



SJD Institutional Review Board

Title: Protocol Assessment Form

Code: SJDIRB Form 5.2

Version: 07

PROTOCOL ASSESSMENT FORM

PROTOCOL NUMBER:		IRB REFERENCE NUMBER:			
PROTOCOL TITLE:					
PRINCIPAL INVESTIGATOR:					
<p><i>To the Principal Investigator: Please indicate the page number of the relevant items in this section applicable to your protocol.</i></p>			<p><i>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.</i></p>		
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					
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)					
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. Outcomes of the Study					
f. Data Analysis Plan					



	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. Name of co-workers					
c. Job Description of co-workers					
d. Responsibilities of each co-workers					
e. Contract with sponsors					
14. Project Sponsors					
a. Complete name					
b. Address					
c. Name of Contact person/s					
d. Telephone/Mobile Number of contact person/s					
e. Statement of sponsor's interest/co-authorship					
15. Ethical Considerations					
a. Conflict of interest – Full disclosure of potential sources of conflict of interest involving any of the authors or granting agency					
b. Recruitment Procedures					
c. Privacy and confidentiality of health information					
i. Handling of data obtained from subject/participants, including data security, archiving and disposal					
d. Vulnerable subjects involved in the study					
i. Are participants vulnerable?					
ii. Appropriate mechanisms in place to protect the vulnerable potential participants					
e. Benefits					
i. Benefits that may derived from the study					
ii. Discussion on how benefits are maximized					
f. Risks					
i. Risk mitigation measures					
ii. Level of Risk					
1. Low					
2. Medium					
3. 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:

Approved

Modifications required prior to approval

Minor Modifications

- 1. _____
- 0 _____
- 0 _____
- 0 _____
- 0 _____

Major Modifications

- 1. _____
- 0 _____
- 0 _____
- 0 _____
- 0 _____

Disapproved

Reasons for Disapproval

- 1. _____
- 0 _____
- 0 _____
- 0 _____
- 0 _____

Signature over Printed Name

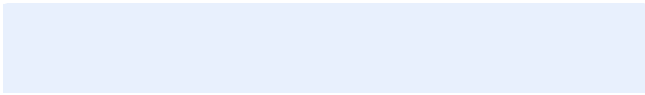
Date



C. Final Action:

Approved

Disapproved



Signature over Printed Name

Date