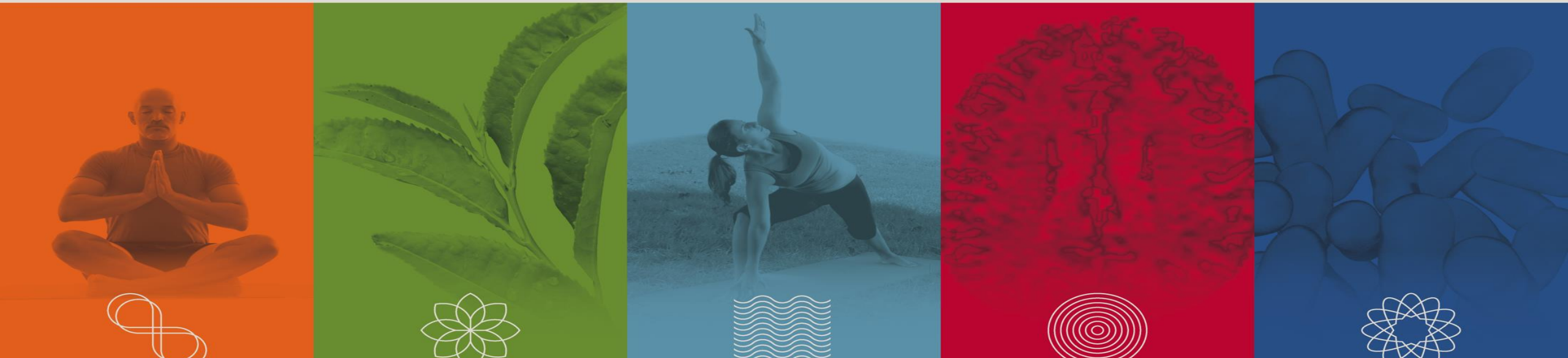




Overview of a Cooperative Agreement

Wendy Weber, ND, PhD, MPH

Acting Deputy Director and Clinical Branch Chief, NCCIH, NIH



What is a U Mechanism?

- U mechanisms – U01, **UG3/UH3**, and U24 – are cooperative agreement awards
 - Used for Investigator-Initiated applications
 - Used by the federal government when the funding agency anticipates federal staff will have involvement in the activities of the award
 - At the time of funding, NIH will assign two staff members to work with investigators:
 1. Program Director/Official who is responsible for the administration of the award, review of progress reports, etc.
 2. Project Scientist who works directly with the investigators as part of the team and participates in trial planning and oversight



Benefits of a Cooperative Agreement with a Shared Coordinating Center

- Allows active partnership between NIH and Investigator Team
- More frequent communication
 - Program Scientist is part of your team
 - Tell us what is really going on so we can help
 - Connect you with resources across NIH to resolve challenges and overcome barriers
- Coordinating Center for the HCS Collaboratory
 - Have assisted 9 ePCTs successfully transition and implement
 - Working Groups/Cores set up to address the challenging areas
 - Additional scientific expertise to help your project



What Is a Phased Award?

- Used when the supported research has two distinct phases (e.g., UG3/UH3) with separate aims
- Transition to the second phase is dependent on whether the first phase achieves the negotiated milestones
 - Examples include: test and refine data extraction methods; IC and DSMB approval of study protocol; finalize all training manuals for sites; active participant in HCS Collaboratory activities, etc.
- If milestones are met, transition to the second phase of funding occurs after administrative review by funding IC (may get input from trans-NIH HCS Collaboratory I-Team)



Transition Process

- Pre-Award negotiation of milestones
 - Want them to be objective
 - Easy to evaluate if they have been met – Yes or No
- Letter from NIH will describe the process
 - Submit per instur2-3 months prior to transition time (build into timelines)
 - Document how you have met milestones
 - Still need to submit progress report electronically



NIH Review Considerations

- UG3 milestones met
- Potential for meeting UH3 milestones
- Participation in HCS Collaboratory Activities
- Input from NIH Implementation Team (possible)
- Fit of UH3 milestones and NIH priorities
- Availability of funds



Questions???

