

Four Modules describing Topics of Pain and Distress and Humane Endpoints in the Laboratory Animal Facility<sup>1</sup>

developed by PRIM&R Group A –August 2016 cohort

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Who: Students, that is the intended audience: operations staff (veterinary, experienced husbandry, and research) versus the IACUC (protocol reviewers)

When: Anticipated amount of time to devote to each module: 45 to 60 minutes

<b>Goals</b>	<b>Objectives</b> - learner will be able to ... - measurable items through assessment	<b>LOC<sup>2</sup></b> <b>HOC</b>	<b>Summative assessment</b>	<b>Formative assessment (rubrics<sup>3</sup>)</b>	<b>Possible Activities, Tasks, Exercises, and Assignments aligned with Active Learning</b>
1) When using animals in science and for the gain of knowledge, individuals must be aware to appreciate and consider the potential for pain and distress (P&D) in research investigations.	Find appropriate reference materials related to P&D issues and discussions.	L	Review the materials in general; apply a jigsaw concept where it is parceled for study and the participants share what they learned in a discussion. Compile charts (use whiteboards) of the specific information on a given species. Develop skills and key words.	Prepare in groups a case study of materials. Demonstrate competently a search for a reference.	Retrieve reference documents electronically. Apply keywords to focus on e-searches. Find: AVMA Guideline on Euthanasia, USDA AWAR, USDA policy 11, Animal Welfare Inspection Guide, ILAR Guide, US government principles, other.
	Recite (paraphrase) the three US government principles pertaining to P&D	L	Declare what the three principles are.	Define what the three principles are meant to address in terms of P&D.	US Government Principles IV, V and VI are the fundamental principles pertaining to the humane treatment and endpoints for animals used in research. Using charts, write each one and lead a discussion of interpretation.

<sup>1</sup> This table and the subsequent training slides should be regarded as starting points for trainers. By no means can the information be considered complete or the only approach to train on the material.

<sup>2</sup> LOC and HOC, abbreviated as L, H, and /H in the table, are lower and higher order cognitive skills, taken from Bloom's Taxonomy.

<sup>3</sup> Rubrics are graduated scales of ability to demonstrate learning of knowledge or a skill.

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	Recite (paraphrase) the three International Guiding Principles for Biomedical Research Involving animals pertaining to P&D and humane endpoints.	L	Declare what the three principles are.	Define what the three principles are meant to address in terms of P&D and humane endpoints.	International Guiding Principles VI, VII and VIII echo the US Government Principles; Both sets of Principles are fundamental to the humane treatment and endpoints for animals used in research. Using charts, write each one and lead a discussion of interpretation.
	Recite several criteria that should/must be met for an experiment to be acceptable (approved for conduct) in a particular context.	L	List the criteria and state why they are considered important in different kinds of studies such as teaching, toxicology, pain management, etc.	After being trained, review an approved protocol and its original draft in which P&D issues were found.	Various teams look at approved animal study protocols to find issues related to P&D.
	Be familiar with the terms “humane care and treatment” and treating animals “humanely”.	L	In teams (pair and share), contemplate the nuances of the terms. Choose a document (protocol, published study, other) and find words that imply the meaning of the terms.	Assume a role of an IAUC member and explain what the terms would mean.	Discuss and debate the terms “humane care and treatment” and “treating animals humanely”.
	Understand and clarify the potential roles of the research assistants, students, investigators, vets and staff, IACUC members, public members, etc., in addressing P&D.	L/H	Find reports of animal usage in both the popular and scientific literature and suggest what the roles should be thinking about.	Presented with a scenario and a role, diagram how an issue of P&D could be handled.	Assign roles to members of a group who describe their job in clarifying P&D.
	Compile statistics and complete USDA category B/C/D/E reports (form 7023).	H	“Pair up and share” to complete form 7023, based upon an animal study description.	Individually complete form 7023, based upon an animal study description.	Analyze protocols based upon categories B/C/D/E per the regulations.
	Define and reword the phrase “Good science and good animal care go hand in hand”.	H	Leader of the training session evaluates group work.	Course leader reads and critiques essays, presentations written by individuals.	Build a concept map of what the phrase means before and after a discussion of the topic.

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2) Individuals must appreciate various positions by experiencing several ethical considerations about P&D and humane endpoints (HE).	Learn what factors can impact P&D.	L	After a discussion, state one or two factors that could impact P&D and provide examples.	Summarize a paper where the effects of P&D were either exacerbated or ameliorated by a factor.	With P&D in the middle of a "wheel," attach as spokes the factors that could have impact.
	Recite the ILAR Guide statement "In general, unless the contrary is known or established, it should be assumed that procedures that cause pain in humans also cause pain in animals".	L	Memorize the phrase.	Recite the phrase.	Use a thesaurus to use other words which can be used to mean the same as the phrase.
	State and define the 3Rs (reduce, refine, replace) as they relate to P&D and HE.	L	Match the 3R terms with various approaches of P&D. Role play a 3Rs "conversation" among a PI and IAUC members discussing a protocol during a review.	Correctly define the 3Rs.	Analyze protocol applications from several institutions to learn how they obligate the research team to relate ethics with potential P&D and HE.
	Be knowledgeable of the effect that enrichment can have on addressing P&D.	L	Describe to others the enrichment value of a tool for a particular species.	Complete an assessment to match enrichment items with particular types of animals.	Using either pictures or actual items, discuss how they can be tools of enrichment. Build a "Jeopardy" type game.
	Remain apprised of current relevant literature.	I/H	Read and report on literature about P&D and HE by parcelling sections and reporting together (jigsaw).	Name several journals that report on the studies of P&D in laboratory animal science.	See suggested papers: - Guidelines for the ethical use of animals in applied ethology studies (2003) - Guidelines for the treatment of animals in behavioural research and teaching (2012)
	Declare why ethics is important.	H	Create a map of the structure of an article (e.g., J. Tannenbaum "Ethics and Pain Research in Animals" ILAR Journal 40 (3): 97-110) related to ethical issues.	Define terms such as ethics, the 3Rs, the privilege of using animals, etc.	Compare and contrast biomedical advocates and animal rights groups' positions on the usage of animals in P&D studies.

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	Search for alternatives.	H	Watch and discuss “impacts” ( <a href="https://www.nc3rs.org.uk/our-impacts">https://www.nc3rs.org.uk/our-impacts</a> ).	Using resources at AWIC, apply search engines with key words.	Utilize training materials from AWIC to conduct searches.
	Learn how P&D can affect and impact scientific results.	H	Diagram an animal body for sites where P&D could manifest.	Select a publication and summarize how the authors predicted P&D	Consider the statement “If it hurts in humans, it hurts in animals” and decide what organs/tissues would respond.
	Decide when P&D could be acceptable. Stated otherwise, why care about it?	H	Compare and contrast three criteria: 1) are the animals fit for purpose (integrity)?, 2) what amount of P&D (suffering) is acceptable?, and 3) how does imposing P&D relate to living (telos)?	Respond to a protocol scenario of P&D.	Create research questions which require a degree of P&D in order to answer (e.g., migraines).
	Analyze “mission creep” in using the USDA C/D/E scale for non-covered species.	H	Debate whether it is mission creep. Find examples from institutions that state (through websites, SOPs, protocols) they apply the categories to non-USDA animals.	Declare what is creep and what is not.  Know and cite the regulations.	Evaluate scenarios and case studies about the pain categories.
3a) Participants will understand and recognize P&D.	Define and describe pain, its various types and possible causes	L	Matching terms Short answer		Somatic, visceral, and neuropathic. Pain of all three types can be either acute or chronic.
	Define and describe different forms of stress	L	Matching terms Short answer Look at pix	Give examples: distress, eustress	
	Recognize species specific behaviors and distinguish them from P&D	L/H	Review and report on pix/video		Clinical signs, based upon the animals in the LAF
	Distinguish what is scientifically justified P&D	H	Read protocol for scenarios		Unexpected outcomes 85 PHS policy
3b) Participants will know how to manage P&D.	Develop skills and apply appropriate methods to alleviate P&D.	H	Do “rounds” with experienced person Label cages with ID cards Animal-quins	Use Flecknell videos	Anticipate and ameliorate role of post-approval monitoring.

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	Use tools (e.g., scoring system) to assess pain level.	L/H	Use scoring sheet with pix Select appropriate tool for P&D assessment Demonstrate use of tool	TPR	Develop pain scoring Utilize pictures to evaluate TPR
	Determine your role in the alleviation of P&D.	H	Describe who does what and when Final case study(ies)	Case study exercises	Vet, vet tech, PI, LAT Institutional dependent
	Document an incident of P&D	L/H	Complete a form with no omissions		Alleviation
	Identify whom to report an incident of P&D	H	Describe the routing process		
4a) Participants will understand and recognize humane endpoints (HE).	Define terms such as humane, endpoint, interventions, humane endpoints; compare to experimental endpoints.	L	Use exercises that explore, illustrate, and define humane and experimental endpoints.	Write a short answer essay that utilizes the terms.	Find definitions and usage in the ILAR Guide, dictionary, and websites. Produce a word cloud from phrases submitted by students ( <a href="http://www.wordle.net/">http://www.wordle.net/</a> )
	Recite (paraphrase) the three US government principles pertaining to HE	L	Declare what the three principles are.	Define what the three principles are meant to address in terms of HE.	US Government Principles IV, V and VI are the fundamental principles pertaining to humane treatment and endpoints for animals used in research. Using charts, write each one and lead a discussion of interpretation.
	Describe what endpoint means and what it can be (how it manifests) in the context of animal research.	L/H	In a group, each individual extracts from the abstract of a published paper where the endpoints have been described.	Defend and critique endpoints as commonly established (e.g., LD50 studies).	Use exercises that explore, illustrate, and define humane and experimental endpoints.
	Examine policies and guidelines about HE from various research institutions.	L/H	Find HE guidelines from another institution. Compare the criteria.	Envision a study from your own institution and how the IACUC would review it.	Find the HE guidelines in your own institution. Read and discuss.

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	Evaluate the role you can play in addressing HE.	L/H	Read protocols for how HE was described. Discuss and debate with others.	Devise “task” statements to include in a position description for someone engaged in PAM related to HE.	Role play as vet, vet tech, PI, IACUC member, etc.
4b) Participants will learn to manage HE.	Develop skills and tactics to identify and recognize HE from a study protocol.	L/H	Find the “buzzwords” in several published papers, such as toxicology and pain disciplines.	List the “buzzwords” you should look for in a protocol related to HE.	Invite an IACUC member to class to discuss an actual occurrence.
	Develop skills and tactics relevant to managing HE.	H	From images and descriptions presented with an HE study, discuss appropriate actions.	Develop a cage-side checklist for a study approved to have HE.	Invite a researcher or veterinarian to class to discuss an actual occurrence.
Content considerations for Module 3a (understand/recognize)	Define analgesia and anesthesia	H			Resource: ILAR’s Recognition and Alleviation of Pain in Laboratory Animals (2009)
	Define alleviation	H			
	Compare, analyze, create	H	Evaluate status of animal in order to minimize P&D		
Content considerations for Module 3b (manage)	Guide, p. 120/1, P&D section and approaches to manage P&D (professional judgement and veterinary consult as appropriate)	H			
	Consider other approaches to manage pain & distress such as non-pharmacologic methods				Create a holistic approach to nursing care that would be in addition to pharmacologic pain management or can be used in place of if pain is mild or if analgesia would confound data. E.g., dimmed lights and other palliative care measures

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	Assess pain level by using scoring system	H			Create a decision tree for staff to use with branching logic to assist in actions to be taken to manage P&D and HE.
	How to report and to whom	H			Create an organizational reporting flow diagram to be posted in facilities
	Anticipate and Ameliorate	H			Create P&D management plans for certain types of studies and develop others as needed that align with protocol endpoints and humane care of animals
	Relevant and reliable	H			On-going assessment by veterinary personnel and IACUC to employ surrogate markers and temporal endpoints, i.e., Refinement
					Carbone, Pain Management Standards in the Eighth Edition of the Guide for the Care and Use of Laboratory Animals. JAALAS. 51(3): 322-328. 2012
Content consideration for Module 4b - managing humane endpoints	Manage diabetic rodents	L/H		Describe management that includes monitoring glucose, ketones, weight, etc. as indicators of disease status.	Examine studies investigating pathology caused by hyperglycemia (e.g., retinopathy); being hyperglycemic for some time.