

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

MINUTES OF THE MEETING (SJDEFIIRB FORM 6.1)

MINUTES OF THE SJDEFI IRB REGULAR MEETING

DATE : _____
TIME : _____
VENUE : _____

1. ATTENDANCE

PRESENT:

ABSENT:

- 2. CALL TO ORDER**
- 3. DETERMINATION OF QUORUM AND PRESENCE OF NON-INSTITUTIONAL MEMBERS**
- 4. DISCLOSURE OF CONFLICT OF INTEREST (COI)**
- 5. READING AND APPROVAL OF THE MINUTES LAST MEETING**
- 6. BUSINESS ARISING FROM THE MINUTES**
- 7. PROTOCOL REVIEW**
 - 7.1. FULL REVIEW**

7.1.1. Approved protocols last en banc meeting dated

IRB Reference Code	
Protocol No.	
Protocol Submission Date	
Protocol Title	
Principal investigator	
Sponsor	
Department	
Study Site	
Conflict of Interest	
Primary Reviewer/s	
Document/s submitted	
Comments/ Discussions	
Action/s	<input type="checkbox"/> Approval

	<input type="checkbox"/> Modifications required prior to the approval <input type="checkbox"/> Minor Modifications <input type="checkbox"/> Major Modifications <input type="checkbox"/> Disapproval
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7.1.2. New Protocols

IRB Reference Code	
Protocol No.	
Protocol Submission Date	
Protocol Title	
Principal investigator	
Sponsor	
Department	
Study Site	
Conflict of Interest	
Primary Reviewer/s	
Document/s submitted	
Comments/ Discussions	
Action/s	<input type="checkbox"/> Approval <input type="checkbox"/> Modifications required prior to the approval <input type="checkbox"/> Minor Modifications <input type="checkbox"/> Major Modifications <input type="checkbox"/> Disapproval

7.1.3. Protocols for Modifications

IRB Reference Code	
Protocol No.	
Protocol Submission Date	
Protocol Title	
Principal investigator	
Sponsor	
Department	
Study Site	
Conflict of Interest	
Primary Reviewer/s	
Document/s submitted	
Comments/ Discussions	
Action/s	<input type="checkbox"/> Approval <input type="checkbox"/> No further action needed <input type="checkbox"/> Request for further information

	<input type="checkbox"/> Suspend the study until additional information is made available to the IRB. <input type="checkbox"/> Suspend the study until recommendations by the IRB are implemented by the PI and found satisfactory by the IRB <input type="checkbox"/> Withdraw approval of the current study <input type="checkbox"/> Others
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7.1.4. Protocol for Clarificatory Interview

IRB Reference Code	
Protocol No.	
Protocol Submission Date	
Protocol Title	
Principal investigator	
Sponsor	
Department	
Study Site	
Conflict of Interest	
Primary Reviewer/s	
Document/s submitted	
Comments/ Discussions	
Action/s	<input type="checkbox"/> Approval <input type="checkbox"/> No further action needed <input type="checkbox"/> Request for further information <input type="checkbox"/> Suspend the study until additional information is made available to the IRB. <input type="checkbox"/> Suspend the study until recommendations by the IRB are implemented by the PI and found satisfactory by the IRB <input type="checkbox"/> Withdraw approval of the current study <input type="checkbox"/> Others

7.1.5. Protocol Amendments

IRB Reference Code	
Protocol No.	
Protocol Submission Date	
Protocol Title	
Principal investigator	
Sponsor	
Department	
Study Site	
Primary Reviewer/s	
Document/s submitted	
Comments/ Discussions	

Action/s	<input type="checkbox"/> Approval <input type="checkbox"/> No further action needed <input type="checkbox"/> Request for further information <input type="checkbox"/> Suspend the study until additional information is made available to the IRB. <input type="checkbox"/> Suspend the study until recommendations by the IRB are implemented by the PI and found satisfactory by the IRB <input type="checkbox"/> Withdraw approval of the current study <input type="checkbox"/> Others
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7.1.6. Continuing Review

7.1.6.1. Progress Reports

IRB Reference Code	
Protocol No.	
Protocol Submission Date	
Protocol Title	
Principal investigator	
Sponsor	
Department	
Study Site	
Conflict of Interest	
Primary Reviewer/s	
Document/s submitted	
Comments/ Discussions	
Action/s	<input type="checkbox"/> Approval <input type="checkbox"/> No further action needed <input type="checkbox"/> Request for further information <input type="checkbox"/> Suspend the study until additional information is made available to the IRB. <input type="checkbox"/> Suspend the study until recommendations by the IRB are implemented by the PI and found satisfactory by the IRB <input type="checkbox"/> Withdraw approval of the current study <input type="checkbox"/> Others

7.1.6.2 Protocol Deviation/ Violation

IRB Reference Code	
Protocol No.	
Protocol Submission Date	
Protocol Title	
Principal investigator	
Sponsor	
Department	

Study Site	
Conflict of Interest	
Primary Reviewer/s	
Document/s submitted	
Comments/ Discussions	
Action/s	<input type="checkbox"/> Approval <input type="checkbox"/> No further action needed <input type="checkbox"/> Request for further information <input type="checkbox"/> Suspend the study until additional information is made available to the IRB. <input type="checkbox"/> Suspend the study until recommendations by the IRB are implemented by the PI and found satisfactory by the IRB <input type="checkbox"/> Withdraw approval of the current study <input type="checkbox"/> Others

7.1.7. End of Study Reports

IRB Reference Code	
Protocol No.	
Protocol Submission Date	
Protocol Title	
Principal investigator	
Sponsor	
Department	
Study Site	
Conflict of Interest	
Primary Reviewer/s	
Document/s submitted	
Comments/ Discussions	
Action/s	<input type="checkbox"/> Approval <input type="checkbox"/> No further action needed <input type="checkbox"/> Request for further information <input type="checkbox"/> Suspend the study until additional information is made available to the IRB. <input type="checkbox"/> Suspend the study until recommendations by the IRB are implemented by the PI and found satisfactory by the IRB <input type="checkbox"/> Withdraw approval of the current study <input type="checkbox"/> Others

7.1.8. Site Visit Reports

IRB Reference Code	
Protocol No.	
Protocol Submission Date	

Protocol Title	
Principal investigator	
Sponsor	
Department	
Study Site	
Conflict of Interest	
Primary Reviewer/s	
Document/s submitted	
Comments/ Discussions	
Action/s	<input type="checkbox"/> Approval <input type="checkbox"/> No further action needed <input type="checkbox"/> Request for further information <input type="checkbox"/> Suspend the study until additional information is made available to the IRB. <input type="checkbox"/> Suspend the study until recommendations by the IRB are implemented by the PI and found satisfactory by the IRB <input type="checkbox"/> Withdraw approval of the current study <input type="checkbox"/> Others

7.1.9.

SAE/AE Reports

IRB Reference Code	
Protocol No.	
Protocol Submission Date	
Protocol Title	
Principal investigator	
Sponsor	
Department	
Study Site	
Conflict of Interest	
Primary Reviewer/s	
Document/s submitted	
Comments/ Discussions	
Action/s	<input type="checkbox"/> Approval <input type="checkbox"/> No further action needed <input type="checkbox"/> Request for further information <input type="checkbox"/> Suspend the study until additional information is made available to the IRB. <input type="checkbox"/> Suspend the study until recommendations by the IRB are implemented by the PI and found satisfactory by the IRB <input type="checkbox"/> Withdraw approval of the current study <input type="checkbox"/> Others

7.2. REPORT OF SUBMISSIONS FOR EXPEDITED REVIEW**7.2.1. Approved Protocols**

IRB Reference Code	
Protocol No.	
Protocol Submission Date	
Protocol Approval Date	
Protocol Title	
Principal investigator	
Sponsor	
Department	
Study Site	
Conflict of Interest	
Primary Reviewer	
Documents Submitted	
Comments/ Discussions	

7.2.2. New Protocols

IRB Reference Code	
Protocol No.	
Protocol Submission Date	
Protocol Approval Date	
Protocol Title	
Principal investigator	
Sponsor	
Department	
Study Site	
Conflict of Interest	
Primary Reviewer	
Documents Submitted	
Comments/ Discussions	

7.2.3. Protocol for Modifications

IRB Reference Code	
Protocol No.	
Protocol Submission Date	
Protocol Approval Date	
Protocol Title	
Principal investigator	
Sponsor	
Department	
Study Site	
Conflict of Interest	
Primary Reviewer	
Documents Submitted	
Comments/ Discussions	

7.2.4. Protocol Amendments

IRB Reference Code	
Protocol No.	
Protocol Submission Date	
Protocol Approval Date	
Protocol Title	
Principal investigator	
Sponsor	
Department	
Study Site	
Conflict of Interest	
Primary Reviewer	
Documents Submitted	
Comments/ Discussions	

7.2.5. Continuing Review

IRB Reference Code	
Protocol No.	
Protocol Submission Date	
Protocol Approval Date	
Protocol Title	
Principal investigator	
Sponsor	
Department	
Study Site	
Conflict of Interest	
Primary Reviewer	
Documents Submitted	
Comments/ Discussions	

7.2.6. End of Study Reports

IRB Reference Code	
Protocol No.	
Protocol Submission Date	
Protocol Approval Date	
Protocol Title	
Principal investigator	
Sponsor	
Department	
Study Site	
Conflict of Interest	
Primary Reviewer	
Documents Submitted	
Comments/ Discussions	

8. OTHER MATTERS
9. ADJOURNMENT

Prepared by: _____ Approved by: _____

IRB Secretary
Date Prepared

IRB Chair