FOURTH SCHEDULE

(r.9)

NATIONAL BIOSAFETY AUTHORITY

APPROVAL TO CONDUCT CONFINED FIELD TRIAL OF A NOVEL RIFT VALLEY FEVER VACCINE IN SHEEP, GOATS, CATTLE AND CAMELS.

APPROVAL NUMBER: **NBA/GMO/C09/18/27**	DATE OF ISSUE : 25th **November, 2016** VALID UP TO : 25th **November, 2021**
In accordance with regulation 9 of the Biosafety (Contained Use) Regulations, of the Biosafety Act 2009, I hereby grant the approval to undertake contained use activity of the genetically modified organism herein stated in the research institution mentioned in this approval.	
Name of the Applicant/ Research Institution	**International Livestock Research Institute (ILRI)**
Specification of the genetically modified organism	**A recombinant DIVA vaccine (ChAdOx1-Gn-Gc) composed of a replication- deficient simian adenovirus vector encoding RVF virus envelope glycoproteins.**
Quantity approved	**A single batch of the ChAdOx1-Gn-Gc vaccine will be used in this project. Both male and female animals will be used in this study. A total of 720 animals will be used i.e. Cattle – 180, Sheep -180, Goats-180 and Camels-180.**
Specification of the genetic modification	**Vaccine (ChAdOx1-GnGc) was prepared by Gateway® recombination between the ChdOx1 vector and an entry plasmid having coding sequence for RVF virus envelope glycoproteins. After viral rescue the vaccine was propagated in HEK293 and subsequently purified by Caesium Chloride (CsCl) gradient ultracentrifugation.**
Risk category	**Low**
Purpose of the use:	**The purpose of this confined field trial is to evaluate ChAdOx1-Gn-Gc recombinant vaccine in a confined field trial at Kapiti Ranch, Machakos County, to further assess its safety, and immunogenicity among sheep, goats, cattle and dromedary camels in Kenya.**
This approval is granted subject to the following conditions:- 1. Import permit for ChAdOx1-Gn-Gc must be obtained from DVS who will ensure that the vaccine is well packaged and securely transported from the airport to ILRI. 2. The Confined Field Trial site must be inspected by NBA and DVS before the	

commencement of the trial.

3. Provide operational manuals/SOPs on biosafety and biosecurity measures before commencement of trials.

4. A representative from NBA and DVS to be present during the vaccination and the disposal of the unused vaccine as well as the destruction of all livestock samples following the termination of the trial.

5. A detailed schedule of activities and the experimental design must be provided both to NBA and DVS before commencement of the trial to aid in monitoring purposes.

6. Put and implement measures to ensure that no transgenic material from the laboratory and the CFT enters the human food or animal feed chain. Contingency measures should also be put in place in case of accidental escape of the trial animals under confinement.

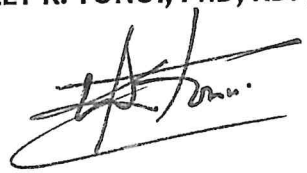
7. All the trial animals and the animal materials must be rendered biologically inactive through autoclaving and or incineration. Strictly adhere to the proposed waste management plan and records must be maintained and availed to biosafety inspectors on request. Any material retained for further analysis shall be counted and accounted for at all times.

8. The applicant to work with DVS to guide them on the data required for vaccine registration.

9. Provide quarterly and annual progress reports to NBA in the prescribed format. The reports should be discussed by and forwarded through the IBC.

10. All staff to be involved in this trial to be trained by DVS and NBA officers on handling transgenic vaccines and overall biosafety and biosecurity matters before the commencement of the trial.

This approval is not transferrable and is valid for: **Five (5) years**

Place: **NAIROBI**	Name: **WILLY K. TONUI, PhD, RBP,EBS**
	Signature: 
Date: 25th **NOVEMBER 2016**	**CHIEF EXECUTIVE OFFICER,** **NATIONAL BIOSAFETY AUTHORITY**