**FORM 8**

**PROTOCOL AMENDMENT APPLICATION FORM**

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Date of submission | | | |  | SJREB Protocol No. | | | |  | | Sponsor Protocol No | |
|  | | | |  |  | | | |  | |  | |
| Principal Investigator | | | |  | Email/ Mobile No. | | | |  | | Sponsor | |
|  | | | |  |  | | | |  | |  | |
|  |  | |  |  |  |  |  |  | |  |  | |
| Title of Study | | |  | | | | | | | | | |
|  |  | | |  |  |  |  |  | |  |  | |
| Study Site/s: | |  | | | | | Date of Initial Approval | | | | |  |
|  |  | | |  |  |  |  |  | |  |  | |
| Items to be Amended | | | | List of Amendments | | | Reasons | | | | | |
|  | | | |  | | |  | | | | | |

|  |  |
| --- | --- |
| Signature of PI: |  |
| Date: |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| FOR REC USE: | | | | |
| Assessment of Primary Reviewers | 1. Type of amendments: | | | |
|  | Minor |  | Major |
| Comment/s: | | | |
| 1. Does the amendment increase the risks to participants | | | |
|  | Yes |  | No |
| Comment/s: | | | |
| 1. **Does the amendment increase the benefits to participants?** | | | |
|  | Yes |  | No |
| Comment/s: | | | |
| 1. **Is there favourable benefit/ risk ratio?** | | | |
|  | Yes |  | No |
| Comment/s: | | | |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Recommendations: | |  | Type of review | |
|  | Approve |  |  | Expedited |
|  | Request for further information/modification |  |  | Exempted |
|  | Others |  |  | Full Board |

**Type of amendments: Minor \_\_\_** **Major \_\_\_**

**Does the amendment increase the risks to participants?**

**Yes \_\_\_ No \_\_\_**

**Does the amendment increase the benefits to participants?**

**Yes \_\_\_ No \_\_\_**

**Is there favourable benefit/ risk ratio? Yes \_\_\_ No \_\_\_**

**Comments:**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Name of reviewer: |  | Signature: |  | Date: |  |

|  |  |
| --- | --- |
| Final Decision: |  |

|  |  |  |
| --- | --- | --- |
| SJREB Chair | Signature | Date |
|  |  |  |