EPPIC-Net Preliminary Application

1. Applicant/PI Information:

1a. First Name:_____ MI:___ Last Name:_____ Suffix:____

1b. Title:_____ Degree _____ If other, identify: _____

1c. Email:_____ Phone #:_____

1d. Organization:_____

Position at Organization: _____

Mailing Address:

1e. Street Address:_____Apt/Suite/Room#:_____

Street Address(Continued):_____

1f. City:_____ US State:_____ ZIP:_____

1g. Country:_____ Non-US State/Division:_____

2. Key Research Personnel Information (Optional):

2a. First Name:_____ MI:___ Last Name:_____ Suffix:____

2b. Title:_____ Degree _____ If other, identify: _____

2c. Email:_____ Phone #:_____

2d. Organization:_____

Position at Organization:_____

Mailing Address:

2e. Street Address:_____Apt/Suite/Room#:_____

Street Address (continued):_____

2f. City:_____ US State:_____ ZIP:_____

2g. Country:_____ Non-US State/Division:_____

3. Project Identification:

3a: Title of Project **(Limit 200 characters):**

3b. Check here if this asset has been previously reviewed: ☐

If an application for this asset was previously submitted and reviewed, briefly identify what new information is being provided to aid reconsideration (e.g., "this application includes additional information on the asset's mechanism of action"). **(Limit 250 words)**

3c. Provide a brief description of the project with rationale. If the asset has been previously reviewed, new information should be incorporated into the rationale, as appropriate**. Do NOT** re-submit your previous rationale. **(Limit 750 words)**

3c. Provide a brief description of the project with rationale. **(Continued)**

4. Asset Information:

4a. Asset Name:_____

4b. Asset Status:_____ If other, please identify:_____

4c. Asset Owner(s):_____

4d. If applicant is owner, identify as originator or licensee:_____

4e. Asset Authorization: If applicant is not owner, attach statement of support from the owner(s) confirming that the applicant has the authorization to access asset in the proposed study. If applicant is owner, provide a statement confirming that the asset may be used for the proposed EPPIC-Net study. The freedom-to-operate letter should be attached as a PDF document. **Upload PDF**

4f. Asset type:_____ If other type or multiple types, identify:_____

_____

4g. If asset type is Drug, complete the following:

i. Drug Type:_____ If other, identify:_____
ii. Pharmacological Class: If other, identify:_____
iii. Mechanism of Action:_____
iv. Target:_____ If other, identify:_____

4h. If asset type is Device, complete the following:

i. Device contact with body:_____
ii. Device interaction with participant:_____
iii. Device target tissue/organ:_____
iv. If brain, identify target brain region:_____

4i. If asset type is Biomarker, complete the following:

i. Purpose of biomarker:_____

_____

ii. Sample type needed:_____
If multiple types or other, identify:_____

_____

a. If body fluid, identify_____
If blood derivative, identify:_____
b. If biopsy, identify_____
If other biopsy type, identify:_____
c. If imaging, identify_____
If other imaging, identify:_____
d. If physiological, identify:_____
If other physiological, identify:_____

e. If behavioral/observational, describe **(Limit 100 words):**

For all asset types, complete items 4j-4p.
Note: Copies of the FDA filing, Investigator Brochure, etc. are not required and should not be included.

4j. Is asset FDA-regulated?_____ IND/IDE exempt:_____

If asset is not FDA-regulated, skip to item #5a, otherwise complete 4k.

4k. IND/IDE granted:_____ If yes, is IND/IDE active and in good standing:_____

If yes, provide IND/IDE number:_____

If IND is granted and in good standing, skip to Item 4p, if not, complete 4l-o.

4l. Pre-IND/IDE meeting with FDA completed:_____ If yes, meeting date:_____

4m. Asset is IND/IDE ready:_____ **4n.** IND/IDE application filed with FDA:_____

4o. Expected time to IND/IDE:_____

4p. Investigator Brochure available:_____ Willing to share data with HEAL/EPPIC-Net:_____

For items 5-6, provide citations for selected published research articles and reports that demonstrate the asset's suitability and readiness for a Phase 2 clinical trial. You may also reference unpublished data. Unpublished data should be provided in summary form, with summaries limited to 5 pages per citation. In addition, upload each cited article or summary of unpublished data as a PDF document attachment to the application. Attachments are limited to no more than 18 articles/summaries, total (i.e., 3 documents per question, for questions 5a, 5b, 5c, 6a, 6b, & 6c).

Do Not Submit raw data or Clinical Study Reports. Do not provide hyperlinks to documents.

5. Relevant prior data on asset:

5a. Background literature citations on asset: Identify up to 3 key references providing context for proposed study and specific asset and upload one copy of each published citation as a PDF document.

Upload PDFs

5b. Preclinical studies completed: _____ If yes, identify up to 3 references with preclinical data. Upload a copy of each cited reference, as a PDF document. Unpublished data should be submitted per instructions provided above. **Upload PDFs**

5c. IND/IDE enabling studies completed to support IND/IDE: _____ If yes, identify up to 3 references with IND/IDE enabling data. Upload a copy of each cited reference, as a PDF document. Unpublished data should be submitted per instructions provided above. **Upload PDFs**

6. Clinical Studies Citations:

6a. Phase 1 Studies Completed:_____ If yes, identify up to 3 references with Phase 1 clinical data, if available. Include clinicaltrials.gov NCT number, if applicable. Upload a copy of each cited reference as a PDF document. Unpublished data should be submitted per instructions provided above. **Upload PDFs**

6b. Phase 2 studies completed:_____ If yes, identify 3 references with Phase 2 clinical data, if available. Include clinicaltrials.gov NCT number, if applicable. Upload a copy of each cited reference, as a PDF document. Unpublished data should be submitted per instructions provided above. **Upload PDFs**

6c. Phase 3 studies completed: If yes, identify 3 references with Phase 3 clinical data, if available. Include clinicaltrials.gov NCT number, if available. Upload a copy of each cited reference, as a PDF document. Unpublished data should be submitted per instructions provided above. **Upload PDFs**

7.Cumulative Information from Prior Studies:

7a. Cumulative number of human subjects studied:_____

7b. Dose range studied in humans:_____

7c. Number of doses/duration of exposure/route in humans:_____

7d. Site(s) of prior studies: _____ If other, enter site(s):_____

_____

7e. Known frequent and/or serious adverse effects (animals and/or humans): _____

_____

_____

7f. Addiction Potential: _____ If no, describe how assessed:_____

_____

7g. Evidence of efficacy for intended indication: If yes, state if efficacy was demonstrated or if there was only a trend towards significance: _____

8. Proposed Study Information:

8a. Pain Acuity:_____

8b. Pain Type:_____

If other, identify: _____

Population:

8c. Disease/Condition to be studied:_____

8d. Population to be studied:_____

8e. Special populations:_____

If other, or multiple vulnerable populations, identify: _____

_____

Proposed Treatment Regimen (For Drugs and Devices):

8f. Dose:_____ Route:_____

Frequency:_____ Duration:_____

9. Outcomes:

9a. Primary outcome measure for efficacy:_____

_____

9b. Primary outcome measure for safety:_____

_____

10. Additional Information:

10a. Summarize currently available treatments for proposed condition **(Limit 200 words)**:

10b. Feasibility/Logistics Concerns: _____ If yes, identify concerns and explain **(Limit 100 words)**:

10c. Availability of asset:_____ Explain **(Limit 50 words)**:

10d. Readiness to start clinical trial:_____ Explain **(Limit 50 words)**: