**MEDICAL DEVICE ASSESSMENT FORM**

**TO THE PRINCIPAL INVESTGATOR:** *OBTAIN AN ELECTRONIC COPY OF THIS FORM AND ENCODE ALL INFORMATION REQUIRED IN THE SPACE PROVIDED. PRINT NAME, DATE AND SIGN THIS FORM BEFORE SUBMISSION.*

|  |  |  |  |
| --- | --- | --- | --- |
| **Date of Submission** **(MMM/DD/YYYY)**  |   | **Protocol Number**  |   |
|  |  |  |  |
| **Sponsor**  |   | **Sponsor’s** **Protocol Number**  |   |
|  |  |  |  |
| **Principal** **Investigator**  |   | **Co-investigator(s)** **(if any)**  |   |
|  |  |  |  |
| **Principal Investigator’s** **Contact Number**  |   | **Principal Signature**  |   |
|  |  |  |  |
| **Protocol Title**  |   |  |  |

|  |  |
| --- | --- |
|  | **GENERAL INFORMATION OF STUDY DEVICE**  |
| **Name of Study Device**  |    |
| **Sponsor/ Manufacturer**  |    |
| **Indication for Use**  |   |

|  |
| --- |
|  ***TO THE PRINCIPAL INVESTIGATOR:*** *ON THE SECOND COLUMN, SPECIFY THE LOCATION AND/OR PAGE NUMBER OF THE ASSESSMENT POINT. INDICATE* ***N/A*** *IF NOT APPLICABLE* ***TO THE REVIEWER/INDEPENDENT CONSULTANT:*** *KINDLY STIPULATE ON THE THIRD COLUMN YOUR COMMENTS OR OTHER CLARIFICATIONS. PLEASE DO NOT USE PENCIL IN ACCOMPLISHING THIS FORM.*  |
| **PROTOCOL EVALUATION ON STUDY DEVICE**  |
| **ASSSESSMENT POINT**  | **LOCATION**  | **REVIEWER’S COMMENT**  |
| 1. Description of the device/ Product information including handling and storage requirements.
 |    |   |
| 1. Proposed investigational plan

(Use of the device in the study) |   |   |
| 1. Reports of prior investigations conducted with the device
 |   |   |
| 1. FDA Approval, IDE Number
 |   |   |
| 1. Risk assessment determination for new investigational device (Significant Risk or

Non-Significant Risk) and its rationale  |   |   |
| 1. Choice of comparator and justification (if applicable)
 |   |   |
| 1. Summary of the necessary training and the experience needed to use the

investigational device  |   |   |
| 1. Device control, access and accountability
 |   |   |
| 1. List of additional procedures (example: surgery), medical device or medication to be used as part of the investigational study
 |   |   |
| 1. Risk-benefit assessment
 |   |   |
| 1. Safety and effectiveness/ performance assessments
 |   |   |
| 1. Prohibition against promotion or commercialization of, and certain other practices relative to, investigational devices
 |   |   |
| 1. References
 |   |   |

|  |
| --- |
| ***TO THE PRINCIPAL INVESTIGATOR:*** *ON THE SECOND COLUMN, PUT A (√) MARK ON THE APPROPRIATE TICK BOX. INDICATE* ***N/A*** *IF NOT APPLICABLE* ***TO THE REVIEWER/ INDEPENDENT CONSULTANT:*** *KINDLY STIPULATE ON THE THIRD COLUMN YOUR COMMENTS OR OTHER CLARIFICATIONS. PLEASE DO NOT USE PENCIL IN ACCOMPLISHING THIS FORM.* |
| **ASSESSMENT OF STUDY DEVICE**  |
| **RISK INVOLVED**  | **Yes**  | **No**  | **REVIEWER’S COMMENTS**  |
| 1. **Significant Risk Study Device**

*\*A Study Device that meets the definition below is considered as Significant Risk Study Device.*  | To be filled out by the Principal Investigator |  |
|    | Intended as an implant and presents a potential serious risk to the health, safety or welfare of a subject.  |[ ] [ ]   |
|   | Is represented to be for use supporting or sustaining human life and presents a potential serious risk to the health, safety or welfare of a subject.  |[ ] [ ]    |
|  | Is for use of a substantial importance in diagnosing, curing, mitigating, or treating disease or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety or welfare of a subject.  |[ ] [ ]    |
|  | Otherwise presents a potential for serious risk to the health, safety, or welfare of a subject; |[ ] [ ]   |
| 1. **Non-Significant Risk Device**

*\*A study device that does not meet the definition of Significant Risk device study is considered as Non-significant Risk device Study.*  |[ ] [ ]    |
| 1. **IDE Exempt Study Device**

 |[ ] [ ]    |

Submitted by:

 **Signature above Printed Name Date (MMM/DD/YYYY)**

|  |
| --- |
| ***TO THE PRIMARY REVIEWER/INDEPENDENT CONSULTANT:*** *PUT A (*√*) MARK ON THE APPROPRIATE TICK BOX. IF THE PAPER IS FOR REVISION, SPECIFY MODIFICATION REQUIRED ON THE SPACE PROVIDED. IF THE PAPER IS DISAPPROVED, STIPULATE THE REASON FOR SUCH DECISION ON THE SPACE PROVIDED. PRINT NAME, SIGN AND DATE THIS FORM. PLEASE DO NOT USE PENCIL.* ***NOTE:*** *FOR PROTOCOLS UNDER FULL BOARD REVIEW, THE PRIMARY REVIEWERS MUST BE PRESENT DURING THE DELIBERATION FOR FINAL DECISION. TO PREPARE FOR THE FULL BOARD MEETING, KINDLY RETURN THE ACCOMPLISHED EVALUATION FORMS (2.7B, 2.8, AND 2.11) TO THE IRB SECRETARIAT AT LEAST ONE (1) WEEK PRIOR TO THE SCHEDULED MEETING. THANK YOU.* |
| **REVIEWER’S RECOMMENDATION (*TO BE FILLED OUT BY THE PRIMARY REVIEWER)*** |
| **RECOMMENDED ACTION:**[ ]  Approval[ ]  For Revision *(pls. specify)* [ ]  Minor Modification: [ ]  Major Modification:[ ]  DisapprovalReason: |

|  |  |  |
| --- | --- | --- |
| **Primary Reviewer’s Name**  | **Signature**  | **Date (MMM/DD/YYYY)**  |
|  |  |  |