Please complete, sign and submit this form to SJCG\_REO@tbh.net. Attach a summary and rationale for any changes. Please also submit any study documents that have changed, including both a tracked changes version and a final revised copy (clean copy).

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| --- | --- |
| SJCG REB # |       |
| Principal Investigator: |       |
| Study Title: |       |

| **PROPOSED CHANGES TO:** **(check all that apply)** | **Revised Version Date** | **Documentation attached** |
| --- | --- | --- |
| NOTE: Significant changes to the originally approved research study may constitute a new application. Please consult the Research Ethics Board at SJCG\_REO@tbh.net if there is a change in the research question, recruitment strategy and/or level of risk.  |
| Research question |       |[ ]
| Study objectives, design or methodology |       |[ ]
| Data Management/Statistical analysis |       |[ ]
| Study instruments, questionnaires, etc. |       |[ ]
| Eligibility criteria (inclusion/exclusion criteria) |       |[ ]
| Recruitment methods |       |[ ]
| Number of participants globally |       |[ ]
| Number of participants locally  |       |[ ]
| Level of risk |       |[ ]
| Information sheet or letter |       |[ ]
| Consent form |       |[ ]
| Study end date |       |[ ]
| Change in Principal Investigator/Co-Investigator |       |[ ]
| Medication dosage or medical procedure |       |[ ]
| Product Monograph (REB approval required) |       |[ ]
| Investigator Brochure (REB approval required) |       |[ ]
| No Objection Letter/Investigational Testing Authorization |       |[ ]
| Other (specify):      |       |[ ]

| **Actions Required when implemented:**  | **Yes** | **No** | **Documentation attached** |
| --- | --- | --- | --- |
| Will the changes impact the implementation of the project locally? Consult the Manager, Research Services regarding the need to submit a revised Organizational Impact Form?  |[ ] [ ]   |
| Will the changes impact recruitment of future participants (e.g., potential harms/benefits, increased risk, discomfort or inconvenience)?  |[ ] [ ]   |
| Will the changes impact current participants (e.g., potential harms/benefits, increased risk, discomfort or inconvenience)?  |[ ] [ ]   |
| What follow-up do you propose for participants who are already enrolled in the study? |  |
| Inform study participants |[ ] [ ]  When? |  |
| Re-consent all participants with revised consent/assent forms |[ ] [ ]  When? |  |
| Re-consent active participants with the revised consent/assent forms |[ ] [ ]  When? |  |
| No action required |[ ] [ ]   |
| Other: attach explanation |[ ] [ ]   |
| Principal Investigator’s Signature: |  |
| Print Name:  |       |
| Date: (month day, year)  |       |

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| **For Research Ethics Board Use Only** |
|  | **FULL BOARD REVIEW & APPROVAL** |  | **DELEGATED APPROVAL** |
| The following amendment(s) have been reviewed and approved by the full board of the SJCG Research Ethics Board at the REB meeting dated \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. The quorum for approval was free from conflict and did not involve any member that is associated with this project.  | The following amendment(s) have been reviewed and approved by the Chair of the St. Joseph’s Care Group (SJCG) Research Ethics Board. This approval will be reported at the next full REB meeting. |

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| --- | --- |
| Signature of Chair: |  |
| Date: |  |
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