



**Shanghai Laboratory Animal Welfare Sharing Conference**  
上海实验室动物福利分享会议  
*IACUC Case Study: Humane Endpoints*  
机构动物管理及使用委员会 (IACUC) 案例分析:人道终结点

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# IACUC Case Study: *Humane Endpoints*

## IACUC 案例分析: 人道终结点



- ▶ **Goal of this presentation is to discuss how an IACUC would address the issues of the following case study**  
这个报告的目的是讨论IACUC如何解决以下案例的这些问题
- ▶ Toxicology safety study using rabbits 用兔子的毒理学安全研究
- ▶ Unexpected deaths in the high dose group 高剂量组的意外死亡
- ▶ Disagreement between Attending Veterinarian and Study Director on: 主治兽医和研究主任之间的不同意见:
  - ▶ What has caused the deaths? 死亡是由什么引起的?
  - ▶ How to relieve the pain? 如何减少疼痛?
  - ▶ What are the humane endpoints of the study? 什么是研究的人道终结点?

# IACUC Case Study: *Humane Endpoints*

## IACUC 案例分析: 人道终结点



- Two months of daily oral dosing of the drug at the laboratory animal facilities. 在实验动物设施给予两个月的每日口服药物。
- Six of the rabbits in the high dose group have died over the last 10 days. 过去10天中, 高剂量组里的兔子死了六只。
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- Remaining two rabbits exhibited central nervous system signs. 剩下的两只兔子表现出中枢神经系统的症状。

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## IACUC 案例分析: 人道终结点



- Attending Veterinarian (AV) blames deaths on test compound. 主治兽医 (AV) 将死亡归咎于实验用的化合物。
- Study Director (SD) blames poor animal husbandry practices and dosing technique combined with inferior quality animals. 研究主任 (SD) 责怪质量差的动物和差劲的给药技术及动物饲养中的操作。

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## IACUC 案例分析: 人道终结点



- Another high dose rabbit seen with clinical signs characterized by diarrhea, inappetance, and “spastic” movements. 另一个高剂量组的兔子出现腹泻, 无食欲, 和“痉挛”运动的临床症状。
- AV examined the rabbit and noted the animal grinding its teeth and appearing to have a painful abdomen. 主治兽医检查了兔子, 注意到动物磨牙齿, 腹部似乎非常疼痛。
- AV characterized the rabbit as in moderate distress in the animal’s record. 主治兽医在动物记录上总结这只兔子在中度痛苦中。
- AV contacted the SD who is out of town. 主治兽医和正在外地的研究主任进行了联系。

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- SD disagreed with the assessment and was adamant that the rabbit did not need analgesics. 研究主任不同意这个评估, 并坚持认为, 没有必要给兔子打止痛药。
- SD stated the use of analgesics would compromise any further data to be gained from the rabbit as the test compound is a pain reliever. 研究主任表示因为测试的化合物是止痛剂, 使用其它的止痛药会损害从兔子实验得到的任何进一步的数据。
- AV then suggested that if analgesics cannot be given, that the rabbit should be euthanized for humane reasons. 主治兽医则建议, 如果不能给予止痛药应该出于人道的原因对兔子实施安乐死。

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- SD was resistant to euthanasia as the death of this rabbit may invalidate the study due to the unusual number of unanticipated deaths in the high dose group. 研究主任不同意使用安乐死, 因为这一兔子死亡可能会使这项研究, 由于在高剂量组非寻常的意外死亡数目, 成为无效。
- SD says that if this rabbit were euthanized, the entire study would need to be repeated, starting all over again with an additional 100 rabbits. 研究主任说, 如果这个兔子被安乐死, 整个研究将需要重复, 要用另外100只兔子重新做。
  - Company would miss the FDA reporting guideline and would delay the release of a proposed \$50 billion dollar a year drug for children that have constant pain. 公司将达不到美国FDA要求的报告准则, 并会延误所提议的每年500亿美元市场的、为患有经常疼痛的儿童研制的药物的上市。

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## IACUC 案例分析: 人道终结点



- Faced with a situation in which she is prohibited from administering analgesics or euthanizing an animal she believes is in pain/distress, the AV reported the incident to the chair of the IACUC for resolution. 面对这个情况, 由于主治兽医被禁止给她认为在疼痛/痛苦中的动物打止痛剂, 或安乐死, 她向IACUC的主席汇报了事件并要求解决。
- Faced with what she knows to be a sensitive issue for the animal caretakers as well as the study director, an emergency meeting of the IACUC was scheduled for the same day. 面对她所知道的一个对研究主任和动物都敏感的问题, IACUC当天就召开了紧急会议。

**As a member of the IACUC, how would you respond?**

**作为IACUC的一员, 你该做何回答?**

# IACUC Case Study: *Humane Endpoints*

## IACUC 案例分析: 人道终结点



- **Questions: 问题:**

1. Who has the final authority for the disposition of the rabbits in this case? 在这种情况下, 谁拥有对兔子处置的最后决定权?
2. What options are available to the IACUC in handling this situation? Legally? Within the framework and written guidelines of the organization? 处理这种情况时, IACUC有哪些选择? 法律上的? 在机构框架内的和书面的准则?
3. Was the veterinary care rendered adequate, excellent, or inadequate and why? 所提供的兽医服务是适当的, 优良的, 或不充分的, 为什么?
4. Should the rabbit be allowed to live without analgesia? 兔子该不该在没有镇痛的情况下继续活下去?

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- **Questions: 问题:**

5. Does your answer change if the rabbit is due to be sacrificed in 24 hours? 如果兔子在24小时后会被牺牲掉, 你的答案是否会改变?
6. What impact should the additional rabbits that will need to be used to repeat the study have on the decision? 如果知道另外的兔子要用来重复这项研究, 这会对你的决定产生什么影响?
7. Do the considerations in this case become different if the study is a toxicity study that has been approved by the IACUC with death as an end-point? 如果是一个经IACUC批准的, 把死亡作为终结点的毒性研究, 在这种情况下, 你的考虑会不同吗?