

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

CONTINUING REVIEW/PROGRESS REPORT FORM (SJDEFIIRB FORM 3.1)

IRB Reference No	
Protocol No.	
Protocol Title	
Principal Investigator	
Approval Date	
Start Date	
Action requested:	<input type="checkbox"/> RENEW - New participant accrual to continue <input type="checkbox"/> RENEW - Enrolled participant follow up only <input type="checkbox"/> TERMINATE - Protocol discontinued
Study has not started due to:	Has any information appeared in the literature, or evolved from this or similar research that might affect the IRB's evaluation of the risk/benefit analysis of human subjects involved in this protocol? <input type="checkbox"/> No <input type="checkbox"/> Yes (discuss in the attached narrative)
Have there been any amendments since the last review? <input type="checkbox"/> No <input type="checkbox"/> Yes (Describe briefly in attached narrative)	Have any unexpected discomforts, complications, or side effects been noted since last review? <input type="checkbox"/> No <input type="checkbox"/> Yes (Discuss in the attached narrative)
Summary of protocol participants: _____ accrual ceiling set by IRB _____ new participants accrued since last review _____ total participants accrued since protocol began	Have any participants withdrawn from this study since the last IRB approval? <input type="checkbox"/> No <input type="checkbox"/> Yes (discuss in the attached narrative)

<p>Investigational New Drug/Device</p> <p><input type="checkbox"/> None</p> <p><input type="checkbox"/> IND</p> <ul style="list-style-type: none"> ▪ FDA No.: ▪ Name: ▪ Sponsor: ▪ Holder: <p><input type="checkbox"/> IDE</p>	<p>Ionizing radiation use (X-rays, radioisotopes, etc)</p> <p><input type="checkbox"/> None</p> <p><input type="checkbox"/> Medically indicated only</p>
<p>Accrual exclusions</p> <p><input type="checkbox"/> None</p> <p><input type="checkbox"/> Male</p> <p><input type="checkbox"/> Female</p> <p><input type="checkbox"/> Other (specify):</p>	<p>Have there been any changes in the participant population, recruitment or selection criteria since the last review?</p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes (explain changes in attached narrative)</p>
<p>Impaired participants</p> <p><input type="checkbox"/> None</p> <p><input type="checkbox"/> Physically</p> <p><input type="checkbox"/> Cognitively</p> <p><input type="checkbox"/> Both</p>	<p>Have any participating investigators been added or deleted since last review?</p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes (Identify all changes in the attached narrative)</p>
<p>Have there been any changes in the informed consent process or documentation since the last review?</p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes (explain changes in attached narrative)</p>	<p>Have any new collaborating sites (institutions) been added or deleted since the last review?</p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes (identify all changes and provide an explanation of changes in the attached narrative)</p>
<p>Change in medical advisor / investigator?</p> <p><input type="checkbox"/> None</p> <p><input type="checkbox"/> Delete</p> <p>_____</p> <p><input type="checkbox"/> Add</p> <p>_____</p>	<p>Have any investigators developed equity or consultative relationship with a source related to this protocol which might be considered a conflict of interest?</p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes (append a statement of disclosure)</p>
<p>Principal Investigator _____ Signature _____ Date _____</p>	

Section 2. FOR IRB USE ONLY

RECOMMENDATIONS

Comments:

IRB FINAL ACTION

Uphold original approval with no further action

Request information

Recommend further action

<i>MEMBER-SECRETARY</i>	<i>Signature</i>	<i>Date</i>
<i>CHAIR</i>	<i>Signature</i>	<i>Date</i>