



SJD Institutional Review Board

Title: Protocol Assessment

Code: SJDIRB Form 3.2

Version: 09

SJDIRB Reference Code		Date of Submission		DD Month YYYY		
Protocol Code		SJREB Code				
Protocol Title						
Name/s		Profession/ Specialty/ Subspecialty				
Principal Investigator/s						
Primary Reviewer						
ICF Reviewer						
Independent Consultant						
Type of Review		<input type="radio"/> Expedited <input type="radio"/> Full Board				
<i>To the Principal Investigator: Please indicate the page number of the relevant items in this section applicable to your protocol.</i>		<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>				
A. The protocol contains the following:		Pages	Yes	No	N/A	Remarks
1. Background of the 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 objectives						
b. Secondary objectives						
6. Statement of Risks of the Project						
a. To study participants						
b. To community						
7. Possible Adverse Events (AE)						
8. Recruitment of Participants						
a. Recruitment procedures						
b. Inclusion/Exclusion criteria						
9. 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						
10. Informed Consent						
11. Total Site Budget						
12. Curriculum Vitae of Investigators						
a. Complete name, titles, institutional affiliation, training certificates, qualifications						
b. Name of Co-investigators						
c. Job Description of Co-Investigator/s						



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d. Responsibilities of each members					
e. Contract with sponsors					
13. Project Sponsors					
a. Complete name					
b. Address					
c. Name of contact person/s					
d. Telephone/Mobile no. of contact person/s					
e. Statement of sponsor/s interest/co-authorship					
14. Conflict of Interest (Full disclosure of potential sources of conflict of interest involving any of the authors or granting agency)					
15. Recruitment Procedures					
16. Privacy and Confidentiality of Health Information					
a. Handling of data obtained from subject/participants,					
b. Data security					
c. Archiving					
d. Disposal					
17. Vulnerable subjects involved in the study					
a. Are participants vulnerable					
b. Appropriate mechanisms in place to protect the vulnerable potential participants					
18. Benefits					
a. Benefits that may derived from the study					
b. Discussion on how benefits are maximized					
19. Risk Mitigation measures					
20. Risks	<input type="radio"/> Low	<input type="radio"/> Medium	<input type="radio"/> High		
Please use this space for additional explanation/comments like use of contraception in SJDEFI which is Catholic institution, other socially-sensitive issues, and funding sources (should not be tobacco industry-related)					
Name of Primary Investigator		Signature		Date	
B. FOR SJDIRB USE ONLY (To be filled by the Primary Reviewer)					
Decision Points		Recommendation			



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<input type="radio"/> Approval <input type="radio"/> Minor modification required (requires minor changes in the documents such as typographical errors, administrative issues, additional explanations, etc.) <input type="radio"/> Major modification required (requires revision of study design, major sections of the protocol or ICF that affect patient safety or credibility of data) <input type="radio"/> Disapproved (due to ethical, legal or scientific concerns). Reasons for a vote of disapproval should be noted in the minutes and communicated to the PI.	1. . 2. . 3. .		
Reviewer (Primary, ICF, IC)	Signature	Date	
SJDIRB Final Action			
Final Decision	Recommendation/Comments		
<input type="radio"/> Approval <input type="radio"/> Minor modification required (requires minor changes in the documents such as typographical errors, administrative issues, additional explanations, etc.) <input type="radio"/> Major modification required (requires revision of study design, major sections of the protocol or ICF that affect patient safety or credibility of data) <input type="radio"/> Disapproved (due to ethical, legal or scientific concerns). Reasons for a vote of disapproval should be noted in the minutes and communicated to the PI.	(e.g. Proceed with the recommendation of the reviewer or full board meeting last _____)		
SJDIRB Officer	Name	Signature	Date
Board/Panel Secretary			
Chair/Panel Lead			