## **SJD Institutional Review Board**

**Title: Resubmission & Modification Summary** 

Code: SJDIRB Form 9

Version: 06

| SJDIRB Reference Code                   |        | Protoc  | ol Code      |            |                | SJREB Code             |                    |       |
|---|--------|---------|--------------|------------|----------------|------------------------|--------------------|-------|
| Study Protocol Title                    |        |         |              |            |                |                        |                    |       |
| Principal Investigator                  |        |         |              |            | Expertise      |                        |                    |       |
| Date of Initial Submission              |        | Date of | Resubmissio  | 1          |                | Resubmission           | n # ● 2nd ●        | 3rd   |
| Primary Reviewer                        |        |         | E            | xpertise   |                |                        | <b>Protocol Ve</b> | rsion |
| ICF Reviewer                            |        |         |              | xpertise   |                |                        | No.                |       |
| Protocol Modifications & Clarifications |        | Page #  | Modified o   | or Added P | aragraph/State | nent Reviewers Remarks |                    |       |
|   |        |         |              |            |                |                        |                    |       |
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| ICF Modifications & Clarifications      |        | Page #  | Modified o   | or Added P | aragraph/State | ment R                 | eviewers Rema      | arks  |
|   |        |         |              |            |                |                        |                    |       |
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|   |        | For     | SJDIRB Use   |            |                |                        |                    |       |
| <b>Decision for the Protocol</b>        | dation |         | sion for the | ICF        | Recomme        | endation               |                    |       |
|   |        |         | •            |            | •              |                        |                    |       |



## FOUNCED LIE

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| · ·   |                           |     |                       | O Appr   |                                      | 1.                        |                          |             |
|---|---------------------------|-----|-----------------------|--|--------------------------------------|---------------------------|--------------------------|-------------|
| O Minor modification  |                           |     | O Minor modification  |  | r modification                       |                           |                          |             |
| required (requires minor changes  | d (requires minor changes |     |                       |  | required (requires minor changes     |                           |                          |             |
| in the documents such as  |                           |     |                       |  | in the documents such as             |                           |                          |             |
| typographical errors, administrative                                    |                           |     |                       |  | typographical errors, administrative |                           |                          |             |
| issues, additional explanations, etc.)                                  |                           |     |                       | issues, additional explanations, etc.) O Major modification        |                                      |                           |                          |             |
| O Major modification  |                           |     |                       |  |                                      |                           |                          |             |
| required (requires revision of  |                           |     |                       | required (requires revision of study design, major sections of the |                                      |                           |                          |             |
| study design, major sections of the protocol or ICF that affect patient |                           |     |                       | protocol or ICF that affect patient                                |                                      |                           |                          |             |
| safety or credibility of data)  |                           |     |                       |  | safet                                | y or credibility of data) |                          |             |
| O Disapproved (due to ethical,  |                           |     |                       | O <b>Disapproved</b> (due to ethical,                              |                                      |                           |                          |             |
| legal or scientific concerns).  |                           |     |                       | legal or scientific concerns).                                     |                                      |                           |                          |             |
|   | Reasons for a vote of     |     |                       |  | Reasons for a vote of                |                           |                          |             |
| disapproval should be   |                           |     | disapproval should be |  |                                      |                           |                          |             |
| noted in the minutes and  |                           |     |                       |  | noted in the minutes and             |                           |                          |             |
| communicated to the PI.   |                           |     |                       | communicated to the Pl.  |                                      |                           |                          |             |
| Name & Signature of Primary Reviewer                                    |                           |     | Dat                   | e  |                                      | Name & Signature          | of ICF Reviewer          | Date        |
|   | -                         |     |                       |  |                                      |                           |                          |             |
|   |                           |     |                       |  |                                      |                           |                          |             |
|   |                           |     | SJ                    | DIRB F   | inal A                               | ction                     |                          |             |
| Final SJDIRB Decision Protocol  |                           | ICF |                       |  |                                      | Comments                  |                          |             |
| Approval  |                           |     |                       | Protocol   |                                      |                           |                          |             |
| Recommend Minor Modifications   |                           |     |                       |  |                                      | (e.g. Proceed with        | ne reviewer)             |             |
| Recommend Major M   | odifications              |     |                       |  |                                      |                           |                          |             |
| Request for Clarificatory Interview                                     |                           |     |                       |  |                                      |                           |                          |             |
| Pending (if substantial clarifications are                              |                           |     |                       | ICF  |                                      | (e.g. Proceed with        | the recommendation of th | e reviewer) |
| necessary prior to reaching a decision)                                 |                           |     |                       |  |                                      |                           |                          | ,           |
| Name & Signature of Board/Panel Secretary                               |                           |     | Dat                   | Date N   |                                      | Name & Signature of       | Chair/Panel Lead         | Date        |
|   |                           |     |                       |  |                                      |                           |                          |             |
|   |                           |     |                       |  |                                      |                           |                          |             |
|   |                           |     |                       |  |                                      |                           |                          |             |

