Overview

- NEW IRBNet Wizard
- Smart form helps create a complete submission
- Streamlined submission process
- Replaces ALL of the following:
  - Form HRP-212 Continuing Review Progress Report
  - Form HRP-213 Modification
  - Form HRP-214 Reportable New Information
How is it used?

**Similar to the Initial Review Application**

**Online Form**
- Complete the document wizard in IRBNet.
- Start a wizard for the **first use only**.
- Use the **pencil icon** to update the form.
- Version history stored in IRBNet for each submission.
- Requires IRBNet **electronic signature**.

**Dynamic Form**
- Changes based on information provided
- Sections not relevant to the submission marked “NA”
- Prompts submitter for required information/documentation
How is it used?

Submit for any of the following

- Continuing review progress report / Closure
- Report of new information
- Modification
- Any combination of the above submission types

Continuing Review & Modification
Modification & Report of New Information
Continuing Review & Report of New Information
Continuing Review, Modification, & Report of New Information
What’s New?

Minor Changes to Questions You’ve Seen Before

- Site language is generic – can be used for non-UC Davis sites.
- Vulnerable population checkboxes; no longer report number enrolled.
- Modifications: "date current/former subjects will be notified” is no longer required.
- Smart form triggers required modifications in some situations.
### What’s New?

Removed one question in the Continuing Review enrollment numbers section

<table>
<thead>
<tr>
<th></th>
<th>HRP-212</th>
<th>Post Approval Submission Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number subjects IRB approved</td>
<td>Number subjects IRB approved</td>
<td>Number subjects IRB approved</td>
</tr>
<tr>
<td>Total subjects consented</td>
<td><em>Question Removed</em></td>
<td><em>Question Removed</em></td>
</tr>
<tr>
<td>Total subjects consented, met eligibility criteria and enrolled</td>
<td>Total subjects consented, met eligibility criteria and enrolled</td>
<td>Total subjects consented, met eligibility criteria and enrolled</td>
</tr>
<tr>
<td>Screen failures</td>
<td>Screen failures</td>
<td>Screen failures</td>
</tr>
<tr>
<td>Discontinued</td>
<td>Discontinued</td>
<td>Discontinued</td>
</tr>
</tbody>
</table>
## New Questions

<table>
<thead>
<tr>
<th>Question</th>
<th>Purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sponsor Verification</td>
<td>Confirm sponsor information in IRBNet Project Overview is accurate.</td>
</tr>
<tr>
<td>Reportable New Information Details</td>
<td>Follow-up questions specific to the type of information being reported.</td>
</tr>
</tbody>
</table>
Completing the Post Approval Submission Form

Two types of questions

The first time the form is completed all fields will be blank. After the first time, some data will carryover and other data will be unique.

Carryover Data
• Answers carryover from previous versions of the form.
• Submitter is responsible to review the information and confirm it is accurate.

Unique Data
• Answers do not carryover from previous versions of the form.
• Submitter must enter this information with each submission.
Creating a Post Approval Submission Form
How to submit the **first** Post Approval Submission Form for any project

1. Go to IRBNet.org, login, and click the project title to open the project.
2. Click “Create a New Package.” Click “Designer” from the left hand menu.
3. Click “Start a New Wizard.”
4. Select “UC Davis – Post Approval Submission Form” from the dropdown list.
5. Click “Next” to move through the form. You may also save and exit at anytime.
6. Upload/edit other study documents as needed, collect signatures and submit the package.
UC Davis – Post Approval Submission Form
How to submit the PAS once it already exists in a project

1. Go to IRBNet.org, login, and click the project title to open the project.
2. Click “Create a New Package.” Click “Designer” from the left-hand menu.
3. Locate the “UC Davis – Post Approval Submission Form” in the “Documents from Previous Packages” section.
4. Click the pencil icon at the far right to open the document for editing.
5. Jump to the desired location or click “Next” to move through the form. You may also save and exit at anytime.
6. Upload/edit other study documents as needed, collect signatures and submit the package.
How to submit PAS once it already exists in a project

Documents in this Package:

There are no documents in this package.

There are no Training & Credentials records linked to this package.

Start a Wizard  OR  Attach New Document

Documents from Previous Packages that you can Revise:

<table>
<thead>
<tr>
<th>Pkg #</th>
<th>Document Type</th>
<th>Description</th>
<th>Last Modified</th>
<th>Submission Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td>Consent Form</td>
<td>HRP-502-TEMPLATE-CONSENT-DOCUMENT-clean</td>
<td>11/30/2017 04:03 PM</td>
<td>11/30/2017</td>
</tr>
<tr>
<td>4</td>
<td>Consent Form</td>
<td>HRP-502-TEMPLATE-CONSENT-DOCUMENT-marked</td>
<td>11/30/2017 04:03 PM</td>
<td>11/30/2017</td>
</tr>
<tr>
<td>4</td>
<td>UC Davis - Post Approval Submission Form</td>
<td>Cont Review, Mod</td>
<td>11/30/2017 04:03 PM</td>
<td>11/30/2017</td>
</tr>
<tr>
<td>2</td>
<td>Protocol</td>
<td>HRP-503-TEMPLATE-PROTOCOL-clean</td>
<td>11/30/2017 03:39 PM</td>
<td>11/30/2017</td>
</tr>
<tr>
<td>2</td>
<td>Protocol</td>
<td>HRP-503-TEMPLATE-PROTOCOL-marked</td>
<td>11/30/2017 03:39 PM</td>
<td>11/30/2017</td>
</tr>
<tr>
<td>1</td>
<td>UC Davis - Initial Review Application</td>
<td>UC Davis - Initial Review Application</td>
<td>11/30/2017 03:24 PM</td>
<td>11/30/2017</td>
</tr>
</tbody>
</table>
Completing the Post Approval Submission Form
UC Davis – Post Approval Submission Form

Start the form by clicking “Next”.

Welcome to the UC Davis - Post Approval Submission Form. Please answer all questions and check all appropriate boxes for this submission. Your progress will be saved each time you click “Next” or “Save and Exit.”

This form is used to submit modifications to approved research, reports of new information, and continuing review reports. You can use this form to submit one item or a combination of items simultaneously. At the end of the form a list of required documents will be presented to assist you with compiling a complete submission.

Jump To: Instructions

Save and Exit  Preview  Next
Current Study Status

• Current study status is recorded with each submission.
• If the form was completed in the past, study status will default to the last option selected.
Continuing Review Submission

- Data pulls from IRBNet Project Overview page
- Data does NOT pull data from the Initial Review Application

If the sponsor information is incorrect select “No”
Continuing Review

Sponsor Update Reminder

- Modification required with this submission
- Sponsor update will appear on the Form Complete Page
- Edit the Project Overview page in IRBNet to correct the sponsor information
- Verify that the correct sponsor is listed on all study documents

Sponsor Update Reminder

You have indicated that the sponsor information is inaccurate or incomplete. Complete the modification section of this form and update the sponsor information. Before you submit this package update the Sponsor field in the Project Overview with the correct sponsor information. Include with this submission updated versions of any study documents which state the sponsor information (e.g. Initial Review Application, consent form, etc.).
Continuing Review Submission

Report cumulative enrollment numbers.

If you have enrolled more subjects than the IRB approved, select “yes.”
Continuing Review Submission

- IRB approved local enrollment numbers found in initial approval letter

OR

- IRB approved study-wide and local enrollment numbers found in the “Participant Information” section of the Initial Review Application.

Dear Dr. Messi:

On November 28, 2017 the UC Davis Clinical Committee A reviewed the following protocol:

<table>
<thead>
<tr>
<th>Type of Review</th>
<th>Continuing Review/Progress Report</th>
</tr>
</thead>
<tbody>
<tr>
<td>Title</td>
<td>Online Post Approval Form - TEST STUDY</td>
</tr>
<tr>
<td>Investigator</td>
<td>Messi, Lionel, PhD</td>
</tr>
<tr>
<td>IRB ID</td>
<td>57292-6</td>
</tr>
<tr>
<td>Funding</td>
<td>Departmental</td>
</tr>
<tr>
<td>Grant ID and Title</td>
<td>None</td>
</tr>
</tbody>
</table>
| IND, IDE or HDE | • INQ Numbers
                  • 543219 |
| Approval Period and Continuing Review Requirement | The IRB approved the protocol from November 28, 2017 to April 16, 2018 inclusive. Before March 2, 2018 or within 25 business days of study closure, whichever is earlier; you are to submit a completed “FORM: Continuing Review (HRP-212)” and required attachments to request continuing approval or closure. If continuing review approval is not granted before the expiration date of April 16, 2018 approval of this protocol expires on that date. |
| Risk Determination | More than Minimal Risk |
| Comments/Conditions | In conducting this protocol you are required to follow the requirements listed in the INVESTIGATOR MANUAL (HRP-103). If applicable add to this section. |
| Subjects | The IRB approved enrollment of up to 50 subjects |
| Consent | A written consent form signed by study participants. |
Continuing Review Submission

Vulnerable Populations

No longer report numbers
Continuing Review Submission

Project Events

“Yes” response will trigger additional submission requirements on the Form Complete page
Continuing Review Submission

Related Financial Interest

“Yes” response will trigger required modification with this submission describing the financial interest.

Related Financial Interest (New RFI/Change to existing RFI) *

Do you or any personnel involved in the design, conduct, or reporting of the protocol have a Related Financial Interest that has not been reported to the IRB or a change to a previously reported Related Financial Interest?

- Yes
- No

Save and Exit  Preview  ( * required )  Previous  Next
Personnel Updates

“Yes” response will trigger additional submission requirements on the Form

Complete page

Personnel Updates *

All personnel assigned to this study must be qualified to perform the protocol procedures assigned to them, must report any and all conflicts of interest, must complete required human research protections training and must receive appropriate training on the protocol prior to engaging in research activities.

For UC Davis sites, individuals included on the research personnel list must be UC Davis faculty, employees, students, volunteers or outside collaborators working under the oversight of the UC Davis Principal Investigator and covered by an Individual Investigator Agreement. Contact the IRB if you have questions regarding research personnel.

Have there been any changes to the research personnel list that have not been reported to the IRB?

- Yes
- No

Save and Exit  Preview  ( * required )  Previous  Next
Continuing Review Submission

Submission Date

• Continuing Review is due at least 45 days before IRB approval expires.
• IRB expiration date is found on the project overview page.

Project Status as of: 12/06/2017

<table>
<thead>
<tr>
<th>Reviewing Board</th>
<th>Initial Approval Date</th>
<th>Project Status</th>
<th>Expiration Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>UC Davis Clinical Committee A, Davis, CA</td>
<td>11/30/2017</td>
<td>Active - Open to Enrollment</td>
<td>11/29/2019</td>
</tr>
<tr>
<td>UC Davis Clinical Committee B, Davis, CA</td>
<td>11/30/2017</td>
<td>Active - Open to Enrollment</td>
<td>11/29/2019</td>
</tr>
<tr>
<td>UC Davis IRB Administration, Davis, CA</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

If submitting late select “No”
Reportable New Information Submission

- Multiple options can be selected.
  Each selection will trigger follow-up questions.
  Click the hyperlink for information about reporting categories.
Modification Submission

Modification List

- There are three questions that can trigger a required modification.
- If a modification is required, you will be taken directly to Modification Detail page.

Modification List

Based on the answers provided modifications to this research are required. Below is a list required modifications.

- Change in sponsor.
- Update to enrollment numbers.
- Related Financial Interest Update.

Save and Exit  Preview  Previous  Next
Modification Submission

**Modifications**

- If there are no required modifications, you will be asked if you are submitting a modification.
- “Yes” response will go to Modification Details page.

**Modifications** *

Are you submitting modifications to the project at this time?

- Yes
- No

Save and Exit    Preview    ( * required )    Previous    Next
Modification Submission

Modification Details

Modification Description *
Describe/summarize the modification. Just listing the documents submitted is not acceptable as a summary.

Note: If modifying/amending the IRBNet Initial Review Application include the following information: Name of the page where changes are being made, information being removed, and/or information being added.

Revision Rationale *
Provide a rationale for the requested revision:

- Why is this change necessary to conduct the research?
- Remember, the research was approved with the expectation that it can be completed as described. Any changes must be justified.
Modification and Reportable New Information Submissions

- Report the number of subjects currently actively participating
- Describe if subjects are receiving any form of treatment.
- The IRB must assess any changes to risk and the need to re-consent subjects.
All Submission Types

**Form Complete**

- List of supporting documents required with this submission.
- Based on the answers provided.
- Must load from the previous page to be accurate (do not use Jump to access)
Electronic Signature

- PI or CoPI must use IRBNet “Sign this Package” to electronically sign submission.
- Designee Signature Mode is not accepted.
Updating the Document Description

**Researcher must update the description**

- Locate the document on the “Designer” page
- Double click in the description field to edit the Document Description
- Describe the submission type

  - Continuing Review (Cont. Review)
  - Report of New Information (RNI)
  - Modification (Mod)

<table>
<thead>
<tr>
<th>Document Type</th>
<th>Description</th>
<th>Last Modified</th>
</tr>
</thead>
<tbody>
<tr>
<td>UC Davis - Post Approval Submission Form</td>
<td>Cont Review, Mod</td>
<td>05/04/2018 01:51 PM</td>
</tr>
</tbody>
</table>
Submit the Package

When you are ready to submit the application to IRB Administration you must click “submit this package” button from the left-hand menu. After you click the button, complete the subsequent steps to submit the package.
How is it used?

What will Reviewers see?

- IRBNet Document Type “UC Davis – Post Approval Submission Form”
- IRBNet Document Description updated with submission type (e.g. Cont Review, Mod, RNI, or any combination of these)

Click the stack of papers to see the document history.
How is it used

What will reviewers see?

- PDF output generated by IRBNet
- Questions truncated and separated into sections
- “NA” marked when a section is not relevant
- Continuing Review (sections 1-9)
- Reportable New Information (sections 1, 10-15, 17)
- Modification (sections 1, 16, 17)
IRB Administration is collecting user feedback.

Complete the PAS Form Researcher Feedback

Thank you
Implementation

Pilot phase – Please provide feedback

Send feedback to IRBNet

Campus-wide training