



Human and Animal Certifications for Resource Analysts and Principal Investigators

Course Number: eSR5260




Course Objectives

- Overview and understand the differences between Proposals (eSRA) and Protocols (HARP)
- Understand the "Request CRF" and "Submit CRF" activities
- What if HARC requests changes?
- What happens when it is certified?

eSRA vs. HARP

4

Research Proposal (eSRA) vs. Protocol (HARP)

- eSRA:
 - Research Proposal submitted to sponsor
 - PI Activity: Certification Request Form
 - Select Protocol(s) from drop-down list
 - IRB or IACUC Activity:
 - Certify
 - HARP:
 - Protocols
 - In Progress
 - Active
 - Expired
- 

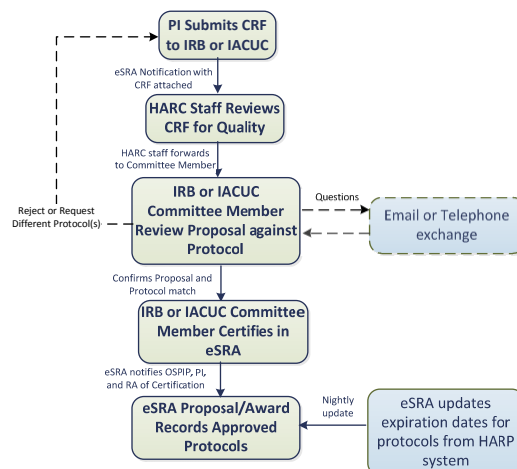
5

Exchange of Information Between eSRA and HARP

- From eSRA to HARP:
 - No information is exchanged in that direction
 - HARP is a closed system
- From HARP to eSRA:
 - CRF drop-down selection of Protocols
 - Protocol Title (first 30 characters)
 - Protocol #
 - Expiration Date
 - Nightly update to awards with new expiration date when protocols are renewed

6

Overview of the Certification Process inside eSRA



7

Institutional Approvals do not cause State changes in eSRA

- **Certification in Proposal**
 - Will store approval in Approvals tab
 - Will link the protocols to the proposal
- **IRB or IACUC Certification is not a hard stop to award activation**
- **Award Generation**
 - Will link the protocols to the award
 - HARP will update the expiration dates
- **Modification CRF**
 - if a new certification is needed at the time of an award modification
 - Will update the certifications in the award

8

The "Request CRF" and "Submit CRF" Activities

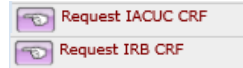
10

How & When to Initiate CRF Request

■ If animals or human subjects are identified in the eSRA proposal:

○ Activity available:

- Available to RA and OSPIP CO
- Functions as an electronic reminder to the PI
- **It is optional – PI can execute “Submit CRF” without it being requested**



○ Activity available:

- Available to PI
- IRB and IACUC CRFs are separate activities

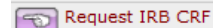


○ Available in all states after the proposal is submitted to the sponsor

○ Also available in award modification states in case there are changes that require new certification

11

Request CRF



○ Available to RA and OSPIP

A screenshot of the "Request IACUC CRF" form. It features a "Comments:" section with a text area, an "Attachments:" section with an "Add" button and a table with columns "Document" and "Description" (containing the text "There are no items to display"), and "OK" and "Cancel" buttons at the bottom. A green callout box with three bullet points points to the form: "Add comments (optional)", "Add attachments (optional)", and "Click 'OK'".

12

PI receives email notification from eSRA system

From: DoNotReply-eSRA@lbl.gov
 Subject: CRF is required for Animal Work for Proposal# FP00000192; Cynthia McMurray; McMurray Chem Fingerprint (Rn)
 To: Parth Banker, Cynthia L Sylvester

Proposal System

Proposal Number : FP00000192 Title McMurray Chem Fingerprint (Rn) requires completion of the Certification Request Form (CRF) for animal work 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/IACUC_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.

If any of the animal protocols that you will be relying on are not yet in the HARP electronic system, you will need to prepare and submit a paper CRF.

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:
 Don't forget to request the CRF

Attachments:
 There are no items to display

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

13

PI Activity: Submit CRF to IRB

Submit CRF to IRB

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

[https://grantsig.lbl.gov/grantsig/ResourceAdministration/Activity/Form?ActivityType=com.webridge.entity.Entry\(OID\)D48E3E638FA88C414C3D25C1413A\(ActivityMacro:com.webridge.entity.Entry\(OID\)82A505FAFD8AD4EE](https://grantsig.lbl.gov/grantsig/ResourceAdministration/Activity/Form?ActivityType=com.webridge.entity.Entry(OID)D48E3E638FA88C414C3D25C1413A(ActivityMacro:com.webridge.entity.Entry(OID)82A505FAFD8AD4EE)

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.

Protocol ID	Protocol Title	Protocol File Number	Expiration Date	NOIR: 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 and justification for the expedited certification here:

IRB Date Required By: 3/21/2014

Expedited Review:

General Comments:

Attachments:

Document	Description
There are no items to display	

- Add to select protocol(s)
- Review date automatically 3 weeks from date of request
- Expedited review requires reason
- Comments (optional)
- Attachments (optional)

14

PI Activity: Submit CRF to IACUC

- Add to select protocol(s)
- If all protocols are not in HARP, can select option #2 and attach a manually prepared CRF to use the eSRA routing and approval process
- Review date automatically 3 weeks from date of request
- Expedited review requires reason
- Comments (optional)
- Attachments (optional)

15

Selecting Protocols

Protocol Lead Investigators are not listed for security reasons.

- Can search and sort
- All protocols ever approved in HARP are listed
- Cannot complete CRF activity if an expired protocol is selected.

<input type="checkbox"/>	Protocol Title	Protocol File Number	Expiration Date	IRB 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"/>			9/17/2014	
<input type="checkbox"/>			3/6/2015	
<input type="checkbox"/>			8/7/2014	UC SAN FRANCISCO
<input type="checkbox"/>			10/3/2014	
<input type="checkbox"/>			8/17/2014	
<input type="checkbox"/>			4/11/2015	
<input type="checkbox"/>			4/11/2015	
<input type="checkbox"/>			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	

Cannot select an Expired Protocol

- PI should contact eSRASHelp@lbl.gov with any needs for assistance.
- The HARC office doesn't provide help with the eSRA system

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 eSRASHelp@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.

17

Additional FAQs

- Comments go with the email notification and are stored in history, but are not included on the CRF.
- Attachments go with the email notification and are stored in history, but are not included inside the CRF.
- No need to include copy of the proposal; the IRB and IACUC Committee members have read-access to the proposal inside of eSRA.

18

What happens with the PI clicks OK?

- CRF Form is created.
- Email Notification is sent to HARC staff (RA receives copy).
- CRF activity is stored in history of proposal.
- Approvals tab updated:
 - Status indicates Certification has been requested
 - Protocols identified in the CRF are listed

Let's look at the CRF

- eSRA Auto-fills top portion
- PI selected protocols are listed
- Electronically signed

eSRA CONTRACT GRANT PROPOSAL CERTIFICATION REQUEST FORM (CRF)

1. Principal Investigator on proposal award: Cynthia McManry

2. Proposal award Title: Chemical Fingerprinting

3. Primary Funding Agency: NIH NEUROLOGICAL DISORDERS & STROKE, NAT

4. Primary Agency Award or Tracking No. (if known): 2R01NS060113-07
(Ask your OSFIP Contract Officer or departmental budget analyst for assistance if needed.)

5. LBNL receives: Primary award_X, Sub-contract____ (If sub-contract, provide name of institution receiving primary award:_____)

6. Certification requested for: New proposal____ Competing Renewal_X, 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 circumstance(s):_____)

7. 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, submit none of the forms in red font.)

8. List animal and/or human use protocols applicable to this proposal (attach additional page if needed)

HARP system ID	Protocol File Number (FFN or HAEC #)	Protocol Title	Reviewing campus (NOIR#s)	Expiration Date
1800000149	996005	For Renewal Test Case 3		
1800000228	235004	3D Structure of Ixmer Est Chater Ha		11/30/2014

For new submissions, initial revised certification requests, and competing renewal/continuation with changes, please send a copy of the proposal identified by agency tracking number, if available, and file to the HARC office. The certification cover will be sent to OSFIP (OSFIP@LBNL.gov) and copied to individuals listed in sections (1), (4) and (10). Note: OSFIP will send the certification to the granting agency as required.

9. Signature of PI from Item (1), assuring that the information presented above is complete and accurate:
 Electronically signed in eSRA Date: 4/8/2014

For HARC use only

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

CRF is reflected in the Approvals Tab and in History

Human Subjects: Submitted

IRB Studies:

Protocol ID	Protocol Title	Protocol File Number	Expiration Date	NOITR	Reviewing Campus
Pro00022918	Assessing User-Reported Versus Sens 325H001				UC BERKELEY





Animals: Submitted 4/30/2014

IACUC Studies:

Protocol ID	Protocol Title	Protocol File Number	Expiration Date
IS00000149	For Renewal Test Case 3	996005	
IS00000228	3D Structure of Inner Ear Outer Hai	256004	

- Approvals tabs show protocol(s) selected and that the CRF was submitted
- CRF document(s) included in history

History Funding Awards

Activity	Author	Activity Date
 CRF Submitted to IACUC  Cert Req form.doc	Sylvester, Cynthia L	4/30/2014 3:02 PM PDT
 CRF Submitted to IRB  Cert Req form.doc	Sylvester, Cynthia L	4/30/2014 2:34 PM PDT

21

What if HARC Requests Changes?

23

What if HARC Staff has questions?

- HARC staff reviews all CRFs before forwarding the email to a Committee Member for review
 - Could email the PI and request a new CRF be submitted
 - Could ask question and then forward the answer with the CRF to the Committee Member for the review

24

What if Committee Member has Questions or Requires Changes?




- Clarification-type questions
 - Email outside of eSRA
 - Phone call
- Requires changes to protocol(s) selected
 - Email outside of eSRA (not optimal)
 - "Email Team" activity inside of eSRA
 - Select the PI from the team list
 - Email is stored in the history section of the proposal
- PI repeats the CRF activity
 - New request replaces the old request
 - New protocol numbers are stored in the Approvals tab

25

What Happens with it is Certified?

26

Notification to PI, RA, and OSPIP CO

From DoNotReply-eSRA@lbl.gov  Reply Reply All Forward Archive Junk Delete
Subject: **Human Use Certification for Proposal# FP00000192; Cynthia McMurray; McMurray Chem Fingerprint (Rn)** 3:08 PM
To: Parth Banker , Cynthia L Sylvester  Other Actions



Proposal System

Proposal Number: **FP00000192** Title McMurray Chem Fingerprint (Rn) has been certified by IRB at HARC .
Office of Sponsored Research and Industry Partnerships
Lawrence Berkeley National Laboratory,
1 Cyclotron Road
Berkeley, CA 94720

27

CRF Certification is reflected in the Approvals Tab and in History

Human Subjects: Certified Cynthia Sylvester 4/30/2014 3:08 PM

IRB Studies:

Protocol ID	Protocol Title	Protocol File Number	Expiration Date	NOIR	Reviewing Campus
Pro00022918	Assessing User-Reported Versus Sens 325H001				UC BERKELEY

Animals: Certified 4/30/2014 Cynthia Sylvester 4/30/2014 3:08 PM

IACUC Studies:

Protocol ID	Protocol Title	Protocol File Number	Expiration Date
IS00000149	For Renewal Test Case 3	896005	
IS00000228	3D Structure of Inner Ear Outer Hai	235908	11/30/2014

- Approvals tab shows protocol(s) certified
- Including the expiration date
- CRF document(s) included in history

History Funding Awards

Activity	Author	Activity Date
Human Subjects Certified	Sylvester, Cynthia L	4/30/2014 3:08 PM PDT
Animals Certified	Sylvester, Cynthia L	4/30/2014 3:08 PM PDT

28

This is the end of Human and Animal Certifications for Resource Analysts and Principal Investigators

Protocol(s) linked to award with expiration date

- Expiration date for each protocol relied upon for this research is recorded with the award
- When a protocol is about to expire:
 - HARP system notifies the Protocol Lead
 - eSRA notifies the Research PIs relying on the protocol
- When the protocol is renewed, the expiration date is updated in eSRA
 - OSPIP will confirm expiration dates when submitting progress reports or accepting award modifications
 - Additional certifications will not be required during the life of an award as long as all the protocols remain active

30

The PowerPoint slides will be available with script in the notes section for refresher self-learning and to train PIs individually.

eSRA.lbl.gov

