Please complete, sign and submit this form to SJCG\_REO@tbh.net

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

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| 1. | Study Status | Yes | No |  | FOR STUDIES INVOLVING CHART REVIEWS  |
|  | Enrollment Closed/Completed |[x] [ ]   | Study Status | Yes | No |
|  | All Assessments/Intervention Completed |[ ] [ ]   | Review of all charts completed |[ ] [ ]
|  | Follow-up Completed |[ ] [ ]   | Total Number of Charts reviewed |       |
|  | Data verification/Data analyses Completed |[ ] [ ]   |

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| --- | --- | --- |
| 2. | Number of local study participants (since study initiation) | **NOTE:**   All participants need to be accounted forA = B + C + D + E + F + G Comments, if needed:       |
|  | Enrolled in Study | A |       |
| In active intervention phase of study | B |       |
| In follow-up phase of study | C |       |
| Completed study | D |       |
| Withdrew from study | E |       |
| Deceased, lost-to-follow up, transferred | F |       |
| Lost-to-follow up or transferred | G |       |

| 3.  | Reports/Updates of Research Study | Yes | No | Check if attachment |
| --- | --- | --- | --- | --- |
| a. | Has an interim data analysis been done?  🡪 If Yes, attach summary. |[ ] [ ] [ ]
| b. | Have articles been published or presentations given using results of the study? 🡪 If Yes, submit a copy of the abstract(s) or a list of references |[ ] [ ] [ ]
| c. | Have all serious adverse events been reported? [ ]  not applicable 🡪 If No, include with this report. |[ ] [ ] [ ]
| d. | Has new literature changed your assessment of risk/benefits for participants? |[ ] [ ] [ ]
|  | 🡪 If Yes, have participants been informed?🡪 If No, attach an explanation of how and when participants will be informed. |[ ] [ ] [ ]
| e. | Have there been any changes in investigators since the last approval? |[ ] [ ] [ ]
|  |  🡪 If Yes, has the REB been notified?  🡪 If No, submit an amendment with this form. |[ ] [ ] [ ]
| f. | Is there new evidence from other studies that impact your study?  🡪 If Yes, attached summary  |[ ] [ ] [ ]
| g. | Have there been any changes to the local study protocol or consent form?  🡪 If Yes, submit an amendment form with this application. |[ ] [ ] [ ]
| h. | Are study results available?  🡪 If Yes, attach a brief summary of study results to date. |[ ] [ ] [ ]

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| Principal Investigator’s Signature: |  |
| Print Name:  |       |
| Date: (month day, year)  |       |

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| **For Research Ethics Board Use Only** |

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| Date Re-approval granted: |  | [ ] Delegated Approval[ ] Full-Board Approval |  |
| Starting on: |  | Expiring on: |  |  |
| Signature of Chair: |  |  |
| Date: |  |  |
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