



IRB Case Number:
Request Date:

REQUEST TO REVIEW A PROPOSED HUMAN SUBJECTS USE IRB Protocol Form

Please respond to all questions. Use extra paper as necessary.

1. Principal Investigator: Division:

- Person completing form (if different): Division:

2. Study Funding Agency
 - a. Federal Agency:
 - b. Public Health Service:
 - c. Foundation or industry:
 - d. Department or personal funds:
 - e. Please state deadline for Human Subjects Committee review

3. Anticipated beginning and completion dates of studies described in this protocol.

4. Project title:

5. If any other organization is to be involved with Cañada in this research, please identify:
 - a. Name of organization:
 - b. Relation to Cañada (*i.e.*, subcontractor, collaborator):
 - c. Specify if Cañada is the Prime for this research:

6. State the known risks to subjects and whether those risks are **minimal** or **greater than minimal**.
Minimal risk is defined as: A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. For example, the risk of drawing a small amount of blood from a healthy individual for research purposes is no greater than the risk of doing so as part of routine physical examination.

7. State the nature of the research, its purpose and objectives, and the anticipated results
8. In lay terms - provide a description of the activity where human subjects will be involved and the procedures for data collection that will be employed.
9. Subjects:
 - a. Number of persons to be recruited for participation in the study:
 - b. Describe the population to be recruited and rationale for their participation (Include age range, gender and ethnicity):
 - c. Vulnerable populations to be recruited (e.g. children, pregnant women, prisoners or cognitively impaired subjects):
 - d. Inclusion and exclusion criteria for study participation:
 - e. Compensation or other inducement*:

* Please see <http://answers.hhs.gov/ohrp/questions/7251> for guidelines regarding compensation and undue influence.

Describe the potential risks that participants could encounter through participation in the project (physical, sociological, financial, economic, privacy, etc) and the steps you will take to minimize these risks and/or minimize their impact. Include steps to minimize risks to the confidentiality of identifiable information.

10. If subjects are to be deceived, describe the circumstances, explain why deception is necessary, and state how the deception will subsequently be cleared up.

11. Describe:
 - a. the procedures you will use to respect and protect the research participant's privacy (physically, behaviorally, or intellectually) during the data collection process (e.g., during the interview the participant will meet with the researcher in a location away from his/her place of employment).
 - b. provisions for monitoring participant safety concerns or identification of or support for distressed participants to ensure their safety (e.g., discovery of suicidal disclosures will prompt disclosure to a physician)

Describe the plan for reporting unanticipated problems involving risks to participants or others and how that information will be managed.

Describe the procedures that will be followed to ensure that the information obtained about the participants will be stored in a secure manner.

Describe the plans for retention and/or destruction of linkages between study data and personal identifying information.

Explain, if applicable, why personally identifying information will not be kept confidential and how you will ensure that subjects are consenting to your sharing this information.

12. Attach consent form

13. CERTIFICATION BY PRINCIPAL INVESTIGATOR

I affirm to the best of my knowledge, information provided in this form is complete and accurate, and that no material changes will be made without advance approval of the IRB Committee. I agree to abide by Cañada policies and procedures. I acknowledge responsibility for the work described here.

Signature of Principal Investigator

Date

Signature of Division Dean

Date