

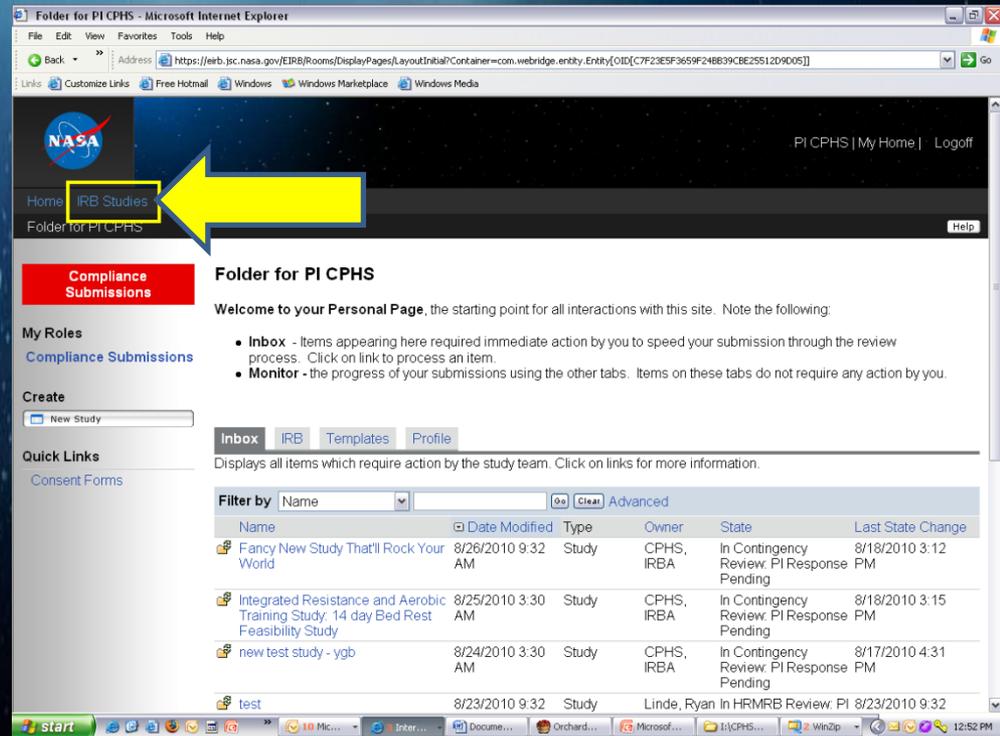


# **Amendments, Continuing Reviews, Reportable Events, and Closeout Reports**

# Submitting an Amendment, Continuing Review, Reportable Event, or Closeout Report

A study must have been previously approved in the e-IRB system to enter an Amendment, Continuing Review, Reportable Event, or Closeout Report.

Selecting IRB Studies.



The screenshot shows the 'Folder for PI CPHS' page in a Microsoft Internet Explorer browser. The page features a NASA logo and a navigation bar with links for 'Home', 'IRB Studies', and 'Folder for PI CPHS'. A yellow arrow points to the 'IRB Studies' link. Below the navigation bar, there is a 'Compliance Submissions' button and a 'My Roles' section with a 'Compliance Submissions' link. A 'Create' section includes a 'New Study' button. A 'Quick Links' section contains a 'Consent Forms' link. The main content area is titled 'Folder for PI CPHS' and includes a welcome message and a list of study items. The study items are displayed in a table with columns for Name, Date Modified, Type, Owner, State, and Last State Change.

Name	Date Modified	Type	Owner	State	Last State Change
Fancy New Study That'll Rock Your World	8/26/2010 9:32 AM	Study	CPHS, IRBA	In Contingency Review: PI Response Pending	8/18/2010 3:12 PM
Integrated Resistance and Aerobic Training Study: 14 day Bed Rest Feasibility Study	8/25/2010 3:30 AM	Study	CPHS, IRBA	In Contingency Review: PI Response Pending	8/18/2010 3:15 PM
new test study - ygb	8/24/2010 3:30 AM	Study	CPHS, IRBA	In Contingency Review: PI Response Pending	8/17/2010 4:31 PM
test	8/23/2010 9:32 AM	Study	Linde, Ryan	In HRMRB Review: PI	8/23/2010 9:32 AM

# Submitting an Amendment, Continuing Review, Reportable Event, or Closeout Report

Select "Approved CPHS" tab and then the Study you wish to edit.

IRB Studies - Windows Internet Explorer

https://eirb-int.jsc.nasa.gov/EIRB/Rooms/DisplayPages/LayoutInitialContainer=com.webbridge.entity.Entity\_CID(4FD...

UnityWeb@ 2.0

IRB Studies

PI CPHS | My Home | Logout

Home IRB Studies Issues

IRB Studies

Other Submission Types

- Amendments
- Continuing Reviews
- Reportable Events

IRB Studies

Welcome to Click Commerce IRB. View all studies by In Progress, Approved, and Archived groupings. Use the 'My Home' link to see the list of submissions related to you.

In Progress Approved CPHS

Filter by ID [ ] [Go] [Clear] Advanced

ID	Name	Date Modified	Owner	State	Review Type	ExpDate	PI
00014	Muscle milk	11/18/2010 3:53 PM	Anderson, Judy	Approved	Full IRB Review	8/3/2011	CPHS
000008	12	10/12/2010 2:02 PM	CPHS, IRBA	Approved	Full IRB Review	8/12/2011	CPHS
Pro0000001	test	8/23/2010 1:39 PM	Linde, Ryan Michael	Suspended	Expedited	7/19/2011	CPHS
Pro0000003	Test Full Committee Workflow	8/23/2010 11:03 AM	CPHS, IRBA	Suspended	Full IRB Review	7/18/2011	CPHS
Pro0000066	test2	8/6/2010 11:28 AM	Linde, Ryan Michael	Approved	Full IRB Review	8/5/2011	CPHS
Pro0000031	Karen's Thursday test	8/5/2010 4:54 PM	Linde, Ryan Michael	HRMRB Review Complete: Correspondence Review	Full IRB Review	8/3/2011	CPHS

# Submitting an Amendment, Continuing Review, Reportable Event, or Closeout Report

Select the type of Project you wish to add.

You will only be allowed to submit one project type.

If a project is pending approval and you wish to make a change, you must either edit the current project or withdraw it, make changes and then resubmit.

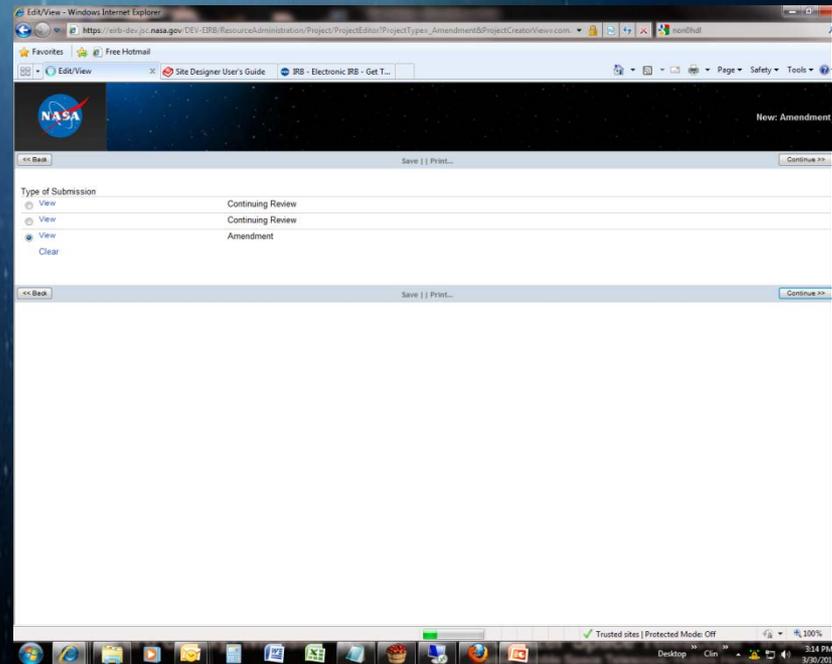
The screenshot shows a web browser window displaying the IRB Studies interface for a study titled "Muscle milk ( Pro0000014 )". The current state is "Approved". The interface includes a navigation menu, a "My Activities" section with options like "PI Suspend", "Copy Study", "Edit Email List", "Edit Guest List", and "Send Email to IRBA". A "Create" section is highlighted with a yellow box, containing options for "New Reportable Event", "New Amendment", "New Continuing Review", and "New Closing Report". A yellow arrow points to the "New Reportable Event" option. The "History" section shows a table of activities:

Activity	Author	Activity Date
Amendment Completed	PI CPHS	11/18/2010 3:53 PM CST
Amendment Completed	PI CPHS	8/5/2010 2:44 PM CDT
Amendment Opened	PI CPHS	8/5/2010 2:42 PM CDT
New Personnel Change workspace	PI CPHS	8/5/2010 2:39 PM CDT
New Project Snapshot	IRB Chair CPHS	8/3/2010 3:29 PM CDT

# Amendment

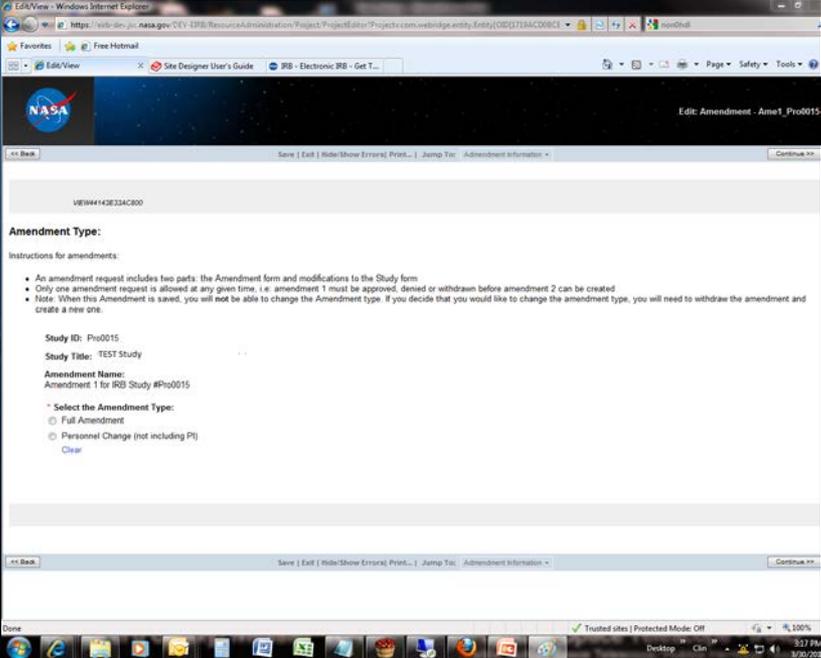
Chose Amendment on the approved study page.

Select Amendment again and then select continue. (This action may take a few minutes.)



# Select the type of Amendment

Select the type of Amendment and verify the study information.



EdAView - Windows Internet Explorer

Address bar: <https://web-ibn.gov.nasa.gov/DEV/CRM/ResourceAdministration/Project/ProjectEdit/Projects.com/webbridge/entity/Edit/080719ACD06C1>

Page Title: Edit Amendment - Amo1\_Pro0015

VIEW#143E23AC800

**Amendment Type:**

Instructions for amendments:

- An amendment request includes two parts: the Amendment form and modifications to the Study form
- Only one amendment request is allowed at any given time, i.e. amendment 1 must be approved, denied or withdrawn before amendment 2 can be created
- Note: When this Amendment is saved, you will not be able to change the Amendment type. If you decide that you would like to change the amendment type, you will need to withdraw the amendment and create a new one.

Study ID: Pro0015  
Study Title: TEST Study  
Amendment Name:  
Amendment 1 for IRB Study #Pro0015

Select the Amendment Type:

Full Amendment  
 Personnel Change (not including PI)

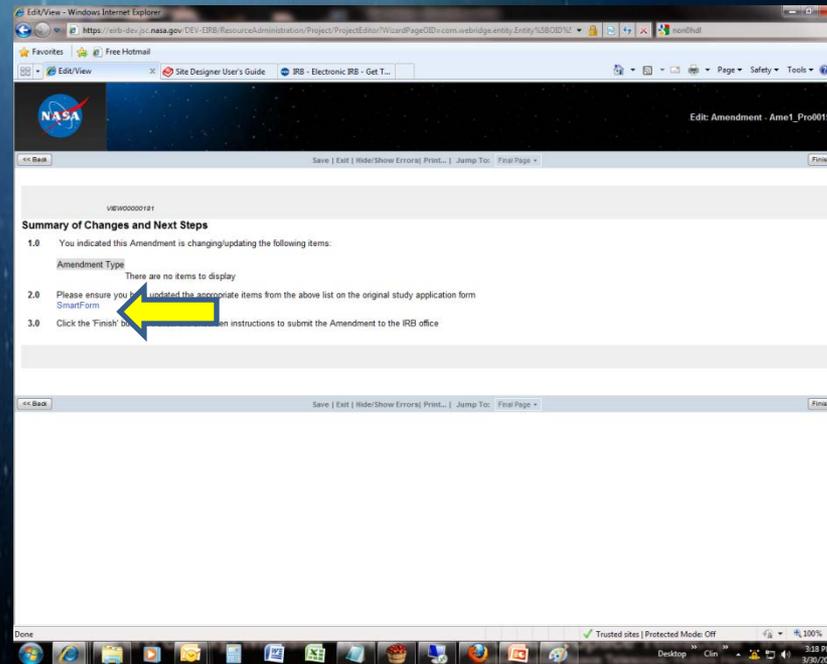
Clear

# Make the changes you wish to make to the study

Please select the smart form link and make any required changes.

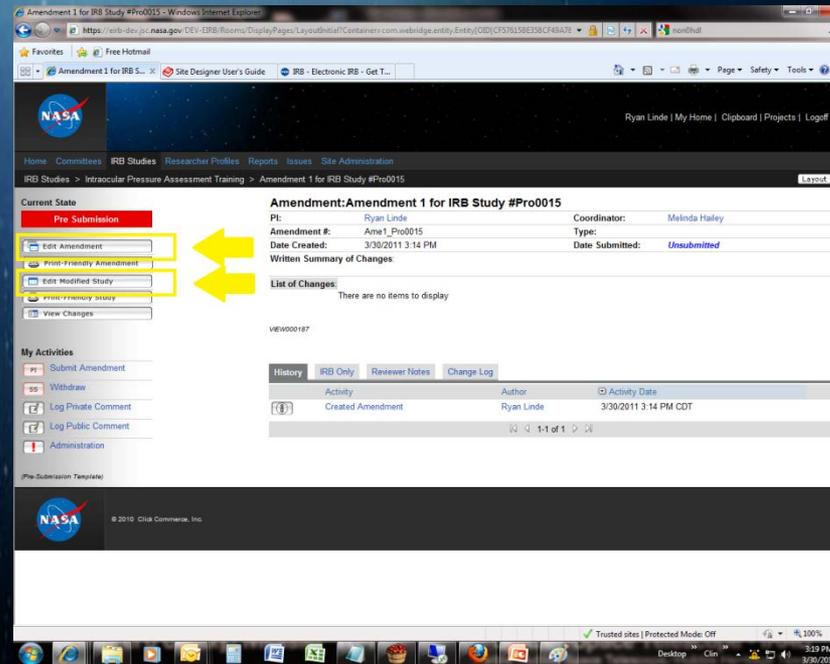
You do not have to finish at one time. You will be allowed to edit your study until it is submitted.

Make your current changes in **red font**; change any previously approved version red font to black.



# Make the changes you wish to make to the protocol or amendment forms

Selecting Edit Modified Study or Edit Amendment.



# Submit Amendment

Select Submit Amendment  
when changes are complete.

The screenshot displays a web browser window showing the NASA IRB Studies website. The page title is "Amendment 1 for IRB Study #Pro0015". The browser address bar shows the URL: <https://arb-dev.jpcc.nasa.gov/DEV/EPB/Rooms/Display/Pages/LayoutInitial/Containers.com.webbridge.entry.Entry/CEB/CFS76158E338CF49476>. The page features a NASA logo and a user profile for Ryan Linde. The main content area is titled "Amendment: Amendment 1 for IRB Study #Pro0015" and includes fields for PI (Ryan Linde), Amendment # (Ame1\_Pro0015), Date Created (3/30/2011 3:14 PM), and Date Submitted (Unsubmitted). A "List of Changes" section indicates "There are no items to display". A "My Activities" section on the left contains a list of actions, with "Submit Amendment" highlighted by a yellow box and a yellow arrow pointing to it. Other activities include "Withdraw", "Log Private Comment", "Log Public Comment", and "Administration". The page footer includes the NASA logo and copyright information for Citra Commercial, Inc. © 2010. The Windows taskbar at the bottom shows the system tray with the time 3:19 PM and date 3/30/2011.