



# ROSEMAN UNIVERSITY

O F F I C E O F R E S E A R C H

## Clinical Trial Risk Assessment

### Initial Submission Questionnaire

**This questionnaire is required to complete an initial risk assessment review for your clinical trial. Please complete each question and attach any documents required as noted.**

1. Trial name: \_\_\_\_\_

2. Principal investigator name: \_\_\_\_\_

3. Investigator type: \_\_\_\_\_ Internal \_\_\_\_\_ Affiliated \_\_\_\_\_ External

Definitions:

Internal Investigator- Roseman employee

Affiliated Investigator- Non-Roseman employee with signed affiliation agreement

External Investigator - Non-Roseman employee

4. IRB that will be reviewing the study protocol: \_\_\_\_\_ Roseman's IRB \_\_\_\_\_ External IRB

If external, name of IRB: \_\_\_\_\_

Is a Master Agreement in place to cover the proposed study? \_\_\_\_\_ Yes \_\_\_\_\_ No

5. Does the trial have a sponsor? \_\_\_\_\_ Yes \_\_\_\_\_ No

If yes, sponsor name: \_\_\_\_\_

Has a contract been proposed or executed? \_\_\_\_\_ Yes \_\_\_\_\_ No

*If yes, please provide a copy of the executed document and an outline of the process and parties utilized in review and approval of the contract.*

Parties to the contract: \_\_\_\_\_

6. Are Roseman faculty, staff, or students involved in any way with performing the study? \_\_\_\_\_ Yes \_\_\_\_\_ No

*If yes, please provide the number of individuals and a detailed description of their individual responsibilities associated with study activities.*

7. Location where study will be conducted?

Campus \_\_\_\_\_ Building \_\_\_\_\_ Other \_\_\_\_\_

8. Has a lease or operating agreement been proposed or executed for use of Roseman facilities? \_\_\_\_\_ Yes \_\_\_\_\_ No

*If yes, please provide a copy of the executed document and an outline of the process and parties utilized in review and approval of the agreement.*