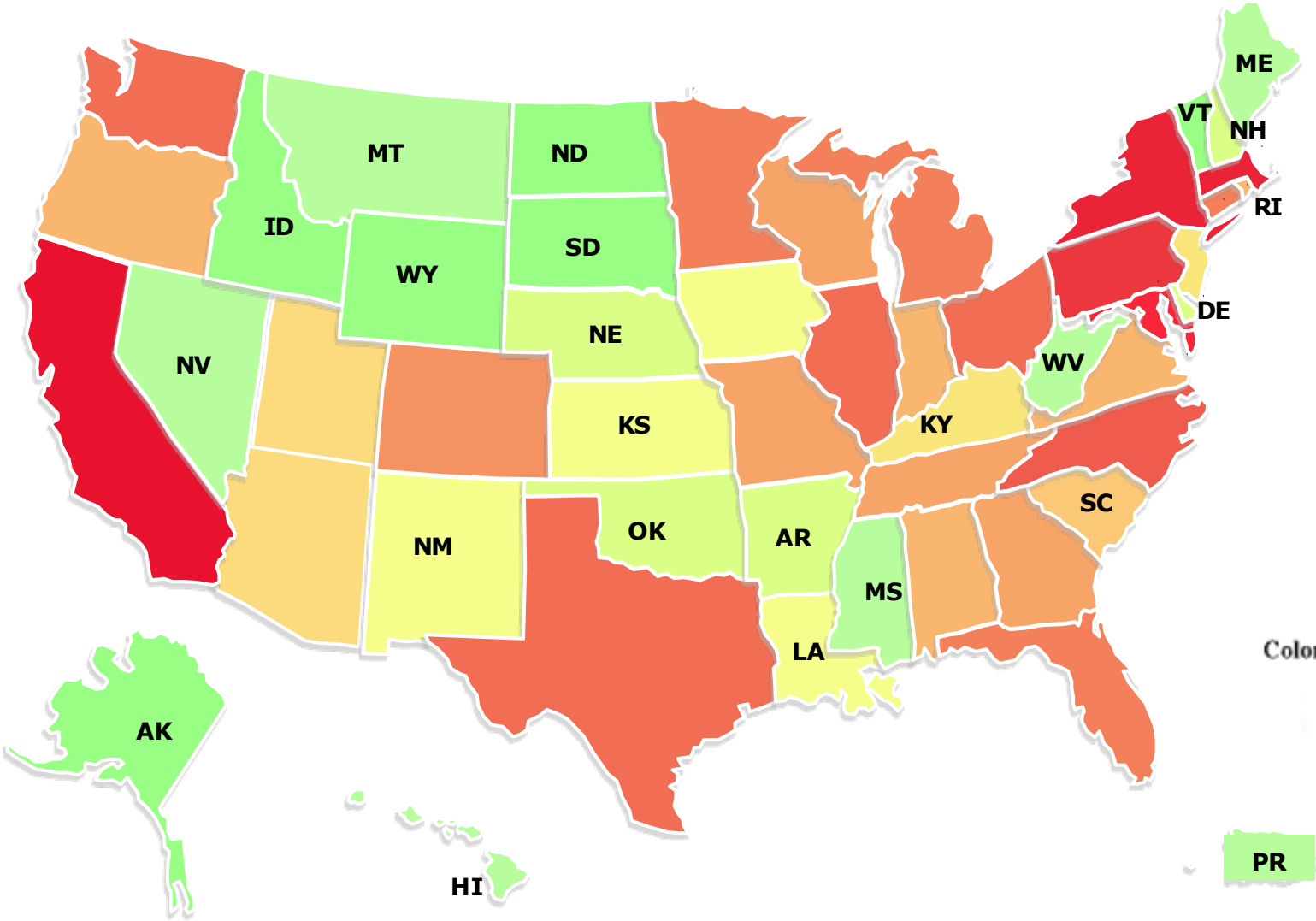
# Building Clinical Research Capacity: A Core Mission of the IDeA Program

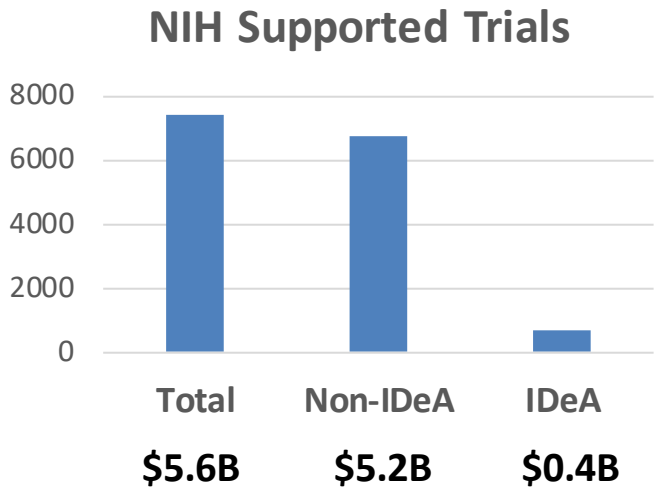
- Supporting infrastructure and human resources development to conduct clinical and translational research in IDeA states
- Strengthening IDeA institutions and investigators' ability to develop competitive clinical and translational research programs
- Enabling clinical and translational research activities that address health conditions prevalent among IDeA state populations.

***Strengthening clinical trial capacity in IDeA states is a pressing need***



# Active NIH Clinical Trials in FY21



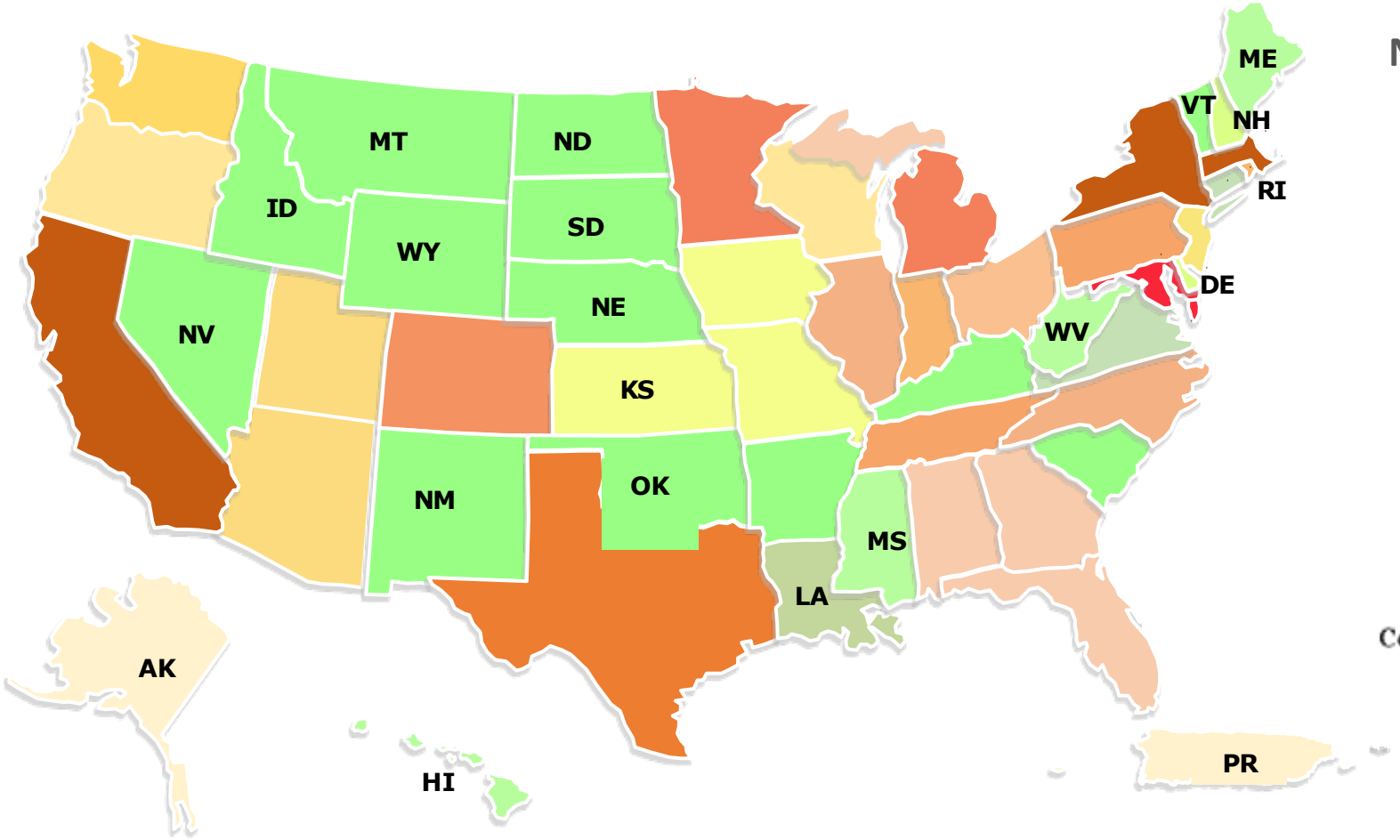




Colors indicate the number of studies with locations in that region.

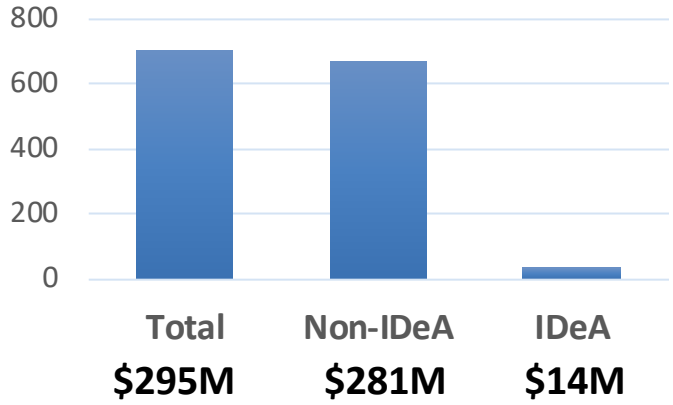
Least — Most

1 20 40 60 80 100 200 800

# Active NIH Observational Studies in FY21




## NIH Supported Observational Studies




Colors indicate the number of studies with locations in that region.

Least — Most

0 5 10 15 20 30 40 50 75

# IDeA Clinical Research Resource Center (I-CRRC) to Address Two Key Barriers

- Lack of effective communication
  - IDeA institutions need to be better informed about ongoing/upcoming clinical trials and complex observational cohort studies and be welcomed to participate
  - Trial sponsors need to be better informed about available trial capacities in IDeA institutions so they can include trial sites in IDeA states

- Lack of clinical trial workforce, especially clinical research coordinators

Hudson et al, 2005; Friedman et al., 2015; Hamel et al, 2016; Hillyer et al., 2020; Levit et al, 2020; Harrington et al., 2020

# I-CRRC: Components, Activities and Award

**A Clinical Trial Service Core** to strengthen communication and develop collaborations between clinical trial sponsors and IDeA institutions

**A Clinical Research Coordinator Development Program** to develop clinical research coordinators with the knowledge and skills needed to manage clinical trials and complex observational studies in IDeA states

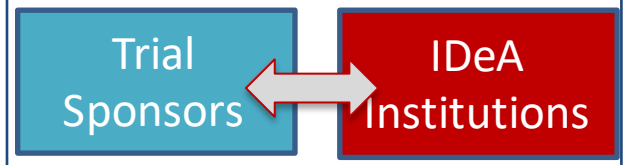
**An experienced and dedicated team to lead I-CRRC**

**NIGMS plans to fund one 5-year award (~ $1.8 million/yr Direct Costs)**

# Clinical Trial Service Core

**Clinical Trial Service Core**

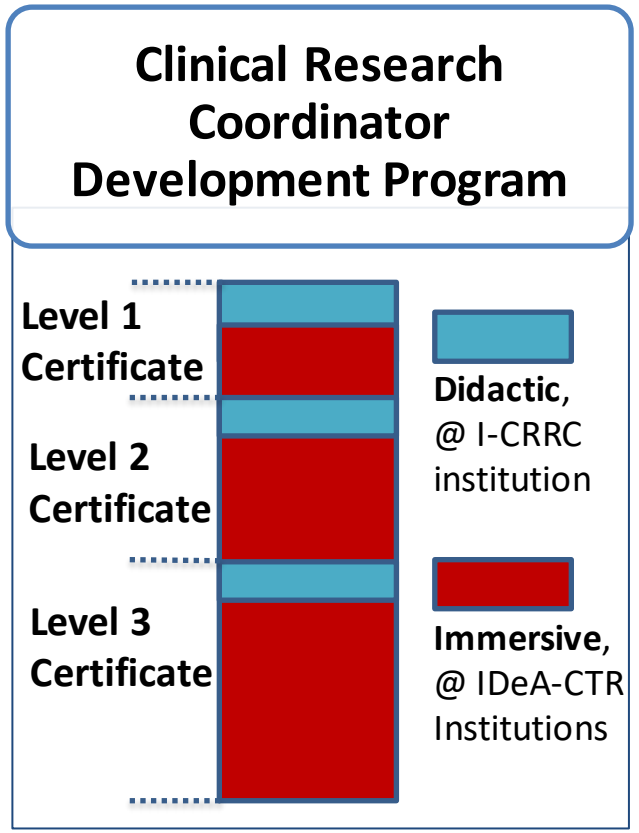
Collects & exchanges trial information and facilitates collaborations between sponsors and IDeA institutions




- Develop and maintain a trial inventory
- Develop and maintain an IDeA database of clinical expertise, capacities, patient catchment areas, and patient population characteristics of IDeA institutions
- Disseminate information to sponsors, Contract Research Organizations (CROs), and IDeA-state clinical researchers
- Proactively match sponsors/CROs with appropriate IDeA institutions

- Budget: approximately $300,000/yr Direct Costs
  - Costs for trial inventory and IDeA database
  - Costs for activities to match and develop collaborations between sponsors and IDeA Institutions
  - Salary support for personnel

# Clinical Research Coordinator Development Program




| | |
|---|---|
| **Participants:** | Nurses and/or others involved in clinical care, non-physician health professionals with experience in clinical research and/or its administration |
| **Duration and effort:** | Up to two years; 75% |
| **Didactic Component:** | Knowledge to manage clinical studies (e.g., policies, billing, participant enrollment, data sharing). Including a syllabus in the application is encouraged |
| **Immersive Component:** | Hands-on experience in commuting distance; apply knowledge from didactic component |
| **CRC Certificate(s):** | Minimum of 1 didactic and 1 immersive module |
| **Budget:** | ~$1.2 M/yr Direct Costs<br>• Didactic instructor's effort<br>• Immersive trial site trainers' effort<br>• Salary support for participants |

# I-CRRC: Grantee Institution, Governance, and Administration

- **Grantee Institution**: track record in conducting clinical trials/complex observational studies and related educational activities; experienced personnel and existing resources
- **Governance:** by a steering committee with diverse and balanced representation. *Don't contact potential members prior to award, or name them in the application*
- **Administration:** led by the PI(s) and key personnel (annual budget: ~ $300,000 DC)
  - PI(s): experienced in leading clinical trials/complex observational studies and programs with multiple stakeholders; knowledgeable about IDeA programs and institutions
  - Salary support for the PI(s) and key personnel
  - Administrative costs such as website development/maintenance and essential travel

# Key Dates

- **Letter of Intent Due Date:** August 26, 2022
- **Application Due Date:** September 26, 2022
- **Scientific Review:** March 2023
- **Council Review:** May 2023
- **Earliest Start Date:** July 2023

Read the FOA PAR-22-150 — applications must be responsive and provide specific plans for the required activities

# Thank you!

## Please Type Questions into the Chat Box

**Slides and Video (including the Q & A) will be posted on the I-CRRC Website**