SAN JUAN DE DIOS EDUCATIONAL FOUNDATION, INC.
INSTITUTIONAL REVIEW BOARD

PROTOCOL ASSESSMENT FORM (SJDEFIIRB FORM 2.3)

PROTOCOL NUMBER:	**IRB REFERENCE NUMBER:**
PROTOCOL TITLE:	
PRINCIPAL INVESTIGATOR:	

To the Principal Investigator: *Please indicate the page number of the relevant items in this section applicable to your protocol.*	***To the Reviewer:*** *Please assess the appropriateness of the contents of the various sections, as outlined in this assessment form, and propose revisions as deemed necessary. You may put your comments in the space provided, or alternatively, an electronic version of this form is available upon request, to facilitate encoding of comments*.

A. The protocol contains the following:	**Pages**	**YES**	**NO**	**NA**	**Comments**
1. Background of Study		[ ]	[ ]	[ ]	
2. Significance of Study		[ ]	[ ]	[ ]	
3. Rationale of Study		[ ]	[ ]	[ ]	
4. Literature Review		[ ]	[ ]	[ ]	
a. Results of animal/human studies		[ ]	[ ]	[ ]	
b. Known risks of procedures		[ ]	[ ]	[ ]	
c. Known benefits of procedures		[ ]	[ ]	[ ]	
d. Known adverse effects of drugs/procedures		[ ]	[ ]	[ ]	
5. Objectives of Study		[ ]	[ ]	[ ]	
a. Primary objective		[ ]	[ ]	[ ]	
b. Secondary objectives		[ ]	[ ]	[ ]	
6. Statement of risks of the project		[ ]	[ ]	[ ]	
a. To study participants		[ ]	[ ]	[ ]	
b. To community		[ ]	[ ]	[ ]	
7. Possible adverse events (AE)		[ ]	[ ]	[ ]	
8. Statement of benefits of the project		[ ]	[ ]	[ ]	
a. To study participants		[ ]	[ ]	[ ]	
b. To community		[ ]	[ ]	[ ]	
9. Recruitment of participants		[ ]	[ ]	[ ]	
a. Recruitment of procedures		[ ]	[ ]	[ ]	
b. Inclusion/Exclusion Criteria		[ ]	[ ]	[ ]	
10. Methods		[ ]	[ ]	[ ]	
a. Type of study design		[ ]	[ ]	[ ]	
b. Setting for project		[ ]	[ ]	[ ]	
c. Duration of project		[ ]	[ ]	[ ]	
d. Procedures to be done		[ ]	[ ]	[ ]	
e. Statistical Treatment					

	Pages	Yes	No	NA	Comments
11. Informed Consent		[ ]	[ ]	[ ]	
12. Total Site Budget		[ ]	[ ]	[ ]	
13. Curriculum Vitae of Investigators					
a. Complete name, titles, institutional affiliations of Principal Investigator, training certificates, qualifications		[ ]	[ ]	[ ]	
b. Names of co-workers		[ ]	[ ]	[ ]	
c. Job description of co-workers		[ ]	[ ]	[ ]	
d. Responsibilities of each co-worker		[ ]	[ ]	[ ]	
e. Contract with sponsor		[ ]	[ ]	[ ]	
14. Project Sponsors					
a. Complete Name		[ ]	[ ]	[ ]	
b. Address		[ ]	[ ]	[ ]	
c. Name of contact person/s		[ ]	[ ]	[ ]	
d. Telephone number of contact person/s		[ ]	[ ]	[ ]	
e. Statement of sponsor's interest/co-authorship		[ ]	[ ]	[ ]	
15. Ethical Considerations					
15.1 Conflict of Interest Full disclosure of potential sources of conflict of interest involving any of the authors or the granting agency		[ ]	[ ]	[ ]	
15.2 Privacy and Confidentiality of Health Information					
a. Full disclosure of publication rights		[ ]	[ ]	[ ]	
b. Amount and method of reimbursement of trial related expenses of the study participants		[ ]	[ ]	[ ]	
c. Handling of data obtained from subject/participants, including data security, archiving and disposal		[ ]	[ ]	[ ]	
d. A plan and timeline for the sharing of information, including the details, with participants, publications and conferences		[ ]	[ ]	[ ]	
15.3 Vulnerable subjects involved in the study					
a. A description of who may solicit consent, how, where and when it will be done		[ ]	[ ]	[ ]	
b. A description of who may give consent (involving minors and not legally competent to give consent)		[ ]	[ ]	[ ]	
c. Discussion of unfamiliar procedures, including information on trial drug, randomization, blinding, placebo, rescue medicines		[ ]	[ ]	[ ]	
d. Appropriate mechanisms in place to		[ ]	[ ]	[ ]	

	Pages	Yes	No	NA	Comments
protect the vulnerable potential participants.					
e. Informed consent procedure/form adequate and culturally appropriate		[ ]	[ ]	[ ]	
15.4 Risks					
a. Probable risks to the human participants are identified		[ ]	[ ]	[ ]	
b. Information on the trial drug, explanation of testing the drug, reason for its development, known side-effects/toxicity and adverse effect					
c. Provision for management of adverse reactions		[ ]	[ ]	[ ]	
d. Interim analysis and provisional or mandatory cessation guidelines in case harmful effects are demonstrated during the study		[ ]	[ ]	[ ]	
e. Non-material compensation to participant such as health education or other creative benefits, where no clear, direct benefit from the project will be received by the participant		[ ]	[ ]	[ ]	
f. Adequately address the risk/benefit balance		[ ]	[ ]	[ ]	
g. Adequate toxicological and/or pharmacological data		[ ]	[ ]	[ ]	
h. Guarantee of medical care/ indemnification of study participants in case of trial-related injuries, which shall not be subject to previous waiver		[ ]	[ ]	[ ]	
i. Proponent/s and staff involve adequately trained and have sufficient experience		[ ]	[ ]	[ ]	
j. Level of risk					
i. Low		[ ]	[ ]	[ ]	
ii. Medium		[ ]	[ ]	[ ]	
iii. High		[ ]	[ ]	[ ]	

Please use this space for additional explanation/comments like use of contraception in SJDEFI which is a Catholic institution, other socially-sensitive issues, and funding sources (should not be tobacco industry-related)

B. COMMENTS:

❑ Approval

❑ Modifications required prior to approval

❑ Minor Modifications

_____
_____
_____

❑ Major Modifications

_____
_____
_____
_____
_____

❑ Disapproval
Reason/s for disapproval:

_____
_____
_____

_____ _____
Signature above printed name Date

C. FINAL ACTION:

❑ APPROVED

❑ DISAPPROVED

_____ _____
Signature above printed name Date