



# **Navigating Studies under CIRB: Regulatory Perspective**

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Munirih R. Taafaki, B.A.  
Clinical Research Regulatory Associate  
University of Hawaii Cancer Center  
Honolulu, Hawaii

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# University of Hawaii Cancer Center



# Hawaii Cancer Consortium



UNIVERSITY OF HAWAI'I  
CANCER CENTER



**THE QUEEN'S  
MEDICAL CENTER**



**HAWAI'I PACIFIC HEALTH**

Kapi'olani • Pali Momi • Straub • Wilcox



# Outline

- Protocol Review Process
- Informed Consent Form Preparation
- Processing Approvals
- Documents to Keep Locally
- Navigating CIRB and CTSU Websites
- Triumphs and Challenges
- Discussion and Questions

# Internal Protocol Review Process for New Protocols

- Use CTSU Website for notice of new protocols
- Clinical Research Advocacy Board (CRAB)
  - Feasibility
  - Community Physician Interest
  - **Clinical Research Professional (CRP) review of protocol, consent form\* and funding sheet**
- Protocol Review and Monitoring Committee (PRMC)
  - Scientific Merit

# Informed Consent Form – Regulatory Preparation

- University of Hawaii Cancer Center Privacy Board\*
  - CIRB-Approved Boilerplate Language
    - HCC-Approved HIPAA
    - Genetic Information Nondiscrimination Act (GINA)
    - Cost
    - Reference and Formatting
  - Issues with Model Consent\*:
    - Grammatical
    - Formatting
    - Clinical content – CRP review\*
  - Partial Waiver of Authorization of Authorization for Recruitment

# Initial Protocol Approval

- (Post Study-Specific Worksheet Submission on CIRB Website, PI Confirmation of Intent to Comply, and Site-Specific Initial Approval Letter)
- Use **CTSU Website** to obtain additional documents
  - Sponsor Initial Application\*
    - Differs from Study-specific Worksheet and useful to HCC partners
  - CIRB Initial/Activation approval
- OnCore – Clinical Trials Management System
  - Notification to research personnel
- Regulatory – eFiles and Spreadsheets

# Initial Protocol Approval

The screenshot displays the CTSU web application interface. At the top, the header includes the CTSU logo, the text "Cancer Trials Support Unit A SERVICE OF THE NATIONAL CANCER INSTITUTE", and navigation links for Home, Contact, Feedback, Public Site, and Log Out. Below the header, a navigation bar contains tabs for Home, Protocols, Dashboard, Regulatory, OPEN, Rave, Clinical Data, Education & Resources, Collaboration, and RUMS. A search bar is located on the left side of the page.

The main content area shows the details for protocol A091202, titled "A Phase II Randomized, Double Blinded Study of the Peroxisome Proliferator-Activated Receptor Gamma Agonist, Efatutazone vs. Placebo in Patients with Previously Treated, Unresectable Myxoid Liposarcoma". The "CIRB Documents" tab is active, displaying a list of documents used for CIRB approval:

- 1 Protocol Version Date 07/31/15
- 2 Consent Form for Protocol Version Date 07/31/15

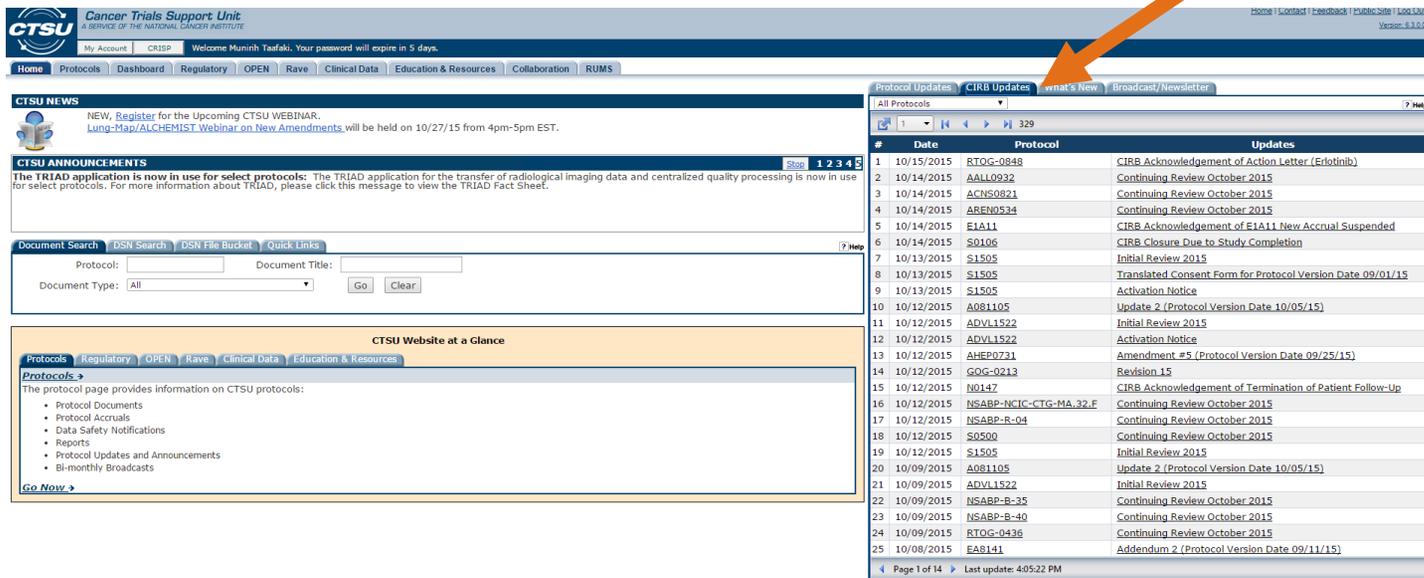
Below this, the "Initial Review Documents" section is expanded, showing the following documents:

- Activation Notice**
  - 1 01/16/15: CIRB Acknowledgement of A091202 Activation (Protocol Version Date 11/21/14)
- Support Documents**
  - 1 01/16/15: Alliance Protocol Notice
- Initial Review 2014**
  - Amendments**
    - 1 Change Memo for Protocol Version Date 11/21/14
    - 2 Change Memo for Consent Form (Protocol Version Date 11/21/14)
    - 3 Change Memo for Protocol Version Date 10/27/14
    - 4 Change Memo for Consent Form (Protocol Version Date 10/27/14)
    - 5 Consensus Review for Protocol Version Date 08/29/14
    - 6 Consensus Review for Consent Form (Protocol Version Date 08/29/14)
  - CIRB Applications**
    - 1 CIRB Application (Protocol Version Date 11/21/14)
    - 2 CIRB Application (Protocol Version Date 11/21/14): Tracked
    - 3 CIRB Application (Protocol Version Date 10/27/14)
    - 4 CIRB Application (Protocol Version Date 10/27/14): Tracked
    - 5 CIRB Application (Protocol Version Date 08/29/14)
  - Consent Forms**
    - 1 Consent Form for Protocol Version Date 11/21/14
  - Correspondence**

An orange arrow points from the "Documents used for CIRB approval" section down to the "Initial Review Documents" section, highlighting the activation notice document.

# CIRB Updates

- Use CTSU Website
  - CIRB Updates - 1<sup>st</sup> and 15<sup>th</sup> of the month
    - Select “More Commands” 
    - Options: Export PDF; Excel; CSV; Print; Refresh
    - Sort as applicable
    - Per CIRB contact, this process may be subject to change



The screenshot displays the CTSU website interface. At the top, there is a navigation bar with tabs for 'Home', 'Protocols', 'Dashboard', 'Regulatory', 'OPEN', 'Rave', 'Clinical Data', 'Education & Resources', 'Collaboration', and 'RUMS'. The 'CIRB Updates' tab is highlighted, and an orange arrow points to it. Below the navigation bar, there is a 'CTSUS NEWS' section with a 'NEW, Register for the Upcoming CTSU WEBINAR' announcement. A 'Document Search' section is also visible. The main content area features a table titled 'Protocol Updates' with columns for '#', 'Date', 'Protocol', and 'Updates'. The table lists 25 entries, each with a date, protocol ID, and a description of the update. An orange arrow points to the 'CIRB Updates' tab in the navigation bar.

#	Date	Protocol	Updates
1	10/15/2015	RTOG-0848	CIRB Acknowledgement of Action Letter (Edotolnb)
2	10/14/2015	AALL0932	Continuing Review October 2015
3	10/14/2015	ACNS0821	Continuing Review October 2015
4	10/14/2015	AREN0534	Continuing Review October 2015
5	10/14/2015	E1A11	CIRB Acknowledgement of E1A11 New Accrual Suspended
6	10/14/2015	S0106	CIRB Closure Due to Study Completion
7	10/13/2015	S1505	Initial Review 2015
8	10/13/2015	S1505	Translated Consent Form for Protocol Version Date 09/01/15
9	10/13/2015	S1505	Activation Notice
10	10/12/2015	A081105	Update 2 (Protocol Version Date 10/05/15)
11	10/12/2015	ADVL1522	Initial Review 2015
12	10/12/2015	ADVL1522	Activation Notice
13	10/12/2015	AHEP0731	Amendment #5 (Protocol Version Date 09/25/15)
14	10/12/2015	GOG-0213	Revision 15
15	10/12/2015	N0147	CIRB Acknowledgement of Termination of Patient Follow-Up
16	10/12/2015	NSABP-NCIC-CTG-MA.32.F	Continuing Review October 2015
17	10/12/2015	NSABP-R-04	Continuing Review October 2015
18	10/12/2015	S0500	Continuing Review October 2015
19	10/12/2015	S1505	Initial Review 2015
20	10/09/2015	A081105	Update 2 (Protocol Version Date 10/05/15)
21	10/09/2015	ADVL1522	Initial Review 2015
22	10/09/2015	NSABP-B-35	Continuing Review October 2015
23	10/09/2015	NSABP-B-10	Continuing Review October 2015
24	10/09/2015	RTOG-0436	Continuing Review October 2015
25	10/08/2015	EAB141	Addendum 2 (Protocol Version Date 09/11/15)

# Amendments Approvals

- Use **CTSU Website** to obtain amendment approval documents
  - Amendment **Activation** Letter – applies to CIRB-approved amendment
  - Activation date marks 90-day approval time-frame
  - **Only CIRB-approved changes to consent\***
- OnCore – Automated notification to research personnel

# Amendments Approvals

**CTSU** Cancer Trials Support Unit  
A SERVICE OF THE NATIONAL CANCER INSTITUTE

Home | Contact | Feedback | Public Site | Log Out  
Version: 6.3.0.0

My Account | CRISP | Welcome Munirh Taafak. Your password will expire in 5 days.

Home | Protocols | Dashboard | Regulatory | OPEN | Rave | Clinical Data | Education & Resources | Collaboration | RUMS

Search:  Go

No filter, showing all protocols

**My Protocols**

- A011104
- A011106
- A011202
- A011203
- A021202
- A031201
- A031203
- A041202
- A051201
- A071102
- A081105
- A091102
- A091105
- A091202
- A091305
- A091401
- A151216
- A221101
- A221102
- A221303
- A221304
- ANZGOG-0902-GOG-0274
- C80405
- CALGB-10603
- CALGB-30801
- CALGB-40502
- CALGB-40603
- CALGB-40903
- CALGB-49907
- CALGB-50904
- CALGB-70807
- CALGB-80101
- CALGB-80701
- CALGB-80702
- CALGB-80802

**Home** | Funding Information | LPO Documents | Drug Safety Notification | Study Agent | **CIRB Documents**

**NCI** National Clinical Trials Network  
A National Cancer Institute program  
**A091202** [Remove from My Protocols](#)

A Phase II Randomized, Double Blinded Study of the Peroxisome Proliferator-Activated Receptor Gamma Agonist, Efatutazone vs. Placebo in Patients with Previously Treated, Unresectable Myxoid Liposarcoma

**CIRB Details**

# Documents used for CIRB approval

- 1 Protocol Version Date 07/31/15
- 2 Consent Form for Protocol Version Date 07/31/15

Initial Reviews | **Amendment Reviews** | Continuing Reviews

**Amendment Review Documents**

**Amendment Update #1**

Amendments

- 1 Change Memo for Protocol (Protocol Version Date 07/31/15)
- 2 Change Memo for Consent Form (Protocol Version Date 07/31/15)

CIRB Applications

- 1 CIRB Application (Protocol Version Date 07/31/15)

Consent Forms

- 1 Consent Form for Protocol Version Date 07/31/15

Correspondence

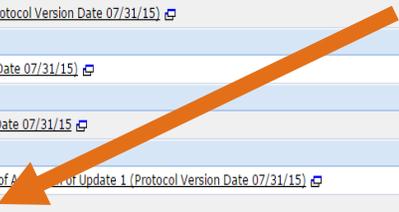
- 1 09/22/15: CIRB Acknowledgement of Amendment for Update 1 (Protocol Version Date 07/31/15)
- 2 09/01/15: Update 1 Activation
- 3 08/12/15: CIRB Approval Letter Update #1 (Protocol Version Date 07/31/15)

Primary Reviews

- 1 Expedited Review Worksheet (Protocol Version Date 07/31/15)

Protocol

- 1 Protocol Version Date 07/31/15



# Continuing Review Approvals

- Use **CTSU Website** to obtain continuing review approval documents
- Expiration is protocol-specific\*
- OnCore
  - Automated notification of study's upcoming annual renewal
  - Triggers PRMC Annual Monitoring
  - Regulatory lookout for continuing review approval
  - Approval letter uploaded to OnCore

# Continuing Review

**Cancer Trials Support Unit**  
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Home | Contact | Feedback | Public Site | Log Out  
Version: 5.3.0.0

My Account CRISP Welcome Munirh Taafaki. Your password will expire in 5 days.

Home Protocols Dashboard Regulatory OPEN Rave Clinical Data Education & Resources Collaboration RUMS

Search: [ ]  
Go

No filter, showing all protocols

**My Protocols**

- A011104
- A011106
- A011202
- A011203
- A021202
- A031201
- A031203
- A041202
- A051201
- A071102
- A081105
- A091102
- A091105
- A091202
- A091305
- A091401
- A151216
- A221101
- A221102
- A221303
- A221304
- ANZGOG-0902-GOG-0274
- C90405
- CALGB-10603
- CALGB-30801
- CALGB-40502
- CALGB-40603

Home Funding Information LPO Documents Drug Safety Notification Study Agent **CIRB Documents**

**NCI National Clinical Trials Network** **A091202** [Remove from My Protocols](#)

A Phase II Randomized, Double Blinded Study of the Peroxisome Proliferator-Activated Receptor Gamma Agonist, Efatutazone vs. Placebo in Patients with Previously Treated, Unresectable Myxoid Liposarcoma

**CIRB Details**

**Documents used for CIRB approval**

- 1 [Protocol Version Date 07/31/15](#)
- 2 [Consent Form for Protocol Version Date 07/31/15](#)

**Initial Reviews** **Amendment Reviews** **Continuing Reviews**

**Continuing Review Documents**

**Continuing Review July 2015**

**Consent Forms**

- 1 [Consent Form \(Protocol Version Date 11/21/14\)](#)

**Continuing Review Forms**

- 1 [CIRB Application \(Protocol Version Date 11/21/14\)](#)

**Correspondence**

- 1 [07/21/15: CIRB Continuing Review Approval Letter \(Protocol Version Date 11/21/14\)](#)
- 2 [06/05/15: Continuing Review Reminder Notice](#)

**Protocol**

- 1 [Protocol Version Date 11/21/14](#)

# What Approval Documents Do We Download and Save Locally?

- Site Initial Approval
- Protocol Initial Approval
- Continuing Review Approval
- Amendment Approval
- Subject Material
- Status changes

# Processing Annual PI Worksheet About Local Context

- CIRB will send notice
- CIRB uses Annual Institution approval date\*
  - Not based on PI Annual Worksheet initial approval date
  - Annual PI Renewals will be due, expire, and be approved on same date for all PIs

# Navigating Between CIRB and CTSU Websites

- CIRB Website
  - CIRB Information
  - List of studies with CIRB oversight
  - IRB Manager - all regulatory submissions
    - Annual Institution Worksheet
    - Annual PI Worksheet
    - Study-specific Worksheet
    - Study Closure or Transfer of Study Review Resp.
    - Unanticipated Problem and/or Noncompliance Form
- CTSU Website
  - CIRB Updates
  - CIRB Documents
    - Initial Application and Approvals\*
    - Amendment and Activation Approvals\*
    - Subject Material Approvals\*
    - Correspondence
    - Application/Submission Forms

# Some Triumphs and Challenges using CIRB

- PI Involvement in initial CIRB application process\*
- Quicker turn-around time for review and opening trials
- Less CRP input in consent document
- Can open studies that another IRB would not open\*
- Avoid other IRB processes when multiple sites have the same study open – IRB review delays due to other sites
- Only change to consent – Boilerplate
- Need for a Privacy Board
- Close communication with CIRB contacts\* - highly receptive

# Some Triumphs and Challenges using CIRB

- Re-Consent
  - Extremely rare that CIRB would mandate re-consent
  - If sponsor mandates re-consenting, CIRB will note this in the approval letter
    - Read approval letter!\*
- Re-consenting subjects is not required on studies transferred to CIRB

# Communication with our current Institutional Review Boards (IRB) regarding the use of CIRB\*

- Modification to contract between Hawaii Cancer Consortium and Western Institutional Review Board (WIRB)
- Modification to Memoranda of Understanding between University of Hawaii Cancer Center and Consortium Partners
- Created process for transferring open studies from WIRB and the University of Hawaii Human Studies Program (the University's IRB)

# Discussion

## Questions and Comments

- How many of you are already using CIRB?
- How many of you are using multiple IRBs?
- What has been your experience transferring open studies to CIRB?
- What has been your experience dealing with consents using CIRB?
- How do you get notified that a study is open or has an approved amendment?
- What are your experiences navigating the CIRB and CTSU sites?

# Mahalo

