

## **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.

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.

**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.

**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.

## **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](https://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.

**6b.** Phase 2 studies completed: \_\_\_\_\_ If yes, identify 3 references with Phase 2 clinical data, if available. Include [clinicaltrials.gov](https://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.

**6c.** Phase 3 studies completed: \_\_\_\_\_ If yes, identify 3 references with Phase 3 clinical data, if available. Include [clinicaltrials.gov](https://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.

**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**):