EPPIC-Net Initial Asset Application

1. Applicant Information:

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

1b. Degree: _____ If other, identify: _____ **1c.** Email: _____ Phone number: _____

1d. Organization: _____ Position at Organization: _____

Mailing Address:

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

1f. Street Address (continued):_____

1g. City: _____ U.S. State: _____ ZIP: _____

1h. Country: _____ Non-US state/division: _____

2. Key Research Personnel Information (optional):

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

2b. Degree: _____ If other, identify: _____ **2c.** Email: _____ Phone number: _____

2d. Organization: _____ Position at Organization: _____

Mailing Address:

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

2f. Street Address (continued):_____

2g. City: _____ U.S. State: _____ ZIP: _____

2h. Country: _____ Non-US state/division: _____

Project Identification:

3. Title of Project (limit 200 characters):

Project Identification (continued):

4. Brief description of project with rationale (limit 750 words). Check here if this is a resubmission for this asset: ☐

*If this application is a resubmission, additionally state what new information is available to aid reconsideration.

Asset Information:

5. Asset name: _____

6. Asset status: _____ If other, identify: _____

7a. Asset owner: If other, identify owner: _____

7b. If applicant is owner, identify if owner is _____

8. Attach a statement of support from the owner confirming that the applicant has the authorization to access and use the asset in the proposed study as an attachment to the application.

Asset Information (continued):

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

10. If asset type is drug, complete the following:

10a. Drug type: _____ If other, identify: _____

10b. Pharmacological class: _____ If other, identify: _____

10c. Mechanism of action: _____

10d. Target: _ If other, identify: _____

11. If asset type is device, complete the following:

11a. Device contact with body: _____ **11b**. Device interaction with participant: _____

11c. Device target: tissue/organ: _____ **11d.** If brain, identify target brain region: _____

12. If asset type is biomarker, complete the following:

12a. Purpose of biomarker: _____

12b. Sample needed: _____ If multiple types or other, identify:_____

- **i.** If body fluid, identify: _____ If blood derivative, identify: _____
- **ii.** If biopsy, identify: _____ If other biopsy type, identify: _____
- **iii.** If imaging, identify: _____ If other imaging, identify: _____
- **iv.** If physiological, identify: _____ If other physiological, identify:_____
- **v.** If behavioral/observational, describe (limit 100 words):

Asset Information (continued):

For all asset types, complete the following:

13. Is asset FDA Regulated?: _____ IND/IDE exempt:

If asset is not FDA-regulated, skip to item #15, otherwise complete 13a.

13a. 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 14, if not, complete 13b-e.*

13b. Pre-IND/IDE meeting with FDA Completed: If yes, Meeting date: _____

13c. Asset is IND/IDE Ready: _____

13d. IND/IDE application filed with FDA: _____

13e. Expected time to IND/IDE: _____

14. Investigator brochure available: _____ Willing to share data with HEAL/EPPIC-Net: _____

Relevant prior data on asset:

15. Background literature citations on asset. Identify up to 3 key references providing context for proposed study and specific asset and upload copies as pdf document.

16. Preclinical studies completed: If yes, identify up to 3 references with preclinical data and upload copies as pdf document

17. IND/IDE enabling studies completed to support IND/IDE: _____ If yes, identify up to 3 references with IND/IDE enabling data and upload copies as pdf document.

Clinical Studies Citations

18a. Phase 1 studies completed: _____ If yes, identify 3 up to references with Phase 1 clinical data, if available. Include clinicaltrials.gov NCT number, if applicable, and upload copies as pdf document.

18b. Phase 2 studies completed: _____ If yes, identify 3 references with Phase 2 clinical data, if available. Include clinicaltrials.gov NCT number, if applicable, and upload copies as pdf document.

18c. Phase 3 studies completed: _____ If yes, identify 3 references with Phase 3 clinical data, if available. Include clinicaltrials.gov NCT number, if applicable, and upload copies as pdf document.

Asset Information (continued):

Cumulative information from prior studies:

19a. Cumulative number of human subjects studied: _____ **19b.** Dose range studied in humans: _____

19c. Number of doses/duration of exposure/route in humans: _____

20. Site(s) of prior studies: _____ If other, enter: _____

21. Known frequent and/or serious adverse effects (animals and/or humans_____
_____
_____

22. Addiction Potential: _____ If no, described how assessed:_____

23. Evidence of efficacy for intended indication: _____ If yes, select: _____

Proposed Study Information:

24. Pain Acuity: _____ **25.** Pain Type: _____ If other, identify:

_____

Population:

26. Disease/condition to be studied: _____ **27.** Population to be studied: _____

28. Special populations: _____ If other, or multiple vulnerable populations, identify:

_____

Proposed treatment regimen (For drugs and devices):

29. Dose: _____ Route: _____ Frequency: _____ Duration: _____

Outcomes:

30. Primary outcome measure for efficacy: _____

31. Primary outcome measure for safety: _____

Additional Information:

32. Summarize currently available treatments for proposed condition (limit 200 words):

33. Feasibility/logistics concerns: _____ If yes, identify the concerns and explain (limit 100 words): _____

34. Availability of asset: _____ Explain (limit 50 words):

35. Readiness to start clinical trial: _____ Explain (limit 50 words):