



中国医学科学院-苏州系统医学系统所

Institutional Animal Care and Use Committee

IACUC Guideline # 129.00

标题 TITLE : 动物不良反应和早期撤出标准政策 Standard Adverse Effects and Early Removal Criteria

目的 PURPOSE : 本政策规范了早期清除标准, 适用于所有方案。This policy provides standard ERC which apply to all research and teaching protocols at ASC unless exceptions have been scientifically justified and approved by the IACUC.

职责 RESPONSIBILITY : IACUC 委员会. IACUC Committee

审核、修订 REVIEW/REVISIONS : 如有需要 IACUC 负责审核及修订本. SOP IACUC Office Staff will review and revise this SOP as needed.

在 IACUC 委员会批准后执行. Implementation will proceed upon

流程 PROCEDURE :

背景 Background:

动物实验必须使用最人道的方法和终点以达到研究的目标。最理想的状态是实验终点最小或无不良反应, 疼痛或不安。不过很多研究为了达到科学目标, 会以疼痛或不安作为研究结果。早期清除标准被用作安乐死的标准, 在发生疼痛或即将恶化的实验计划的终点前施行。此外, 很多诱导或自发的临床症状会意外发生, 或未在方案中提及。此时, 应与兽医积极沟通。Animal research must utilize the most humane methods and endpoints while accomplishing the research goals. Ideally, experimental endpoints occur with minimal or no adverse effects, pain, or distress to the animal. In some cases however, studies will result in pain/distress in order to accomplish the scientific objectives. In all cases, early removal criteria (ERC) are utilized as a basis for euthanasia in the event pain and/or distress or imminent deterioration occurs prior to the planned study endpoint. Furthermore, the IACUC recognizes that experimentally induced or spontaneous clinical signs in animals may be unexpected or otherwise not specifically identified in the IACUC protocol. Consultation with the veterinary staff is expected when unanticipated adverse effects are observed.



要求 Requirements:

研究人员要确保对实验动物的人道关怀，至少每周使用方案中列出的清楚标准检查动物。一旦有动物情况吻合，首席研究员需要尽早（24 小时内）将动物撤出方案，或采取方案中描述的治疗措施。也可以兽医沟通合理的应对方案。以下项目为早期撤出标准：Investigators must ensure humane care of their research animals by checking animals at least weekly to utilize ERC as listed in their protocol. Once an animal meets the ERC, the principal investigator is responsible for promptly (< 24 hrs.) removing the animal from the study or initiating treatment as outlined in the protocol. Alternatively, consultation with a veterinarian would be required to discuss treatment options. The following items are standard ERC:

1. 体重丧失：基础体重下降 20%或年龄相应比例。Weight loss: a. Loss of 20% baseline body weight or compared to an age-matched control (for young growing animals)
2. 健康评分 Body Condition Score（附件一）：
 - a. 啮齿动物 Rodents
 - 恶劣状况得分 2~4 分之间。Poor body condition scores ≤ 2 or ≥ 4
 - 详见体况评分表 See Body Condition Score chart (Lab Anim Sci.1999;49(3):319-323).
 - b. 非啮齿动物 Non-rodents
 - 恶劣状况由方案中特定物种为参考尺度。Poor body condition based on the species-specific reference scale as defined in the protocol
3. 无法移动或对物理刺激无应答 Immobile or non- responsive to physical manipulation
4. 无法采食、摄水 Weakness/inability to obtain feed or water:
 - a. 24 小时不愿或不愿站/走动 Inability or extreme reluctance to stand/ambulate for 24 hours
5. 荷瘤动物 Tumor production:
 - a. 25 克体重小鼠肿瘤表面积不得超过 350mm^2 ，250 克体重大鼠肿瘤直径尺寸不能超过 3.6 厘米。多肿瘤情况直径需要累加计算，或根据方案进行描述。Tumor size must not exceed a surface area of 350mm^2 in a 25 gram mouse, or 3.6 cm diameter in a 250 gram rat. When multiple tumors are present, tumor size must be based on cumulative diameter or endpoint criteria otherwise described in your protocol.
 - b. 根据解剖位置的不同，动物的肿瘤会干扰重要器官的正常功能（呼吸等）或阻碍正常移动（必须能够四肢在地面上正常行走）必须被撤出。Depending on the anatomic location, animals with tumors



that interfere with normal function of vital organs (breathing, etc.) or impede the expression of normal activities (must be able to place all four feet on the ground and walk normally) must be removed.

c. 2 毫米以上溃疡和/或肿瘤感染。Ulceration greater than 2mm and/or infection of tumors.

被 IACUC 批准的疼痛实验必须要有清晰的标识，包括但不限于以濒死转台为唯一终点的方案。

Experiments that necessitate unrelieved pain and/or distress as approved by the IACUC must be clearly identified to care staff at the cage level. This includes but is not limited to protocols using moribund as sole criteria for removal and death as an endpoint.






参考文献

Health Research Extension Act of 1985 and Public Health Service (PHS) Policy on the Humane Care and Use of Laboratory Animals.

批准时间 Approved : 20/6/2018



附件一：体况评分表 Body Condition Score

	BC 1 Mouse is emaciated. ◦ <i>Skeletal structure extremely prominent; little or no flesh cover.</i> ◦ <i>Vertebrae distinctly segmented.</i>
	BC 2 Mouse is underconditioned. ◦ <i>Segmentation of vertebral column evident.</i> ◦ <i>Dorsal pelvic bones are readily palpable.</i>
	BC 3 Mouse is well-conditioned. ◦ <i>Vertebrae and dorsal pelvis not prominent; palpable with slight pressure.</i>
	BC 4 Mouse is overconditioned. ◦ <i>Spine is a continuous column.</i> ◦ <i>Vertebrae palpable only with firm pressure.</i>
	BC 5 Mouse is obese. ◦ <i>Mouse is smooth and bulky.</i> ◦ <i>Bone structure disappears under flesh and subcutaneous fat.</i>

A "+" or a "-" can be added to the body condition score if additional increments are necessary (i.e. ...2+, 2, 2-...)