Navigating Studies under CIRB: Regulatory Perspective

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University of Hawaii Cancer Center

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Hawaii Cancer Consortium

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

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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

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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

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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

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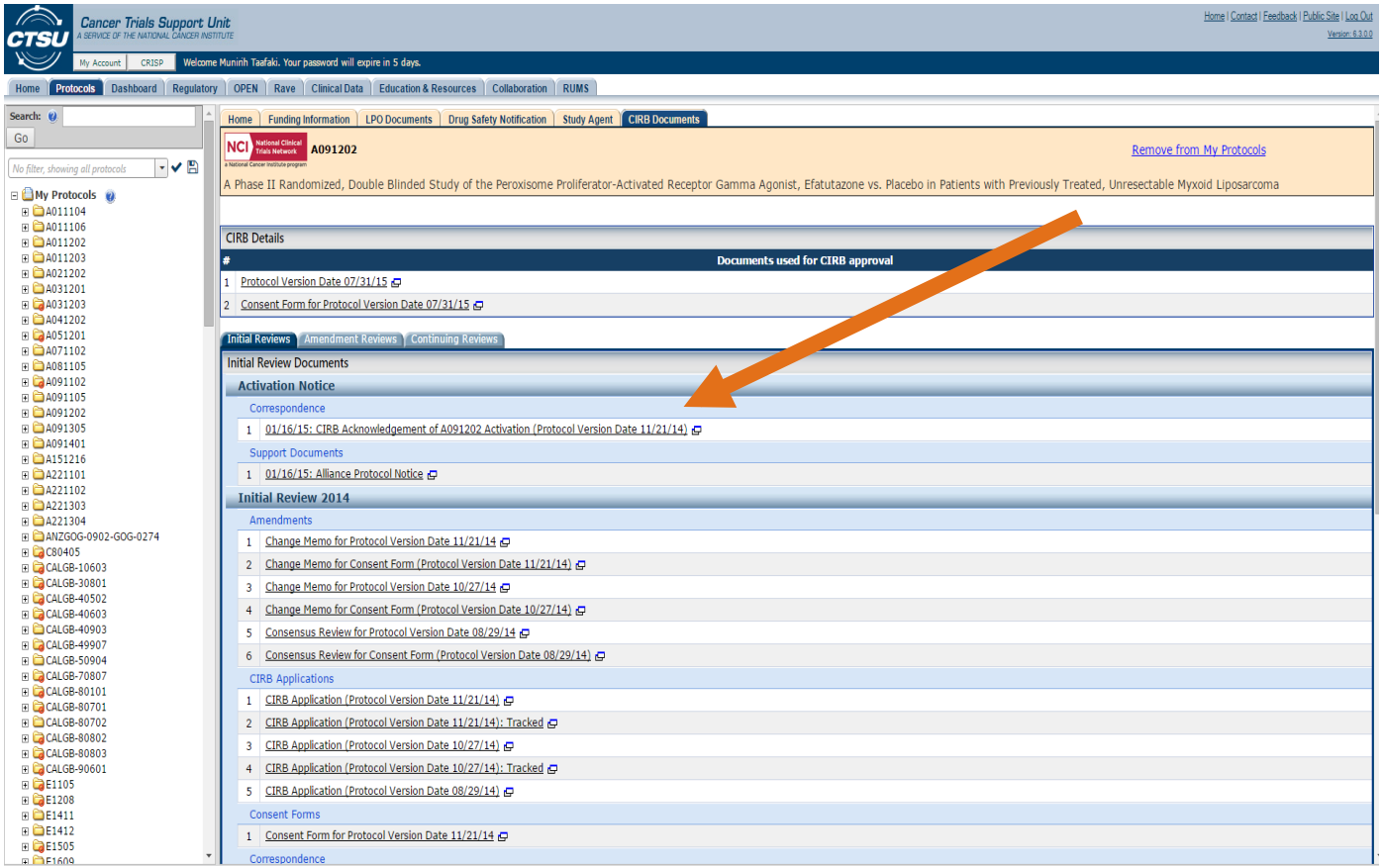
Initial Protocol Approval



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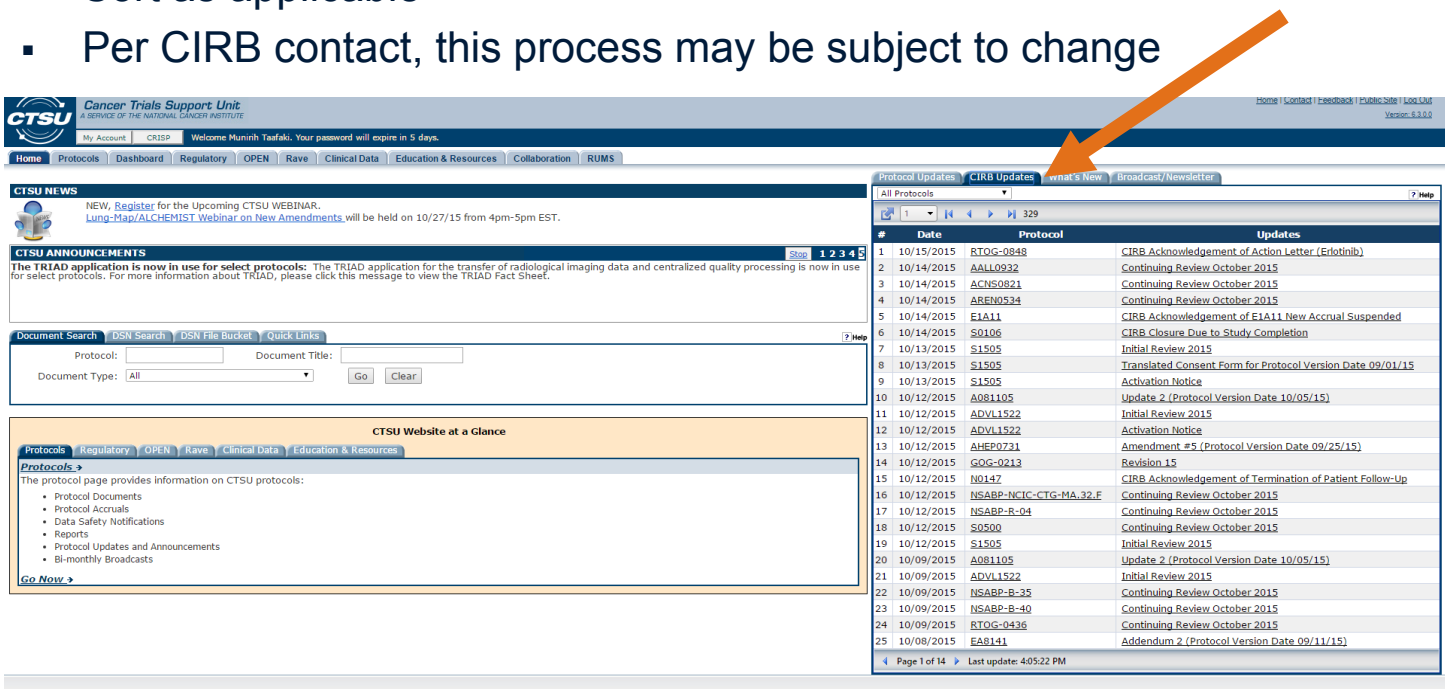
CIRB Updates

- Use CTSU Website
  - CIRB Updates - 1st and 15th 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



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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

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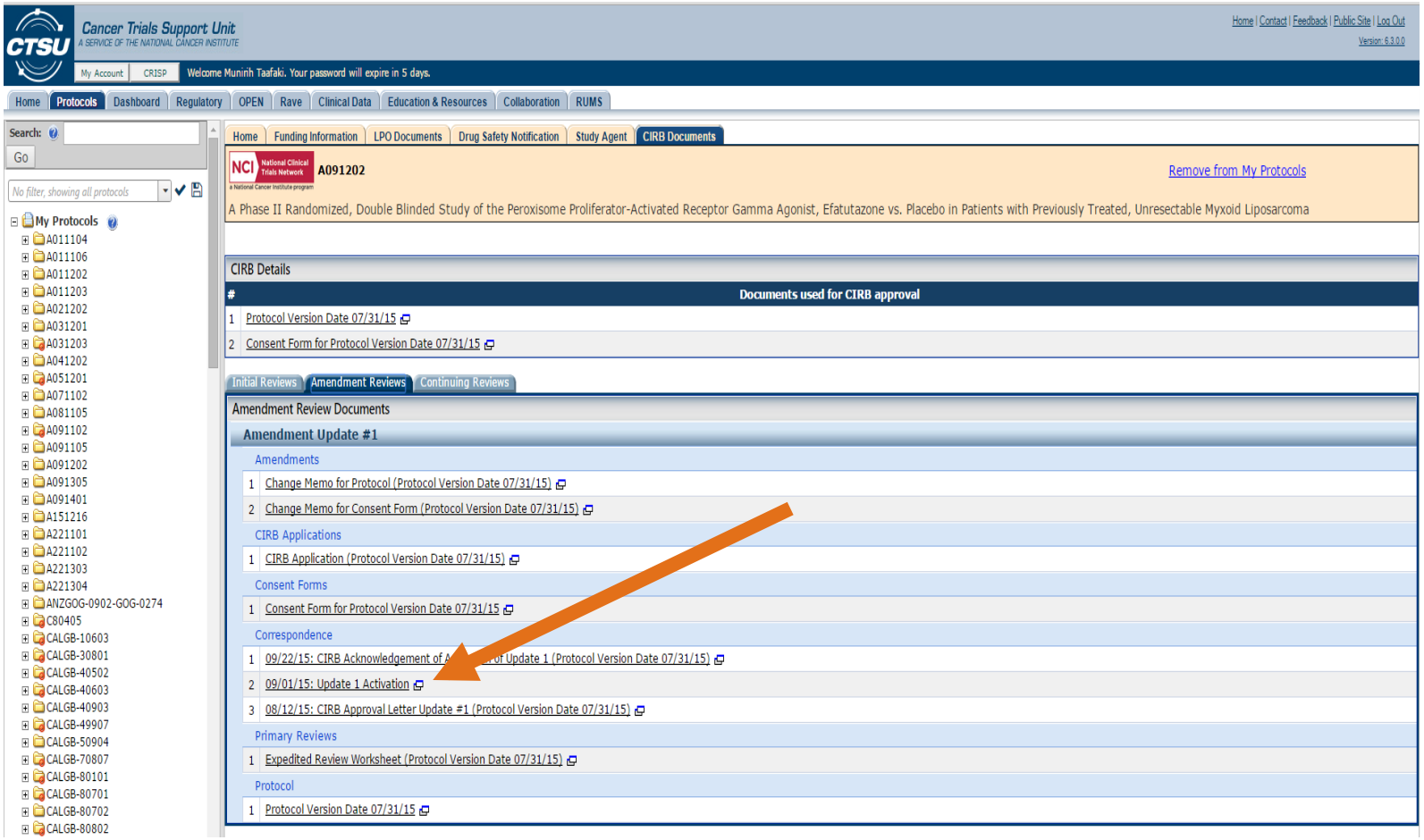
Amendments Approvals



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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

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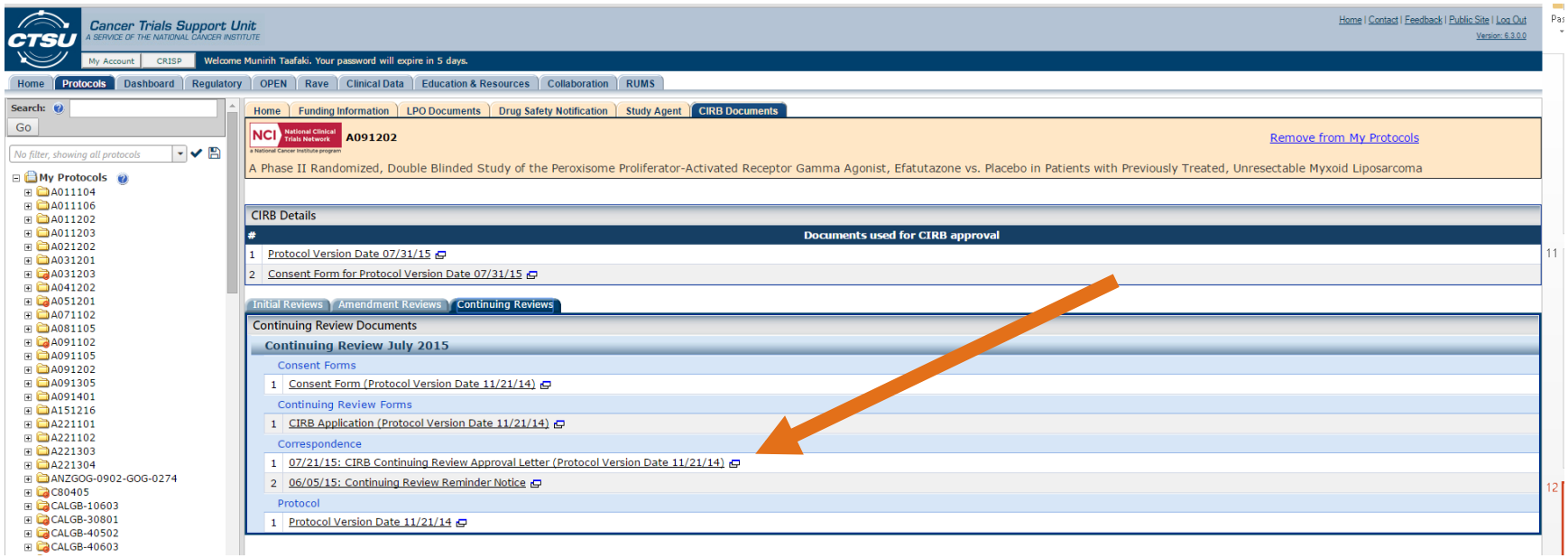
Continuing Review



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What Approval Documents Do We Download and Save Locally?

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

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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

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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

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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

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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

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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)

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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?

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Mahalo

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