health
Department:
Health
PROVINCE OF KWAZULU-NATAL

CHECKLIST FOR TRIAL APPLICATIONS

Please ensure that the following is included in the submission of a Clinical Trial application on the NHRD website: http://nhrd.hst.org.za. The items below are mandatory for each application. In the absence of the below items, the turn-around time and approval by the Department of Health cannot be guaranteed.

ITEM:	DETAILS:	YES/NO
1.	Trial Research Protocol according to the Department's Guidelines For Submitting a Research Proposals.	
2.	Contact Details, CV and GCP registration of the Principal Investigator (PI).	
3.	KwaZulu-Natal Department of Health Trial Application Form (See Trial Application Form).	
4.	Details of how the intended Trial is relevant to the Department of Health's needs and priorities and the benefit to the population of KwaZulu-Natal (See Clinical Trial Application Form).	
5.	Letter of support from the relevant Facility Manager for EACH site.	
6.	Letter from PI motivating the selection of sites for the Trial.	
7.	Letter of support from the relevant Programme Manager at the KwaZulu-Natal Department of Health's Head Office e.g. HAST Programme Manager for HIV/AIDS Trial.	
8.	Ethical Clearance from an accredited Ethics Committee in South Africa.	
9.	MCC Approval.	
10.	Insurance Certificate.	
11.	Information and Consent Forms.	
12.	Budget and Timeline.	
13.	Information regarding the management of study participant's treatment during the Trial and how the study will ensure smooth transition to public health services after the Trial. Details on the referral mechanism of study participant's back to the Department of Health (if required), the mechanism for communication between investigators and referral institutions/clinicians, interim treatments provided to study participants and the duration of the transition period (See Trial Application Form).	
14.	Outline the details of the storage and dispensing of Trial drugs at Department of Health's facilities, if applicable (See Trial Application Form).	
15.	Details of study participant's access to trial treatment after the Trial should also be detailed (See Trial Application Form).	
16.	Details on the provision of all resources that will be used during the Trial e.g., equipment, study drugs, laboratory tests, number of visits for study participants, study participant transport, non-medical treatment and HCWs required (See Trial Application Form)	