



## Exemption for using single-dose non-bacteriostatic sterile injectable saline or water

**Responsible Official:** Research Administration

**Administering Division/Department:** IACUC / Research Compliance and Regulatory Affairs

**Effective Date:** IACUC approved on 07/06/2022

**Last Revision Date:** NA

Emory Primate Center and SOM DARs requested an Emory wide exemption to the policy 366- Injectable Agents. Due to a known nation-wide backlog to obtain either multidose bacteriostatic sterile injectable saline or water, **this exemption allows the Emory Research community to use single-dose non-bacteriostatic sterile injectable saline or water under the following conditions:**

The exemption allows the use of the single-dose saline and water for all routes, up to 30 days. The solution must be filtered with a sterile 0.22 µm or smaller porosity filter. The filtration process must be done every time for all routes of administration past 24 hours, except for SC administration which is allowed, without filtration, for up to 30 days.

Use in immunocompromised animals is still limited to the first 24 hours.

This exemption is only applicable to mice, rats, hamsters, voles, spiny mice, gerbils.

**The Policy 366 Injectable Agents states:** For single-dose drug vials (without preservatives), the following guidelines for expiration should be followed:

- The drug may be given for up to 24 hours after opening for any of the approved routes of administration of the drug – for example, intravenous (IV), intraperitoneal (IP), subcutaneous (SC), intracerebral (IC) or intramuscular (IM)
- Providing it has been labeled with the date the container was first used, the drug may be stored in a refrigerator for up to 30 days if the vial has a sealed rubber stopper or is sterilely transferred to a vial with a sealed rubber stopper.
- **This drug may only be used for SC injection.** It cannot be used for IP, IV, IM or IC injection. It may not be used for immunocompromised animals after 24 hours.

**Related policy: 366 Injectable Agents**

### Contact Information

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### Revision History

- Next review: 01/18/2023