

**ACTIVE MONITORING FORM**

**SITE MONITORING TEMPLATE CHECKLIST**

Active monitoring of approved projects will be conducted for approved projects classified as high risk/ selected medium risk expedited applications.

*The tool has been adapted from the University of Zululand Site Monitoring Checklist.*

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| --- | --- | --- | --- | --- |
| **Project Title:** | | | | |
| **REC REF No:** | | | | |
| **Principal Investigator:** | | | | |
| **Date of monitoring:** | | | | |
| **Monitoring classification** (*Tick the applicable)* | **High risk** |  | **Medium/**  **Expedited** |  |

|  |
| --- |
| **Attendees:**  **Project Team**  **Name Designation Signature**      **REC representatives**  **Name Designation Signature** |
| **Report signoff:**  Chair of the task team: PI/project representative: |
| **Reporting to the REC meeting of**:  Date |

**Section A: Monitoring of high-risk projects (Human participants)**

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| **Documentation assessed** | |
| **Document** | **Task Team comment** |
| 1. Signed informed consent forms |  |
| 2. Signed gatekeeper permission letters |  |
| 3. Data collection instruments (participant  response records) |  |
| 4. Valid ethical clearance letter |  |
| 5. Study related meeting minutes for focus groups/semi structured  interviews/workshops |  |
| 6. Conditions of research site |  |
| 7. Number of participants present |  |
| 8. Protocol deviation |  |
| 9. Recertification/ renewal |  |
| **Overall Comments by Task Team:** | |
| **Study site observations** | |
| 10. Psychosocial support (*if applicable*) |  |
| 11. Data handling |  |
| **Interviews with principal investigator/s** | |
| General discussion between HSSREC task team and the principal investigator/s |  |
|  | |

**FINDINGS AND ACTION PLANS**

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| Finding 1 | |
| Date |  |
| Risk ranking |  |
| Description of observation |  |
| Why this is problematic |  |
| Recommendation |  |
| Principal Investitator  Action Plan | |
| Title & full name |  |
| Root cause |  |
| Action |  |
| Responsible person |  |
| What will be done |  |
| Finding 2 | |
| Date |  |
| Risk ranking |  |
| Description of observation |  |
| Why this is problematic |  |
| Recommendation |  |
| Principal Investitator  Action Plan | |
| Title & full name |  |
| Root cause |  |
| Action |  |
| Responsible person |  |
| What will be done |  |
|  |  |