Supplementary Material 4: Clinical Risk Assessment

| **ACTIVITY** | **IDENTIFIED RISK** | **LIKELIHOOD** | **GRAVITY** | **RISK MITIGATION** | **WHO** |
| --- | --- | --- | --- | --- | --- |
| Household screen and informed | Interaction between staff and community members during epidemic period | Moderate | High | Household visits replaced with phone calls | Research assistants |
| Informed consent process | Interaction between staff and community members during epidemic period  Administratively intense process with limited staff | Moderate | High | Verbal consent for study procedures | Research assistants, |
| Mobile clinic procedures | Clinical staff contact with COVID suspects | High | High | Strict PPE procedures: gloves, masks, visors, lab coats, disinfectant for surfaces, hand sanitisers | Study nurses |
| Identification of ill participants at clinical screen | Participants requiring clinical care | Moderate | High | Partnership with Department of Health or organize ambulance service and referral to Ngwelezane Hospital | CRD |
| Home referral of COVID suspects | Household transmission of COVID | High | High | Provision of suspects with soap, masks, educational materials on home hygiene, including isolation and quarantine consistent with DoH guidelines | Research assistants, research nurses |
| Case definitions, isolation guidelines and referral pathways | As the epidemic evolves, the DoH guidelines are likely to change, and AHRI teams will need to adapt accordingly | Moderate | High | The AHRI COVID19 Response Team and Clinical Research Department will keep close communication with the Department of Health and readily adapt study materials and protocols | CRD |
| Referrals to Ngwelezane | Burdening of Department of Health staff in the midst of the epidemic Ngwelezane | High | Moderate | Embedding an AHRI research nurse at the Ngwelezane hospital if required by DoH | CRD |
| Follow-up of COVID positive cases | Failure to identify COVID cases with worsening clinical course | Moderate | High | Daily follow-up calls for all positive cases | Study nurses |
| COVID-19 Testing | Unclear validity of novel diagnostic assays | Low | Moderate | Expert review of testing modalities and internal and external Q/C procedures | AHRI diagnostic laboratory |
| Results Reporting | Failure to promptly report results to both the Department of Health and Participants | Moderate | High | Incorporate laboratory results reporting into NICD system and establishment of clinical results review committee | Data and CRD |