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

ICF ASSESSMENT FORM (SJDEFIIRB FORM 2.4)

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. ASSESSMENT FOR INFORMED CONSENT	**PAGES**	**YES**	**NO**	**N/A**	**COMMENTS**
1. Readable informed consent form (in English and the vernacular or in a language understandable to the study participants), addressing the subject in the second person pronoun "you"		[ ]	[ ]	[ ]	
2. Contains the following of an informed consent:					
2.1 The study is investigative in nature		[ ]	[ ]	[ ]	
2.2 The number of study participants in the trial		[ ]	[ ]	[ ]	
2.3 The purpose/objective of the study		[ ]	[ ]	[ ]	
2.4 The trial treatments and probability for random assignment to each treatment		[ ]	[ ]	[ ]	
2.5 The trial procedures to be done, including all invasive procedures		[ ]	[ ]	[ ]	
2.6 The expected duration of a subject's involvement and number of follow-up visits		[ ]	[ ]	[ ]	
2.7 Potential or direct benefits (if any) from participation		[ ]	[ ]	[ ]	
2.8 Alternative procedure(s) or course(s) of treatment that may be available		[ ]	[ ]	[ ]	
2.9 The risks, discomforts and inconveniences associated with the study, or when applicable, to an embryo, fetus or nursing infant		[ ]	[ ]	[ ]	

A. ASSESSMENT FOR INFORMED CONSENT	PAGES	YES	NO	N/A	COMMENTS
2.10 The study participant's responsibilities		[ ]	[ ]	[ ]	
2.11 The provision for management of adverse reaction		[ ]	[ ]	[ ]	
2.12 A statement that participation is voluntary		[ ]	[ ]	[ ]	
2.13 A statement giving study participants the option to withdraw		[ ]	[ ]	[ ]	
2.14 That a study participant shall be given information that may be relevant to his/her willingness to continue participation		[ ]	[ ]	[ ]	
2.15 A statement guaranteeing confidentiality		[ ]	[ ]	[ ]	
2.16. Circumstances/reasons under which the subject's participation may be terminated		[ ]	[ ]	[ ]	
2.17 A statement on reimbursement of trial-related expenses of participants (if applicable)		[ ]	[ ]	[ ]	
2.18 A statement guaranteeing medical care/indemnification for adverse events not subject to previous waiver		[ ]	[ ]	[ ]	
2.19. Whom to contact in case of questions on adverse event (telephone number of contacts included)		[ ]	[ ]	[ ]	
2.20. The contact number of the SJDEFI IRB in the ICF, with instructions to contact the IRB/ERC in case of research related questions, risks, or injury		[ ]	[ ]	[ ]	

Please use this space for additional explanation/comments

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