

# PAM REPORTING

The Age of Auditing  
February 3, 2015

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# The PAM Audit

- You have
  - ▣ Reviewed the protocol
  - ▣ Interviewed the PI and technicians
  - ▣ Checked the study data
  - ▣ Observed the in-life procedures



# The Observations

- Rate the observations
  - ▣ Minor
  - ▣ Major
  - ▣ Critical
- Categorize the observations
  - ▣ Animal handling
  - ▣ Protocol deviation
  - ▣ Veterinary care
  - ▣ Recordkeeping
- Count the observations
  - ▣ Rate the overall audit





# Algorithm – Overall Rating

	# minor observations	# major observations	# critical observations
<b>Effective</b>			
<b>Opportunity to Enhance</b>			
<b>Requires Improvement</b>			
<b>Unsatisfactory</b>			

# The Overall Rating

overall audit rating	Year	Quarter	Start	End	Auditee	Location	Critical	Major	Minor	Critical Observations / Comments	Major Observations	CAPA Status
effective	2014	1			Washington		0	0	2			complete
opportunity to enhance	2014	1			Lincoln		0	0	5			complete
unsatisfactory	2014	1			Johnson		1	0	4	This would be critical observation		complete
unsatisfactory	2014	1			Obama		2	1	0	There would be 2 critical obs listed here	One observation would be listed here	complete
effective	2014	2			Nixon		0	0	2			complete
effective	2014	2			Kennedy		0	0	1			complete
opportunity to enhance	2014	3			King		0	1	1		One minor observation would be here.	complete

**Fictitious data**

# The Review

- Colleague review meeting
  - Multiple perspectives
  - Consistency
  - Accountability



# The Close-Out meeting



- Auditor and PI review the observations and suggestion for improvement.
- No surprises – be transparent throughout audit process.
- Changes to the observations can happen at this meeting.
- Report is sent to the PI to complete the corrective action, responsible person and completion date.



# The Anatomy of a Report

1.

Observation:	The facts supported by policy, SOP or regulation.
Suggestion for Improvement:	What does success look like. Not a “how to” statement.
Risk Category:	Minor, major, critical
Corrective Action:	This section is completed by the PI.
Responsible Individual:	
Completion Date:	

# The Anatomy of a Report

To: Principal Investigator

CC:  
Site IACUC Manager  
Site IACUC Chair  
Site Attending Vet  
Compliance Director  
LAR Director

From: Auditor


APS #:  
APS Title:  
PAM Dates:

1.

Observation:
Suggestion for Improvement:
Risk Category:
Corrective Action:
Responsible Individual:
Completion Date:

2.

Observation:
Suggestion for Improvement:
Risk Category:
Corrective Action:
Responsible Individual:
Completion Date:

Risk Category Defin  (Ctrl) ▾

**Minor** – The deviation to an internal guideline, company policy or procedure has little or no effect on the health and welfare of laboratory animals and is not considered to be systemic in nature.

**Major** – A deviation from applicable regulatory requirements or guidelines, company policies or procedures, or study protocol was observed that meets one of the following criteria:

- Deviation is not considered systemic but could have a potential negative impact on the health and/or welfare of laboratory animals.
- Deviation is considered to be systemic and does not appear to negatively impact the health and/or welfare of laboratory animals.

**Critical** – A deviation from applicable regulatory requirements or guidelines, company policies or procedures, or study protocol was observed that meets one of the following criteria:

- Deviation has or will have a negative impact on the health and/or welfare of laboratory animals.
- Deviation is system and has a potential negative impact on the health and/or welfare of laboratory animals.

## Header



Communicates the key information about the audit and identifies the recipients of the report.

## Body



Documents the observation, SFI and risk category.

## Footer



Defines the risk assessment categories for easy reference.

# Metrics



- Number of audits by
  - Site
  - PI
  - Species
- Risk area
  - Gaps in program
  - Focused education
- Overall assessment of program
  - Effective.....Unsatisfactory