

*United States Department of*

# **Health & Human Services**

**Office of the Assistant Secretary for Preparedness & Response (ASPR)  
Biomedical Advanced Research & Development Authority (BARDA)**



# ***BARDA Animal Model Development Program***

**Tom Dreier, Ph.D.**

**Subject Matter Expert**

**Division of Chemical, Biological, Radiological, and Nuclear  
Countermeasures**

**Tunnell Contractor in Support**

**of the**

**Biomedical Advanced Research and Development Authority**

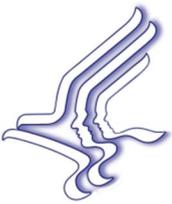
**October 17, 2011**



# Goals of Animal Model Development Program



- **Support the development and approval/licensure of medical countermeasures (MCMs) against CBRN, pandemic influenza and emerging infectious diseases**
- **Develop models that are harmonized with the framework of the regulatory processes employed within the FDA – Qualified Models.**



# Contract Structure



- **Indefinite Delivery Indefinite Quantity (IDIQ)**
- **One year base with four one year options**
- **\$20M/yr ceiling per contractor**
- **\$7.5M ceiling per task order**
- **All task orders are competitively bid subject area**



# BARDA Animal Model Development Contractors



- Battelle Memorial Institute (Columbus, OH)
- Battelle PNWD (Richland, WA)
- Bioqual (Rockville, MD)
- DSTL (Salisbury, UK)
- Health Protection Agency (Salisbury, UK)
- IIT Research Institute (Chicago, IL)
- Lovelace (Albuquerque, NM)
- MRI Global (Kansas City, MO)
- Southern Research Institute (Birmingham, AL)
- SRI International (Menlo Park, CA)
- University of Illinois at Chicago (Chicago, IL)
- University of Texas Medical Branch (Galveston, TX)



# Essential Data Element of an Animal Model<sup>1</sup>



- A. Characteristics of the CBRN Agent that Influence the Disease or Condition**
- B. Host Susceptibility and Response to Etiologic Agent**
- C. Natural History of Disease: Pathophysiologic Comparability**
- D. Trigger for Intervention**
- E. Characterization of the Medical Intervention**
- F. Design Considerations for Animal Efficacy Studies**

1. <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm078923.ugdanceComplianceRegulatoryInformation/Guidances/ucm078923.pdf>



# Priorities



- **Natural history studies to support current BARDA programs**
- **Qualification of models**
- **Cooperate with FDA to define the qualification process**
- **Team with industry to assess new programs**
- **Studies to support less mature programs**



# Teaming with BARDA



- **BARDA is interested in teaming with industry**
- **How?**
  - CRADA
  - OTA
- **All data animal model data belongs to the government**
- **IP will be retained by the owner (must be declared prior to start of study)**
- **Study priorities are set by the government in accordance with mission objectives**
- **Contact BARDA if interested**



# Points of Contact



- **COTR (Adey Smith)**

- Primary technical point of contact for Animal Model contract
- [Adeyinka.Smith@hhs.gov](mailto:Adeyinka.Smith@hhs.gov) , 202-260-0981

- **SME**

- Tom Dreier ([thomas.dreier@hhs.gov](mailto:thomas.dreier@hhs.gov))
- Mike Merchlinsky ([michael.merchlinsky@hhs.gov](mailto:michael.merchlinsky@hhs.gov))

- **RQA**

- Jim Little ([james.little@hhs.gov](mailto:james.little@hhs.gov))