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 500 words):

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. Attach Statement

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 3 key references providing context for proposed study and specific asset and upload copies as pdf document. Attach References

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

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. Attach References

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. Attach References

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. Attach References

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. Attach References

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):