Protocol Review and Monitoring System – Protocol or Concept Submission Form

Appendix 8.3 Form only See SOP 2.1 Attachment A for completion instructions.

Please complete all fields and save the form as a separate word document or PDF. No alterations to requirements may be made. Incomplete forms will be returned. Submission will not proceed to review until all information is complete. Please submit the completed form to: humansubjectsresearch@cc.hawaii.edu . Please include Protocol/Study, ICF if applicable and Data Safety Monitoring Plan if separate from Protocol/Study. This form is also available as a fillable PDF (Appendix 8.3), please contact the Clinical Trials Office for assistance.

Form Completed by: _____ **Date:** _____

This is a protocol submission for review and approval Yes ___ or No ___

This is a concept submission for feedback from the CRAB/PRMC only Yes ___ No ___

Study Funded? Yes ___ No ___ **If yes source:**
Non Funded studies/Studies awaiting funding are only eligible for concept review. Unless there is a requirement for IRB approval prior to funding. If so, please document requirement:
_____
_____
_____

1. **Title of Protocol or Concept:**

2. **Short Title:**

3. **Objectives:**

   Includes Adults _____ Children (<18y/o) _____ or both: ____

4. **Sponsor /Group and Protocol Number:**

5. **Primary Purpose:**

6. **Phase:** I ___ I/II ___ II ___ II/III ___ III ___ III/IV ___ IV ___ Pilot ___ N/A ___

   Other please specify: _____

Observational ____ or **Interventional ____**

Ancillary ____ or **Correlative ____** or **Both ____**

Cancer Primary Site: _____

7. **Scope:** Local ___ or National ___

8. **Investigator Initiated Protocol:** Yes ___ or No ___

9. **NCI Designated as Cancer Control (please review definition in instructions)**:

   Yes ___ or No ___

10. **Principal Investigator Name:**

Email:

Phone:

11. **Study Contact/Coordinator Name:**

Email:

Phone:

12. **Sub-Investigators (list all):**

13. **Has this protocol or concept had a national peer review?** Yes ___ or No ___

If yes when and where _____ (please include copies of the reviews).

14. **Target enrollment for study: _____ Anticipated enrollment: locally_____**

15. **Anticipated study start date: _____ Anticipated study end date: _____**

16. **Investigational Drug:** Yes ___ or No ___ **If Yes IND Holder**: _____

IND #: _____

17. **NCT #: _____**

18. **Would you like Cancer Center Clinical Translational Research Services regulatory support for this trial?** Yes ___ or No ___ (Investigators not utilizing CTO support will be responsible for maintaining all regulatory documents in OnCore CTMS).

19. **Is this a multisite trial?** Yes ___ or No ___

List Local sites anticipated to enroll subjects:

20. **What other, if any, local studies are open for similar group of patients that may be competing with this study? List:**

21. **Is this a rare cancer?** Yes ___ or No ___

22. **Does this study involve drug accountability?** Yes ___ or No ___

Investigational Drug? Yes ___ or No ___

23. **Does this study involve therapy?** Yes ___ or No ___

24. **Does the study include specimen banking?** Yes ___ or No ___

25. **Does the study involve an investigational device?** Yes ___ or No ___

26. **Does the study involve adjuvant treatment?** Yes ___ or No ___

27. **Data Safety Monitoring provided by:** PI __ or UH CC ___ DSMC ___ or External ___.

28. **Anticipated study start (accrual) date: _____**

29. **Anticipated study completion date: _____**

Please provide a justification to open the study at UH Cancer Center/Consortium Member Site/Local Provider (e.g., reason to open, programmatic strategy, good use of available time and resources, patient need, etc. not otherwise documented on this form or within the Protocol/Concept).

Do all research staff have access to OnCore® Clinical Trial Management System: (staff access will be set based on this information): Yes _____ or No _____

If no, please request staff to request OnCore access from UH Cancer Center Clinical Trials Office via email at oncore@cc.hawaii.edu .

Do all research staff have current required training on file in OnCore (Human Subject Research Protection, Good Clinical Practice and HIPAA)? Yes ___or No ___ If unsure, please contact humansubjectsresearch@cc.hawaii.edu for a report.

If not on file, please forward documents with this submission for all staff. If not complete, please complete these UH required trainings prior to this submission.

PI Signature/Designee and date:

Valid electronic signature acceptable

Please submit this form and a copy of the research project document (Protocol) and Informed Consent Document (if applicable) and Data Safety Monitoring Plan to humansubjectsresearch@cc.hawaii.edu .