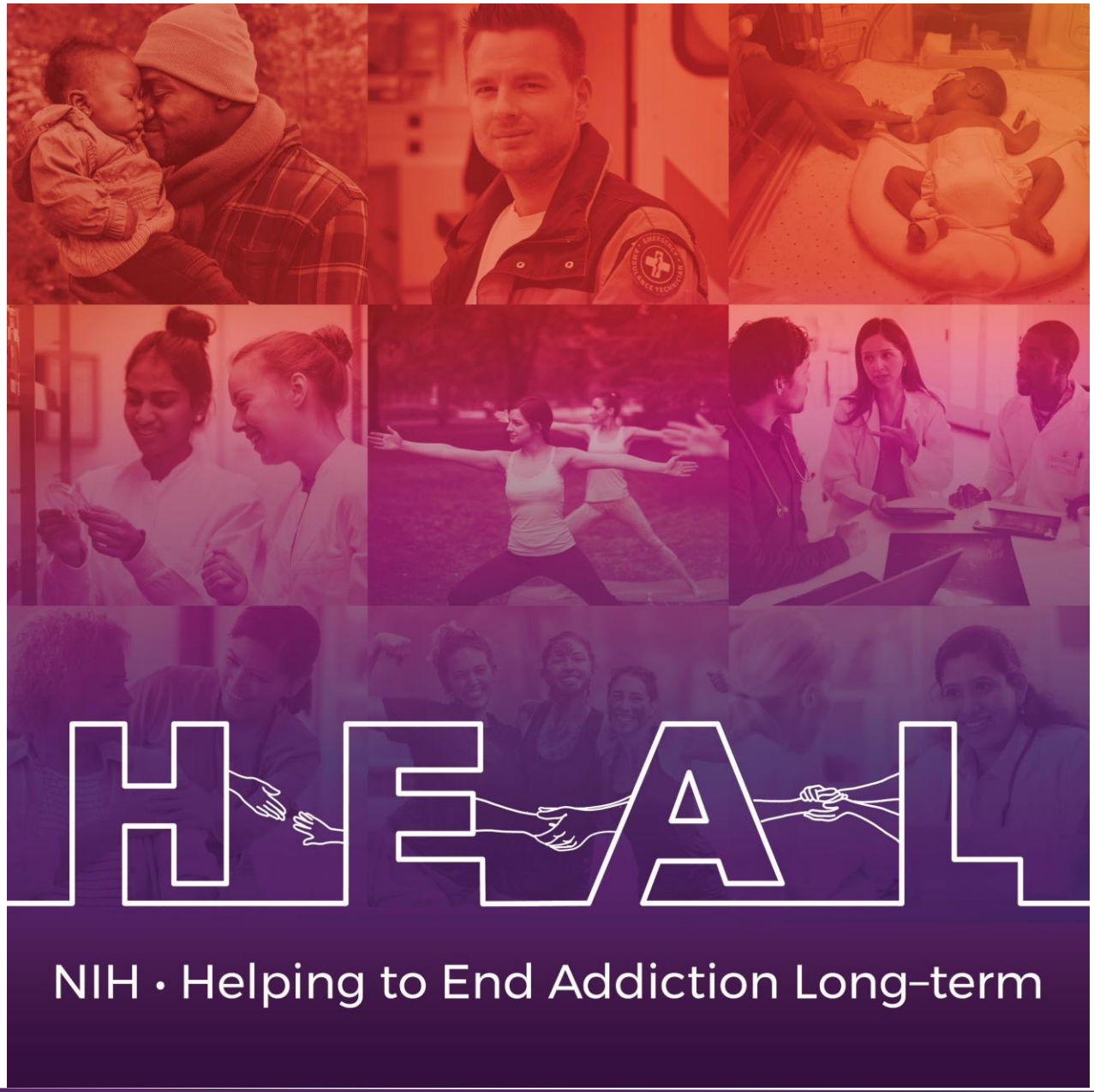


Technical Assistance Webinar

RFA-DA-21-030 HEAL Initiative: Integrative Management of chronic Pain and OUD for Whole Recovery (IMPOWR): Research Centers (RM1 Clinical Trial Required)

RFA-DA-21-029 HEAL Initiative: Integrative Management of chronic Pain and OUD for Whole Recovery (IMPOWR): Coordination and Dissemination Center (R24 Clinical Trial Optional)

RFA-MH-21-145 HEAL Initiative: Optimizing Multi-Component Service Delivery Interventions for People with Opioid Use Disorder, Co-Occurring Conditions, and/or Suicide Risk (R01 Clinical Trials Optional)

Agenda

NIH HEAL INITIATIVE

Time	Topic
1:00-1:10	Opening Remarks & Introductions to NIH staff
1:10-1:50	IMPOWR FOA Review and Application Requirements: 1. Research Centers (RFA-DA-21-030) 2. Coordination and Dissemination Center (RFA-DA-21-029)
1:50-2:10	Optimizing Multi-Component Service Delivery Interventions for People with Opioid Use Disorder, Co-Occurring Conditions, and/or Suicide Risk (RFA-MH-21-145)
2:10-2:20	Synergy between initiatives & Expected activities
2:20-2:55	Questions from Participants
2:55-3:00	Closing

Brief Technical Orientation

NIH HEAL INITIATIVE

- This webinar is being recorded.
- All participants, except NIH staff, have been muted.
- Questions will be taken at the end and read by a moderator.
- Submit questions to "All Hosts" using the chat feature, and identify a speaker.
- We will answer questions about eligibility, technical requirements, and budget requirements.
- **We will not answer questions about specific designs or study ideas. Please email POs to set up a time to discuss such questions.**
- Today's slides and a recording will be posted here.
- If you experience technical difficulties during the webinar, please send a chat to Tessa Hall. If no response, email tessa.hall@nih.gov.

NIH Participants

NIH HEAL INITIATIVE

Program Staff	IC
Shelley Su	NIDA
Mike Freed	NIMH
Marcy Fitz-Randolph	NIDA
Tisha Wiley	NIDA
Laura Kwako	NIAAA
Leslie Derr	NIAMS

Review Staff	IC/Office
Yvonne Ferguson	NIDA
Nick Gaiano	NIMH

Grants Management Staff	IC
Pam Fleming	NIDA
Tamara Kees	NIMH

Executive Overview

NIH HEAL INITIATIVE

Title	IMPOWR Research Centers	IMPOWR Coordination and Dissemination Center (C&DC)	Optimizing Multi-Component Service Delivery
FOA	RFA-DA-21-030 (RM1)	RFA-DA-21-029 (R24)	RFA-MH-21-145 (R01)
Duration	5 years		4 years
Target Patient Population	Patients must have CP and OUD/opioid misuse; may have AUD, GAD, MDD		Patients must have OUD and Mental Health Disorders and/or Suicide; may have CP
Program goals	Identify integrated interventions, care delivery models, and/or implementation strategies for both CP and OUD/opioid misuse	Provide support to the IMPOWR network including: logistical support, stakeholder engagement, Research education infrastructure, Data harmonization, novel tool development	Determining the value of each component that drives clinical improvement and the optimal sequence of each component

Integrative Management of chronic Pain and OUD for Whole Recovery (IMPOWR)

IMPOWR Key Dates

NIH HEAL INITIATIVE

• Earliest Submission Date	Feb 26, 2021
• Letter of Intent Due Date	Feb 26, 2021
• Application Due Date	**Mar 26, 2021**
• Scientific Merit Review	June 2021
• Advisory Council Review	August 2021
• Earliest Start Date	September 2021

IMPOWR: Background

NIH HEAL INITIATIVE

- An estimated 2 million individuals have an opioid use disorder (OUD) and nearly 10 million Americans misuse opioids.
- More than 50 million Americans suffer from chronic pain, resulting in an estimated $635 billion spend on CP treatment and loss of productivity.
- Health care services that effectively treat both CP and OUD remain fragmented, and there is a lack of treatment approaches to effectively treat both conditions.
- Managing CP and OUD may be further complicated by additional comorbid mental health or substance use disorders.
  - General Anxiety Disorder
  - Major Depressive Disorder
  - Alcohol Use Disorder
- Emphasizes treatment of the whole patient, including exposure stigma and sex/racial discrimination within the health care system

IMPOWR Network Structure

NIH HEAL INITIATIVE

- NIH intends to establish a national network consisting of investigators conducting research to rapidly create actionable, sustainable, and translatable treatments for individuals who have comorbid CP and OUD.
  1. Integrative Management of chronic Pain and OUD for Whole Recovery (IMPOWR): Research Centers: RFA-DA-21-030
  2. Integrative Management of chronic Pain and OUD for Whole Recovery (IMPOWR): Coordination and Dissemination Center: RFA-DA-21-029
- This network is part of the NIH Helping to End Addiction Long-term (HEAL) initiative.

Key Definitions Across FOAs: OUD & opioid misuse

NIH HEAL INITIATIVE

- The DSM-5 identifies OUD as a problematic pattern of opioid use leading to clinically significant impairment or distress.
  - OUD severity can range from Mild (2-3 symptoms) to Moderate (4-5 symptoms) to Severe (6 or more symptoms)
  - Individuals in OUD recovery are also included as a population of interest
- Opioid misuse Definition: taking a medication in a manner or dose other than prescribed; taking someone else's prescription; or taking a medication to feel euphoria (i.e., to get high).
- Of importance, tolerance and withdrawal symptoms represent iatrogenic consequences of chronic opioid consumption and do not meet DSM criteria for mild OUD.
- **Individuals with physical dependence who do not meet any DSM-5 criteria for OUD/misuse are NOT a priority for this initiative.**

Key Definitions Across FOAs: CP

NIH HEAL INITIATIVE

- CP is the presence of pain for at least 3 months.
- CP is a biopsychosocial condition, resulting from complex genetic-environment interactions and is influenced by dynamic changes in physiological, psychological, and social factors.
- This RFA will only address non-cancer chronic pain.
- **Chronic cancer pain and acute pain are NOT a priority for this RFA.**

Key Definitions Across FOAs: Co-morbid Conditions

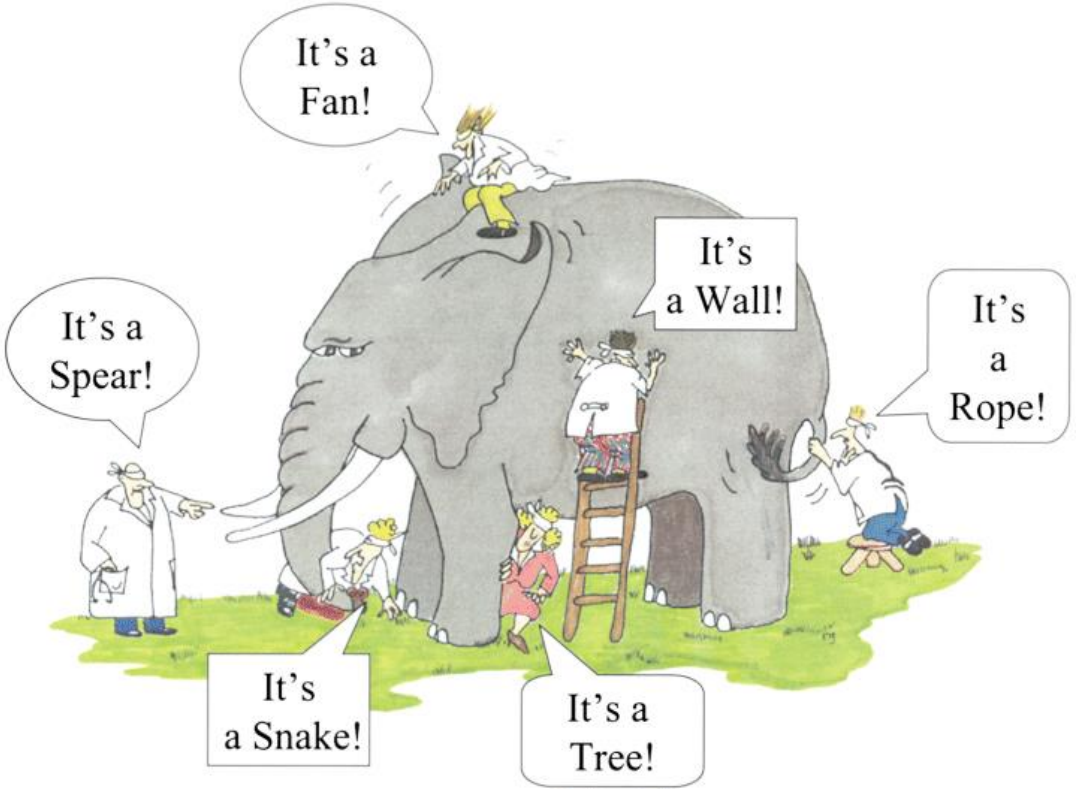
NIH HEAL INITIATIVE

- Individuals with frequently occurring comorbid conditions may complicate effective treatment of CP and OUD.
- Alcohol Use Disorder (AUD) or heavy alcohol consumption
  - Men: > 4 drinks on any day and > 14 per week
  - Women: >3 drinks on any day and > 7 per week
- Generalized Anxiety Disorder (GAD)
- Major Depressive Disorder (MDD)
- Importantly, patients with these common comorbidities should be not be excluded from studies.
- Applicants are encouraged to measure these outcomes if they are present in the enrolled participants.

PWLE & Stakeholder Engagement

NIH HEAL INITIATIVE

- Patients are the consumers of the interventions developed by NIH supported clinical trial research
- Projects must include persons with lived experience (PWLE)/representatives from patient advocacy groups
- Relevant stakeholders may include, but are not limited to: payors, care takers, health care providers from multiple disciplines, policymakers, advocacy groups, or professional organizations that create clinical care guidelines
- **PWLE, stakeholders, and researchers are EQUAL partners in this network**
- Collect holistic and patient-centered outcomes



IMPOWR: Clinical Research Centers

IMPOWR Research Centers

NIH HEAL INITIATIVE

- **FOA#:** RFA-DA-21-030
- **Title:** Integrative Management of chronic Pain and OUD for Whole Recovery (IMPOWR): Research Centers
- **Clinical Trial:** Required
- **Expected # of Awards:** 2-4
- **Budget Limit:** $1.75M Direct Cost/year
- **Award Period:** 5 years
- **Funding Mechanism:** RM1

Study Design & Intervention Selection

NIH HEAL INITIATIVE

- 2 research projects must be included in each application. A third research project is **OPTIONAL**.
- Intervention designs must be selected from the following research clusters:
  1. Efficacy/Effectiveness trials on integration of evidence-based interventions for CP and OUD/misuse
  2. Evaluation of Integrated Models of Care Delivery for evidence-based treatments for CP and OUD/misuse
  3. Implementation strategies to maximize reach and sustainability of integrated evidence-based practices for pain and OUD/misuse
- Applications **DO NOT** have to address all three research clusters
- Study designs may include pragmatic clinical effectiveness, implementation, and hybrid effectiveness-implementation studies
- Pilot projects can be included, and are **OPTIONAL**

Common Data Elements (CDEs)

NIH HEAL INITIATIVE

- OUD populations: treatment engagement and retention, remission, relapse, mortality, reduced harm reduction, and other adverse health events.
  - Encouraged use of OUD cascade of care framework to guide outcome selection
- Opioid misusing populations: the PI must justify the approach to measuring reductions in **harmful** behaviors associated with misuse.
  - *Of note, a singular measure of reduced opioid consumption indicated by decreased morphine in milligrams equivalents and/or days of opioid consumption is not a sufficient measurement of reduced opioid misuse.*
- AUD/heaving drinking, MDD, & GAD outcomes are encouraged. If interventions are not intended to change these outcomes, these disorders should be measured.
- Follow-up should be at least 6 months; 1 year or longer is strongly encouraged.
- Rigorous economic evaluations are required. Societal outcomes (e.g., costs of treatment, healthcare utilization, etc.) should be considered.

HEAL Core & Supplemental Pain CDEs

NIH HEAL INITIATIVE

- Unprecedented opportunity for the pain research community to compare results across trials to quantify the impact of interventions. (Pain CDE catalog).

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-2/8/9	GAD-2/7	PGIC	TAPS 1

- Any outcome measures specific to a CP condition should be validated measures appropriate for the pain condition, and may already exist in the Supplemental CDE catalog.

Project/Performance Site Locations

NIH HEAL INITIATIVE

- Selection of the health care setting should include a justification as to why this setting is expected to be a high impact setting from a public health perspective
  - Prefer site selection with high rates of individuals with CP & OUD
  - Consider low resourced settings, rural areas, and other systemic challenges

Research Cluster	Research Design
Efficacy/Effectiveness trials	Multisite design is encouraged
Integrated Care Models	Multisite design is required
Implementation of EBPs	Multisite design is required

- Applications that opt to include two research projects within one research cluster are encouraged to identify study designs that are synergistic
- **Letters of support from each clinical site are required.**

PWLE and Stakeholder Engagement

NIH HEAL INITIATIVE

- Applications must include a **minimum of 3 persons with lived experience (PWLE) and/or patient organization representatives.**
- There is no minimum requirement for the number of stakeholders included in the research team, but applicants must justify the diversity and selection of these stakeholders.
- Engagement with PWLE & stakeholders throughout the research process, including research design, conduct, and dissemination of study findings
- It is expected that PWLE and stakeholders from each research center will form a subcommittee and meet every 6 months or more frequently, if needed.
- Letters of support from patient community and stakeholders are encouraged, but not required at the time of application submission.

Additional Points to Consider

NIH HEAL INITIATIVE

- Applicants are strongly encouraged to individuals who are underrepresented in biomedical research including individuals of diverse racial/ethnic, gender, rural and low-income backgrounds.
- Appropriate applicants at early stages in their research careers are strongly encouraged to participate
- Applicants are strongly encouraged to use psychometrically validated instruments, such as those found in PROMIS, and harmonized measures, such as those found in the PhenX Toolkit.
- **All awardees will harmonize common data elements in Sept/Oct 2021, prior to protocol launch.**

Responsiveness Criteria

NIH HEAL INITIATIVE

Applications with the following specifics will be considered non-responsive and will not be reviewed:

- Applications that do NOT measure **BOTH non-cancer** CP and OUD/misuse outcomes as primary measures. AUD/heavy drinking, MDD, and GAD outcomes are encouraged
- Applications that do not commit to collaborating across the network, including executive meeting and workgroup participation, data harmonization, and other activities of synergy
- Applications that do not include two-three research projects from the prioritized research clusters
- Applications that do not include a multisite design for integrated care models or implementation research clusters
- Applications that do not include plans for meaningful engagement with PWLE or representatives from patient advocacy groups **and** stakeholders relevant to the research project
- Research sites with communities outside the US and its territories
- PIs who do not commit at least 2.0 person months of effort to the application per year for the life of the award

Research Centers: Research Plan Overview (Section IV)

NIH HEAL INITIATIVE

- One-page Specific aims describing the overall center

Sub-section	Content	Page Limit	Requirements
A	Research Site Overview, Management, and Operations	6	Required
B	Stakeholder Engagement and Outreach	6	Required
C	Research Project 1	12	Required
D	Research Project 2	12	Required
E	Research Project 3	12	OPTIONAL
F	Data Collection, Management, and Harmonization	3	Required
G	Pilot projects	6	OPTIONAL

A: Research Site Overview, Management, and Operation

NIH HEAL INITIATIVE

- Overall structure to promote interactions among sites
- Administrative organization for the proposed research center with qualifications, roles, responsibilities, and lines of authority for personnel involved in the collaborative grant;
- Project management plans listing study deliverables and timelines
- Plans for quality control to ensure rapid problem identification and resolution
- Communication plan between projects within the research center, across IMPOWR research centers, and with Coordination & Dissemination Center

B: Stakeholder Engagement and Outreach

NIH HEAL INITIATIVE

- Plan for involving PWLE or representatives from patient organizations and stakeholders in the designing conducting, and dissemination stages of the research projects.
  - A minimum of 3 PWLEs/patient advocacy representatives
  - No minimum requirements for stakeholders, but justification is needed on the number and diversity of these partners
  - Describe experience, expertise, and record of working collaboratively with relevant stakeholders and PWLE and engaging them in meaningful and collaborative manner.
- Establishment and regular meetings of a Stakeholder Consultation Board
- Plans for how stakeholder engagement will address stigma and health disparities as they relate to this complex patient population and health care systems.
- PWLEs and stakeholders are **equal partners** in the research enterprise

C, D, E: Research Project 1, 2, (3)

NIH HEAL INITIATIVE

- Each application must include a minimum of 2 research projects. **A third research project is optional.** The topics must be selected from the research clusters specified in the RFA. **Applicants do NOT have to address all of three research clusters.**
- Research strategy should include:
  - Detailed description of research project
  - Rigorous study design
  - Description of study outcomes
  - Justification for selected follow-up period
  - Description of clinical performance sites
  - Generalizability of clinical performance sites
  - Sustainability of proposed intervention

F: Data Collection, Management, and Harmonization

NIH HEAL INITIATIVE

- Describe the plan for data collection, management, quality control, integration and any harmonization across common data elements for the research site
- Plan for collecting high quality data for the primary outcomes of OUD/misuse, CP and any data outcomes as they relate to changes in AUD, MDD, and GAD treatment.
- Approach to dealing with issues that may arise
- Applicants should detail the data platform and provide a plan on how data will be shared (i.e. format, frequency of updates, what type of data, level of data detail).
- Plan for sharing enrollment data with Coordination & Dissemination center on a quarterly basis

G: Pilot projects (OPTIONAL)

NIH HEAL INITIATIVE

- Pilot projects do not count toward the required 2-3 research projects.
- Pilot projects may be "research and development" pilots, feasibility studies, or other pilot work broadly defined as foundation work for further research.
- **Pilot projects do not have to involve a clinical trial. Pilot project ideas can extend beyond the high priority research clusters identified in the RFA, but must be concentrated on CP and OUD/misuse.**
- The support for individual pilot project studies is typically of relatively short duration (e.g., 1-2 years)
- Applicants may propose and request funding in the first year for specific, already conceptualized pilot projects, and also for pilot projects to be added in subsequent years of the project
- Applications must describe a process for within-program scientific review of new pilot projects, a process for evaluation of ongoing pilot projects for adequate progress, and describe plans for adherence to federal regulations, policies, and guidelines.

Letters of Support

NIH HEAL INITIATIVE

1) Letters from all clinical research sites proposed across the 2-3 research projects are required.
   - In general, it is expected that applicants will be able to pre-specify their expected clinical research sites. If there is a compelling reason why this cannot or should not be done, applicants should provide similar details on the potential sites and what criteria will be used for selecting sites. No letters of support will be required for this scenario.

2) Letters from stakeholders relevant to the research projects are **recommended**. A list of suggested stakeholders is outlined in Part 2, Section I of this announcement.

3) A minimum of three letters from representatives from patient organizations and/or PWLE are **recommended**. Describe how these individuals will contribute to the research projects.

Resource Sharing Plan

NIH HEAL INITIATIVE

- Data Sharing Plan should explicitly acknowledge understanding that common data elements collected as part of this initiative will be expected to be shared with other research centers awardees. Plans for transmitting this data and ensuring appropriate sensitivities with regard to personally identifying information (PII) should be outlined.
- Data Sharing Plan should explicitly acknowledge understanding that metrics related to human subjects research will be shared with Coordination & Dissemination center to compile quarterly reports to share with NIH.
- The award recipient and its collaborators must comply with all *NIH HEAL Initiative* Data Sharing policies established during the project period.

Budget preparation

NIH HEAL INITIATIVE

- The budget should be **commensurate with the number and complexity of the research projects** within the application.
- In the budget justification, provide budget breakout for activities under each sub-section of the research strategy
- See details in the FOA, Section IV., 2. R&R Budget
- Budgets should include funds for:
  - Personnel
    - **For stakeholders & PWLEs: include salary support/honorarium, travel, per-diem (executive meetings; workgroup participation)**
  - Travel to annual in-person executive committee meetings
    - PIs, one stakeholder representative, one PWLE representative, and up to 3 team members
  - Data harmonization kick-off meeting: Fall 2021
  - Annual travel to HEAL Investigators meeting

IMPOWR: Coordination & Dissemination Center

Coordination & Dissemination Center

NIH HEAL INITIATIVE

- **FOA#:** RFA-DA-21-029
- **Title:** Integrative Management of chronic Pain and OUD for Whole Recovery (IMPOWR): Coordination and Dissemination Center
- **Clinical Trial:** Optional
- **Expected # of Awards:** 1
- **Budget Limit:** $575K Direct Cost/year
- **Award Period:** 5 years
- **Funding Mechanism:** R24
- **Page Limits:** 12 pages

Key Responsibilities

NIH HEAL INITIATIVE

1. Administrative coordination and communication
   - Logistical support for Executive Committee (EC) meetings and any workgroups
     - EC will meet quarterly virtually, with an annual in-person meeting (COVID19 permitting)
   - Providing quarterly updates on clinical trial progress across awarded research centers
   - Maintain awareness of emerging research findings of relevance to the network, including knowledge of other initiatives funded by the NIH HEAL initiative (e.g., RFA-MH-21-145, BRIM, ERN, PRISM, and BACPAC)
2. Data harmonization
   - Facilitate harmonizing of common data elements between IMPOWR and Optimizing Multi-Component Services (RFA-MH-21-145) awardees
   - Facilitate establishment of data sharing agreements between these programs

Key Responsibilities

NIH HEAL INITIATIVE

3. Provide research education infrastructure
   - **Required** development of educational strategies for reducing stigma and health disparities.
   - Other infrastructure activities (workshops, webinars, resources, etc)
   - If existing meritorious resources already exist, applicants may propose a multi-pronged approach to disseminate existing resources as appropriate and develop new activities to address any remaining training gaps.
4. Create innovative research resources appropriate to co-occurring CP and OUD, composite outcomes measures, and screening tools for both OUD and CP.
   - **Required**: ONE composite outcome measure tool for both conditions that is patient-centered, defined, and valued and includes function/behavior and well-being, and patient goals that can be aggregated to populations.
     - Dissemination of this tool to research centers and beyond upon completion
   - Optional: measuring craving in this population, screening tools to distinguish subgroups of responders to assist in developing tailored integrated treatment, subgroup phenotyping tools, etc.

Key Responsibilities

NIH HEAL INITIATIVE

5. Stakeholder engagement and information dissemination
   - Facilitate bidirectional communication and translation between network investigators and external stakeholders.
   - Engage stakeholder communities not formally involved in the network and identifying strategies for assisting those communities in applying insights that emerge from research supported by the awarded research centers within this network. It is expected that research centers and the Coordination and Dissemination center will interact collaboratively to accomplish this goal.
   - Disseminate protocols, resources, products and information generated by the research centers, including educational/training content generated by the Coordination and Dissemination center.
   - Identify opportunities for informing the development or updating of practice guidelines, and facilitate the engagement of funded researchers with those efforts.
   - Disseminate educational materials generated by the Coordination & Dissemination Center, with a concerted effort on reducing stigma and health disparities.

Budget preparation

NIH HEAL INITIATIVE

- See details in the FOA, Section IV., 2. R&R Budget
- Budgets should include funds for:
  - Personnel
    - Stakeholders should **not** be pre-identified, rather a plan for engaging with a broad range of stakeholders relevant to the research centers
  - Travel and support to coordinate a kick-off data harmonization meeting and annual in-person executive committee meetings
  - Annual travel to HEAL Investigators meeting

Responsiveness Criteria

NIH HEAL INITIATIVE

Applications with the following specifics will be considered non-responsive and will not be reviewed:

- Applications that do not commit to collaborating in efforts across the network, including executive meeting and workgroup participation, data harmonization, and other activities of synergy
- Applications that do not include a plan for supporting engagement with diverse stakeholders and PWLE or representatives from patient organizations relevant to this RFA
- Applications that do not include innovative tool development, including developing a single composite outcomes measure tool for CP and OUD
- Applications that do not include an education infrastructure plan targeting CP and OUD, including addressing stigma and health disparities in this patient population
- Applications with activities outside the US and its territories
- PIs who do not devote at least 2.0 person months of effort to the application per year for the life of the award

Expected Synergies

Executive Overview

NIH HEAL INITIATIVE

Title	IMPOWR Research Centers	IMPOWR Coordination and Dissemination Center (C&DC)	Optimizing Multi-Component Service Delivery
FOA	RFA-DA-21-030	RFA-DA-21-029	RFA-MH-21-145
Duration	5 years		4 years
Target Patient Population	Patients must have CP and OUD/opioid misuse; may have AUD, GAD, MDD		Patients must have OUD and Mental Health Disorders and/or Suicide; may have CP
Program goals	Identify integrated interventions, care delivery models, and/or implementation strategies for both CP and OUD/opioid misuse	Provide support to the IMPOWR network including: logistical support, stakeholder engagement, Research education infrastructure, Data harmonization, novel tool development	Determining the value of each component that drives clinical improvement and the optimal sequence of each component

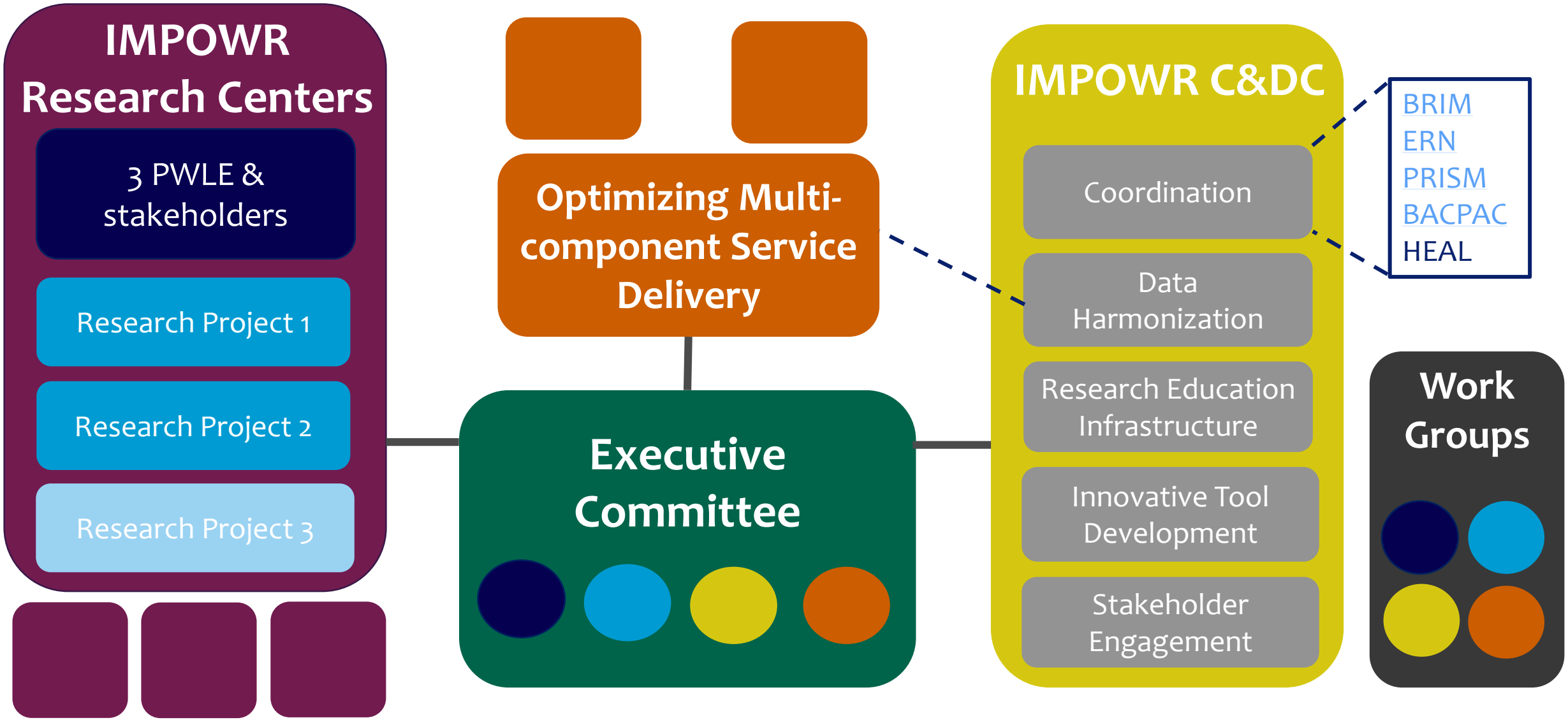
Expected Synergy

NIH HEAL INITIATIVE

- Participation in quarterly executive committee meetings; with one in-person meeting annually
- Awardees will participate in workgroups that arise to support synergistic activities across these networks
- Awardees are expected to participate in break-out sessions with other HEAL programs of relevance to this initiative at the annual HEAL PI meeting
- Harmonize measures prior to protocol launch (Oct/Nov 2021)
- Applicants are encouraged to budget for these activities, including financial support for PWLE/stakeholders in IMPOWR

Network Schematic

NIH HEAL INITIATIVE



Questions

NIH HEAL INITIATIVE

- For a copy of today's webinar and slides, please go to:

https://www.drugabuse.gov/news-events/meetings-events/2021/01/technical-assistance-webinar-heal-initiative-programs-nida-impowr-nimh-optimizing-multi-component

Inquiries about RFA-DA-21-029 and RFA-DA-21-030 should be directed to:

Shelley Su, Ph.D.
National Institute on Drug Abuse (NIDA)
Email: IMPOWR@nih.gov

- Inquiries about RFA-MH-21-145 should be directed to:

Michael C. Freed, Ph.D., EMT
National Institute of Mental Health (NIMH)
Email: michael.freed@nih.gov