UNIVERSITY OF HAWAI'I
CANCER CENTER

Clinical Trials Office

Dear Sponsor:

We are very pleased that you have expressed an interest in pursuing clinical research in the State of Hawaii through the Hawaii Cancer Consortium (HCC)/University of Hawaii Cancer Center (UHCC). HCC was established in 2010 and in conjunction with UHCC is geared to promote cancer research in Hawaii. The 70 physicians in our consortium are engaged in the care and treatment of cancer patients and include specialists in medical, surgical, radiation, pediatric, gynecologic, and hematological oncology.

These physicians come from both private practice and the following major institutions:

- Queen's Medical Center
- Hawaii Pacific Health
- Kuakini Medical Center
- OnCare Inc.
- Cancer Center of Hawaii
- Tripler Army Medical Center

There are significant advantages of working in Hawaii with HCC/UHCC. Although an oncology clinical trial maybe carried out at multiple sites in our consortium, sponsors can work with HCC/UHCC as a single point of contact for all administrative functions related to the trial at the respective sites, including regulatory management, contracting, budgeting, database management, statistical analysis, and auditing. We utilize the Western IRB (WIRB). HCC/UHCC will coordinate all IRB activities for sites within our consortium. While HCC/UHCC would like all sites to be able to participate in the majority of trials, HCC/UHCC recognizes that studies may vary significantly in the intensity of procedures and that it may be inappropriate for studies to be opened at all sites. We will work with you to assure that the protocol is activated at sites who fully meet the requirements of the study.

As the Protocol Coordinator, I will be your contact for this trial as it is reviewed by our scientific review committee. I would like to clarify a few operational preferences that will help us work together most efficiently and describe our general time frame for processing this trial. Our goal is to open this trial within 12 weeks of receiving the full, final protocol.

1) Confidentiality Disclosure Agreement (CDA) Process: If you require a CDA, it will be completed with UHCC as the party to the agreement. UHCC has been authorized to sign agreements with sponsors of clinical trials on behalf of the physicians in our consortium who will be participating.

Typically, CDAs are processed within 5 working days. Please send me an institutional (not an investigator) CDA in word document format (not pdf). When the CDA is fully executed, I look forward to receipt of the full, final protocol, although I would appreciate receiving the protocol in advance, if at all possible.

2) Review Process: Upon receipt of the full, final protocol, this trial will be reviewed by two committees: a Community Research Advisory Board (CRAB) and the Protocol Review and Monitoring Committee (PRMC). Our goal is to attain approval by the CRAB and PRMC within 3 to 5 weeks. During the review process I will inform you of the progress of the study.

3) Feasibility Questionnaires & Site Selection Process: We usually complete site selection activities, including completion of feasibility questionnaires, site assessment forms and pre-study site visits, after the study has been approved by the CRAB. If required by the sponsor and approved by the CRAB leader, a feasibility analysis may be completed prior to the CRAB meeting upon receipt of a detailed summary of a protocol or draft protocol in lieu of the final protocol document. Such a document must include: scientific background and justification, eligibility criteria, summary of study procedures and calendar and justification for the number of patients to be enrolled. A formal site selection meeting may occur after approval of a study by the CRAB.

4) IRB Process: After the trial has been approved by the PRMC, a regulatory coordinator will be assigned to the trial who will work with you to submit the trial to the Western IRB for review for all UHCC investigators and sites. Our goal is to submit all studies to the Western IRB within 4 weeks after PRMC approval.

5) Budget/Contracting and Regulatory/IRB: We will initiate these activities before this study has been approved by the PRMC and upon receipt of the formal site selection notification.

6) External Safety Reports: It is important for you to know the UHCC's procedure for handling external events. UHCC does not accept individual external adverse event reports (alerts, Medwatch or CIOMS). UHCC will review IND Safety Reports (SUSAR) that the sponsor highlights in the report and meets all three of the following conditions:

1. Unexpected;

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2. Related or possibly related to participation in research AND;

3. Serious, placing the subject or others at a greater risk of physical or psychological harm that was previously known or recognized.

UHCC will retain and manage IND Safety Report or SUSARs that meet the criteria above if they are deemed unanticipated and therefore reportable to the IRB of record. IND Safety Reports (SUSARs) that are not reportable to the IRB of record will not be retained by UHCC or its Investigators.

We utilize the Western IRB for our industry studies. Unless a Medicare Coverage Analysis is provided with this study, there will be a $3,000.00 fee assessed up front.

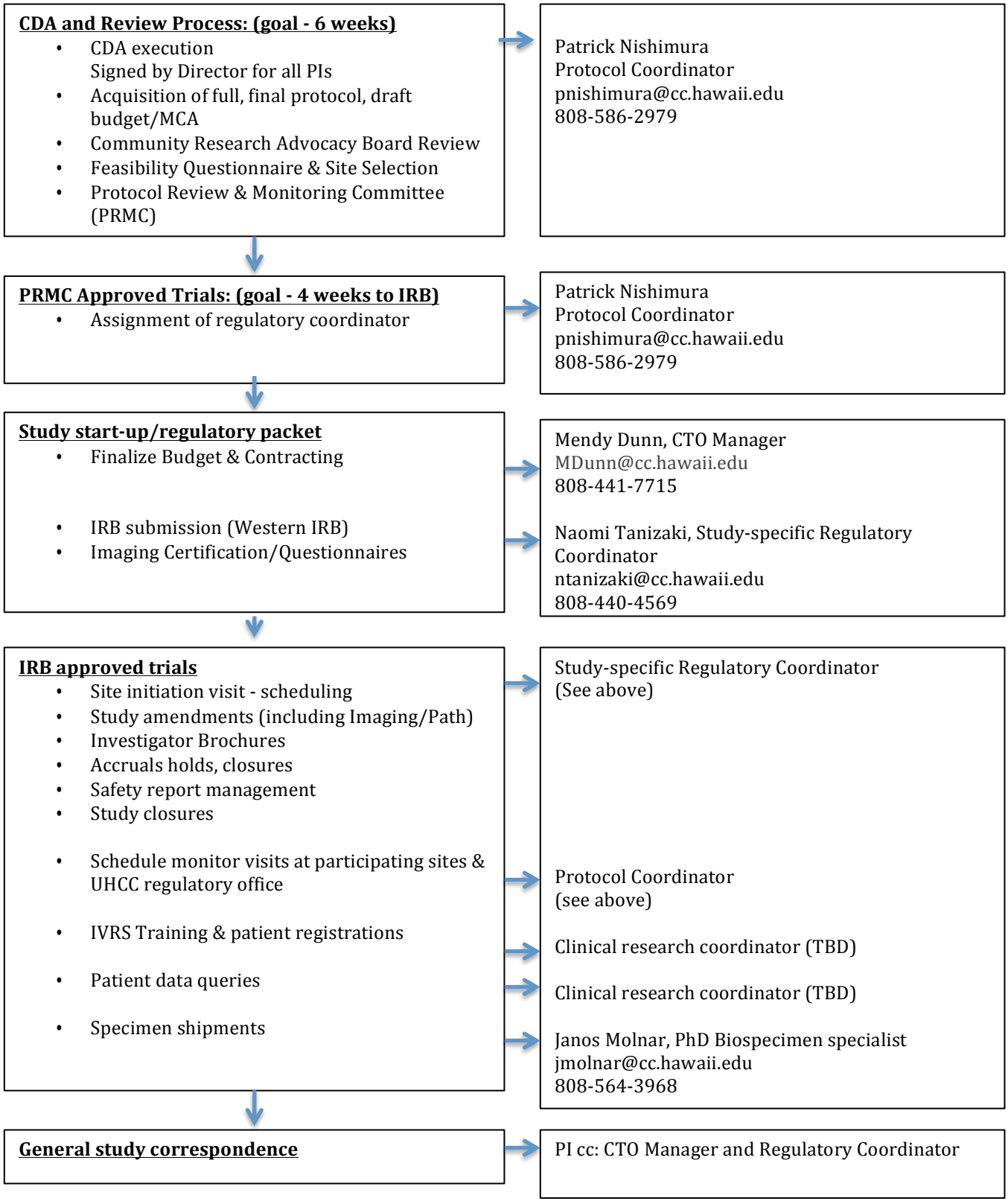
Attached you will find the Clinical Trial Process Flow Chart and our Sponsor Contact/Questionnaire. Please complete the Questionnaire and return it to me within two weeks.

Please do not hesitate to contact me if you have any questions or require additional information. I am available to assist you in anyway I can. I look forward to working with you on this trial.

Best regards,

Patrick Nishimura, Protocol Coordinator
University of Hawaii Cancer Center
Clinical Trials Office
701 Ilalo St.
Honolulu, HI 96813
Tel: 808-586-2979
Fax: 808-586-3016

Hawaii Cancer Consortium/University of Hawaii Cancer Center - Clinical Trial Process Flow Chart



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Hawaii Cancer Consortium/University of Hawaii Cancer Center

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These physicians come from both private practice and the following major institutions:
Queen's Medical Center, Hawaii Pacific Health, Kuakini Medical Center, OnCare Inc., Cancer Center of Hawaii and Tripler Medical Center.

Sponsor Contact/Questionnaire

Complete and return to Patrick Nishimura, Protocol Coordinator pnishimura@cc.hawaii.edu

Sponsor	
Study number	
IND# (if applicable)	
Full study title	
Sponsor contact name or CRO	
Contact phone # and email	
Study sites	How many total sites are planned for the trial? How many sites are currently approved?
Study Accrual	What is the total (study wide) accrual goal? What is the overall accrual to date?
If we are interested will there be a Pre-study Site Qualification Visit? Y____N____	
How many Hawaii Cancer Consortium clinical sites may participate? Queen's Medical Center Y____N____ Hawaii Pacific Health Y____N____ Kuakini Medical Center Y____N____ OnCare Inc. Y____N____ Cancer Center of Hawaii Y____N____ Tripler Medical Center Y____N____	
Imaging Certification	Does study require central Radiology? If yes please specify: 1) phantom scan 2) other: 3)
Study Support/Material Which study materials, tests and other items will be provided by the study sponsor? Please be specific or attach proposed budget.	Study drug(s) and/or agents (specify): Imaging: MRI, CT, PET-CT, Dexa, other (specify): Patient reimbursement funds Other (please specify):

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Hawaii Cancer Consortium/University of Hawaii Cancer Center Policies for Sponsor Acknowledgement

1. Nonrefundable study start-up fee, which include: Administrative, PI oversight and other start-up activities.

2. HCC/UHCC does not review, report or retain individual external safety reports sent by sponsor. External adverse events that are summarized by sponsor as a) unexpected, b) related or possibly related to participation in research, c) serious, placing subjects or others at a greater risk of physical or psychological harm that was previously known or recognized, will be accepted by Hawaii Cancer Consortium (HCC)/University of Hawaii Cancer Center (UHCC). HCC/UHCC will only retain and manage IND safety reports (SUSAR) that are unanticipated and therefore reportable to IRB. IND safety reports (SUSARs) that are not reportable to the IRB of record will not be retained by UHCC or its investigators. Individual safety reports (alerts, Medwatch or CIOMS) will not be accepted by HCC/UHCC.

3. Sponsor agrees to either pay UHCC $3,000 for Medicare Coverage Analysis or provide one for the study.

Sponsor/CRO, please sign and date.

Name: _____ Date: _____