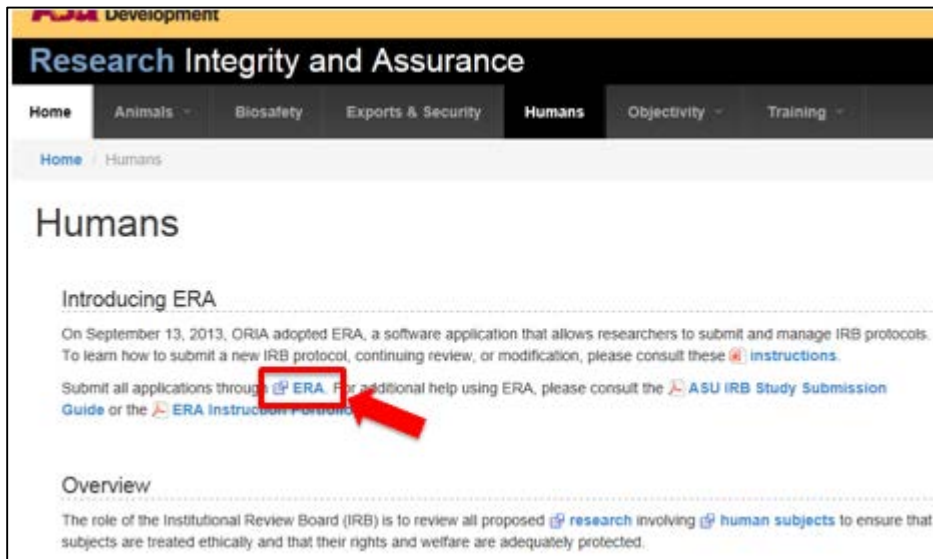


CREATING A MODIFICATION APPLICATION

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 1

IRB Records 2

IRB Records

IRB Records

3

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/

4

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

The screenshot displays the IRB Records interface for study 0912004639: Intestinal Micro Ecology. The status is 'Approved'. Key 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 coordinator is Susan Metosky. The IRB office is ASU IRB with no letter. A workflow diagram shows stages: Pre-Submission, IRB Pre-Review, IRB Review, Post Review, and Review Complete, with 'Clarifications Requested' and 'Modifications Required' loops. The 'My Current Actions' sidebar includes buttons for View Study, Printer Version, View Differences, **Create Modification / CR** (highlighted with a red arrow), and Report New Information. Below the sidebar is a 'History' section with a filter by 'Activity' and a table listing activities like 'Continuing Review Deadline Reminder'.

Step 4: Select the type of application you wish to submit, making your selection based on the changes you need to make to the application.

Click **Continue** to save and proceed through each page of the application.

The image shows two sequential screenshots of the 'Modification / Continuing Review' application form. Both screenshots start with 'You Are Here: > >' and a '<< Back' button. The title is 'Modification / Continuing Review'. The first question is 'What is the purpose of this submission?' with radio button options: Continuing Review, Modification, and Modification and Continuing Review (selected). Below this is a 'Clear' link. The second section is 'Modification Scope:' with checkboxes for 'Study team member information' (checked) and 'Other parts of the study' (unchecked). The final section is 'Active modification for this study'. The second screenshot shows the same form but with 'Other parts of the study' checked and 'Study team member information' unchecked.

Step 5: Upload documents using the **Update** function, for revisions to existing documents, or the **Add** Function to upload copies of new documents in the sections designated for the document type.

Click **Continue** to save the changes and advance to the next page, and **Finish** on the final page.

The image shows two overlapping screenshots from a web application. The left screenshot is titled 'Basic Information' and contains several form fields: 'Title of study' (Examples of ERA - IRB New Study Creation and Submission), 'Short title' (New IRB Application), 'Brief description' (Demonstrating how to create and submit new IRB applications using the online ERA submission system.), 'Principal investigator' (Dayna Molyneaux), and several yes/no questions. A red arrow labeled '1' points to the 'Update' button for a document. The right screenshot is titled 'Edit Attachment' and contains fields for 'File to attach' (HRP-502a - CONSENT SOCIAL BEHAVIORAL (tracked changes).docx(0.01)), 'Name', and 'Version number'. A red arrow labeled '2' points to the 'Browse' button, and another red arrow labeled '3' points to the 'OK' button.

Step 6: 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.*

The image shows a screenshot of the ASU Knowledge Enterprise Development interface. The main content area displays details for 'STUDY00000128: PI training', including the Principal Investigator (Anna Moser), Submission type (Initial Study), Primary contact (Anna Moser), and IRB coordinator. A flowchart shows the submission process: Pre-Submission, IRB Pre-Review (Certifications Requested), IRB Review (Certifications Requested), Post Review (Modifications Requested), and Review Complete. On the left, a 'My Current Actions' list includes 'Submit', 'Discard', 'Assign Primary Contact', 'Manage Guest List', 'Copy Submission', 'Add Comment', and 'Manage Ancillary Reviews'. A red arrow points to the 'Submit' button. Below the screenshot, there are two bullet points: 'If you wish to review, click "Printer Version" or "Edit Study" click continue when done.' and 'To submit, click "Submit" from the My Current Actions list on the left.'

Step 7: 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