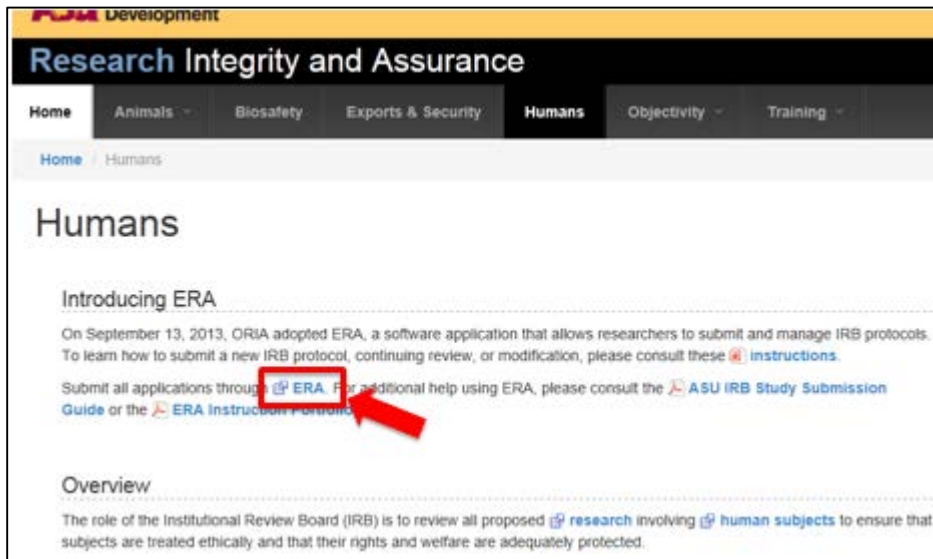


CLOSING A STUDY

Step 1: You can access the new system by going to the IRB website: <http://researchintegrity.asu.edu/humans>.



Step 2: Click IRB (#1) → Click IRB Records (#2) → Click Active (#3) ** → Click on the title under the heading “Name” (#4)

***This will show you All Active Studies you are designated as a team member on, not just those where you are PI (Expiration dates are shown, if no expiration date is listed, it is an exempt study)*

ASU Knowledge Enterprise Development
Dayna Molyneaux | My Inbox

Master Data COI **IRB**

IRB Records

IRB Records

In Review: Any “Pending” IRB Applications (In-Progress)
Active: All Active/Open IRB approved studies
Archived: All Closed or Lapsed IRB studies
New Information Reports: Studies with pending reports (such as adverse events, reports of non-compliance, etc.)
All Submissions: All studies, open or closed

In-Review **Active** Archived New Information Reports All Submissions

Filter by ID 1301008660 Go Clear Advanced

ID	Name	Date Modified	State	PI First Name	PI Last Name	Coordinator	Expiration Date
1301008660	TEXT2COPE: A Pilot Test of an Intervention for Parents with Overweight or Obese Preschoolers	10/18/2013 9:01 AM	Approved	Eric	Hekler	Metosky	1/24/

1 to 1 of 1 25

Step 3: To Close a study, or create a Continuing Review or Modification, click **Create Modification/CR**

The screenshot displays the IRB Records system interface for study 0912004639: Intestinal Micro Ecology. The top navigation bar includes 'Master Data', 'COI', and 'IRB'. The main header shows 'IRB Records > Intestinal Micro Ecology' and 'Approved'. The study details include: Entered IRB: 12/29/2009; Initial approval: 12/29/2009; Effective: 11/5/2013; Approval end: 11/5/2013; Modified: 10/6/2013 12:00 AM. The principal investigator is Rosa Krajmalnik-Brown, submission type is Initial Study, and the IRB office is ASU IRB with no letter. The IRB coordinator is Susan Metosky. A flowchart illustrates the review process: Pre-Submission leads to IRB Pre-Review, which can lead to IRB Review or Clarifications Requested. IRB Review can lead to Post Review or Clarifications Requested. Post Review can lead to Review Complete or Modifications Required. Clarifications Requested can lead to IRB Review or Post Review. A 'My Current Actions' menu on the left includes 'View Study', 'Printer Version', 'View Differences', 'Create Modification / CR' (highlighted with a red arrow), and 'Report New Information'. Below the menu is a 'History' section with a filter by 'Activity' and a table of activities, including 'Continuing Review Deadline Reminder' by 'Administrator, System' on '10/6/2013 12:00 AM GMT-07:00'.

Step 4: Select **Continuing Review**. Click **Continue** to save and advance to next page.

The screenshot shows the 'Modification / Continuing Review' form. The top navigation bar indicates 'You Are Here: Revamping Literacy Practices > Continuing Review for Study ST...'. The form has a '<< Back' button on the left and a 'Continue >>' button on the right. The main heading is 'Modification / Continuing Review'. The question is '* What is the purpose of this submission?'. There are three radio button options: 'Continuing Review' (selected), 'Modification', and 'Modification and Continuing Review'. To the right of the form, red text instructions state: 'Answer each question' and 'Click continue at the end of each page to proceed to the next section'. The bottom of the form has another '<< Back' button and 'Continue >>' button.

Step 5: In question 2, check each statement that is true. If the first four statements are marked, the system will prompt closure of the study.

Upload a progress report in the supporting document section of the “Continuing Review Page”. Click “Continue” to save and advance to the next page.

Continuing Review / Study Closure Information

1. * Specify enrollment totals:

Subjects Enrolled	Total
At this investigator's sites:	<input type="text"/>
Study-wide:	<input type="text"/>

2. Research milestones: (select all that apply)

- Study is permanently closed to enrollment
- All subjects have completed all study-related interventions
- Collection of private identifiable information is complete
- Analysis of private identifiable information is complete
- Remaining study activities are limited to data analysis
- Study remains active only for long-term follow-up of subjects

Important! If the first four research milestones above are complete, the study will be closed to discontinue IRB overs

3. * Do any investigators or research staff have a financial interest related to the research that was not described in a
 Yes No Clear

4. Check the items that are true since the last IRB continuing review for all sites involved in the study:

- NO subjects experienced harm (expected or unexpected)
- NO subjects experienced benefit
- NO subjects withdrew from the study
- NO unanticipated problems involving risks to subjects or others
- NO complaints about the study
- NO publications in the literature relevant to risks or potential benefits
- NO interim findings
- NO multi-center trial reports
- NO data safety monitoring reports
- NO regulatory actions that could affect safety and risk assessments
- NO other relevant information regarding this study, especially information about risks
- In the opinion of the PI, the risks and potential benefits are unchanged
- All modifications to the protocol have been submitted to the IRB
- All problems that require prompt reporting to the IRB have been submitted

5. Attach supporting documents: (include an explanation of each item left unchecked above)

Name

There are no items to display

Step 5: Click **Submit** to send to IRB for review

***Note: Only the PI can SUBMIT an application. If you are not the PI, you will not see the Submit button. Once the application is created, the PI should see it in their inbox (following directions 1-2 in Step 2 above). Click on the blue link for the modification then submit as shown below.*

IRB Records > Marital Biography and Chronic Disease in Older Adults > Continuing Review for 5

Pre-Submission

Entered IRB:
Approval:
Effective:
Modified: 3/17/2014 12:00 AM

CR0000277: Continuing Review fo

Investigator: Jennie Kronenfeld
Submission type: Continuing Review
Primary contact:
IRB coordinator:

Pre-Submission → IRB Pre-Review → IRB Review
Clarifications Requested ← IRB Pre-Review
Clarifications Requested ← IRB Review

My Current Actions

Edit Modification / CR
Printer Version

←

History Project Contacts Documents IRB Ass

Filter by Activity

Activity
Continuing Review Deadline Reminder

Step 6: You will know the study application has successfully been submitted when the dark blue circle moves from the “Pre-Submission” to the “IRB Pre-Review” bubble. You can check the status at any time to see the progress from the flow chart and view any notes made by IRB reviewers.

STUDY00000089: A Report on Obesity in the Clientele of Terros, Inc. IRB office: ASU IRB

Principal investigator: Cindy Sangalang
Submission type: Initial Study
Primary contact: Cindy Sangalang
IRB coordinator:

```
graph LR; A[Pre-Submission] --> B[IRB Pre-Review]; B --> C[IRB Review]; C --> D[Post Review]; D --> E[Review Complete]; B --> B1[Clarifications Requested]; B1 --> B; C --> C1[Clarifications Requested]; C1 --> C; D --> D1[Modifications Required]; D1 --> D;
```

History | Project Contacts | Documents | IRB Assignment Details | Reviews | Snapshots

Filter by: Activity Go Clear Advanced

Activity	Author	Activity Date
Submitted	Sangalang, Cindy C	10/7/2013 2:04 PM GMT-07:00