National Institutes of Health
Turning Discovery Into Health

Subject: EPPIC-Net Asset Owner Acknowledgement

An applicant (the "Participant") to the Early Phase Pain Investigation Clinical Network (EPPIC-Net) who is accepted at the end of Stage 2 (Dossier application) to move forward to Stage 3 (Protocol development and application, (see https://heal.nih.gov/research/clinical-research/eppic-net for a description of all application stages), acknowledges and agrees to the following:

- **Existing Patent Rights Ownership:** Participant retains all ownership rights to its existing patent applications and patents that may pertain to Participant's Asset ("Asset Patent Portfolio"). No rights to the Asset Patent Portfolio are granted to NINDS, the EPPIC-Net Clinical Coordinating Center (CCC) or its subcontractors, nor the EPPIC-Net Data Coordinating Center (DCC) as a result of Participant applying to or subsequently participating in an EPPIC-Net clinical trial.

- **Invention Ownership:** Participant acknowledges and agrees that ownership of any new discoveries or inventions ("new EPPIC-Net inventions") that result from participation in EPPIC-Net network are owned based on inventorship in accordance with U.S. patent law. Under the Bayh-Dole Act (see 35 USC 201 et. seq.) and 37 Code of Federal Regulations Part 401, EPPIC-NET (CCC, DCC, Sites) has the right to elect full title to any invention they conceive or first actually reduce to practice in the performance of a study under NINDS funding, provided that neither NINDS nor the company (if involved) shares ownership of the invention by virtue of co-inventorship.

- **Provision of investigational product:** If the clinical trial for the Participant's Asset is approved for HEAL funding, the Participant agrees to provide the Investigational Product without charge and on a schedule that will ensure adequate and timely performance of the research, a sufficient quantity of formulated and acceptably labeled, clinical-grade Investigational Product (and, as required by the Protocol, Placebo) to complete the clinical trial agreed to.

  Participant's obligation to provide Investigational Product in sufficient quantities extends as needed to complete the Protocol, unless trial termination is for safety concerns, the trial is stopped by the applicable IRB, or the NIH accepts a DSMB recommendation to stop the trial.

  Participant will provide a Certificate of Analysis to NINDS and the CCC for each lot of any pharmaceutical Investigational Product or Placebo provided.

- **Data Ownership and Sharing:** Participant acknowledges and agrees that the data generated through use of Participant's Asset in EPPIC-Net are owned by the EPPIC-Net Clinical Research Site or entity that generated it. Participant acknowledges that Participant does not own any data generated by EPPIC-Net sites or investigators.
    - **Participant de-identified data receipt:** Per agreement between CCC and Participant and/or DCC and Participant, a copy of all de-identified data, as defined by the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") will be shared with the Participant. The deidentified data will be provided to the Participant after data cleaning and quality check and within 90 days after database lock by the EPPIC-Net CCC and DCC. The Participant will be given a copy of de-identified data in a format as determined by the DCC. The Participant will be free to utilize data for their own purposes, including internal research and business and regulatory purposes. The Participant will not transfer raw data to any third party except as required by law. Participant will not publish or publicly disclose data without the written permission of NINDS and in accordance with applicable law, human subject/participant informed consent and applicable IRB approval.

Data sharing: The Participant understands that the Other Transactions award recipient (the CCC for EPPIC-Net clinical trials) and their collaborators must and will comply with all NIH and HEAL Initiative Data Sharing policies established during the project period. These policies are outlined on the NIH websites:
https://heal.nih.gov/data/public-access-data
https://grants.nih.gov/policy/sharing.htm
https://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm).

- This includes compliance with the NIH HEAL Initiative central data platform requirements and timelines developed through the HEAL consortium. It is expected that all data collected by EPPIC-Net investigators 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.

Regulatory filing(s): Participant acknowledges and agrees that if the Participant's Asset is selected for a clinical trial through EPPICC-Net, the CCC will be the sponsor of a research Investigational New Drug (IND) application with the U.S. Food and Drug Administration (FDA), unless there is a strong, compelling reason for the Participant or another entity to serve as the IND sponsor. For clarity, this is the equivalent of an Investigator initiated IND.

If the CCC is the IND/IDE sponsor, the CCC will assume all of the responsibilities associated with being IND sponsor while the EPPIC-Net-conducted clinical trial involving Participant's Asset is active. Upon completion or termination of the EPPIC-Net clinical trial, CCC will transfer sponsorship to the Participant or will provide Participant with the appropriate documentation to be able to cross-reference the EPPIC-Net research IND.

If the Participant is the IND/IDE sponsor, the EPPIC-Net CCC and/or DCC will provide the deidentified data, in a format as determined by the DCC, that is required to meet Participant's obligation as the IND/IDE sponsor.

Publication(s): Participant acknowledges and agrees that EPPIC-Net, CCC and its subcontractors, and/or DCC have a mission to publish or present the outcome of clinical trials run through the EPPIC-Net network. Participant may request a delay, of no more than 30 days, in the submission of publications to ensure that its confidential and proprietary data, in addition to any intellectual property rights, are protected. Before publication, EPPIC-Net, CCC and its subcontractors, and/or DCC will provide a copy of the publication to the Participant for advisory review for the purpose of identifying the presence of any Asset-related confidential information belonging to Participant. Participant can require removal of Asset-related confidential information belonging to Participant and will endeavor to replace it with suitable information if critical to the publication. Participant does not have decision-making authority regarding whether a manuscript will be submitted for publication. Publications from EPPIC-Net must acknowledge the funding source provided by NINDS and other groups as appropriate.