**Site Visit Report Form**

**INSTRUCTIONS TO THE MMMC-RERC MEMBER/ REPRESENTATIVES:** *A Site Visit is conducted as result of full board action for purposes of monitoring study protocol compliance in the study site. The visit is limited to the review of study protocol related documents and procedures that have been approved by the MMMC-RERC that issued the ethical clearance or approval of the study. The visit should not in any way compromise the obligation to protect the privacy and confidentiality of research-related information of study participants/subjects. The Chair should ensure that the Site Visit Team is well-prepared to conduct the visit through a complete review of the study protocol folder prior to the visit. This form should reflect the consensus opinion of the Site Visit Team; the results of which are reported in the next MMMC-RERC meeting.*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **MMMC-RERC CODE:** | | | | |
| **STUDY PROTOCOL TITLE:** | | | | |
| **APPROVAL DATE:** <dd/mm/yyyy> | | | | |
| **PRINCIPAL INVESTIGATOR:** | | | | |
| **Email:** | | **Telephone:** | | **Mobile:** | | |
| **STUDY SITE NAME:** | | | | | | |
| **STUDY SITE ADDRESS:** | | | | | | |
| **SPONSOR:** | | | | | | |
| **SPONSOR CONTACT PERSON:** | | | | | | |
| **Email:** | | **Telephone:** | | **Mobile:** | | |
| **SITE VISIT DATE:** <dd/mm/yyyy> | | | | | | |
| 1. **Total participants expected:** | | | | |
| 1. **Total participants enrolled:** | | | | |
| 1. **Are site facilities appropriate?**    1. □ YES    2. □ NO    3. COMMENTS: | | | | |
| 1. **Are informed consent documents updated to the version approved by the MMMC-RERC Panel?**    1. □ YES    2. □ NO    3. COMMENTS: | | | | |
| 1. **Are there any SAE/SUSAR reports not previously reported to the MMMC-RERC?**    1. □ YES    2. □ NO    3. COMMENTS | | | | |
| 1. **Are there any events of protocol noncompliance not previously reported to the MMMC-RERC?**    1. □ YES    2. □ NO    3. COMMENTS | | | | |
| 1. **Are investigation products and study documents secured adequately?**    1. □ YES    2. □ NO    3. COMMENTS | | | | |
| 1. **Are all other MMMC-RERC Panel-approved documents (e.g. advertisements) used in accordance with the approved study protocol?**    1. □ YES    2. □ NO    3. COMMENTS | | | | |
| 1. **Are there any significant findings in this visit that could affect participant’s/subject’s rights, safety or welfare**    1. □ YES    2. □ NO    3. COMMENTS | | | | |
| 1. **Overall, does the study site provide adequate protection for the rights, safety or welfare of study participants/subjects?**    1. □ YES    2. □ NO    3. COMMENTS | | | | |
| 1. **How well are study participants/subjects protected?**    1. □ GOOD    2. □ FAIR    3. □ NOT GOOD    4. COMMENTS | | | | |
| 1. **Are there further actions or queries resulting from this site visit?**    1. □ YES    2. □ NO    3. COMMENTS | | | | |
| 1. **Additional remarks** | | | | |
| 1. **Duration of visit:** <hours >**/** From <hh:mm> to <hh:mm> | | | | |
| **COMPLETED BY THE FOLLOWINGMMMC-RERC PANEL MEMBER/ REPRESENTATIVES:** | | | | |
| **NAME** | | **SIGNATURE** | | **DATE** |
| Name 1 | |  | | <dd/mm/yyyy> |
| Name 2 | |  | | <dd/mm/yyyy> |
| Name 3 | |  | | <dd/mm/yyyy> |

|  |  |  |  |
| --- | --- | --- | --- |
| **RECOMMENDED ACTION:** (For MMMC-RERC use only)   * NO FURTHER ACTION * REQUEST INFORMATION: (specify) * RECOMMEND FURTHER ACTION: (specify) | | | |
| **PRIMARY REVIEWER** |  | Signature |  |
| Date: <dd/mm/yyyy> |  | Name | <Title, Given Name, Surname> |
| **MEMBER-SECRETARY** Signature  Date: <dd/mm/yyyy> Name | | |  |
| <Title, Given Name, Surname> |
| **CHAIR** Signature | | |  |
| Date: <dd/mm/yyyy> Name | | | <Title, Given Name, Surname> |