**PRMC Protocol Submission Form**

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Submission Packet (indicate N/A if document is not applicable):

1. Protocol Submission Form (this form)
2. Protocol
3. HawkIRB or WIRB Application
4. Informed Consent/Assent
5. Investigator’s Brochure
6. G-12 Drug Form
7. Signed MOG Approval Form

Submission in OnCore:

1. Send an e-mail to PRMC@uiowa.edu with a copy of each document attached. Please do NOT submit a document in mark-up view.
2. Create a new protocol record in ePRMS/OnCore and press “Send” to PRMC Administrative staff (contact us for training or assistance, if needed).

Required information for protocol record in OnCore:

**Items marked with \* do not need to be completed on this form if you have provided the information in OnCore**

1. **\***Protocol Title (Use official title from protocol or trial record at [www.clinicaltrials.gov](http://www.clinicaltrials.gov)):
2. **\***IRB#:
3. **\***Principal Investigator:
4. **\***Primary Study Coordinator:
5. **\***Study Site Contact for Inquiries:
6. **\***Is this a multi-site trial?
7. **\***Local protocol target accrual (i.e. the number of subjects enrolled on study):
8. **\***Local **annual** accrual goal (i.e. the number of subjects enrolled on study):
9. **\***Investigational Drug or Device (Y/N)?
	1. **\***IND/IDE number:
	2. **\***IND/IDE holder:
	3. **\***IND/IDE grantor (e.g. CDER, CBER, CDRH):
10. **\***All applicable disease sites for subjects to be enrolled
11. **\***Does this protocol have MOG approval (which MOG)?
12. **\***Does this study include specimen banking? If yes, are the specimens de-identified?
13. **\***Sponsor:
14. **\***Registration number with [www.clinicaltrials.gov](http://www.clinicaltrials.gov):
	1. NCT#:
15. Does this study include radiation therapy?
	1. If yes, is a radiation oncologist included as a Sub-I?
16. Does the study involve PET or Nuclear Medicine?
	1. If yes, has approval been granted from PET or Nuclear Medicine?
17. If grant-funded, provide the grant number assigned by Sponsored Programs:
18. Will the study population for this protocol include children? Yes\_\_\_ No\_\_\_ N/A\_\_\_

If “No”, please provide an explanation for excluding children as participants. Potential justifications for exclusion include (Please indicate all that apply to this study):

\_\_\_\_ the research topic is irrelevant to children (such as tumors that are not found in children)

\_\_\_\_ there are laws or regulations barring the inclusion of children in the research

\_\_\_\_ the knowledge being sought is already available for children or will be obtained from another study

\_\_\_\_ a separate, age-specific study in children is warranted and preferable

\_\_\_\_ insufficient data are available in adults to judge potential risks in children

\_\_\_\_ the study is designed to collect additional data on pre-enrolled adult study participants (e.g., the study is a longitudinal follow-up on a study that did not include data on children

\_\_\_\_ Other:

1. Is the target disease for this protocol considered a **Rare Cancer**? Yes\_\_\_ No\_\_\_ Not sure\_\_\_

Rare cancers include the following:

* 1. Cancers with an incidence of less than 6 per 100,000 persons / year
	2. Cancers of narrower molecular subtypes
	3. Cancers with uncommon clinical presentations (e.g., uncommon clinical subsets of more common cancers).

<http://www.rarecancerseurope.org/?-Families-and-List-of-Rare-Cancers>

<http://www.rarecare.eu/rarecancers/rarecancers.asp>

1. Please provide the current number of subjects enrolled across all participating sites and the date the information was obtained (request current information from sponsor):
2. Identify all applicable cancer types and/or categories the trial should appear under on HCCC’s clinical trials website: <https://uihc-oncore-prod.forteresearchapps.com/sip-mobile/flowchart.html>

(See flowchart map below for options)

1. **For investigator-initiated institutional trials only** (describe below or attach as a separate document):

Provide an accrual plan for the protocol considering the following:

1. The plan should set a realistic accrual goal and time frame based on the nature of the study, the type of cancer, the patient population, and other relevant factors.
2. Study-specific accrual rates planned by the PI may be less than or greater than three years, or non-uniform across active years.
3. The PRMC will expect a minimum of 30% accrual per period for planned enrollment.
4. Additional comments or information to convey to the PRMC and reviewers for this protocol: