

**Appendix 2: Data Abstraction Form**

Study ID:

Year of original submission: \_\_\_\_\_

Reviewed by HiREB:  Panel A  Panel B  Unidentified**Protocol Data:**Randomized study:  Yes  NoMethodology:  Quantitative  Qualitative  MixedType of clinical study:  Interventional  Observational

Desired sample size: \_\_\_\_\_

Source of Funding:  Industry Sponsored Grant Title and Organization: \_\_\_\_\_ No Funding  Source of Funding Not StatedType of study (terms used):  Pilot  Feasibility  Both

Do the objectives or purpose of the study clearly state the intent to assess feasibility?

 Yes  No  UnclearAre the specific feasibility objectives of the study stated?  Yes  No  UnclearSpecific feasibility objectives:  Process related: \_\_\_\_\_  Other: \_\_\_\_\_ Resource related: \_\_\_\_\_  Management related: \_\_\_\_\_

Are the criteria for the feasibility study to successfully lead to the main study stated?

 Yes  No  UnclearStudy approved?  Yes  No**Initial Consent Form Data:**Is the term "pilot" or "feasibility" in the title?  Yes  NoIs the definition of a pilot or feasibility study stated?  Yes  No  Unclear

Do the objectives or purpose of the study clearly state the intent to assess feasibility?

 Yes  No  UnclearAre the specific feasibility objectives of the study stated?  Yes  No  Unclear

Version 2: March 16, 2020

Is the criteria for the feasibility study to successfully lead to the main study stated?

Yes       No       Unclear

### Revised Consent Form Data:

Is the term “pilot” or “feasibility” in the title?     Yes       No

Is the definition of a pilot or feasibility study stated?     Yes       No       Unclear

Do the objectives or purpose of the study clearly state the intent to assess feasibility?

Yes       No       Unclear

Are the specific feasibility objectives of the study stated?     Yes       No       Unclear

Is the criteria for the feasibility study to successfully lead to the main study is stated?

Yes       No       Unclear