



Submit Certification Request Forms to IRB

For Principal Investigators – a “How To” Guide

Course Number: eSR5261

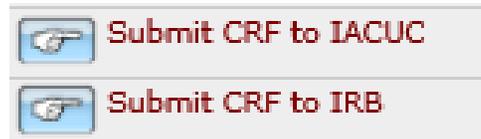


Human Subject and Animal Certifications Overview

- You may find it helpful to review the slides from course #eSR5260 (Human and Animal Certifications for Resource Analysts and Principal Investigators). These slides include the following:
 - an overview of the relationship between eSRA and the HARP system
 - a reminder notification that can be sent to the PI by the Resource Analyst or OSPIP Contracts Officer when a CRF is needed
 - an understanding of the workflow surrounding the entire process
- The slides are posted on the eSRA website:
eSRA.lbl.gov/training

How & When to Initiate CRF Request

- If animals or human subjects are identified in an eSRA proposal:
 - The following activities are available to the PI:



- Note: IRB and IACUC CRFs are separate activities, and must be submitted separately.
- A CRF may be submitted through eSRA at any time after the proposal has been submitted to the sponsor.
- A CRF may be submitted through eSRA during the award period when new certification is required because of changes to the research plan or the protocol(s).

PI might receive an email notification from eSRA system



Proposal Number : **FP00000197** Title Williams _Exercise-induced requires completion of the Certification Request Form (CRF) for human subjects and submission to HARC.

Please submit your request at least 3 weeks prior to the date you need the Certification to provide HARC adequate time to complete their review and issue the Certification. Detailed instructions can be found at: http://www.lbl.gov/Workplace/CFO/assets/docs/ospip/training/eSRA/HARC/IRB_CRF.pdf

The eSRA system will create the actual form for you and submit it electronically to HARC. You will need to specify the protocols that will cover your research. The eSRA drop-down list of protocols links with the HARP system and you can select from that list. We recommend that you confirm with the Protocol Lead Investigator that the protocols you plan to use haven't changed recently and that they are still active protocols. You will not be able to submit a CRF with an expired protocol.

The CRF must be submitted by the PI on the research proposal/award. You are not able to delegate this activity and your submission will serve as your electronic signature on the form.

The activity to submit your CRF to HARC will be on the left of your screen.

If you have questions about this process, or need assistance, please contact eSRAHelp@lbl.gov and someone on the eSRA Help Desk will contact you to assist.

Comments:

Attachments:

There are no items to display

Office of Sponsored Research and Industry Partnerships
Lawrence Berkeley National Laboratory,
1 Cyclotron Road
Berkeley CA 94720

- You will receive this email if the Resource Analyst or OSPIP Contracts Officer sends a reminder that a CRF is needed.
- You can submit a CRF without receiving an email reminder.

PI might receive an email notification from eSRA system



Proposal Number : **FP00000197** Title Williams _Exercise-induced requires completion of the Certification Request Form (CRF) for human subjects and submission to HARC.

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This email includes:

- a link to the proposal
- a link to this training documentation
- some information about the process

In your Home Workspace, select the proposal

STAGING
eSRA Proposal System
LAWRENCE BERKELEY NATIONAL LABORATORY

U.S. DEPARTMENT OF ENERGY
Paul Williams | My Home | Projects | Logoff

Awards Proposals Researcher Profile Company Profiles

Page for Paul T Williams Layout

Principal Investigator

My Roles
Principal Investigator
Registered User

Page for Paul T Williams
Welcome to your eSRA Proposal System Personal Workspace.

My Inbox **Proposals** Awards in Preparation Awards Award Mods Sponsor Requests

Proposals you are working on for submission

Filter by **Advanced**

| Name | SmartForm | Date Modified | State | ID | Primary Sponsor | Submission Type | Due Date | PI |
|--------------------------------|-----------|--------------------|--------------------------------|------------|------------------------------------|-----------------|----------|----------|
| Salary Cap Test | [Edit] | 5/12/2014 3:22 PM | Award Pending | FP00000795 | NIH HEART, LUNG & BLOOD, NATL INST | Resubmission | 3/5/2013 | Williams |
| Williams_Exercise-induced | [Edit] | 5/14/2014 12:24 PM | Awaiting Response from Sponsor | FP00000197 | NIH HEART, LUNG & BLOOD, NATL INST | New | 6/5/2013 | Williams |
| Williams_Cross sectional Rs Rn | [Edit] | 5/12/2014 8:56 AM | Award Activated | FP00000185 | NIH HEART, LUNG & BLOOD, NATL INST | Resubmission | 3/5/2013 | Williams |

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In the Proposal Workspace, select the "Submit CRF to IRB" activity



eSRA Proposal System
LAWRENCE BERKELEY NATIONAL LABORATORY



Paul Williams | My Home | Projects | Logoff

Awards
Proposals
Researcher Profile
Company Profiles

Proposals > Williams_Exercise-induced

Williams_Exercise-induced

FP00000197
Proposal

CURRENT STATE

Awaiting Response from Sponsor

Proposal Information

NEPA-CEQA

DOE

Approvals

Comments

Attachments

Contacts

New Sponsor Requests

Change Log

| PROPOSAL INFORMATION | | BUDGET TOTALS | | SUBMISSION INFORMATION | |
|---------------------------|--|-----------------------------------|--------------|-----------------------------|---|
| Direct Sponsor: | NIH HEART, LUNG & BLOOD, NATL INST | Starting Date: | 4/1/2014 | SF424 Tracking#: | GRANT11416634 |
| Prime Sponsor: | | Number of Periods: | 5 | SF424 Received Date/Time: | 6/5/2013 10:34 AM PDT |
| Foreign Location: | | Total Direct: | \$2,467,235 | SF424 Status Updated: | 6/6/2013 12:30 AM PDT |
| PI: | Paul Williams | Total LDRD: | \$0.00 | SF424 Current State: | Federal Funding Agency Tracking Number Assigned |
| Fellow or Mentor: | There are no items to display | Total FAC: | \$129,918.00 | PDF Version | View |
| OSPIP CO: | David Garcia | Total Other Indirect Costs: | \$1,863,365 | Date Submitted to Sponsor | 6/5/2013 |
| RA: | Karen Dickinson-Mazzei Elma Serrano | Total LBNL Costs (including FAC): | \$4,460,518 | | |
| Status of Science: | Finalized | Sponsor Costs: | \$4,330,600 | | |
| Submission Deadline: | 6/5/2013 | Awarded Total: | \$0.00 | | |
| Application #: | 1R01HL122470-01 | | | | |
| UCOP Transmission Date: | 2/18/2014 10:54 AM | | | | |

My Activities

- Edit Post Award RAs
- Edit Proposal RAs
- Email Proposal Team
- Log General Comment
- Submit CRF to IRB**
- Copy Proposal
- Request New Sponsor

(Proposal - Proposed)

History | Funding Awards

| Activity | Author | Activity Date |
|--|----------------------|------------------------|
| IRB CRF Requested | Sylvester, Cynthia L | 5/14/2014 12:24 PM PDT |
| Updated Sponsor And Application Number | Garcia, David A | 8/6/2013 10:58 AM PDT |
| Submitted to Sponsor | Garcia, David A | 6/5/2013 10:37 AM PDT |
| SF424 Updated | Garcia, David A | 6/5/2013 10:21 AM PDT |
| Issued OSPIP Approval | Garcia, David A | 6/5/2013 10:21 AM PDT |

Activity: Submit CRF to IRB



Execute "Submit CRF to IRB" on FP00000192 - Mozilla Firefox

https://grantstg.lbl.gov/grantstg/ResourceAdministration/Activity/form?ActivityType=com.webridge.entity.Entity[OID[DA4BE36E3658FA48BC414C3D25DC1143]]&ActivityMacro=com.webridge.entity.Entity[OID[82A505EAF3DBA04EE]

Submit CRF to IRB

This process will create a complete Certification Request Form (CRF) and submit it to the IRB at HARC for review and certification. A full set of instructions can be found at: [IRB CRF](#). If you still have questions or need assistance, please contact eSRAHelp@lbl.gov and someone on the eSRA Help Desk will contact you to assist.

The IRB will have access to your proposal in eSRA, so you do not need to submit it separately. When you click "OK" at the bottom of this View, you are electronically signing the CRF and sending it to the IRB. If you need to stop this process, click on "Cancel" and come back to the Activity at another time.

You need to know which active protocols you will be relying upon for your research. You will select the protocol(s) from a list provided by the HARP system when you click "Add." If you do not find the protocol(s) you need, or if you find a protocol has expired, click on "Cancel" and come back when all of the protocols you need to rely upon are active and available for you to select. If you select a protocol that is not in "Active" state in the HARP system, you will not be able to save and submit the CRF.

IRB Studies:

| Protocol ID | Protocol Title | Protocol File Number | Expiration Date | NOITR Reviewing Campus |
|-------------------------------|----------------|----------------------|-----------------|------------------------|
| There are no items to display | | | | |

IRB will be notified that the certification is needed within the standard 3 week review and certification period. If you have an expedited review request, provide the justification for the expedited certification here:

IRB Date Required By:

Expedited Review:

General Comments:

Attachments:

| Document | Description |
|-------------------------------|-------------|
| There are no items to display | |

- Click "Add" to select protocol(s).
- Review date is automatically 3 weeks from date of the request.
- If you require expedited review, provide the justification for expedited review to HARC.
- Comments and other attachments are optional.

There is no need to attach your proposal.
Members of the IRB Committee have the ability
to view your proposal within eSRA.

This is what the Protocol selection list looks like:

Submit CRF to IRB

This process will create a complete Certification Request Form (CRF) and submit it to the IRB at HARC for review and certification. A full set of instructions can be found at: [IRB CRF](#). If you still have questions or need assistance, please contact eSRAHelp@lbl.gov and someone on the e

The IRB will have access to your proposal in eSRA, so you do not need to submit it separately to the IRB. If you need to stop this process, click on "Cancel" and come back to the Activity

You need to know which active protocols you will be relying upon for your research. You can select one or more protocol(s) you need, or if you find a protocol has expired, click on "Cancel" and come back to the Activity. A protocol that is not in "Active" state in the HARP system, you will not be able to save a

IRB Studies:

Add

| Protocol ID | Protocol Title | Protocol File Number |
|-------------------------------|----------------|----------------------|
| There are no items to display | | |

IRB will be notified that the certification is needed within the standard 3 week review period. You can specify the required date and justification for the expedited certification here:

IRB Date Required By:

6/4/2014

Expedited Review:

General Comments:

Attachments:

Select One or More IRBStubs

Filter by Protocol Title Go Clear Advanced

Deselect All

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| Protocol Title | Protocol File Number | Expiration Date | NOITR Reviewing Campus |
|--|----------------------|-----------------|------------------------|
| <input type="checkbox"/> 2013 Renewal _Correlation of Age or | 148H002 | 6/25/2014 | UC SAN FRANCISCO |
| <input type="checkbox"/> 2013 Renewal for Dynamic Cardiac SP | 184H007 | | UC SAN FRANCISCO |
| <input type="checkbox"/> 2013 Renewal for Proteomic Analyses | 154H003 | 5/17/2015 | UC SAN FRANCISCO |
| <input type="checkbox"/> 2013_Renewal_Prediction of Individu | 306H002 | 6/11/2014 | UC SAN FRANCISCO |
| <input type="checkbox"/> 2014 Renewal for Effects of Chemoth | 073H023 | 2/13/2015 | UC SAN FRANCISCO |
| <input type="checkbox"/> A Field Study of Water Heating Syst | 307H001 | 9/17/2014 | |
| <input type="checkbox"/> A Field Study of Whole-home Dehumid | 313H003 | 3/6/2015 | |
| <input type="checkbox"/> A retrospective study of outcomes o | 91H003 | 8/7/2014 | UC SAN FRANCISCO |
| <input type="checkbox"/> Aging Brain, Cognition, and Dopamin | 073H024 | 10/3/2014 | |
| <input type="checkbox"/> Alterations in gut microbiota in re | 272H002 | 8/17/2014 | |
| <input type="checkbox"/> Amyloid Imaging with Florbetapir | 299H001 | 4/11/2015 | |

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OK Cancel

Select the specific protocol(s) by checking the boxes

Protocol Lead Investigator names are not listed for security reasons.

- You can search and sort your protocols.
- All protocols ever approved in HARP are listed

| <input type="checkbox"/> | Protocol Title | Protocol File Number | Effective Date | Institution |
|--------------------------|-------------------------------------|----------------------|----------------|------------------|
| <input type="checkbox"/> | 2013 Renewal _Correlation of Age or | 148H002 | 6/25/2014 | UC SAN FRANCISCO |
| <input type="checkbox"/> | 2013 Renewal for Dynamic Cardiac SP | 184H007 | 6/25/2014 | UC SAN FRANCISCO |
| <input type="checkbox"/> | 2013 Renewal for Proteomic Analyses | 154H003 | 5/17/2015 | UC SAN FRANCISCO |
| <input type="checkbox"/> | 2013_Renewal_Prediction of Individu | 306H002 | 6/11/2014 | UC SAN FRANCISCO |
| <input type="checkbox"/> | 2014 Renewal for Effects of Chemoth | 073H023 | 2/13/2015 | UC SAN FRANCISCO |
| <input type="checkbox"/> | A | | 9/17/2014 | |
| <input type="checkbox"/> | A | | 3/6/2015 | |
| <input type="checkbox"/> | A | | 8/7/2014 | UC SAN FRANCISCO |
| <input type="checkbox"/> | Ag | | 10/3/2014 | |
| <input type="checkbox"/> | Al | | 8/17/2014 | |
| <input type="checkbox"/> | Ar | | 4/11/2015 | |
| <input type="checkbox"/> | Amyloid Imaging with Pittsburgh Com | 073H007 | 4/11/2015 | |
| <input type="checkbox"/> | Analysis of the Effect of Changes i | 315H001 | 12/13/2014 | |
| <input type="checkbox"/> | Assessing User-Reported Versus Sens | 325H001 | | UC BERKELEY |
| <input type="checkbox"/> | Automated Demand Response Demonstra | 322H001 | 6/10/2014 | |

You cannot select an Expired Protocol

- If the protocol you need has expired, you should contact the Protocol Lead Investigator to determine the status and whether the protocol is being renewed.
- If you accidentally select a protocol that is expired, you will receive an error message when you click “OK”:

Could not execute the Submit CRF to IRB activity due to one or more errors: You have selected a protocol 'CHAMACOS Cohort Study (9-12 Years)' that has expired and cannot be used for your research at this time. Please contact the Protocol Lead Investigator directly to determine if and when this protocol can be renewed. If you have questions about this process in the eSRA system, contact eSRAHelp@lbl.gov and one of our support staff will contact you to assist. Do not contact the HARC office directly. They cannot assist you with this issue.

- You should contact eSRAHelp@lbl.gov if you need assistance. The HARC office doesn't provide help with the eSRA system.

What happens with the PI clicks OK?

- The Certification Request Form (CRF) is created.
- An email notification is sent to HARC staff, and the Resource Analyst receives copy.
- The “Submit CRF to IRB” activity is stored in the eSRA proposal history of proposal, with a copy of the CRF attachment.
- The approvals tab in the Proposal Workspace is updated:
 - The status indicates certification has been requested.
 - The protocol(s) identified in the CRF are listed.

Let's look at the CRF

- eSRA auto-fills top portion (#1-7).
- PI selected protocol(s) are listed (#8)
- The CRF is electronically signed in eSRA (#9) and routed as needed.

eSRA CONTRACT/GRANT/PROPOSAL CERTIFICATION REQUEST FORM (CRF)

- Principal Investigator on proposal/award: Paul Williams
- Proposal/award Title: Exercise-induced heart disease, diabetes, cancer & infection morbidity reductions
- Primary Funding Agency: NIH HEART, LUNG & BLOOD, NATL INST
- Primary Agency Award or Tracking No. (if known): 1R01HL122470-01
(Ask your OSPIP Contracts Officer or departmental budget analyst for assistance if needed.)
- LBNL receives: Primary award Subcontract (If subcontract, provide name of institution receiving primary award: _____)
- Certification requested for: New proposal Competing Renewal Continuation Other (such as a proposal revision, or a new certification request for an ongoing project, or a correction to an existing certification; please briefly describe the circumstances):

- If competing renewal/continuation, have there been changes to the research since last certification significant enough to require new protocols or protocol modification?
A) Human: Yes No (check one) B) Animal: Yes No (check one)
(If yes to (A) or (B), attach modified proposal; if no to both, submission of this form is sufficient.)
- List animal and/or human use protocols applicable to this proposal (attach additional page if needed)

| HARP System ID | Protocol File Number (PFN or HARC #) | Protocol Title | Reviewing campus (NOITRs) | Expiration Date |
|----------------|---|-------------------------------------|---------------------------|-----------------|
| Pro00022794 | 107H05 | National Runners and Walkers Health | | 10/28/2014 |

For new submissions, initial/revised certification requests, and competing renewal/continuations with changes, please send a copy of the proposal identified by agency tracking number (if available) and title to the HARC office. The certification letter will be sent to OSPIP (SPOHARC@lbl.gov) and copied to individuals listed in sections (1), (8) and (10). Note: OSPIP will send the certification to the granting agency as required.

- Signature of PI from Item (1), assuring that the information presented above is complete and accurate:
_____ Electronically signed in eSRA Date: 5/14/2014

For HARC use only

Current Status: Request received Side-by-review Clarification needed? Y N Certification approved Certification letter sent to OSPIP, Others

By: _____

Notification to PI, RA, and OSPIP CO

From DoNotReply-eSRA@lbl.gov★

Subject **Human Use Certification for Proposal# FP00000197; Paul Williams; Williams_Exercise-induced**

To Parth Banker★, Cynthia L Sylvester★

2:59 PM

Other Actions ▾

 Proposal System

Proposal Number: **FP00000197** Title Williams_Exercise-induced has been certified by IRB at HARC .

Office of Sponsored Research and Industry Partnerships
Lawrence Berkeley National Laboratory,
1 Cyclotron Road
Berkeley, CA 94720

This is the end of “Submit CRF to IRB” slides.
If you have questions, contact eSRAHelp@lbl.gov
