AKC Canine Health Foundation
Adverse Event Report (AER)

CHF Grant Number	
Project Title	
Institution	
Investigator(s)	
Project Start Date	
Current Date	

When an adverse event or serious adverse event occurs, the Principal Investigator will notify the Foundation by submission of the Adverse Event Report by email to chfgrants@akcchf.org. The Principal Investigator will provide follow-up information as reasonably requested by the Foundation. A serious adverse event (SAE) must be reported to the Foundation within 72 hours of the discovery of the adverse event. An adverse event (AE) must be reported to the Foundation within ten (10) business days of the discovery of the adverse event. Reporting an adverse event or serious adverse event to the Foundation does not relieve the Grantee or Principal Investigator of responsibility for reporting such adverse events to appropriate regulatory authorities, if required.

Definition of Adverse Event (AE): any unanticipated result of ACUC-approved animal activities that is an unfavorable occurrence in a research participant, which may or may not have a causal relationship with the study intervention/treatment. AE's are any abnormal clinical sign that is newly observed in the dog (i.e. was not present prior to start of the study) or is a pre-existing abnormal clinical sign that worsened.

Definition of Serious Adverse Event (SAE or SAEs): Any Adverse Event, without regard to causality, which is life- threatening, results in death, hospitalization or prolongation of existing hospitalization, persistent or significant disability or incapacity, or a congenital anomaly or birth defect. Any other medical event that, in the medical judgment of the Principal Investigator, may jeopardize the health of the subject or may require medical or surgical intervention to prevent one of the outcomes listed above is also considered an SAE.

IACUC Protocol Number:_____ Date Incident was reported: _____

Patient ID: _____

1. Date of Adverse Event/Onset:
2. Date of Adverse Event Stop:
3. Was this serious or non-serious? ☐ Yes ☐ No
4. What was the location of the event?

☐ Internal (within grantee research facility)

☐ External (outside of grantee research facility)

5. Describe the nature of the adverse event. In this description, please include the investigator's analysis of the event:

6. If a serious adverse event occurs, select the category of the SAE:

☐ Death

☐ Persistent or significant inability to perform activities or daily living []

☐ Life-threatening

☐ Hospitalization-initial or prolonged

☐ Required intervention to prevent permanent impairment

☐ Other, Describe:

7. Based on your consideration of the event, what is the event's relationship to the research supported by the AKC Canine Health Foundation?

- ☐ 1 = unrelated (clearly not related to the research)
- ☐ 2 = unlikely (doubtfully related to the research)
- ☐ 3 = possible (may be related to the research)
- ☐ 4 = probable (likely related to the research)
- ☐ 5 = definite (clearly related to the research)

8. Have similar adverse events occurred on this protocol? ☐ Yes ☐ No

9. What steps do you plan to take as a result of the adverse event reported above? Provide documentation for review and approval of any of the steps checked below. If the protocol needs to be modified, you must submit a *Protocol Amendment Request* and *updated and approved IACUC.*

- ☐ No action required
- ☐ Amend consent document
- ☐ Amend protocol
- ☐ Inform current subjects/owners
- ☐ Terminate or suspend protocol
- ☐ Other, describe:

10. What is the status of the adverse or serious adverse event?

☐ Resolved Date Resolved

☐ Ongoing/unknown

11. What is the current project status?

- ☐ Participants are still being recruited and/or receiving study treatment/interventions/procedures
- ☐ Participants have completed study treatment/interventions/procedures; continue in follow-up observations
- ☐ Participant involvement is complete, and data analysis is underway

Signature of principal investigator: Date: