IACUC Policy for Non-Pharmaceutical Grade Drugs

Responsible Official: **VP for Research Administration**
Administering Division/Department: **IACUC**
Effective Date: **November 16, 2005**
Last Revision: **March 4, 2009**

I. Policy

Emory University follows guidance provided by the PHS Office of Laboratory Animal Welfare (OLAW) which states:

OLAW and USDA consider that the use of non-pharmaceutical grade compounds should be based on: scientific necessity; no availability of an acceptable veterinary or human pharmaceutical-grade compound; and specific review and approval by the IACUC.\(^1\)

Investigators are expected to use pharmaceutical-grade medications whenever they are available, even in non-survival procedures. Non-pharmaceutical grade chemical compounds, whether for experimental or veterinary use, may only be used after specific review and approval by the IACUC, based upon the combination of scientific necessity and non-availability of an acceptable veterinary or human pharmaceutical-grade product. Cost savings alone do not adequately justify the use of non-pharmaceutical-grade compounds in animals. Refer to the IACUC policy on injectable drugs for proper constitution, storage, and documentation of prepared agents.\(^2\)

II. Definitions of Key Terms Specific to this Policy

1) Pharmaceutical grade refers to a standard or level of purity suitable for the production of medicine within the pharmaceutical community.

2) Non-pharmaceutical grade agents refer to chemical compounds that have not been formulated for production of medicine.

III. Applicability

This policy applies to all Emory research related animal activities that fall under the IACUC’s jurisdiction.

IV. Contact Information

<table>
<thead>
<tr>
<th>Subject</th>
<th>Contact</th>
<th>Phone</th>
<th>Email</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clarification of Policy</td>
<td>IACUC Office</td>
<td>404-712-0734</td>
<td><a href="mailto:IACUC@emory.edu">IACUC@emory.edu</a></td>
</tr>
<tr>
<td>Guidance on Posting Policies</td>
<td>AAIT Web &amp; Communications Team</td>
<td>404-727-5440</td>
<td><a href="mailto:Policies-l@listserv.emory.edu">Policies-l@listserv.emory.edu</a></td>
</tr>
<tr>
<td>Anonymous Concerns</td>
<td>Emory Trust Line</td>
<td>1-888-550-8850</td>
<td></td>
</tr>
</tbody>
</table>

V. Revision History

Effective Date: **November 16, 2005**
Last Revision: **March 4, 2009**

\(^1\) [http://grants.nih.gov/grants/olaw/faqs.htm#useandmgmt_4](http://grants.nih.gov/grants/olaw/faqs.htm#useandmgmt_4)

\(^2\) [http://www.emory.edu/IACUC/pdfs/injectable_drugs.pdf](http://www.emory.edu/IACUC/pdfs/injectable_drugs.pdf)