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| **IACUC Module 6: Use of Non-pharmaceutical-grade substances in live animals**  |

1. The USDA (Policy #3) and The Guide (8th Edition) require the use pharmaceutical-grade substances (medications, experimental compounds, diluents, and extenders) whenever they are available, even in acute procedures. Pharmaceutical-grade compounds are those with US Pharmacopeia (USP) or equivalent labeling. See the **IACUC Policy** on Non-Pharmaceutical-Grade Substance Use for details.
2. Non-pharmaceutical-grade chemical compounds may be used in animals **only** after specific review and approval by the IACUC for reasons such as **scientific necessity** or **non-availability of an acceptable USP** veterinary or human pharmaceutical-grade product. Cost savings is not a justification for using non-pharmaceutical-grade compounds (exceptions for extraordinary costs of substances may be considered).
3. The Principal Investigator needs to consider the following attributes of the proposed use of non-pharmaceutical-grade compounds in live animals: grade, purity, sterility, pH, pyrogenicity, osmolality, stability, site and route of administration, formulation, compatibility, and pharmacokinetics. A plan for controlling these variables needs to be presented to the IACUC for their consideration.
4. When determining whether to approve the use of a non-pharmaceutical-grade substance, the IACUC will place special emphasis on animal welfare and scientific issues relating to the proposed use.

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| Animal species involved (e.g., frog, rat, mouse, rabbit, etc.): |  |
| Name of the non-pharmaceutical-grade compound proposed for use: |  |
| Dosage and route of administration to be used: |  |
| **Yes** | **No** | **Is the above-named compound available as a pharmaceutical-grade material?** (insert **X** in appropriate box)* If “yes,” complete Section A below.
* If “no,” complete Section B below.
 |
|  | **X** |

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| 1. **Yes,** a USP version of compound is **available**, but will **not** be used for the following reason(s): (insert **X** in appropriate boxes below)
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| **Yes** | **No** |  |
|  |  | The available human or veterinary drug is not concentrated enough to meet experimental requirements. |
|  |  | Although an equivalent veterinary or human drug is available, dilution or change in formulation is required, thereby compromising the value of USP formulation. |
|  |  | The chemical-grade reagent is required to replicate methods from previous studies because results of the proposed study will be directly compared to those of published studies. |
|  |  | The available USP human or veterinary drug does not meet the non-toxic vehicle requirements for the specified route of injection. |
|  |  | Use of the highest-grade reagent has the advantage of single-stage formulation and results in purity that is equal to or higher than the human or veterinary drug. |
|  |  | Other (please specify): |

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| **B NO,** a pharmaceutical-grade version of this compound is **not available**.The following measures will be implemented to optimize use of this material. (insert **X** in appropriate boxes below) |
| **Yes** | **No** |  |
| **X** |  | The highest-grade equivalent chemical reagent will be used and formulated aseptically with a non-toxic vehicle as appropriate for the route of administration. |
| **X** |  | For compounds to be injected in live animals, the pH and osmolality of the compound will be appropriately adjusted. |
| **X** |  | Consideration of the pharmacokinetics of the compound will be based on the scientific literature and the proposed use of the agent in this study. |
| **X** |  | The scientific literature will be consulted to establish a safe “use by” date for the agent. In the absence of good data, the “use by” date will be 2 weeks or less.  |
| **X** |  | Appropriate storage conditions will be used to optimize stability of the compound. |
| **X** |  | Animals will be monitored as described in protocol to assess potential toxicity or pyrogenicity of the compound. |
|  | **X** | Other (please specify): |