|  |  |
| --- | --- |
| Name |  |
| Physical address |  |
| Contact person (Director)  |  |
| Declaration of capacity & interests  |  |

* 1. For each site list the following:
	2. Site Identifier (Name)

Physical address: (include GPS coordinates)

Telephone & fax numbers

E-mail address

* 1. Description of the site facility & staff

(a) Infrastructure on the farm;

(b) Facility for special examination (if required);

(c) Capacity to collect, prepare, store and transport field samples;

(d) Storage and handling facility for the trial product; and

(e) Name and qualification of person with responsibility for dispensing trial product.

* 1. **Site Principal Investigator**

|  |  |
| --- | --- |
| Name |  |
| Qualifications  |  |
| Contact details  |  |
| Physical address  |  |
| Declaration of capacity & interests  |  |

* 1. **Site Sub-investigator and trial-specific support staff**

|  |  |
| --- | --- |
| Name:  |  |
| Qualifications  |  |
| Contact details  |  |
| Physical address  |  |
| Declaration of capacity & interests  |  |

* 1. **For animal farm Sites**

(a) Responsible administrator or farmer;

(b) Contact details; and

(c)Append signed letter of agreement for trial to take place.

* 1. Append signed agreement between the Investigating institution and the Sponsor or field research organization. (Appendix 13)
	2. **Trial Animals**
		1. Number of animals as stipulated in the table below

|  |  |
| --- | --- |
| Number of trial sites  |  |
| Total number of animals to be enrolled in all sites  |  |
| Intended number of animals at each site – evidence of availability |  |

* + 1. Duration
		2. Estimated trial duration: Date initiated to end
		3. The intended compensation in case of loss or injury to the animals in the trial shall be un understanding between the applicant and the investigating institution.

**NB.** This will be after confirmation that the loss or injury of was due to the trial product.

* 1. **Trial monitoring and reports**
		1. Describe the safety and monitoring plan for each site.
		2. Describe the system to be used to detect, record, assign causality and the actions for adverse events.
		3. Describe the actions to be taken following reports of suspected adverse events.
		4. When will interim reports be submitted?
		5. Final report - estimated due-date?
	2. **Insurance**
		1. Provide a copy of the current insurance certificate.
		2. Provide evidence that each member of the investigating team is covered by relevant malpractice insurance for this trial
	3. **Description of the Trial**
		1. Is the title of the trial fully descriptive?
		2. Summarized rationale for this trial, including relevance to Uganda
		3. Brief background information shall include:
1. The problem statement and the justification of the trial;
2. Properties of the trial product- hypothesis for action
3. Description of risks of the protocol and the potential harms of the trial product.
4. summary report that establishes probable safety and efficacy of the investigational product in animals.
5. Include evidence that the formulations used in the pre-field and previous trials are identical to that in this application. Any variations should be highlighted and justified. \*
6. Published reviews or reports relevant to the indicated ectoparasites and this type of product
	1. Objectives of this trial (List as primary and secondary objectives and provide justification)
	2. Trial design: describe and justify each component;
	3. The eligibility of the animals involved in the trial in relation to:

(a) Inclusion criteria - list and justify each

(b) Exclusion criteria - list and justify each

* 1. The treatment regimens for each group.
	2. Follow-up, sampling collection and monitoring plans; immediate monitoring - intermediate monitoring - long term monitoring.
	3. Outcomes measurements and analysis
	4. Describe each outcome or variable (including safety and efficacy)
	5. Describe the samples that will be collected and the analyses to be conducted on each sample
	6. Provide evidence that the laboratories that will conduct the safety screening, and the end-point assays are accredited and competent to do the assays. (where applicable)
	7. Describe the intended statistical analysis to be conducted. Provide evidence that the study is powered to provide the intended outcome.
	8. Are any sub-studies intended? Provide full details.
	9. Will field samples be stored for any period beyond the duration of this trial?
	10. What is the purpose of such archiving?
	11. What controls are to be placed on their confidentiality and possible future use?
	12. Informed consent from animal owners.
	13. Append a copy of informed consent from animal owners.
	14. Are there separate informed consent from animal owners for sub-studies.
	15. Publication policy
	16. Provide details of the investigators and Sponsors intentions and freedom to publish the outcomes of this trial