60th Medical Group (AMC), Travis AFB, CA

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC)

FINAL REPORT SUMMARY

(Please type all information. Use additional pages if necessary.)

PROTOCOL #: FDG20170015A **DATE:** 15 August 2018

PROTOCOL TITLE: Establishing Reference Intervals for Rotational Viscoelastometry Evaluated Via ROTEM® in the Pig (*Sus scrofa*)

PRINCIPAL INVESTIGATOR (PI) / TRAINING COORDINATOR (TC): Dr. Guillaume Hoareau

DEPARTMENT: SGSE **PHONE #:** 215-275-0395

INITIAL APPROVAL DATE: 23 March 2017 **LAST TRIENNIAL REVISION DATE:** N/A.

FUNDING SOURCE: AF Surgeon General

1. RECORD OF ANIMAL USAGE:

Animal Species:	Total # Approved	# Used this FY	Total # Used to Date
Sus scrofa	80	65	65

2. PROTOCOL TYPE / CHARACTERISTICS: (Check all applicable terms in **EACH** column)

___ Training: Live Animal ___ Medical Readiness ___ Prolonged Restraint

___ Training: non-Live Animal ___ Health Promotion ___ Multiple Survival Surgery

___ Research: Survival (chronic) ___ Prevention ___ Behavioral Study

_X__ Research: non-Survival (acute) ___ Utilization Mgt. ___ Adjuvant Use

___ Other ( ) ___ Other (Treatment) ___ Biohazard

3. PROTOCOL PAIN CATEGORY (USDA): (Check applicable) ___ C __X_ D ___ E

4. PROTOCOL STATUS:

***Request Protocol Closure:**

___ Inactive, protocol never initiated

___ Inactive, protocol initiated but has not/will not be completed

__X_ Completed, all approved procedures/animal uses have been completed

5. Previous Amendments:
List all amendments made to the protocol. **IF none occurred, state NONE. Do not use N/A.**

For the Entire Study Chronologically

Amendment Number	Date of Approval	Summary of the Change
None		

6. FUNDING STATUS: Funding allocated: $ 2,557.80 Funds remaining: $ 0.00

7. PROTOCOL PERSONNEL CHANGES:

Have there been any personnel/staffing changes (PI/CI/AI/TC/Instructor) since the last IACUC approval of protocol, or annual review? ___ Yes __X_ No

If yes, complete the following sections (Additions/Deletions). For additions, indicate whether or not the IACUC has approved this addition.

ADDITIONS: (Include Name, Protocol function - PI/CI/AI/TC/Instructor, IACUC approval - Yes/No)

NAME	PROTOCOL FUNCTION	IACUC APPROVAL

DELETIONS: (Include Name, Protocol function - PI/CI/AI/TC/Instructor, Effective date of deletion)

NAME	PROTOCOL FUNCTION	DATE OF DELETION

8. PROBLEMS / ADVERSE EVENTS: Identify any problems or adverse events that have affected study progress. Itemize adverse events that have led to unanticipated animal illness, distress, injury, or death; and indicate whether or not these events were reported to the IACUC.

None.

9. REDUCTION, REFINEMENT, OR REPLACEMENT OF ANIMAL USE:

REPLACEMENT (ALTERNATIVES): Since the last IACUC approval, have alternatives to animal use become available that could be substituted in this protocol without adversely affecting study or training objectives?

No.

REFINEMENT: Since the last IACUC approval, have any study refinements been implemented to reduce the degree of pain or distress experienced by study animals, or have animals of lower phylogenetic status or sentience been identified as potential study/training models in this protocol?

No.

REDUCTION: Since the last IACUC approval, have any methods been identified to reduce the number of live animals used in this protocol?

No.

10. PUBLICATIONS / PRESENTATIONS: (List any scientific publications and/or presentations that have resulted from this protocol. Include pending/scheduled publications or presentations).

- European veterinary emergency and critical care annual congress, Venice, June 2018.
- Military Health Research Symposium, Kissimmee, August 2018, pending.

11. PROTOCOL OBJECTIVES: (Were the protocol objectives met, and how will the outcome or training benefit the DoD/USAF?)

Yes. The results will allow establishment of reference intervals for thromboelastometry in pigs, the most commonly used animals in CIF trauma research.

12. PROTOCOL OUTCOME SUMMARY: (Please provide, in "ABSTRACT" format, a summary of the protocol objectives, materials and methods, results - include tables/figures, and conclusions/applications.)

Objectives: Pigs are commonly used in translational research and accurate assessment of coagulation is essential. We sought to establish porcine Rotem® normal values for pigs following the American Society for Veterinary Clinical Pathology reference interval guidelines.

Materials and Methods: Sixty-five healthy Yorkshire cross pigs (39 males and 26 females) were anesthetized for other protocols with an intramuscular injection of tiletamine and zolazepam. Using a 18G needle attached to a Vacutainer®, blood was acquired from the cranial vena cava. Tubes were filled in the following order: evacuation clot tube, EDTA tube, heparin tube, and 2 citrate tubes. The citrate tubes were randomly assigned to 30 minutes with or without constant agitation on a rocker. The following Intem® and Extem® parameters were reported according to manufacturer's recommendations: CT, CFT, alpha, A10, A20, MCF, ML, LI30, LI45. Reference intervals were reported as 2.5th and 97.5th percentile of the population's results. The effects of sex, sampling order, and agitation on Rotem® results were analyzed via linear regression.

Results: Sex, sampling order, or agitation did not influence any of the Rotem® parameters. Pooled reference intervals were established for each Rotem® parameter combining data from male and female animals from the non-agitated tubes.

Conclusions: This is the first study establishing Rotem® reference intervals in a large number of both male and female adult pigs, while also providing detailed pre-analytical sample processing. Our results provide valuable information for researchers utilizing porcine models.

(PI / TC Signature) **(Date)**

Attachments:
Attachment 1: Defense Technical Information Center (DTIC) Abstract Submission **(Mandatory)**

Attachment 1

Defense Technical Information Center (DTIC) Abstract Submission

This abstract requires a brief (no more than 200 words) factual summary of the most significant information in the following format: Objectives, Methods, Results, and Conclusion.

Objectives: Pigs are commonly used in translational research and accurate assessment of coagulation is essential. We sought to establish porcine Rotem® normal values for pigs following the American Society for Veterinary Clinical Pathology reference interval guidelines.

Methods: Sixty-five healthy Yorkshire cross pigs (39 males and 26 females) were anesthetized with an intramuscular injection of tiletamine and zolazepam. Using a 18G needle attached to a Vacutainer®, blood was acquired from the cranial vena cava. Tubes were filled in the following order: evacuation clot tube, EDTA tube, heparin tube, and 2 citrate tubes. The citrate tubes were randomly assigned to 30 minutes with or without constant agitation on a rocker. The following Intem® and Extem® parameters were reported according to manufacturer's recommendations: CT, CFT, alpha, A10, A20, MCF, ML, LI30, LI45. Reference intervals were reported as 2.5th and 97.5th percentile of the population's results. The effects of sex, sampling order, and agitation on Rotem® results were analyzed via linear regression.

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Conclusion: This is the first study establishing Rotem® reference intervals in a large number of both male and female adult pigs, while also providing detailed pre-analytical sample processing. Our results provide valuable information for researchers utilizing porcine models.

Grant Number:_____

From:_____

****If you utilized an external grant, please provide Grant # and where the grant came from. Thank you.**