SJDIRB Reference Code		Date of Submission	DD Month YYYY
Protocol Code		SJREB Code	
Protocol Title			
	Name/s	Profession/ Specialty/ Subspecialty	
Principal Investigator/s			
SJDIRB Reviewers			
	Name/s	Profession/ Specialty/ Subspecialty	
ICF Reviewer			

Type of Review ○ Expedited ○ Full Board

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, a hardcopy of this form is available upon request, to facilitate encoding of comments.*

	Pages	Yes	No	N/A	Remarks
1. Readable ICF (in English and the vernacular or in a language understandable to the study participants), addressing the subject in the second person pronoun "you"					
2. **The ICF contains the following**					
a. The study is investigative in nature					
b. The number of study participants in the trial					
c. The purpose/objective of the study					
d. The trial treatments/interventions and probability for random assignment to each treatment					
e. Research procedures/interventions					
f. The expected duration of a subject's involvement and number of follow-up visits					
g. Potential or direct benefits (if any) from participation					
h. Alternative procedure(s) or course(s) of treatment that may be available					
i. The risks, discomforts and inconveniences associated with the study or when applicable to an embryo, fetus or nursing infant					
j. The provision for management of adverse reaction					
k. A statement that participation is voluntary					
l. A statement giving study participants the option to withdraw					
m. That a study participants shall be					

given information that may be relevant to his/her willingness to continue participation					
n. A statement guaranteeing confidentiality					
o. Circumstances/reasons under which the subject's participation may be terminated					
p. A statement on reimbursement of trial-related expenses of participants (if applicable)					
q. A statement guaranteeing medical care/indemnification for adverse events not subject to previous waiver					
r. Whom to contact in case of questions on adverse event (telephone number of contacts included).					
s. The contact number of the SJDIRB in the ICF, with instructions to contact the IRB in case of research related questions, risks, or injury					

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
○ **Approval** ○ **Minor modification required** (requires minor changes in the documents such as typographical errors, administrative issues, additional explanations, etc.) ○ **Major modification required** (requires revision of study design, major sections of the protocol or ICF that affect patient safety or credibility of data) ○ **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
○ **Approval** ○ **Minor modification required** (requires minor changes in the documents such as typographical errors, administrative issues, additional explanations, etc.) ○ **Major modification required** (requires revision of study design, major sections of the protocol or ICF that affect patient safety or credibility of data) ○ **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			