**Site Specific Review Form**

| **STUDY PROTOCOL INFORMATION** | |
| --- | --- |
| **Reference Number:** |  |
| **SJREB Code:** |  |
| **Study Protocol Title:** |  |
| **Site Principal Investigator:** | <Title, Name, Surname> |
| **Study Protocol Submission Date:** |  |
| **Documents submitted** | * Study protocol * ICF * CV of the study team * GCP of the study team * IB * Site-specific protocol addendum * Other (specify) |
| **Primary Reviewer 1**  **(assigned by Panel Chair/Member Secretary** |  |
| **Date assigned** |  |
| **Primary Reviewer 2**  **(assigned by Panel Chair/Member Secretary** |  |
| **Date assigned** |  |

|  | **To be filled out by the Primary Reviewer** | |
| --- | --- | --- |
| **ASSESSMENT POINTS** | **REVIEWER COMMENTS** | **REVIEWER RECOMMENDATIONS** |
| 1. *Have you filled out SJREB FORM 5 Protocol Assessment form to assess the methodology and objectives of the study?* | * NO * YES |  |
| 1. *Do you have any comments regarding the objectives and methodology?* | * NO * YES, Specify: |  |
| **SITE SPECIFIC REVIEW** |  |  |
| 1. *Qualifications of the site principal investigator (training certificates, specialty, prior similar studies)* |  |  |
| 1. *Site feasibility (recruitment, site sample size, facilities)* |  |  |
| 1. *Appropriate LGU permits, training, facilities (for any community-based study)* |  |  |
| 1. *Amount of payment to participants and other benefits* |  |  |
| 1. *Are the site recruitment and informed consent processes detailed enough to determine the following:*    1. *How will participants be identified?*    2. *Who will consent to the participants?*    3. *How will participants be consented?*    4. *Where will participants be consented?*    5. *Will the recruitment process address safety issues?*    6. *Will the consent process insulate the patient from PI, if the PI is the primary physician?*    7. *Will the recruitment and consent process provide site specific protection as necessary?* |  |  |
| 1. *Site specific privacy and confidentiality and data protection plan* |  |  |
| 1. *Matters concerning other documents, as applicable (MTA, MOA, NCIP approval, FDA approval, case report forms, recruitment materials, patient facing materials, etc.)* |  |  |

| RECOMMENDED ACTION: | | | |
| --- | --- | --- | --- |
| * APPROVE | | | |
| * MINOR MODIFICATIONS | | | |
| * MAJOR MODIFICATIONS | | | |
| * DISAPPROVE * PENDING, IF MAJOR CLARIFICATIONS ARE REQUIRED BEFORE A DECISION CAN BE MADE | | | |
| SUMMARY OF RECOMMENDATIONS: | | | |
| JUSTIFICATION FOR RECOMMENDED ACTION: | | | |
| **PRIMARY REVIEWER** |  | Signature |  |
| Date: <dd/mm/yyyy> |  | Name | <Title, Name, Surname> |