Republic of Guinea
Ministry of Health and Public Hygiene
National Coordination for the Fight against Ebola
Ebola Research Commmision in Guinea

Procedures for the Submission and Evaluation of Research Projects and Protocols on Ebola Virus Disease

- Procedures for Submission
- All research projects or protocols within the framework of the epidemic and Ebola virus disease in Guinea shall be submitted to the Ebola Research Commission. The Commission will analyze all scientific aspects including the methodology and budget estimate.
- The research commission will give their opinion within a minimum of two weeks without exceeding one month. In exceptional circumstances, with a reasoned opinion, that time may be reduced to one week.
- Once the opinion of the Research Commission is obtained, the project or protocol is transferred to the National Ethics committee for Health research (CNERS)

II. Documents to be provided

1. The project (in electronic format; hard copies are acceptable)
2. A cover letter (1 copy) including the contact information of the Principal Investigators (PI) or the person responsible for the study (Full Name, address, phone number and email)
3. Synopsis (summary in French) according to the format below:

Titre Scientifique de l'étude / Scientific Title of the Study	
Investigateur Principal (PI)/ Principal Investigator (PI)	
Co-Investigateur Principal (co-PI)/ Co-Principal Investigator (co-PI)	
Organisations Partenaires / Partner Organizations	
Sponsors/Sponsoring organisations	
Produit fournit par/Product provided by:	
Produit à investiguer/Investigational Product :	

Phase de Développement Clinique/Clinical Development phase**:**	
Coordonnateur de l'Étude/Coordinating Investigator:	
Équipe Investigateurs/Team Investigators (Study Field Coordinator, Medical Coordinator, Community Based Monitors, Medical Field Team, Lab Team, Data Management Team)	
Équipes de soutien à l'étude/Study support (Scientific Committee, Steering Committee, Study Monitoring, Data Safety Monitoring Board-DSMB	
Sites des études/Study Centers	
Période et durée de l'étude/Planned Study Period	
Objectif general/Primary Objective	
Principaux Résultats attendus/Primary Endpoints	
Objectifs secondaires/Secondary Objectives	
Résultats secondaires attendus/Secondary Endpoints	
Méthodologie et Description de l'étude ou de l'essai Clinique/Methodology - Trial Design	
Taille des échantillons/Planned Sample Size	
Modalités et périodes de collecte des échantillons, durée du suivi/Treatment and Specimen Collection Schedules and Duration of Follow-up	
Caractéristiques du produit/Investigational Product:	
- Form (Forme):	
- Composition:	
- Route (Voie) d'administration/Route of administration:	

- Batch Number / No du lot:	
Critères d'inclusion/Inclusion Criteria	
Critères d'exclusion/Exclusion Criteria	
Précautions & Contre Indications**/Precautions and Contraindications**	
Méthodes statistiques et analyses**/Statistical Methods and Analyses**	

4. Complete Protocol (in French or English) according to the format below:
   (Background, rationale for the study, objectives, methodology, progress and duration of the study, data collection, statistical analysis, ethical aspects, expected results, detailed budget, and references)
5. The Investigator's Brochure (for clinical trials). (All members on the research commission are required to sign a confidentiality certificate and a non-disclosure of received documents*).*
6. The informed Consent Form *(in French and to be translated to the local languages in the administration of this form)*
7. List of Investigators (attached abstracts/summaries of CVs)
8. Data collection tools
9. The study budget