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|  | **IRB #** |

**Institutional Review Board**

**Application for Research Involving**

**Anonymous Surveys**

*HUMAN RESEARCH & COMPLIANCE*

LOMA LINDA UNIVERSITY HEALTH | Office of the Vice President of Research Affairs

 24951 Circle Drive, Loma Linda, CA 92350

*(909) 558-4531 / email: IRB@llu.edu*

**REMINDER:** **If your study involves ANY research procedures other than administering an anonymous survey, you must complete the “Minimal Risk” IRB application or other relevant IRB application. Submit application, study protocol and survey to IRB@llu.edu**

**I. STUDY PERSONNEL (ALL study personnel must have all human subject education and conflict of interest training complete and SFI disclosures submitted prior to submission to the IRB or your submission will be rejected; For questions please contact irb@llu.edu)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **A. Principal Investigator** **(name, degrees)** | **Dept./Section** | **Ext.** | E-Mail | **Role (Principal Investigator must hold a faculty appt)** |
|  |  |  |  |  |
| **B. All other study staff personnel** |  |
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|  |  |  |  |  |
| **C. Preferred study contact, if additional to PI**      | **Ext.**      | **E-Mail**      | **FAX**      | **Building - Room #**      |
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**II. STUDY INFORMATION**

**A. TITLE OF PROTOCOL:**

**B. PROJECT START DATE:**

**C. FUNDING SOURCE(S) (response required)**

**1. If intramural, what department or fund?**

**2. If extramural, what is the name of the sponsor?**

# II. STUDY SUMMARY

# Research question or hypothesis:

# Rationale for the proposed study, with key citations from the literature, if applicable:

**III. STUDY RISKS V. BENEFITS**

1. **Does the survey contain questions relating to any of the following (check all that apply):**

**[ ]  Mental health**

**[ ]  Substance abuse**

**[ ]  Outpatient psychotherapy**

**[ ]  Suicide or self-destructive behavior**

**[ ]  Private health information**

**If any of the above are checked, describe how you will assure that any potential risk (emotional, legal, social, etc.) is minimized, including provision to opt out, skip questions, referrals for assistance or treatment, etc.**

**B. State the expected benefits to the subjects. None [ ]  Or, if any, describe**

**C. State the expected benefits to society (e.g. your profession, your field of study, future patients or populations.)**

**IV. DESCRIPTION OF SUBJECTS**

**A.**

|  |  |
| --- | --- |
| **Type of Subject(s)** | **# Subjects required** |
| **[ ]  Employees** | **­­** |
| **[ ]  Healthy subjects** | **­­** |
| **[ ]  Students** | **­­** |
| **[ ]  Patients** | **­­** |
| **[ ]  Prisoners** | **­­** |
| **[ ]  Other- specify: ­­­­     ­­**  | **­­** |

 **TOTAL      ­­**

1. **Statistical Justification – How was this number derived/calculated:**
2. **Criteria for inclusion of subjects:**

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

**V. SOURCE OF CONTACT INFORMATION FOR PROSPECTIVE PARTICIPANTS**

1. **How will survey be distributed?**

 **[ ]  In person by investigator**

 **[ ]  In person by individual on behalf of investigator; describe:**

 **[ ]  By mail with cover letter**

 **[ ]  By email using electronic survey software, i.e., Qualtrics, Survey Monkey**

 **[ ]  Posted on website or similar social media; describe:**

 **[ ]  Other - specify:**

1. **Will a distribution list be obtained or created? No, none required [ ] ; If yes, choose from list below:**

 **[ ]  LLUH entity (e.g. LLU/LLUMC) – data to be obtained from investigators’ patients, students, employees**

 **[ ]  LLUH department (for any department not represented by an investigator listed in section I above.)**

**Department name:**

#####  [ ]  Non-LLUH entity - specify:

##### [ ]  Prior research list of participants or research database – IRB #\_\_\_\_\_\_\_\_\_\_\_\_\_;

##### [ ]  Other - specify:

**VI. PROTECTION OF CONFIDENTIALITY/ANONYMITY**

1. **Will the investigator be able to identify the subjects by name or other identifiable information at any time? No [ ] Yes. Describe:**
2. **What is format of contact information?**

**[ ]  Email addresses**

**[ ]  Mailing list**

**[ ]  Personal encounter by investigator**

**[ ]  Representative of investigator makes personal encounter**

**[ ]  Other; describe:**

1. **Special conditions: If results from more than one survey for a given subject must be linked or if survey must be linked to other data, describe how this will be done while maintaining anonymity:**
2. **Will participants be given an incentive?**

**[ ]  None.**

**[ ]  Gift; describe, including value of item:**

**[ ]  Financial; amount**

**[ ]  Cash**

 **[ ]  Check**

 **[ ]  Gift card; describe**

1. **How will incentives be distributed without associating contact information and survey responses?**
2. **Does survey include any questions regarding individual’s health**? **No [ ] ; Yes. Describe:**

**VII. CONSENT (Anonymous survey research does not require documentation of signed consent; nonetheless some form of consent-type communication with subjects is an ethical way to enhance effective participation. Choose one:**

 **[ ]  Verbal? Attach text of verbal script as Appendix.**

 **[ ]  Cover letter on departmental stationery. Attach draft of letter.**

 **[ ]  Cover information to be inserted as preface to electronic survey. Attach draft of text.**

**[ ]  Parental permission, for children; describe in detail how parental permission will be obtained, assent from child; independent voluntary assent of child, privacy, etc.**

# VIII. 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 Health 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 as described in this Application.

B. Assuring that all personnel working on the project are qualified personnel who have received training in human subject protections.

C. 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).

**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

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

I accept my responsibilities in complying with Loma Linda University Health 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 REPRESENTATIVES:**

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

Division Chief (optional, if applicable):

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

 Date

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

Department Chair or Designee (required):

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

 Date

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