

**HUMAN RESEARCH PROTECTION PROGRAM (HRPP)
QUALITY ASSURANCE & IMPROVEMENT**

REPORTING FORM FOR RESEARCH CONCERNS OR GRIEVANCES

Instructions for submitting this form:

Please complete this form to the best of your ability, and submit in one of the following ways:

- Email to Loma Linda University Medical Center Patient Relations at patientrelations@llu.edu
- Fax to (909) 558-0312
- Mail in the self-addressed, postage-paid envelope, or in your own envelope to the following address: Attn: Patient Relations, Room 1120
Loma Linda University Medical Center
P.O. Box 2000
Loma Linda, CA 92354
- If you would prefer to speak to someone in person, you may call (909) 558-4647

Please note: All research concerns and complaints are taken very seriously. The information you provide on this form will be kept as confidential as possible. However, we may need to share this information with others in order to follow-up with your concern or complaint. **Your report will not affect any rights to which you are otherwise entitled, including your ability to receive current or future medical care at this institution.**

| A. General Information | |
|---|-----------------|
| Name (optional): | Date of Report: |
| May we reveal your identity to the study's principal investigator and staff while following up on this report? <input type="checkbox"/> Yes <input type="checkbox"/> No | |

| B. Personal Contact Information (required if you wish to receive follow-up information regarding your complaint) | |
|---|----------------|
| Phone: | Email Address: |
| Mailing Address: | |
| Other Contact Information: | |
| Except as required by law, your personal contact information will not be released to anyone outside the HRPP, unless you authorize us to do so. | |

| C. Study Information (Please complete as much information as possible) |
|--|
| 1. Study Name or Description: |
| 2. Name of Study Investigator(s): |

| |
|---|
| <p>3. Are you or were you a participant in this study?</p> <p><input type="checkbox"/> Yes (proceed to #4)</p> <p><input type="checkbox"/> No, I am reporting on behalf of someone else. Please describe: _____ (proceed to #6)</p> |
| <p>4. When did you start participating in the study?</p> |
| <p>5. Are you still participating in the study? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> |
| <p>6. Please provide us with details regarding your concern/complaint:</p> |
| <p>7. Have you discussed this concern or complaint with the Principal Investigator or any other member of the study staff? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If yes, please provide us with the name(s) of with whom you spoke and any response you received (if you have not already provided this information above):</p> |
| <p>8. Please provide us with an explanation of how you would like to see this problem resolved:</p> |
| <p>9. Do you have a consent form for this study? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If yes, please provide the expiration date (located on page 1 of consent form) _____, and the 5-digit number in the stamp at the bottom of the consent form _____.</p> |
| <p>10. Do you have any other written information for this study? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If yes, please provide the name or a short description for each type of written material you received, along with any expiration dates that may be associated with each document:</p> |
| <p>11. Please provide any additional information you feel is necessary in the space below:</p> |

For Use by Patient Relations & Research Integrity Only

Institutional Case #: _____ Research Integrity Case #: _____

Date Received: _____ Received by: _____

Referred to: _____ Date of Referral: _____

Protocol #: _____ Principal Investigator(s): _____

Title of Study: _____ Date of IRB Approval: _____

PI / Dept Contact Information: _____