**Institutional Review Board**

**REQUEST TO CHANGE IRB STUDY PERSONNEL**

*HUMAN RESEARCH & COMPLIANCE* | LOMA LINDA UNIVERSITY HEALTH | Office of Research Affairs

24887 Taylor Street, Suite 201 Loma Linda, CA 92350 *(909) 558-4531 / e-mail:* *irb@llu.edu*

Principal Investigator:

Department:

Protocol Title:

IRB #: Approval End Date:

Is this a change of Principal Investigator?

 No

Yes: Complete section V.

# Are you adding Study Personnel?

es: List new personnel below.

No

Y

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **FIRST NAME** | **LAST NAME** | **Degree(s)** | **E-mail address (preferably LLU – if none, use other)** | **Role on Study** | **Obtaining consent?****Yes/No** |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
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|  |  |  |  |  |  |

# Are you removing Study Personnel?

 No

Yes: Select name(s) of person(s) to be removed.

**Print Name**

1. **Are you changing the name of the Study Contact?**

 No

Yes: Complete the following:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Name** | **Ext.** | **E-Mail** | **FAX** | **Building - Room #** |

# For change of Principal Investigator, complete this section and have new PI sign the attestation below. Current PI must sign section VI.

* 1. Is proposed individual eligible to serve as PI per University policy? See [**Principal Investigator Eligibility Policy**](http://www.llu.edu/pages/handbook/lluahsc_policies/H-Research%20Affairs/H-11%20Principal%20Investigator%20Eligibility.pdf)**.** No Yes
	2. Proposed PI will read and sign the following:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Principal Investigator (name, degrees)** | **Dept./Section** | **Ext.** | **E-Mail** | **Status – Full Time Faculty** |

|  |
| --- |
| **Declaration of New Principal Investigator:****I understand** that as Principal Investigator**, I have ultimate responsibility** for the conduct of the study in accord with the Ethical Principles & Guidelines for Research Involving Human Subjects (the "Belmont Report") including the following:* The ethical performance of the project.
* The protection of the rights and welfare of human subjects.
* Strict adherence to any stipulations imposed by the IRB.

**I agree to comply** with all Loma Linda University policies and procedures, as well as with all applicable Federal, State, and local laws regarding the protection of human subjects in research, including, but not limited to, the following:1. Performing the project according to the IRB-approved protocol.
2. Assuring that all personnel working on the project are qualified personnel who have received training in human subject protections.
3. Obtaining legally effective informed consent from human subjects (or their legally responsible representative, if IRB approved), and using only the current IRB-approved, stamped consent form (unless the IRB has specifically waived this requirement).
4. Implementing no changes in the approved human subject study without prior IRB review and approval (except where necessary to eliminate apparent immediate hazards to the subjects).
5. Reporting progress of approved research to the IRB, as often as and in the manner prescribed by the IRB on the basis of risks to subjects, but no less than once per year.
6. Complying with the Privacy Rule (Health Insurance Portability and Accountability Act) as it applies to the privacy of health information in research.

**If I am the faculty sponsor** of a student I further certify that:1. The student is knowledgeable about the regulations and policies governing research with human subjects and has sufficient training and experience to conduct this particular study in accord with the approved protocol.
2. This project has been reviewed and approved by the thesis/dissertation committee.
3. I agree to meet with the student or guest investigator on a regular basis to monitor study progress. Should problems arise during the course of the study, I agree to be available, personally, to supervise the investigator in solving them.
4. If I will be unavailable, as when on sabbatical leave or vacation, I will arrange for an alternate faculty sponsor to assume responsibility during my absence, and I will advise the IRB by letter of such arrangements.

I certify that the information provided in this application is complete and accurate.Signature of PI: Date: Signature of New PI’s Department Chair:  |

# Does the Informed Consent Document, Authorization for Use of PHI Form, recruitment material, or other documents need to be updated to reflect the proposed change of study personnel?

 No

Yes: Attach affected items, as appropriate.

1. Revised consent, PHI Authorization, recruitment material, etc.

# PI’s Attestation:

I confirm that the personnel listed on this study have the expertise to conduct the study, will perform duties within the scope of clinical practice (as applicable), and have received appropriate protocol training.

Signature of Principal Investigator Date

**OFFICE USE ONLY**

**HRC ACKNOWLEDGEMENT and REPORT TO PRINCIPAL INVESTIGATOR.**

Change Report is accepted as submitted. Summary will appear in the Research Report for this study at the conclusion of this study’s approval period.

Further information required, as follows: PI needs consultation with IRB chair.

Amendment requires full board review

Signature of IRB Representative Date