



Overview of a HEAL Cooperative Agreement

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 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 PRISM/HCS Collaboratory
 - Have assisted 19 ePCTs successfully transition and implement
 - Working Groups/Cores set up to address the challenging areas
 - Additional scientific expertise to help your project



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- If milestones are met, transition to the second phase of funding occurs after administrative review by funding Institute/Center (may get input from trans-NIH PRISM/HCS Collaboratory Implementation Team)



Transition Process

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 - Easy to evaluate if they have been met – Yes or No
- Letter from NIH will describe the process
 - Submit per instructions, **2-3 months prior to transition time** (build into timelines)
 - Document how you have met milestones
 - Still need to submit progress report electronically on due date



NIH Review Considerations

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



HEAL Initiative Additional Requirements (Terms in NOA)

- **Declaration of Exceptional Circumstances (DECs)**
 - This award is funded through the NIH HEAL Initiative (<https://www.nih.gov/researchtraining/medical-research-initiatives/heal-initiative>).
 - The requirements here include but not limited to **reporting requirements and data sharing** ... due to the need to respond to the national opioid public health crisis
 - NIH intends to maximize the availability of publications and the sharing of underlying data for NIH HEAL Initiative supported research projects
 - Award recipients are expected to cooperate and comply with all NIH data sharing including ... central data sharing platform requirements developed for this public health emergency during the project period



HEAL Initiative Additional Requirements (Terms in NOA)

- **Participation in Annual Investigator Meetings**
 - The NIH HEAL Initiative will require a high level of coordination and sharing between investigators.
 - It is expected that NIH HEAL Initiative awardees will cooperate and coordinate their activities after awards are made by participating in Program Director/Principal Investigator (PD/PI) meetings
- Next annual HEAL Investigators Meeting being planned with date to be announced soon
 - 1-2 Investigators per project attend



HEAL Initiative Additional Requirements (Terms in NOA)

- **HEAL Central Data Sharing Platform Requirements**
 - The award recipient and its collaborators must comply with all NIH HEAL Initiative Data Sharing policies established during the project period.
 - Compliance with the NIH HEAL Initiative central data platform requirements and timelines developed through the HEAL consortium.
 - Expected that all data collected by award recipients and their collaborators, as part of the NIH HEAL Initiative, will be shared with the NIH HEAL Initiative central data platform.
 - All data collected as part of the NIH HEAL Initiative are so collected under a Certificate of Confidentiality and entitled to the protections thereof.
 - Institutions who receive Data and/or Materials from this award for performance of activities under this award are required to use the Data and/or Materials only as outlined by the NIH HEAL Initiative...



HEAL Initiative Public Access

- Given the urgency of this crisis, as highlighted by the declared public health emergency, rapid availability of Publications and the primary data behind them promotes dissemination of new knowledge, enhances reproducibility and accelerates the ability of researchers to build upon NIH HEAL Initiative research to make new discoveries.
 - NIH HEAL Initiative Research Projects are required to submit a Public Access and Data Sharing Plan that
 - 1) Describes their proposed process for making resulting Publications and, to the extent possible, the Underlying Primary Data immediately and broadly available to the public or
 - 2) If applicable, provides a justification to NIH if such sharing is not possible. Underlying Primary Data should be made as widely and freely available as possible while safeguarding the privacy of participants and protecting confidential and proprietary data.
- <https://heal.nih.gov/about/public-access-data>



HEAL Initiative Public Access

- The Public Access and Data Sharing Plan should, at a minimum, address the following general elements:
 - Release of Publications
 - How publications will be made **immediately** available to the public
 - The methods through which the public, including other researchers, will locate and access the publication
 - Any anticipated limitations to the immediate and broad release of publications with an associated justification
 - Sharing of Underlying Primary Data
 - The type of data that is expected to be generated by the research
 - The data that will be shared
 - Who will have access to the data
 - The timing and the medium for immediate sharing of the data
 - The methods through which the public, including other researchers, will locate and access the data
 - Any anticipated limitations to the immediate and broad sharing of data with an associated justification



HEAL Initiative Data Sharing

- Must think about this now!
- Informed consent documents must describe the data sharing aspect of the HEAL Initiative
 - Per the public access policy:
 - “Before submitting Underlying Primary Data, Awardees through their institutional review boards (IRBs), privacy boards, or equivalent bodies will assess the informed consent materials to determine whether the Underlying Primary Data may be shared as contemplated in this Policy.”
- <https://heal.nih.gov/about/public-access-data>



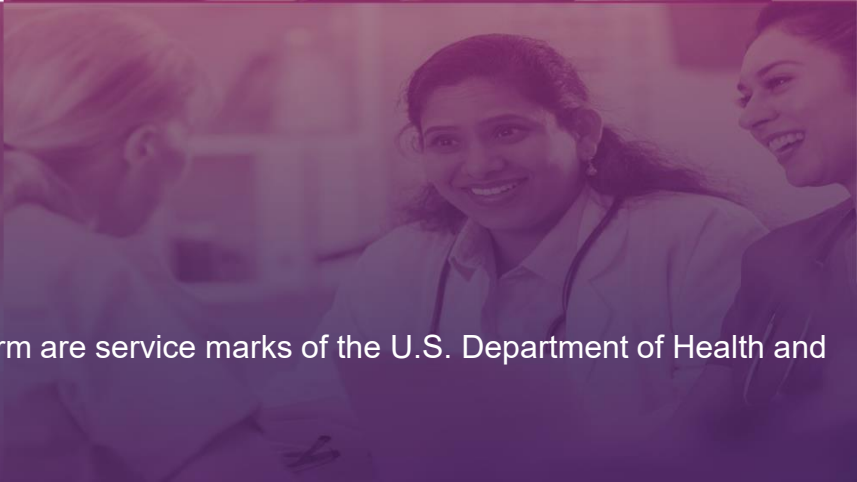
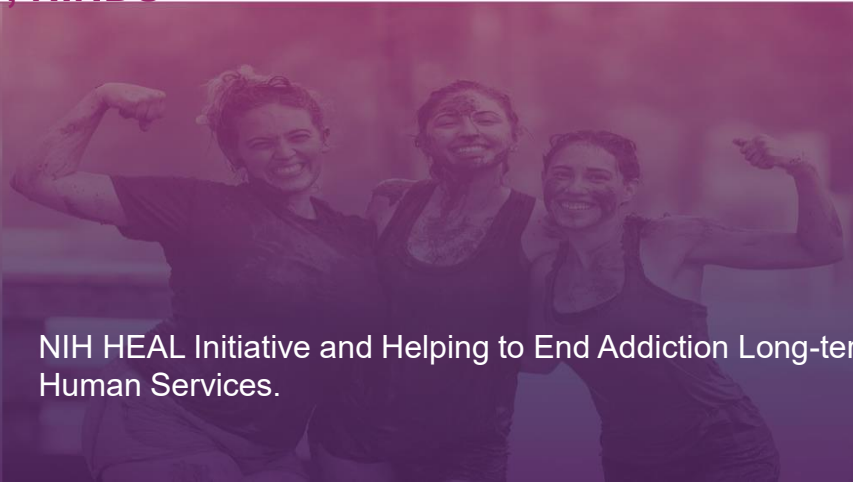


**NIH
HEAL
INITIATIVE**

Common Data Elements (CDE) Initiative

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NIH National Institutes of Health
HEAL Initiative

NIH HEAL Initiative and Helping to End Addiction Long-term are service marks of the U.S. Department of Health and Human Services.

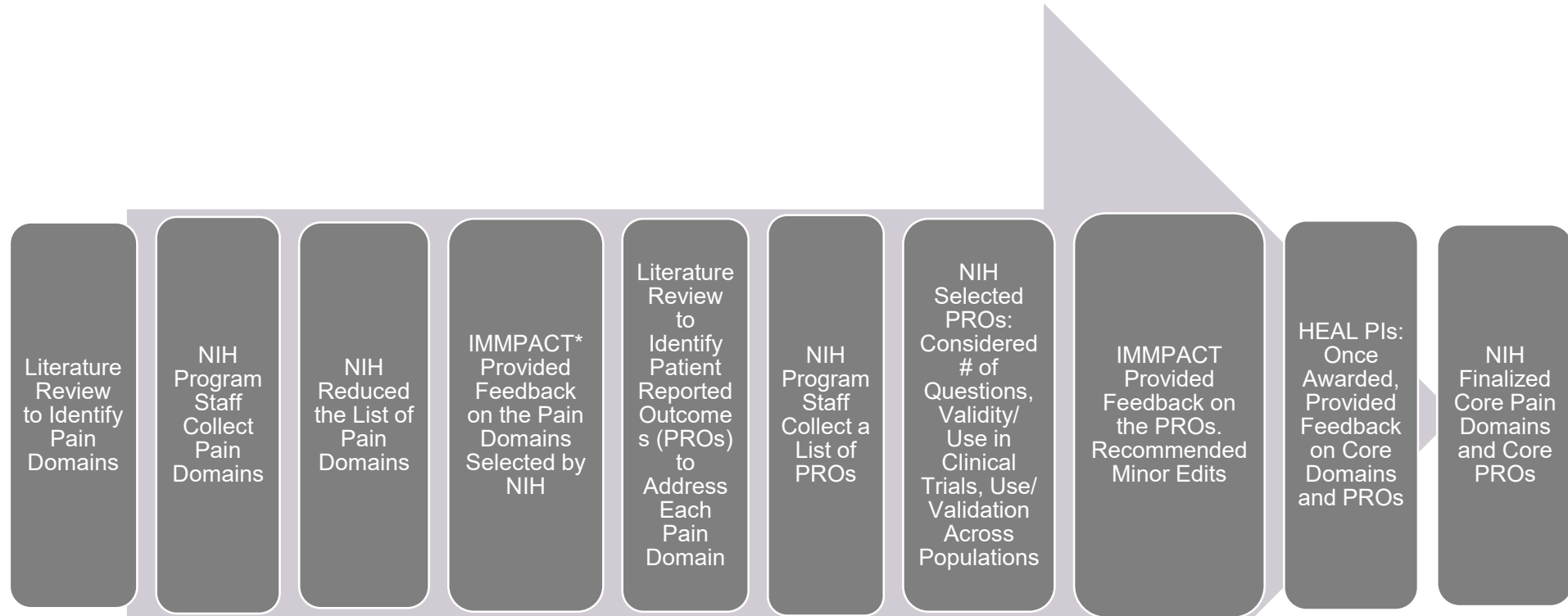
Why did the NIH undertake the HEAL CDE Initiative?

- NIH Data Sharing policy has been implemented to increase the value of HEAL science.
 - One goal of the policy is to support investigators in coordination, management of data, and making data findable, accessible, interoperable, and reusable (FAIR) for future research.
 - The HEAL CDE initiative is one way to achieve the NIH Data Sharing policy.

Rationale for the HEAL CDE Initiative

- Facilitate cross-study comparisons and improve the interpretability of findings for patient-reported outcomes.
- Unprecedented opportunity for the pain research community to access quality and meaningful data across pain conditions, in diverse populations, and multiple interventions.
- Ability to compare results across trials to quantify the impact of interventions.

Overview of the HEAL CDE Process



*Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT)

CORE CDEs

- **Core CDEs:** a minimal and defined set of patient report outcome screening tools for each pain domain that all HEAL pain clinical trials are required to collect.
- Core CDEs were released on 1/14/20.
- Core Demographics were re-released on 3/16/20
 - Demographics were made CDISC compliant.

Core – Adult CDEs

Adult Acute Pain*

Pain Intensity	Pain Interference	Physical Functioning/ QOL	Sleep	Pain Catastrophizing	Depression	Anxiety	Global Satisfaction with Treatment	Substance Use Screener
BPI Pain Severity	BPI Pain Interference	PROMIS Physical Functioning Short Form 6b	PROMIS Sleep Disturbance 6a + Sleep Duration Question	Pain Catastrophizing Scale – Short Form 6	PHQ-2	GAD-2	PGIC	TAPS 1

Adult Chronic Pain*

Pain Intensity	Pain Interference	Physical Functioning/ QOL	Sleep	Pain Catastrophizing	Depression	Anxiety	Global Satisfaction with Treatment	Substance Use Screener
	PEG	PROMIS Physical Functioning Short Form 6b	PROMIS Sleep Disturbance 6a + Sleep Duration Question	Pain Catastrophizing Scale – Short Form 6	PHQ-2	GAD-2	PGIC	TAPS 1

*Monitoring opioid use will be required by HEAL, however, the method by which it will be assessed is still pending. PIs will be asked to monitor opioid use (including dosage) by appropriate PRO, EHR, or other measures.

Core – Pediatric CDEs

Pediatric Acute and Chronic Pain*

	Pain Intensity	Pain Interference	Physical Functioning / QOL	Sleep	Pain Catastrophizing	Depression	Anxiety	Global Satisfaction with Treatment	Substance Use Screener
Child	BPI Pain Severity	BPI Pain Interference	PedsQL Inventory	AWS + Sleep Duration Items	Pain Catastrophizing Scale for Children	PHQ-2	GAD-2	PGIC	NIDA Modified Assist Tool - 2
Parent					Pain Catastrophizing	PHQ-2	GAD-2		

*Monitoring opioid use will be required by HEAL, however, the method by which it will be assessed is still pending. PIs will be asked to monitor opioid use (including dosage) by appropriate PRO, EHR, or other measures.

Re-released* The Core Demographics (Adult and Pediatric) - Domains

- Date of Birth
- Age
- Sex at Birth
- Gender Identity
- Ethnicity, Race
- Highest Level of Education
- Employment Status
- Relationship Status
- Annual Household Income
- Applied for Disability Insurance
- Pain Duration

*Demographics are, for the most part, CDISC compliant

Supplemental Questionnaires

- **Supplemental CDEs:** a comprehensive set of screening tools selected by HEAL PIs for use in their studies. They may be unique to the study; e.g., pain condition-specific or study-relevant measures.
- The NIH has been collecting supplemental questionnaires from the PIs in the ERN, PRISM, BacPac, HOPE, HEAL Biomarker studies, and A2CPS.
- 380 distinct supplemental questionnaires have been submitted to the NIH for this initiative.
- The contractor created 378 measures as of 10/28/2020.

Accessing the NIH CDE Box Account

- The Core and Supplemental Measures can be found on the NIH CDE Box account.
- Your team will need to request access to the NIH CDE Box account:
 - Email me, and I will provide you or your staff access to the NIH CDE Box account.
 - My email is Laura.Wandner@nih.gov.
- Please accept the invitation as soon as you receive the email. The invitation will expire after a period of time.
- Once you have access to the account, you shouldn't lose access to it.
 - The only time this has happened was when one of the funded Universities no longer supported Box.

Accessing the NIH CDE Box Account

- Some Universities require PIs to sign into the NIH CDE Box account every time they sign into Box. This is a security measure.
- Please be sure to click on the “Not a part of National Institute of Health (NIH)?” button vs the “Continue” button.

*Please note that you will need to complete the same process. Erin Spaniol provided PIs access to the HEAL Box account accounts are separate.



What Do I Need to Do?

- Review the CORE CDEs
 - NIH OD is asking you to use the CORE CDE's in your study

- NIH OD will buy the licenses for the copyrighted CORE CDEs
 - Please fill out the below form so NIH can order the licenses in the planning year.

PI Name	Project # and Title	HEAL Research Program	Estimated Recruitment Number for Your Study
<i>Dr. Example</i>	<i>1UG3XXXXXXXX-01 TITLE of HEAL GRANT</i>	<i>ERN</i>	<i>3,600 participants</i>

BPI Short-Form		BPI-Long Form		Pain Catastrophizing Scale		PedsQL 8-12		PedsQL 13-18	
English CRF	English & Spanish CRF	English CRF	English & Spanish CRF	English CRF	English & Spanish CRF	English CRF	English & Spanish CRF	English CRF	English & Spanish CRF
<i>X</i>				<i>X</i>					

What Do I Need to Do?

- Please review the list of Supplemental Questionnaires.
 - Saved Excel sheet is found in the supplemental folder. The name of the Excel sheet is “List of HEAL Supplemental Questionnaires”
- If your study is planning on using a supplemental measure that isn’t listed on the list of measures that have been converted, please email (Laura.Wandner@nih.gov) the following information:
 - Send the name of the measure
 - Send a copy of the CRF
 - Send the reference for the CRF
 - Send the scoring instructions for the CRF

Question: “Why do I need to do this if my study is not using paper forms?”

- We are posting CRFs for multiple reasons:
 - Multiple PIs have submitted questionnaires where the wording of the questionnaires had been changed slightly over the years, and they hadn't realized that this had occurred
 - Sometimes domains can be assessed differently. Posting CRFs can help bring awareness of those differences.
 - As we fund new HEAL PIs, they will access the NIH CDE Box account prior to finalizing their measures. If they aren't familiar with a measure, they can look at the wording others have used to determine if they want to use the measure in their study.
 - Since the NIH CDE Box account is a government website, all of the documents we post must be Section 508 compliant.

Question: “What are the ramifications if I realize that one of my instruments is missing after data collection has begun?”

- Please send the instrument to Dr. Laura Wandner
 - If the questionnaire is already in use within HEAL, we will ask the group to use the existing CDE details.
 - If you are proposing to use a new questionnaire, send Dr. Wandner the CRF, CDE details, scoring instructions, and reference.
- NIH will continue to employ a contractor, since we will need to create measures for grants that are funded in out years.

Questions?

