



Simpson University Institutional Review Board Status Report

INSTRUCTIONS

Please fill out this form on your computer (independent of your web browser). You must download and save it to your computer before filling it out and saving your edits, prior to submitting it via email to the IRB.

PERSONAL INFO

Date (mm/dd/yy)

IRB Title

IRB Approval Exp. Date

Principal Investigator

PI Signature

Email

School / Dept.

Faculty Sponsor

Faculty Sponsor Signature

PROJECT STATUS

A. RESEARCH ACTIVITY STATUS

1. RENEW IRB application because:
- New subject enrollment still in progress
 - Enrollment closed but subjects are still providing data
 - Enrollment not yet begun
 - Other, explain:

**2. CLOSE IRB application
because:**

**Enrollment closed, research completed, & data
analysis described in initial application completed**

Research never begun

Other, explain:

B. SUBJECT NUMBERS

**No. of Subjects Approved
to complete the research**

**No. of Subjects Enrolled
since initial IRB Approval**

**No. of Subjects Enrolled
since last IRB Approval**

**No. of Subjects actively
involved in research
projects**

**No. of Additional Subjects
needed to complete
research**

C. SUMMARY

**Provide a summary of the
research progress to date.
If you have not yet enrolled
subjects, please explain
why.**

D. ADVERSE EVENTS AND OTHER PROBLEMS:

Provide this information about adverse events and/or other issues surrounding non-compliance for the approval period since your last status report by answering the questions below. If there were no adverse events or other problems, check "None" :

None

1. Number of adverse events related to research procedures that were serious and unexpected :

Explain

2. Number of adverse events related to research procedures that were expected, but were more severe or occurred at a greater frequency than expected :

Explain:

3. List the adverse events that were related, non-serious, but unexpected below. Please list the a) Event/Type (i.e. NAUSEA) b) Number of Events, and c) Number of Subjects Affected:

Event 1

of Occurrences (E1)

of Subjects Affected (E1)

Event 2

of Occurrences (E2)

of Subjects Affected (E2)

Event 3

of Occurrences (E3)

of Subjects Affected (E3)

4. Does the occurrence of any of the adverse events listed above suggest that the risk(s) to subjects are greater than described in your initial IRB application?

Yes

No

Not applicable

If yes, provide an explanation:

5. Number of other problems (*unanticipated problems, protocol violations, protocol deviations*)

Yes

No

Not applicable

If yes, provide an explanation:

6. Number of complaints:

**Describe each complaint,
and explain how you
handled each one.**

**7. Number of subject
withdrawals:**

For each withdrawal, explain:

- **Why the subject chose to withdraw, or**
- **Why you withdrew the subject from the research, and/or**
- **How the withdrawal affects your subject enrollment numbers for the past year as well as your overall enrollment totals.**

For IRB Office Use Only

Date Received:

Approved

Conditional Approval

Denied

Withdrawn

IRB Chair Signature:

Date:

Submit the application to the IRB Chair for review:

- One electronic copy of the application via email to the IRB Chair (irb@simpsonu.edu)
- One hard copy of the application with any additional documentation

(such as the consent forms, questionnaires, recruitment advertisements, debriefing forms, etc.)

Mail to:

Simpson University - IRB c/o Dr. Danielle Beck
2211 College View Drive, Redding, CA 96003