



March 27, 2023

MEMORANDUM OF ACTION

To: Users of Animals in Cancer Research

From: Jeffrey H. Boatright, PhD
Chair, Emory University Institutional Animal Care and Use Committee

Michael H. Huerkamp, DVM, DACLAM
Attending Veterinarian
Executive Director Emory University School of Medicine Division of Animal Resources

RE: Revisions to IACUC Policy 304 Tumor Burden Scoring and new requirements for monitoring and monitoring recordkeeping

Dear Users of Animals in Cancer Research,

Thank you to the researchers who provided feedback on the revisions made to the Emory IACUC policy 304 Tumor Burden Scoring (TBS). We have addressed your concerns below. The IACUC reviewed the updated scoring scales and documentation requirements during the Full Committee meeting on March 1, 2023. The IACUC voted to adopt the changes effective March 1, 2023.

This Memorandum of Action serves as a means of communicating the updated policy to the users of animals in cancer research.

The deployment of this updated policy will have three phases:

Phase 1: Communication to users between now and June 1, 2023. Researchers will be reminded during site inspections, and other communications.

Phase 2: Soft enforcement between June 1, 2023, and November 30, 2023. Researchers will be asked to provide the monitoring logs during site inspections. Findings will be logged as **Comments**. The IACUC Office will continue to hold Lunch & Learn sessions to answer questions related to this policy.

Phase 3: Full enforcement of the policy: After December 1, 2023, incomplete or missing monitoring logs will be logged as a **minor deficiency**.



What is changing? The Emory IACUC policy 304 TBS has been updated as follows:

- The scoring for Body Condition, tumor size, tumor ulceration, and mobility have been adjusted to three categories scoring 0, 1, and 3.
- The Animal Health and Tumor Monitoring Requirements table includes four categories with scoring of 0, 1, 2, and ≥3. The cumulative score of 2 already provides an alert to the researcher that euthanasia may be needed. Thus, careful scoring of the parameters is key to ensure that euthanasia is done when the score of 3 is reached.
- The tumor monitoring includes details for non-peripheral inoculations and use of the Pulmonary Assessment of Advanced Metastasis (PAAM) in mice.
- Recordkeeping requirements are new to this policy.
- A new section on spontaneous, naturally-occurring tumors has been included in this policy.

What is not changing?

- Specific monitoring is needed for specific types of tumors. It is not the intent of the Committee that daily monitoring be performed for an extensive period, such as in cases of slow-growing tumors. For those models, a different monitoring regimen may be needed (such as 3x/week) and it should be included in the protocol.
- Daily monitoring is limited to what is included in the approved protocol and minimally to the updated policy, for example daily monitoring after surgical resection, at the time of lesion detection by imaging or onset of related clinical signs, etc.
- The scoring system included in the updated policy maintains the same threshold for euthanasia as the previous version, **except for when the tumor is >20 mm and “euthanasia may be required” in the previous version, and it is now mandatory.** The table below provides a comparison of the highest scoring categories between the previous version and the version approved on 3/1/2023.

Scoring category	TBS Policy (2022)	Policy as of March 1, 2023	Appropriate Action
Body Condition	BCS=1 score of 18	BCS=1 score of 3	EUTHANASIA IS MANDATORY
Tumor Size	>20 mm score of 17 (euthanasia may be required)	>20 mm score of 3	
Tumor ulceration	Infection and ulceration score of 18	Infection and necrosis score of 3	
Mobility/ambulation	Impaired ability to ambulate and unable to acquire food and water score of 18	Impaired ability to ambulate and unable to acquire food and water score of 3	



Additional Information about the Tumor Burden Scoring Policy

1. What is the goal of the scoring system and tumor monitoring requirements?

The goal of this updated and adjusted scoring system is to increase the frequency of monitoring as the animal progresses towards endpoint. Monitoring does imply that tumor burden scores will be assessed during that observation period, and Appendices 4 and 5 are references to aid in this process. The intent is that daily monitoring will only be required when animals are truly nearing endpoint (for example, the last week of life). The committee believes this will likely be when the tumor reaches 15 mm. Appendix 5 is an example of recordkeeping; this template may be modified to add any other parameters that may need to be tracked according to the approved protocol. As animal subjects are reaching experimental endpoint, the review of the log will help the researcher determine if the humane endpoint has been reached.

2. For the ulceration score, at what point can animal subjects be treated with antibiotics instead of euthanizing them?

Treatment with antibiotics would need to be included in the IACUC protocol. Thus, the PI's ability to include supportive care within their protocol remains unchanged. Common options include applying triple antibiotic ointment to ulcerations (preventing them from becoming infected and precluding the animals from reaching endpoint) and providing moist chow +/- Napa Nectar on the cage floor (allowing the animals to acquire food and water and precluding them from reaching endpoint).

3. Will more experimental animals be needed to start an experiment so that finish the study with a large enough cohort to draw meaningful conclusions?

The veterinary staff will monitor the implementation of this policy and will communicate to the Committee any challenges encountered during the implementation of the new scoring system between June 1, 2023 and November 30, 2023. The cancer model studies will be given a period of adaptation to the requirements of the updated policy (for example, monitoring and monitoring recordkeeping). Therefore, monitoring logs will be requested during inspections after December 1, 2023 (2024 P1 inspection period).

The Committee considered that an experimental endpoint of >20 mm as the default and not the exception. Exemptions may be included in the approved IACUC protocol by submitting an amendment. This decision was made with reference to numerous other institutional policies, including the NIH Office for Animal Care and Use "Guidelines for Endpoints in Animal Study Proposals."



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Since this policy is written in general and for the majority, several aspects may not be applicable to specific tumor models. Therefore, Principal Investigators are encouraged to request exemptions in their protocol as deemed necessary.

On behalf of Emory IACUC, I thank you again for your attention to this policy update. Please direct any questions to iacuc@emory.edu.

Thank you,

A handwritten signature in blue ink that reads "Jeffrey H Boatright".

Jeffrey H. Boatright, PhD, FARVO

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