

IRB Administration

Post Approval Submission Form



UC Davis – Post Approval Submission Form (PAS) 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

| HRP-212 | Post Approval Submission Form |
|--|--|
| Number subjects IRB approved | Number subjects IRB approved |
| Total subjects consented | *Question Removed* |
| Total subjects consented, met eligibility criteria and enrolled | Total subjects consented, met eligibility criteria and enrolled |
| Screen failures | Screen failures |
| Discontinued | Discontinued |



What's new?

New Questions

| Question | Purpose |
|------------------------------------|---|
| Sponsor Verification | Confirm sponsor information in IRBNet Project Overview is accurate. |
| Reportable New Information Details | Follow-up questions specific to the type of information being reported. |



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.

<u>Unique Data</u>

- 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 <u>first</u> Post Approval Submission Form for any project





UC Davis – Post Approval Submission Form

IRBNet ID: 57292-10 LOGOUT **USER PROFILE** Designer Welcome to IRBNet **Davis Researcher** [57292] Online Post Approval Form - TEST STUDY Help Package: V 57292-10 Work in progress (Not submitted) My Projects D Click to add a package description or notes. Create New Project Y My Reminders (21) | Need Forms? Show Form Libraries Project Administration Assemble your document package here. You can add new project documents, revise existing project documents while Project Overview maintaining version history, and link your project team's Training & Credentials to your package. | Learn more | Designer Share this Project Documents in this Package: Sign this Package Submit this Package Delete this Package There are no documents in this package. Send Project Mail Reviews Project History There are no Training & Credentials records linked to this package. | Link / Un-Link Training Records | Messages & Alerts (6) Other Tools Forms and Templates Start a Wizard OR Attach New Document (When should I do this?) Augusta - Continuing Review Form Augusta - Core Data Form Orlando Health - IRB Application Revise: (When should I do this?) SUNY Stony Brook - Registration Form for Expedited or F ... UC Davis - Initial Review Application Last Submission UC Davis - Post Approval Submission Form Modified Date UC Davis - Project information worksneet UC Davis - Post Approval Submission Form 11/28/2017 📄 🖓 🤣 UMCP - IRB Initial Application - Part 1







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. | Link / Un-Link Training Records |

Start a Wizard

OR Atta

Attach New Document

(When should I do this?)

Documents from Previous Packages that you can Revise: (When should I do this?)

| Pkg # | Document Type | Description | Last Modified | Submission Date | |
|----------|---|--|------------------------|--------------------|---------|
| 4 | Consent Form | HRP-502-TEMPLATE-CONSENT- DOCUMENT-clean | 11/30/2017 04:03 PM | 11/30/2017 | 📄 🖆 🤌 |
| 4 | Consent Form | HRP-502-TEMPLATE-CONSENT- DOCUMENT-marked | 11/30/2017 04:03 PM | 11/30/2017 | 📄 🖓 🖉 |
| 4 | UC Davis - Post Approval Submission Form | Cont Review, Mod | 11/30/2017 04:03 PM | 11/30/2017 | <u></u> |
| 2 | Protocol | HRP-503-TEMPLATE-PROTOCOL-clean | 11/30/2017 03:39 PM | 11/30/2017 | 📄 🖆 🤌 |
| 2 | Protocol | HRP-503-TEMPLATE-PROTOCOL-marked | 11/30/2017 03:39 PM | 11/30/2017 | 📄 🖓 🖉 |
| 1 | UC Davis - Initial Review Application | UC Davis - Initial Review Application | 11/30/2017 03:24 PM | 11/30/2017 | 📄 🗘 🤌 |



Completing the Post Approval Submission Form



UC Davis – Post Approval Submission Form

Start the form by clicking "Next".



Current Study Status

My I
 Crea
 My M

Proj Proj Des Sha Sigr Sub Dele Sen Rev Proj

Othe Forr

- 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.

| lelp | Jump To: Current Study Status ▼ Jump |
|------------------------|---|
| Projects | Current Study Status * |
| ate New Project | Indicate the current study statue |
| y Reminders (34) | Indicate the current study status. |
| ect Administration | Research not started at this site or any site relying on this site's IRB. |
| ect Overview | Open to Accrual of new participants/Collecting data about new participants. |
| igner | |
| re this Project | Closed to Accrual: Accrual is temporarily closed. |
| this Package | Closed to Accrual: Clinical interventions, surveys, or similar participant interactions continuing or |
| mit this Package | collection of new data about participants is ongoing. |
| ete this Package | Closed to Accrual: Remaining activities limited to collection of participant long-term follow-up data and |
| d Project Mail | participants are not participating in any protocol required procedures involving more than minimal risk |
| iews | including imaging studies involving radiation. |
| ect History | Closed to Accrual: Remaining activities limited to analysis of identifiable specimens/data that have |
| lessages & Alerts (12) | been already collected. |
| er Tools | Closed: Final Continuing Review Progress Report All research activities and all identifiable data |
| ns and Templates | analysis is complete, requesting Closure of IRB File. |
| | Save and Exit Preview (* required) Previous Next |



• Data pulls from IRBNet Project Overview page

Forms and Templates

• Data does NOT pull data from the Initial Review Application

| IRBNet ID: 57292-10 | USER PROFILE LOGOUT |
|-------------------------|---|
| IRBNet | FROM CONTRACTOR |
| Welcome to IRBNet | It the sponsor |
| Davis Researcher | UC Davis - Post Approval Submission Form - [57292-10] Online Post Approval Information IS |
| 😢 Help | Jump To: incorrect select |
| My Projects | Sponsor Verification * |
| Create New Project | |
| Y My Reminders (21) | List of sponsors from the Project Overview page: Departmental |
| Project Administration | Is this a complete and accurate list of the financial sponsors of this research? |
| Project Overview | Yes |
| Designer | |
| Share this Project | © N0 |
| Sign this Package | |
| Submit this Package | Save and Exit Preview (* required) Previous Next |
| Delete this Package | |
| Send Project Mail | |
| Reviews | |
| Project History | |
| 🏠 Messages & Alerts (6) | |
| Other Tools | |



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.).



Report cumulative enrollment numbers.



• 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.

| VIII.Pa | rticipant Information | | | NAC |
|---------|---|-----------|-----------------------------|-----|
| What i | the anticipated number of participan | ts to be | enrolled in this study? | |
| St | ady-Wide: 15 | | | |
| Lo | cally: 15 | | | |
| Vulner | able Participants: | | | |
| P | Children | R | Pregnant Women/Fetuses | |
| P | Neonates | P | Cognitively Impaired Adults | |
| P | Prisoners | E | Employees of UC Davis | |
| | Students of the principal investigator, justification: | E | None | |
| Will pa | rticipants receive payment for particip | ation in | this research? | |
| 0 | Participants will be compensated for the | oir time. | | |
| | Participants will be reimbursed for their | expense | 95. | |
| F | Participants will not be compensated or | reimbu | sed. | |
| To | tal Compensation: | | | |
| | | | | |

UNIVERSITY OF CALIFORNIA, DAVIS BEEKELEY + DAVIS + INVINE + LOS ANDELES + MERCED + RIVERSIDE + SAN DEGO + SAN FRANCISCO OFFICE OF RESEARCH SACRAMENTO, CALIFORNIA 95817

OFFICE OF RESEARCH IRB Administration TELEPHONE: 916 703-9151 FAX: 916 703-9160

November 28, 2017

Lionel Messi, PhD Department: Exercise Science Phone: 916-709-9151 Email: lionelmessi@ucdavis.edu

Dear Dr. Messi:

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

| Type of Review: | Continuing Review/Progress Report |
|----------------------|---|
| Title: | Online Post Approval Form - TEST STUDY |
| Investigator: | Messi, Lionel, PhD |
| IRB ID: | 57292-5 |
| Funding: | Departmental |
| Grant ID and Title: | None |
| IND, IDE or HDE: | IND Numbers |
| | 543210 |
| | |
| Approval Period and | The IRB approved the protocol from November 28, 2017 to April 16, 2018 |
| Requirement: | inclusive. |
| | Before March 2, 2018 or within 25 business days of study closure, whichever is earlier, you are to submit a completed "EORM: 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 |
| | [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

| Neseal Chel | UC Davis - Post Approval Submission Form - [58579-5] Post Approval Submission Form Training |
|----------------------|---|
| р | Jump To: Project Events |
| ojects | Project Events |
| New Project | Provide answers for all study sites since the last continuing review progress report. |
| Reminders (34) | Relevant Publications on Risk/Benefit * |
| t Administration | Have there been any publications in the literature relevant to risks or potential benefits? |
| t Overview | |
| ner | • Yes |
| this Project | No |
| his Package | , in the second s |
| it this Package | Interim Findings * |
| this Package | Have there been any interim findings? |
| Project Mail | 💽 💿 Yes |
| WS | |
| t History | |
| ssages & Alerts (12) | Multi-center Trial Reports * |
| Tools | Have there been any multi-center (annual) trial reports? |
| and Templates | • Yes |
| | ○ No |
| | Data Safety Monitoring Board (DSMB) Reports * |
| | Have there been any data safety monitoring beard reports? |
| | (• Yes |
| | O No |
| | |

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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 |
| | | |



Submission Date

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

| | Pro | ject Status as of: 12/06/2017 | | | |
|--|-----|---|--|--|-----------------|
| | Re | viewing Board | Initial Approval Date | Project Status | Expiration Date |
| IRBNet ID: 57292-10 | UC | Davis Clinical Committee A, Davis, CA | 11/30/2017 | Active - Open to Enrollment | 11/29/2019 |
| | UC | Davis Clinical Committee B, Davis, CA | 11/30/2017 | Active - Open to Enrollment | 11/29/2019 |
| IKRNS | UC | Davis IRB Administration, Davis, CA | | | |
| Welcome to IRBNet Davis Researcher | | UC Davis - Post Approval Submission Form - [5729 | 2-10] Online Post App | IRBNet Document Wizar | d |
| Help | | Jump To: Submission | n Date | - Jump | |
| My Projects Create New Project V My Reminders (22) | | Submission Date * Federal regulations require the IRB to conduct of IRB requires information from the investigator to time to conduct this review. For this reason the | continuing review before complete the continuing administrative due date | the expiration of IRB approval. The g review process and needs sufficient for continuing review is 45 days | |
| Project Overview | | before the expiration of IRB approval. | | | |
| Designer | | Is this continuing review report being submitted | on or before the adminis | strative due date? | |
| Share this Project | | | Yes | | |
| Sign this Package | | | 0 103 | | |
| Delete this Package | | | © No | It submitting late | |
| Send Project Mail | | Save and Evit Proview | (* required) | select "No" | DAVIS |
| Reviews | | | (| | OF RESEARCH |

Reportable New Information Submission

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

| IRBNet ID: 57292-10 | USER PROFILE LOGOUT |
|----------------------------|--|
| | |
| Welcome to IRBNet | IRBNet Document Wizard |
| Davis Researcher | UC Davis - Post Approval Submission Form - [57292-10] Online Post Approval Form - TEST STUDY |
| 🕜 Help | Jump To: Reportable New Information - Jump |
| My Projects | Reportable New Information * |
| Create New Project | Click here for information about what must be reported to the IRB. |
| Y My Reminders (29) | Do you have any of the following to report to the IRB? You may select more than one. |
| Project Administration | |
| Project Overview | Information that indicates a new or increased risk or increase in frequency or severity of a known risk. |
| Share this Project | Change (e.g. protocol violation) made to research to prevent imminent harm to subjects or others. |
| Sign this Package | Non-Compliance with the federal regulations governing human research, with the protocol or with the |
| Submit this Package | requirements or determinations of the IRB. |
| Delete this Package | Ancillary approval not previously reported (e.g. Radiation Use Committee, Institutional Biosafety |
| Send Project Mail | Committee, etc.). |
| Reviews Project History | Subject complaint that cannot be addressed by research team. |
| Messages & Alerts (7) | Incarceration of a research subject. |
| Other Teels | Other |
| Forms and Templates | None of the above |
| | |
| | Save and Exit Preview (* required) Previous Next |

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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 a 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.

| USER PROFILE LOGOUT |
|--|
| |
| IRBNet Document Wizard |
| UC Davis - Post Approval Submission Form - [57292-10] Online Post Approval Form - TEST STUDY |
| Jump To: Current Enrollment Numbers - Jump |
| Current Enrollment Numbers * |
| |
| this research at this institution? |
| |
| |
| |
| Save and Exit Draview (* required) Draviews Next |
| |
| |
| |



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)

| JC Davis - Post Approval Submission F | orm - [57292-10] Online Post | Approval Form - TEST STUDY | |
|---|--|---|-----------------------------|
| Jump To: | Form Complete | • | Jump |
| Form Complete | | | |
| Thank you for completing the UC D please include the following with yo | Davis - Post Approval Submis our submission to the IRB: | sion Form. Based upon your res | ponses, |
| Update the Sponsor field in submission updated version Review Application, consent Ancillary approval document | the Project Overview with the c s of any study documents whic t form, etc.). t. | orrect sponsor information. Includ ch state the sponsor information (e | e with this a.g. Initial |
| Save and Exit Preview | | Pre | evious |



Electronic Signature

- PI or CoPI must use IRBNet "Sign this Package" to electronically sign submission.
- Designee Signature Mode is not accepted.

| Welcome to IRBNet | [58579-5] Post Approval Submission Form Training | | | | |
|------------------------|--|--------------------------|--|---------------------------|--|
| Davis Researcher | | | | | |
| 🕜 Help | I Davis Researcher, | as | , certify that to the best of my knowledge | the information contained | |
| My Projects | in this package is a | curate and complete, has | been prepared in accordance with all applicable ir | nstitutional requirements | |
| Create New Project | and is ready for submission. I further certify that this electronic signature is intended to be the legally binding equivalent of a traditional bandwritten signature. | | | | |
| Y My Reminders (35) | traditional nandwrite | en signature. | | | |
| Project Administration | | | Sign | | |
| Project Overview | | | | | |
| Designer | To sign on behalf of another person, switch to Designee Signature Mode . | | | | |
| Share this Project | | | | | |
| Sign this Package | This package has b | een signed by: | | | |
| Submit this Package | Date | Signed By | Role | | |
| Delete this Package | 12/07/2017 09:59 AM | Davis Researcher | Principal Investigator | Details | |
| Send Project Mail | | | | | |
| Reviews | | | | | |
| Project History | | | | | |

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)

Documents in this Package:

| Document Type | Description | Last Modified | |
|---|----------------|------------------------|---------|
| UC Davis - Post Approval Submission Form | Cont Review, M | 05/04/2018 01:51 PM | 📄 🔱 🖉 🗙 |



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.

| Welcome to IRBNet | | | | | Project Overview | |
|--|---|--|-----------------------|------------------|--------------------------|--|
| Davis Researcher | [57255-1] Example S | tudy Title | | | | |
| @ Help | You have Full acces | You have Full access to this project. (Edit) | | | | |
| My Projects | F | Research Institution University of California Davis, Davis, CA | | | | |
| Create New Project | | Title Example Study Title | | | | |
| Y My Reminders (12) | Principal Investigator Researcher, Jane | | | | | |
| Project Administration Project Overview | The documents for th | is project can be acces | sed from the Designer | 6 7 | | |
| Designer | Project Status as of: 0 | Project Status as of: 05/01/2017 | | | | |
| Share this Project | Deviaurian Read | | Initial Approval Data | Designet Status | Evaluation Data | |
| Sign this Package | Reviewing board | | Initial Approval Date | Project Status | Expiration Date | |
| Submit this Package | There is no Project Status information to display as of 05/01/2017. | | | | | |
| Delete this Package | | | | | | |
| Send Project Mail | See stands | 12/22/ | | ALC N PROFESSION | the second second second | |
| Project History | Package 57255-1 is: Work in progress | | | | | |
| 1 Messages & Alerts | Submitted To | Submission | Submission | Board Action | Effective | |
| Other Tools | Summer 10 | | 000 | | | |
| Forms and Templates | This package has not been submitted. | | | | | |



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)



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)







Send feedback

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

