



# Institutional Review Board Application Form

OSR # \_\_\_\_\_

OFFICE OF SPONSORED RESEARCH  
Loma Linda University • 11188 Anderson Street • Loma Linda, CA 92350  
(909) 558-4531 (voice) / (909) 558-0131 (fax)

**Instructions:** Your application includes a completed printout of this form and the checklist, together with your proposed consent form, protocol, questionnaires, and any appendices that might be helpful to the IRB's consideration. **Failure to properly complete this application will delay final review of your protocol.** Refer to [LLU Guidelines for Protection of Human Subjects in Research](#) for directions in completing this form and submitting your application to the IRB. Note that links to guidance available are in color and are underlined in blue. Links to LLU guidance can only be accessed on-campus.

Ia. Principal Investigator (name, degrees)	Dept./Section	Ext.	E-Mail	<a href="#">HSE</a> Expiration	Status
					Full Time Faculty
Ib. All persons conducting Human Subjects Research (names, degrees)					
Ic. Preferred study contact, if additional to PI:	Ext.	E-Mail	FAX	Building - Room #	
<b>II. TITLE OF PROTOCOL</b>					
<b>III. PROJECT PERIOD:</b> From _____ to _____					
<b>IV. FUNDING SOURCE(S) (response required):</b>					
A. If intramural, what department or fund?					
B. If extramural, what is the name of the sponsor?					
<b>FOR SUPPORTING SIGNATURES SEE SECTION X (ON THE LAST PAGE)</b>					

**V. REQUIRED INFORMATION:**

A. Is this study initiated by:

- Local investigator
- Cooperative group
- External sponsor/manufacture
- Other, specify: \_\_\_\_\_

B. Are investigational drugs , biologics , or devices  used in this study?

No  Yes: FDA IND# \_\_\_\_\_ FDA IDE# \_\_\_\_\_

Check appropriately: Phase I , Phase II , Phase III , Phase IV , [Humanitarian Use Device](#) , Emergency Use , Other, specify: \_\_\_\_\_

- C. Will any Schedule I or II drugs be investigated in this study?  
 No  Yes: This use must be approved by the California State [Research Advisory Panel](#). Indicate whether you  or the sponsor  will obtain this approval.
- D. Is the research project a clinical trial? (Defined as “a research study with clinical intent in human volunteers.”  
*Examples: prevention options, new treatments or new ways to use existing treatments, new screening and diagnostic techniques, and options for improving the quality of life for people with serious medical conditions*)  
 No  Yes
- E. Will resources (including personnel such as nurses, pharmacists, laboratory technologists, radiology technologists, therapists, etc.) from outside the department sponsoring the study be involved in the conduct of this study?  
 No  Yes: Letter(s) of agreement must be attached from the appropriate LLU, LLUMC, BMC, or LLUHC department head.
- F. Are non-Loma Linda University institutions involved (other than a sponsor)?  
 No  
 Yes: Letter of agreement or contract must be attached.
- G. Is this a student project? *The term “student” includes fellows, residents, interns, as well as graduate and undergraduate students, from any department of the University or Medical Center or from another institution.*  
 No  Yes
- H. Will subjects be exposed to any ionizing radiation?  
 No: Radiation Safety Committee (RSC) review not required.  
 Yes: Will participants in this study receive direct medical benefits?  
 No: [RSC](#) review REQUIRED.  
 Yes: Is the proposed use and/or combination of uses of radiation/radioactive materials normally considered to be routine? (*Examples: X-ray, nuclear medicine scan, conventional radiotherapy*)  
 No: [RSC](#) review REQUIRED.  
 Yes: Will subjects participating in the study receive a greater radiation dose than patients undergoing routine treatment for the same medical condition?  
 No: RSC review not required.  
 Yes: [RSC](#) review REQUIRED.
- I. Are [hazardous materials](#) (carcinogens, mutagens, toxic substances, etc.) used in this study?  
 No  Yes: Letter of approval from Hazardous Materials Committee required.
- J. 1. After completing the [Disclosure of Research Conflict of Interest Form](#), did any persons answer “Yes” to any questions in Section II?  
 No  Yes: Please note that scheduling of IRB review will be coordinated with review by the Research Conflict of Interest Committee.
2. Is compensation for key personnel (involved in subject recruitment, the consenting process, or subject retention) linked to the number of subjects who will be recruited to or complete the study?  
 No  Yes, describe:
- J. Is the study being submitted to Public Health Service for sponsorship?  
 No  Yes: PHS policy requires assurance that the composition of the proposed study population benefits all persons at risk of the condition under study. The gender and racial/ethnic composition, together with a rationale for inclusion/exclusion, should be described in the funding proposal and in Section VI-C and D which follows.

**VI. DESCRIPTION OF POPULATION:**

**A.**

Subjects	Number at LLU	Number Study-wide	Age Range
Healthy (normal) subjects			
Patients	*		
<b>Total Number</b>			

\* If any LLUAHSC patients or their data are to be entered in the study, complete the questions in section IX-F.

**B. Classification of subjects (check all that apply)**

Vulnerable populations	Special populations	Other populations
<input type="checkbox"/> Abortuses/Embryos <input type="checkbox"/> Diminished decision-making capacity <input type="checkbox"/> Economically disadvantaged <input type="checkbox"/> Educationally disadvantaged <input type="checkbox"/> Fetuses <input type="checkbox"/> <a href="#">Minors/Children (under 18 years of age – see Special Conditions and Populations)</a> Also see <a href="#">45 CFR 46 Subpart D</a> <input type="checkbox"/> Neonates <input type="checkbox"/> Pregnant women <input type="checkbox"/> Prisoners	<input type="checkbox"/> Elderly/aged <input type="checkbox"/> Illiterate <input type="checkbox"/> Institutionalized <input type="checkbox"/> Patients: <input type="checkbox"/> Inpatients <input type="checkbox"/> Outpatients <input type="checkbox"/> Terminally ill patients <input type="checkbox"/> Traumatized <input type="checkbox"/> Other, specify:	<input type="checkbox"/> Employees <input type="checkbox"/> Female (excludes males) <input type="checkbox"/> Healthy (non-patient) <input type="checkbox"/> Male (excludes females) <input type="checkbox"/> Minorities <input type="checkbox"/> Non-English speaking populations <input type="checkbox"/> Physically handicapped <input type="checkbox"/> Seventh-day Adventist cohort <input type="checkbox"/> Students <input type="checkbox"/> Other, specify:

**C. Criteria for inclusion of subjects:**

**D. Criteria for exclusion of subjects (other than those opposite the inclusion criteria):**

**E. Recruitment plan *Note: In addition to providing details in the protocol, complete the questions below:***

**1. Source of subjects:**

- a.  PI/collaborators will recruit his/her/their own patients/clients/students/employees.
- b.  PI will send an IRB-approved letter to colleagues asking for referrals. *If patients, clinical personnel will make initial contact. If the patient is interested, the patient will contact the PI or (with permission of the patient) the treating physician will invite the PI to talk with the patient about enrollment.*
- c.  PI will send an IRB-approved letter to colleagues asking the physician to send out IRB approved general “Dear Patient” letters describing the research study. *The PI may draft the letter with the treating physician’s signature but may not have access to the patient names or addresses for mailing. If the PI wants the letters to be personalized (Dear Mr. Doe), the personal information would have to be entered by the treating physician.*

**d. Other, specify:**

**2. Will recruitment require use of flyers, posters, hand-outs, or other forms of advertising?**

- No     Yes: Attach copy for IRB review/approval.

**3. Will recruitment require verbal (including telephone) recruitment?**

- No     Yes: Attach script; See [Phone Script Elements](#)

**4. Will recruitment involve electronic (web or e-mail) recruiting?**

- No     Yes: Describe:

F. Describe your plan for obtaining consent (*Note: provide a detailed section in the protocol and complete the questions below*):

1. Who will conduct the consent process, including involvement, if any, of PI (*NOTE: all such personnel must have completed [Human Subjects Education \[HSE\]](#)*):
  - PI
  - Other key personnel (*listed in section I.*)
  - Other (*fill out additional information below*)

Name	Title	<a href="#">HSE Expiration</a>

2. What location will be used for the subject to sign the consent?
3. Relative to the performance of research interventions, is consent obtained  in conjunction with or  at a separate appointment from the performance of research interventions?
4. Are consent documents required (*check all that apply*):
  - [Informed Consent Document\(s\)](#)
  - [Consent/Permission of Parent/Guardian](#)
  - Assent of Minor (13 – 17 yrs old; provide signature with parent on Consent Permission Form)
  - Assent of Minor (7 – 12 yrs old; simplified text)
  - [Authorization for Use of Protected Health Information](#) or [Authorization for Use of Protected Health Information \(for children\)](#) when using patient information for research
5. If a consent waiver is requested, select one of the following and respond to guidance:
  - Waiver of consent ([Waiver request form, Part A](#))
  - Waiver of written consent (*Provide text of verbal consent*)
  - Waiver of signed consent (*Provide text for Information sheet*)
  - Waiver of HIPAA authorization ([Waiver request form, Part B](#))

G. Amount of inducement being offered to the subjects, if any (*include plan for pro-rated payment, if appropriate*):

VII. SUBJECT-RELATED METHODS AND RISKS:

A. What venue (location) will subject-related procedures take place?

\*Complete question 4 OR 5

**B. Check applicable study-related procedures (only items that exceed the standard of care):**

**Usually Minimal Risk**

- Archived data
- Biopsy
- Blood drawing
- Data bank (existing data, not prospective)  
Date range: From \_\_\_\_\_ to \_\_\_\_\_
- Data collection by non-invasive means (prospective)
- Diet alteration
- ECG
- Electrical stimulation
- Fetal tissue
- Focus groups
- Interviews
- Materials (data, documents, records, or specimens) to be collected solely for nonresearch purposes
- Medical records (existing data):  
Date range: From \_\_\_\_\_ to \_\_\_\_\_
- Observation
- Physical exercise or activity
- Physical manipulation
- Randomization
- Specimens - anonymous
- Specimens – discard
- Specimens – prospective collection by non-invasive means
- Surgical or autopsy tissue
- Survey/questionnaire
- Test, pen/pencil/computerized
- Tissue bank (existing, not prospective)
- Treatment
- Underwater weighing
- Urine or fecal sample
- Voice, video, digital, or image recordings
- Other (describe): \_\_\_\_\_

**Potentially Greater than Minimal Risk\***

- Device - approved
- Device - approved, but non-approved use
- [Device - Investigational](#)
- Drug – FDA-approved
- Drug – FDA-approved, but non-approved use
- Drug – experimental
- [Humanitarian Use Device](#)
- Invasive procedures (possibly involving general anesthesia or sedation)
- Placebo(s)
- Proton beam
- Questions relating to disclosure of legal vulnerability (illegal activities such as illicit drug use), sexual activity and preference, and domestic violence and/or questions resulting in risks of psychological, physical, legal, social, and economic harm
- [Radiation](#)
- Radioisotopes
- Randomization
- Treatment (investigational/experimental)
- Other (describe): \_\_\_\_\_

\*Each study greater than minimal risk MUST have a detailed description of the data safety monitoring plan in the protocol.

**C. For more information on the categories of Administrative and Full Board review, see:**

[Expedited Reviewer's Checklist](#)

[Exempt Reviewer's Checklist](#)

Administrative Initial Review SOP

[Initial Full Board Review SOP](#)

<http://www.hhs.gov/ohrp/humansubjects/guidance/expedited98.htm>

<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm> [46.101(b) for exempt]

<http://www.hhs.gov/ohrp/humansubjects/guidance/decisioncharts.htm>

**D. List the risks that might result from study-related procedures. When the subjects are patients, clearly identify the risks that would be in addition to routine therapy. Do NOT say "None": consider breach of confidentiality or privacy as a risk for all study participants.**

**E. Estimate the magnitude of risks the subject assumes by entering this study:**

- Minimal risk
- Greater than minimal risk, but holds prospect of direct benefit to subjects\*
- Greater than minimal risk, no prospect of direct benefit to subjects, but likely to yield generalizable knowledge about the subjects' disorder or condition\*
- Moderate risk\*
- High risk\*

\*Each study greater than minimal risk MUST have a detailed description of the data safety monitoring plan in the protocol.

**F. State plan for preventing or minimizing these risks.**

**VIII. BENEFIT:**

**A. State the expected benefits to the subjects. (It is acceptable for subjects not to benefit individually in some studies.)**

B. State the expected benefits to humanity.

**IX. CONFIDENTIALITY AND DATA SECURITY:**

Research data is considered proprietary and confidential. LLU/LLUMC requires that appropriate safeguards be in place for the protection of data.

A. Electronic data -- collection & storage. Will you collect and store research data (either with identifiers or without) electronically?

No. Research data will not be collected or stored electronically (i.e., via desktop computer, laptop, PDA, USB flash drive, or other computing device).

OR

Yes. Research data will be collected and stored electronically. All the following required protections must be in place. Confirm each:

Password protection.

Data saved only to a secure storage location i.e., a LLU/LLUMC secured server or network. *Note: Saving to the c: or local drive is not secure.*

If a portable device is used (e.g., laptop, PDA), data will be saved only if (1) the device is encrypted, (2) the storage is temporary, and (3) the portable device is in a physically secure location. *Note: Leaving a portable device in any unattended vehicle is not secure.*

Devices and removable media no longer needed used at one point to collect/capture, or store PHI will be forwarded to IS for proper destruction.

If unable to secure the data as indicated above, briefly summarize the reason:

*For guidance on creating a strong password and assistance with secure storage locations and proper encryption methods, contact the IS Help Desk. LLU (x48611), LLUMC (x48889).*

B. Electronic data -- transmittal & transport. Will you transmit or transport electronic research data?

No. Electronic research data will not be transmitted via Internet, email, or fax system applications, and will not be transported (i.e., the carrying of a USB flashdrive, disk, CD, or removable hard drive that contains research data).

OR

Yes; Electronic research data will be transmitted and/or transported. Check proposed method and add the corresponding security measure to your IRB protocol:

Email. *LLU/LLUMC email system will be used only (for on/off site use). \*\**

Web interface. *Only as required/provided by the research sponsor or a contracted entity, and the research sponsor or contracted entity assumes full responsibility for the security of the data collected and maintained in its systems. Note: A secure web page will have https in the address line.*

Fax (through system application). *The system application must be an IS approved application.*

Portable device and/or Removable media e.g., laptop, disk, CD, back up device. *Data must be encrypted using IS approved methodology. Device or medium must not be unattended during transport and must be maintained in a physically secure area (e.g., locked file, cabinet.)*

Other, specify:

**\*\* Transmittal of unencrypted patient data via email sent outside of LLU/LLUMC's Outlook System is prohibited. Instant Messaging is prohibited under any condition.**

C. Hardcopy data -- storage. Will you store research data (either with identifiers or without) in hard copy format?

No. Research data will not be stored in hard copy format.

OR

Yes; Research data will be stored in hard copy format. Check all security measures that will be taken and describe the details in your IRB protocol:

N/A

Locked suite

Locked office

Locked file cabinet

Data coded by PI or research team with a master list secured and kept separately

Data de-identified by PI or research team

Other, specify:

D. Hardcopy data -- transmittal & transport. Will any hard copy research data be transmitted (e.g., via fax) or transported?

No. Hard copy research data will not be transmitted or transported.

OR

Yes; Hard copy research data will be transmitted and/or transported. Check proposed method and describe in your IRB protocol.

Fax. *Cover sheet with confidentiality statement*

- Courier. *Data in sealed envelope marked confidential*
- Hand-delivery. *Data in sealed envelope marked confidential*
- U.S. Mail.
- Express Mail service (e.g., FedEx, DHL).
- Vehicle. *Data must not be left in vehicle unattended*
- Hardcopy data no longer needed will be shredded or placed in a designated blue bin for shredding.
- Other, specify:

E. For “healthy” subjects, will the investigator(s) be able to identify the subjects by appearance, name, or data? (Do NOT say “No” if viewing identifiable records, interviewing subjects, etc., even if no identifiers are recorded.)

- No     Yes: Please state what steps will be taken to create anonymity or insure confidentiality:

F. For “patients,” complete the following sections:

1. Protected Health Information (PHI) Sharing (Before answering, please review the [19 identifiers](#) outlined by the HIPAA regulations.):

Will PHI be shared with individuals outside LLUAHSC [the OHCA (Organized Health Care Arrangement)] during the course of the research study?

- No, no PHI will be shared outside LLUAHSC(OHCA) during the course of the research study

OR

- Yes; PHI will be shared with: (*check all that apply*)

- |   |   |
|---|---|
| <input type="checkbox"/> Statistician                   | <input type="checkbox"/> Consultant(s) or Contractor(s)**   |
| <input type="checkbox"/> Other Research Laboratory(ies) | <input type="checkbox"/> Data, Tissue, Specimen Registry(s) |
| <input type="checkbox"/> Publication(s)*                | <input type="checkbox"/> Coordinating Center                |
| <input type="checkbox"/> Data Monitoring Committee(s)   | <input type="checkbox"/> Subjects***                        |
| <input type="checkbox"/> Sponsor(s)                     | <input type="checkbox"/> Other                              |

2. The following steps are required. Please confirm each.

- Sharing of PHI (i.e., data with subject identifiers) requires Authorization or Waiver of Authorization.
- For publication purposes, Authorization must be obtained.\*
- If utilizing a Consultant and/or Contractor to assist with research, consult section “X” of the Researcher’s *Guide to HIPAA* to determine if a Business Associate Agreement is required.\*\*
- If using a consent document, the level of participant access to the study data must be discussed in the consent form even if no access is granted.\*\*\*
- Disclosures will be tracked according to section “XV” of the *Researcher’s Guide to HIPAA* when Waiver of Authorization has been obtained and/or information has been shared with an individual/entity outside LLUAHSC/OHCA.

3. How will PHI be shared?

- With a linked code. *Requires a [Code Access Agreement-Outgoing](#)*
- As a [Limited Data Set](#). *Requires a [Data Use Agreement](#)*

4. Patient Billing for Study Procedures:

a. **For all studies involving patients as subjects:** List all exams, procedures, tests, devices, drugs and other items that will be conducted for research purposes (e.g.: CBC, MRI, lumbar puncture, ECG, pacemaker, atenolol). Include drugs and devices used for study purposes, whether or not they are investigational. Identify who will be financially responsible for these items. *Prior to the initiation of any charges, appropriate arrangements must be made with Associate Director of FPBO (ext. 33161) and/or Director of PBO (ext. 44456).*

Itemize study exams, procedures, tests, devices, drugs, etc.	No. exceeding standard care	Who will be financially responsible, e.g., patient, insurance, other (explain)?	Addressed in the consent?

If more space is needed, this format can be recreated in a simple spread sheet and attached to the IRB application.

b. Identify person to whom bills for study related charges should be sent:

Name                      Ext                      Mailing address

Note: All LLUMC under- or non-reimbursed tests/procedures must be approved by the LLUMC Vice President for Medical Affairs.

**X. SUPPORTING SIGNATURES:**

**A. DECLARATION BY 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:

- A. Performing the project according to the IRB-approved protocol.
- B. Assuring that all personnel working on the project are qualified personnel who have received training in human subject protections.
- C. 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).
- D. 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).
- E. 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.
- F. 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 or guest investigator, I further certify that:

- A. The student or guest investigator 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.
- B. This project has been reviewed and approved by the thesis/dissertation committee.
- C. 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.
- D. 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.

Signed: \_\_\_\_\_  
Principal Investigator Date

**B. DECLARATION BY STUDENT INVESTIGATOR(S):**

I accept my responsibilities in complying with Loma Linda University policies and procedures for protection of human subjects in research and supporting the responsibility of my faculty sponsor, described above.

Signed: \_\_\_\_\_

**C. SIGNATURE OF DEPARTMENT CHAIR:**

This project has been reviewed for scientific merit and has the academic endorsement of the department.

Signed: \_\_\_\_\_  
Department Chair Date

Printed Name: \_\_\_\_\_