PLEASE NOTE: EPPIC-NET ACCEPTs APPLICATIONS ON A CONTINUOUS, ROLLING BASIS.
PLEASE CHECK THIS SITE FOR UP-TO-DATE INFORMATION AND ANNOUNCEMENTS

EPPIC-NET APPLICATION PACKET INFORMATION SHEET

This packet contains:
1. **This information sheet**
2. **The EPPIC-Net preliminary application: a fillable pdf form**
3. **Line-by-line instructions for completing the preliminary application**
4. **Instructions for application submission via eRA Commons**

INFORMATION FOR EPPIC-NET APPLICANTS

The NIH HEAL Initiative

The Helping to End Addiction Long-term℠ Initiative, or NIH HEAL Initiative℠, (https://heal.nih.gov/) is an aggressive, trans-agency effort to speed scientific solutions to stem the national opioid public health crisis. Almost every NIH Institute and Center is accelerating research to address this public health emergency from all angles.

The initiative is funding hundreds of projects nationwide. Researchers are taking a variety of approaches to tackle the opioid epidemic through:
- Understanding, managing, and treating pain
- Improving treatment for opioid misuse and addiction

The Early Phase Pain Investigation Clinical Network (EPPIC-Net)

The Early-Phase Pain Investigation Clinical Network (EPPIC-Net), (https://www.ninds.nih.gov/Current- Research/Trans-Agency-Activities/NINDS-Role-HEAL-Initiative/NINDS-Role-HEAL-Initiative-EPPIC) led by the NINDS, seeks to fulfill the HEAL Initiative mission by establishing a clinical trials network for highly meritorious assets for the treatment of pain.

Through EPPIC-Net, NIH aims to:

- Provide academic and industry investigators with expert infrastructure that will design and conduct early-phase clinical testing of new or repurposed pain therapeutics across populations and the lifespan
- Reduce reliance on opioids by accelerating early-phase clinical trials of non-addictive pain therapeutics, including drugs and devices

Studies in EPPIC-Net will:

- Test new, non-addictive pain therapeutics in early-stage trials of drugs, biologics, and devices
- Provide proof-of-concept testing and validation of potential biomarkers for utility in assessing target engagement or pain outcomes
- Develop and test innovative clinical trial paradigms to engineer adaptive, ever-improving early-phase testing of new pain therapies
- Establish multiple well-characterized cohorts of different pain conditions for clinical trials

For assets submitted to EPPIC-Net, NIH will prioritize applications for:

- Drugs or biologics with an existing IND or devices with an existing IDE and phase 2 ready. EPPIC-Net will not consider applications for assets without preliminary data in humans.
- Drugs, biologics or devices with potential to treat pain conditions of high unmet need
- Drugs, biologics or devices that have high potential to move to industry-funded phase 3 efficacy trials and into clinical use

The EPPIC-Net infrastructure

The EPPIC-Net Infrastructure, established through a competitive grant process, includes:

The Clinical Coordinating Center (CCC) provides protocol development, overall trial management, site and investigator training, and interface with IRB.

The Data Coordinating Center (DCC) provides data management and analysis expertise and tools, quality assurance, and centralized data and biorepositories.

Clinical Research Sites (Hubs) provide clinical researchers with pain expertise, focused patient populations, and wide outreach into pain communities, and conduct the research procedures.

The application and review process for EPPIC-Net has 3 stages.

Stage 1: The applicant completes the **brief preliminary application in this packet** and submits it via eRA Commons. The preliminary application is a high-level, general overview of the asset, proposed pain population and proposed clinical trial. In preparing the application, please be sure to comply with attachment and page limits specified in the application instructions. Following review, highly-assessed applications are selected to proceed to Stage 2.

Stage 2 (by invitation only): the applicant works with an NIH contractor to prepare a **dossier** with detailed information on the asset, including drug pharmacology or device specifications. Following further review, highly-assessed applications are selected to proceed to Stage 3.

Stage 3 (by invitation only): The applicant works with the EPPIC-Net CCC, in consultation with the EPPIC-Net DCC and appropriately-matched Clinical Research Sites to develop the **clinical protocol**. The clinical protocol undergoes a final review. Highly-assessed protocols are presented to the NINDS Council and HEAL Leadership who make the final funding decision for study implementation within EPPIC-Net.

At each application stage, independent, objective review is followed by NINDS administrative review for fit with the EPPIC-Net mission.

IMPORTANT NOTES:

- Stage 1 application is open to all; Stages 2 and 3 are by invitation only.
- No funding is associated with application stages 1 and 2.
- Successful asset applicants receive access to EPPIC-Net resources for the development and conduct of the clinical trial for their asset. **Asset applicants do not receive funding.** Funding for selected clinical protocols is provided to the EPPIC-Net infrastructure components for conduct of the trial.
- ***Potential applicants are strongly encouraged to talk to EPPIC-Net staff prior to application submission***

Intellectual property and products studied within EPPIC-Net remain the property of the asset owner

Data from EPPIC-Net clinical trials is subject to the NIH HEAL Initiative Public Access and Data Sharing Policy and will be made available in accordance with the study-specific Public Access and Data Sharing Plan.

How to apply to EPPIC-Net

1. *Register in eRA Commons using ASSIST.* ***The ROA NUMBER to be used in eRA Commons*** is ROA OTA-22-002
2. *Complete the EPPIC-Net preliminary application pdf form.*
3. *Assemble all required documents as pdf forms.*

4. *Submit the preliminary application and required documents to EPPIC-Net via eRA Commons*

- *APPLICANTS WILL RECEIVE A SUBMISSION RECEIPT.*
- *APPLICANTS WILL RECEIVE NOTIFICATION OF DECISIONS ONCE REVIEW IS COMPLETE*

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