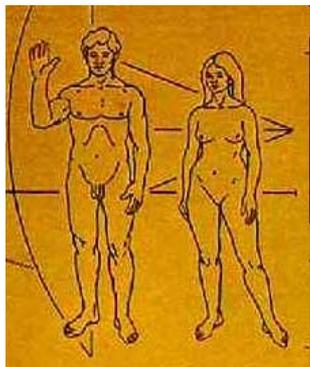


Protocols vs. Proposals

(research involving humans and/or animals)



Cynthia Sylvester

**Office of Sponsored Projects
& Industry Partnerships**



Chris Byrne

**Human and Animal
Regulatory Committee**



HARC

HARC = Human and Animal Regulatory Committees Office

- **Protect the research subjects**
- **Keep the institution (LBNL) in compliance with regulations regarding animal welfare and protection of human subjects**
- **Assist investigators in reaching compliance**



OSPIP = Office of Sponsored Projects & Industry Partnerships

- **OSPIP submits proposals and accepts awards from non-DOE sponsors**
- **OSPIP certifies compliance with sponsor policies on the use of human and animal subjects**
- **OSPIP ensures that the use of human or animal subjects has been approved by HARC prior to acceptance of funds**



Protocol vs Proposal

1. **Systematic description of an experimental procedure involving humans and/or animals**
2. **Needs to meet regulatory requirements to justify research and protect subjects**
3. **Reviewed and approved by the appropriate regulatory committee (IRB or IACUC)**

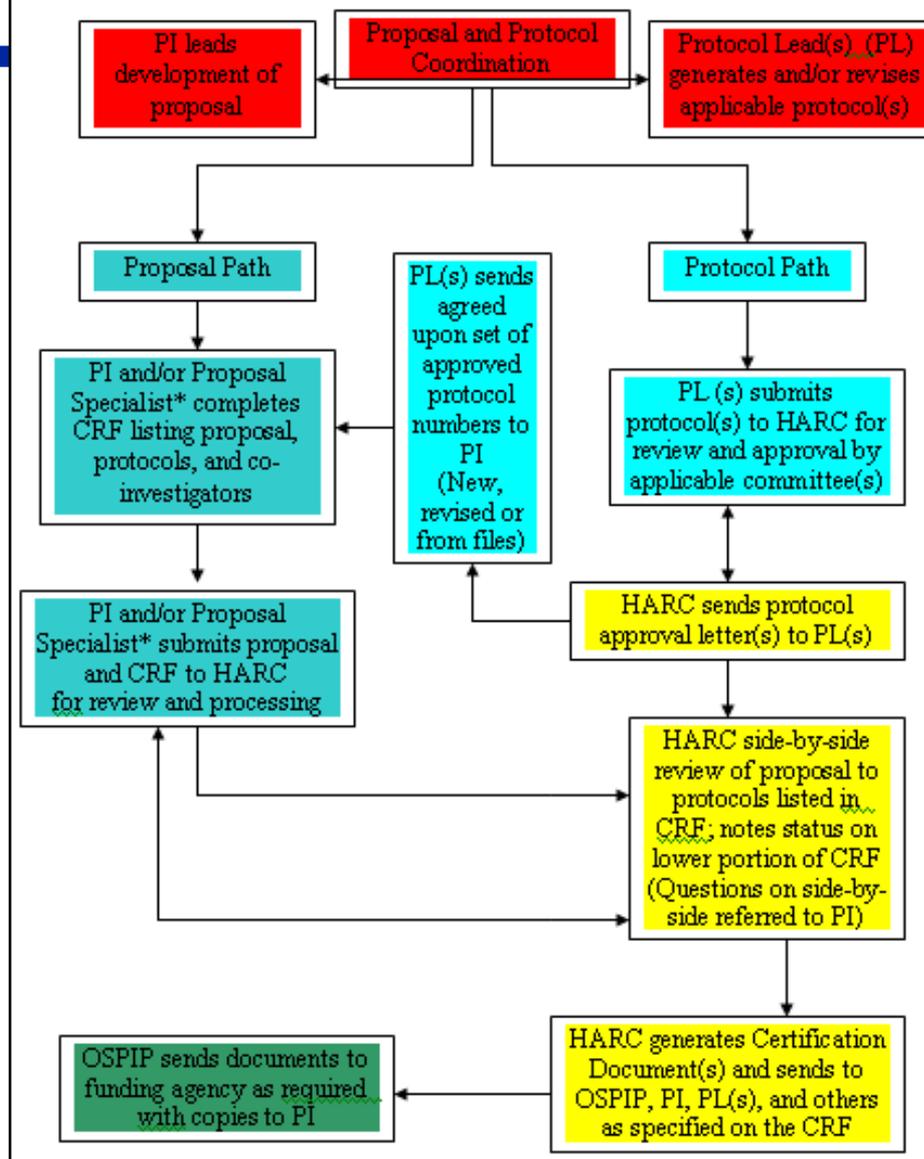
1. **Statement of work for research that might involve humans and/or animals**
2. **Needs to meet requirements of UC, DOE, and the funding sponsor**
3. **Reviewed and approved by the funding agency**



Protocol vs Proposal Certification

- | | |
|--|---|
| <ol style="list-style-type: none">1. Systematic description of an experimental procedure involving humans and/or animals2. Prepared by the <u>Protocol Lead Investigator (PLI)</u> and Submitted to HARC for review and approval3. Reviewed annually by the appropriate regulatory committee (IRB or IACUC) | <ol style="list-style-type: none">1. A Certification from the HARC Office that research described in a proposal has valid and complete human and/or animal protocols approved for this research2. Prepared by HARC for OSPIP and the funding agencies3. Reviewed and issued by HARC when needed and requested by the PI on the <u>Proposal (PIP)</u> |
|--|---|

Human and Animal Use Approval Certification Process for Grant Proposals:
New, Revised, or Continuations with Modifications*





How to Get a Certification

1. Protocol PI must have a fully approved protocol
2. Download the CRF from the HSC or AWRC websites
3. PI on the Proposal must submit a Certification Request Form (CRF) with a copy of the proposal (for new awards)
4. PI on the Proposal must submit a Certification Request Form (CRF) with a copy of the proposal (for amendments and supplements)
5. PI on the Proposal must submit a Certification Request Form (CRF) for NIH non-competing continuations when there is no change to the research plan
6. PI on the Proposal must submit a Certification Request Form (CRF) with a copy of the NIH non-competing continuations when there is change to the research plan

Where is the CRF located? AWRC/HSC websites

- Certifying approval for a grant agency
- Ethical Training for researchers at LBNL
- Animal Use Guidelines
- Frequently Asked Questions and AWRC charter documents
- Schedule of AWRC meetings
- Links to other useful sites

CERTIFYING ANIMAL USE APPROVAL FOR A GRANT

When certification of IACUC (Institutional Animal Care and Use Committee) review is needed for a funding agency: once your animal use protocol has been approved by the Animal Welfare and Research Committee (LBNL's ICAUC), researchers or their proposal specialists should fill in the [certification request form](#) and submit it along with a copy of the grant proposal to the HARC office (MS 26-145, harc@lbl.gov). The HARC office will perform a side by side review with the protocol and the grant proposal and if it appears that all



CONTRACT/GRANT/PROPOSAL CERTIFICATION REQUEST FORM (CRF)

- Principal Investigator on proposal/award: _____
- Proposal/award Title: _____
- Primary Funding Agency: _____
- Primary Agency Award or Tracking No. (if known): _____
(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.)

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

Protocol LBNL Lead Investigator	Protocol HARC #	Protocol Title	Reviewing campus (NOITRs)	Expiration Date

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:

Date: _____

10. HARC – please provide additional copy of certification to:

Print name(s) and email address(es) in box



The Certification Request Form

CONTRACT/GRANT/PROPOSAL CERTIFICATION REQUEST FORM (CRF)

1. Principal Investigator on proposal/award: _____
2. Proposal/award Title: _____
3. Primary Funding Agency: _____
4. Primary Agency Award or Tracking No. (if known): _____
(Ask your OSPIP Contracts Officer or departmental budget analyst for assistance if needed.)
5. LBNL receives: Primary award ___ Subcontract ___ (If subcontract, provide name of institution receiving primary award: _____)
6. 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):



The Certification Request Form

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, submission of this form is sufficient.)

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

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The Certification Request Form

9. Signature of PI from Item (1), assuring that the information presented above is complete and accurate:

Date: _____

10. HARC –please provide additional copy of certification to:

Print name(s) and email address(es) here _____



Submitting the CRF

- **Principal Investigator on Proposal (PIP) completes CRF (with assistance from division staff)**
- **Send CRF to HARC by email at HARC@lbl.gov**
- **HARC does not use RAPID #s for reference – use the #s specified on the CRF in the email subject lines and for follow-up inquiries**
- **Allow 2 weeks !!!**



Who Gets What Paperwork ?

Protocol – from Protocol Lead Investigator (PLI) to HARC

Protocol Approval letter– from the AWRC or HSC through HARC to PLI only

Certification Request Form – from PI on Proposal (PIP) to HARC

Certification – from HARC to OSPIP with copies to those named on the CRF

Proposal – from PI on Proposal to OSPIP when the application is submitted

Proposal – from PI on Proposal to HARC when the CRF on new research is submitted



When is a Certification Needed?

Certification that human and/or animal research for a specific research project is approved is required whenever it is specifically requested by a funding sponsor

(If already issued Certification is still valid, a new one is not required.)

- **Anytime it is specifically requested by a funding sponsor**
- **Whenever the OSPIP CO “signs and certifies” something to the sponsor agency**



When Does OSPIP “Sign and Certify”?

- **NIH JIT (PI will be notified by NIH and OSPIP)**
- **Acceptance of a new award**
- **Submission of NIH non-competing continuation**
 - **Is the previous Certification still valid?**
 - **If not, submit CRF when you begin preparing the continuation progress report**
- **Acceptance of an increment on an award**
 - **Is the previous Certification still valid?**
 - **If not, submit CRF at least 2 weeks before anticipated increment**



Questions

Question: Why is HARC not getting the proposals from OSPIP?

Answer:

- 1. The Proposal should go with the CRF and the PI is the one that submits that form.**
- 2. OSPIP does not know when the copy of the proposal is needed by HARC.**



Not Human Use vs Exemption 4

- In 2004 and again in 2007, the Office of Human Research Protections issued guidance that effectively reclassified what had been 'exempt 4' human subjects research to 'not human use.'
- 'Guidance on Research Involving Coded Private Information or Biological Specimens'
- <http://www.hhs.gov/ohrp/humansubjects/guidance/cdebiol.htm>
- There is no requirement to have findings of 'NHU' confirmed by the IRB



Not Human Use vs Exemption 4

- **Pre-existing**

and

- **Publicly available**
(census data; cells from ATTC)

or

- **Coded or anonymous**
(with a data use agreement that prevents access to the code key and/or documents agreement that there will be no effort to re-identify subjects)

- **Pre-existing** (on the shelf at the time the research begins; not collected for the purpose of this research)

and

- **Publicly available**
(census data; cells from ATTC)

or

- **Unidentifiable** (“subjects *cannot* be identified, directly or through identifiers...”)



Proposals and NHU/Exemption 4

- The human subjects section of the proposal should address and justify the qualifying points on the preceding slide
- PI on a Proposal can ask HARC for a brief review of proposal prior to submission for advice on determining if it should be classified “not human use” or exemption 4
- No new NIH proposals should specify exemption #4
- Some agencies don’t recognize the guidance (DOD; possibly NASA or some NCI offices) --exemption reviews should be done only when there is a funding agency request



Problems !!!!

- If a proposal is submitted by a PI who makes the wrong determination of human (or animal) use or exemptions, the award could be issued with the funding agency requesting something from HARC that is not possible.
- Justification in a proposal didn't address *why* a particular research project should be “exempt” or “not human use” (Example: The prior competitive period was exempt therefore it should still be exempt.)
- Misconception: “Exempt” is a safer category than “not human use” Reality – it either is or it isn't – they each have specific definitions (and some “NHU” research is not exempt!)



What Happens if Proposal is Wrong ?

- **HARC cannot provide the sponsor with the documentation the sponsor is requesting**
- **DELAY in funding**
- **Restrictions on research pending corrections**
- **LOTS of extra work for PI, HARC, OSPIP**



What about Subawards?

If LBNL is Prime award recipient.....

- 1. Must have LBNL protocol approval #s for human and/or animal work**
 - a) That covers work at LBNL and at the subrecipient location**
 - b) Even if *all* human and/or animal work is done at a subrecipient institution**
- 2. Must have LBNL Certification for the proposal**