



**Office of Research and Development  
and  
Office of Information Security – Research Support Division  
Joint Guidance on Considerations for  
The Protection of Sensitive Data from VA Research with Animals**

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**This is a new guidance document.**

**For questions on the content of this guidance, please contact the Office of the Chief Veterinary Medical Officer for the Office of Research and Development (ORD) by email ([Alice.Huang@va.gov](mailto:Alice.Huang@va.gov)).**

**Background:**

On January 8, 2021, VHA Directive 1200.01(1) “Research and Development Committee” was amended to include the requirement for VA Investigators to submit an Enterprise Research Data Security Plan (ERDSP) for each research study. The ERDSP details the plan for implementing reasonable standards of safeguards for the security of research data collected, processed, stored, or transmitted during the study, consistent with VA Directives, handbooks, and other regulatory requirements. The ERDSP form and User Guide are not statements of policy, but instead make up a toolset for implementing policy. The form and the User Guide use a data classification system that assists in classifying research data so that Information System Security Officers (ISSO) can evaluate whether the security controls/safeguards planned are commensurate to the sensitivity level of research data. Data from research with animals differs from data from research with human subjects in that the standards for protection of the privacy of human subjects do not apply to the data from animal subjects, but security safeguards are important for data from research with animals because of the risks to VA associated with those data being taken out of context and misused to misrepresent the work done at VA.

**Scope:**

This guidance document addresses the information security and data sensitivity considerations that apply to data from VA research with animals. The guidance is for all VA Research & Development (R&D) stakeholders involved in conducting or overseeing work with animals: Principal Investigators (PI), Research Staff, Research Administrative Officers, members of the Institutional Animal Care and Use Committee (IACUC), members of the R&D Committee, and Information System Security Officers (ISSO).

**Guidance:**

**1. Defining Animal Research Data Sensitivity**

Principal Investigators are responsible for determining whether the data to be collected in their



research with animals are “sensitive” and therefore require implementation of particular security measures. The ERDSP toolset provides the following guidance about which data from research with animals are considered “sensitive” and therefore subject to the requirements specified in VA Directive 6500, “VA Cybersecurity Program” and VHA Directive 1200.01(1), “Research and Development Committee”:

- a. “Sensitive” includes the following DATA TYPES: Individually Identifiable Information (III), Personally Identifiable Information (PII), Protected Health Information (PHI), photographic or video images of Category D or E procedures in Animal Research, Genomic (Human), Intellectual Property, (Federal Information Security Modernization Act (FISMA) Requirement = Moderate FISMA Baseline Impact).

Sensitive Data: Confidentiality=Moderate, Integrity=Moderate, Availability=Low

- b. “Non-Sensitive” includes the following DATA TYPES: De-Identified Information from humans, Unpublished Research (Animal Research other than photographic or video images of Category D or E procedures, Non-Human Basic Lab), (FISMA Requirement = Moderate FISMA Baseline Impact)”

Non-Sensitive Data: Confidentiality=Low, Integrity=Moderate, Availability=Low

- c. “Public” includes the following DATA TYPES: Published Research (Aggregate data, submitted for peer review journals and/or presented at conferences, included in grant applications), (FISMA Requirement = Low FISMA Baseline Impact)

Public Data: Confidentiality=Low, Integrity=Low, Availability=Low

Categories D and E are defined by the United States Department of Agriculture / Animal Plant Health Inspection Service (USDA/APHIS) Animal Welfare Regulations.

These definitions are applied as follows, to data from VA research with animals, for purposes of ISSO determination of the appropriate security measures required:

- a. Only photographic or video images of animals showing Category D or Category E procedures being or having been performed are considered “sensitive” as defined in VHA Directive 1200.01 (3.g) for purposes of ISSO determination of the appropriate security measures required. For example, a photograph of a recognizable surgical scar would be considered “sensitive”.
- b. Other data from VA research with animals (even if collected from protocols that include recording of photographic or video images of Category D or Category E procedures) are generally not considered “sensitive” as defined in VHA Directive 1200.01 (3.g) for purposes of ISSO determination of the appropriate security measures required. Some examples of data that are not considered “sensitive data” for purposes of ISSO determination of the appropriate security measures required include:
  - 1) Any data from research with animals that are not in the form of photographic or video images, even if collected from protocols for which photographic or video recording of images of animals is approved, are not considered “sensitive”.



- 2) Any photographic or video images of research with animals that do not show Category D or Category E procedures are not considered “sensitive”. For example, a photograph of an animal fully recovered from surgery, with fur grown back in so that the scar is not visible, would not be considered “sensitive”.

## **2. Managing and Protecting Data from Research with Animals**

There may be specific circumstances under which it is appropriate to treat data as sensitive, even though the definitions above do not require it. Such determinations are best made on a case-by-case basis by the PI and the IACUC working together and in consultation with the office of the CVMO. Suitable information security safeguards and controls can then be determined in consultation with the ISSO for the specific circumstances involved. Please notify the office of the CVMO of the circumstances and extra security measures to be taken when it is determined that this is appropriate.

## **3. Publication of Sensitive Data from Research with Animals**

Unlike sensitive data collected from human subjects, there are cases in which it is appropriate to publish data collected from animal subjects and defined as “sensitive” for the purposes of requiring ISSO review. These are generally cases in which the assurance that the data will be published in an appropriate context for correct interpretation reduces the risk of misinterpretation to a level that is outweighed by the scientific value of the data. The individual images remain “sensitive” for purposes of storage within VA or transmission to the publisher, even though the images published in context become “public”.

### **References:**

[VHA Directive 1200.01 \(1\), “Research and Development Committee”, dated January 8, 2021](#)

[VHA Directive 6500, “VA Cybersecurity Program”, dated February 24, 2021](#)

[OIS Research Support Division \(RSD\) Enterprise Research Data Security Plan Resource Page](#)