# CONTINUING REVIEW/PROGRESS REPORT FORM (SJDEFIIRB FORM 3.1)

***Section 1.To be filled up by the Principal Investigator***

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| IRB Reference No | |
| Protocol No. | |
| Protocol Title | |
| Principal Investigator | |
| Approval Date | |
| Start Date | |
| Action requested: | ☐ RENEW - New participant accrual to continue<br>☐ RENEW - Enrolled participant follow up only<br>☐ TERMINATE - Protocol discontinued |

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| 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?<br>☐ No<br>☐ Yes (discuss in the attached narrative) |
| Have there been any amendments since the last review?<br>☐ No<br>☐ Yes (Describe briefly in attached narrative) | Have any unexpected discomforts, complications, or side effects been noted since last review?<br>☐ No<br>☐ Yes (Discuss in the attached narrative) |
| Summary of protocol participants:<br>_____ accrual ceiling set by IRB<br>_____ new participants accrued since last review<br>_____ total participants accrued since protocol began | Have any participants withdrawn from this study since the last IRB approval?<br>☐ No<br>☐ Yes (discuss in the attached narrative) |

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

| Principal Investigator | Signature | Date |
|---|---|---|
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*Section 2. FOR IRB USE ONLY*

*RECOMMENDATIONS*

*Comments:*

*IRB FINAL ACTION*

☐ *Uphold original approval with no further action*
☐ *Request information*

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☐ *Recommend further action*

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|---|---|---|
| *MEMBER-SECRETARY* | *Signature* | *Date* |
| *CHAIR* | *Signature* | *Date* |