

Office of Research Integrity and Compliance Breakout Room



6

Research Compliance and Regulatory Affairs Research Administration

Welcome!

Thanks for joining our session!

We will go over two scenarios covering:

- Preventing research misconduct

Research Compliance

and Regulatory Affairs

- CS/DD issues

EMORY



Jamie is a new postdoc in Dr. Blakes' lab. Jamie has been working with Dr. Blake and others on a publication, and Jamie is in charge of putting the graphics together. While looking at the graphics provided by the other lab members, it seemed as if there could be some improvements to those graphics by using Photoshop or even the computer image program to make the images look clearer. What should Jamie do?

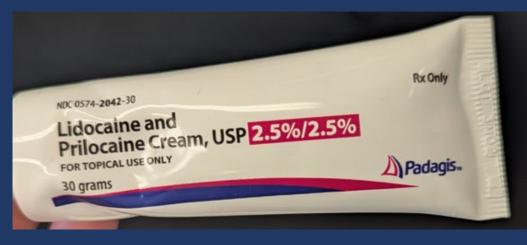
- 1. Jamie should go ahead and do these changes as the publication will just improve with these minor modifications
- 2. Jamie should review the publisher requirements and do these modifications if the publisher does not have any issues with it
- 3. After consulting the corresponding author, Jamie can make the changes as long as they are disclosed, do not change the results, and the publisher is notified.

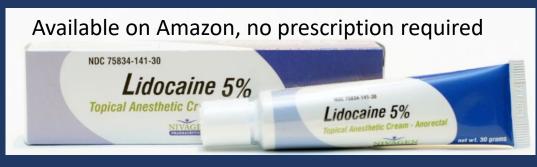
Scenario 1



- Make sure that any change that you make in the publication is not only authorized by the publisher, but also is not changing the meaning of what the graphic represents
- Make sure all members of the team, including the corresponding author, are aware of any graphic change
- Disclose to the publisher what was changed
- Make sure you are keeping the raw data to support the information in case the publisher wants it later.

Scenario 1-explanation





Joan is a lab manager under a PI that has a research protocol that requires the use of Topical Anesthetic Cream (3% to 5% Lidocaine or 2.5% Lidocaine/2.5% Prilocaine) for a surgery procedure.

Under Georgia law O.C.G.A. § 26-4-49, every person conducting research with a dangerous drugs must be licensed to purchase, store, dispense and destroy a dangerous drug. According to O.C.G.A. § 16-13-71 Georgia defines a dangerous drug as a drug that may only be dispensed by prescription. In addition, the Georgia Assembly declared over 2000 drugs be listed as dangerous, including topical lidocaine above 4%.

CVSHealth. MAXIMUM STRENGTH Compare to the active ingredient in Gold Bond® with 4% Lidocaine Pain & Itch Relief Cream* In the images to the left, which Lidocaine cream would not require recordkeeping?

Scenario 2

Lidocaine Cream

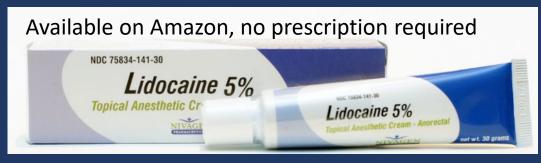
DOCAINE HCI 4% - TOPICAL ANALGESIC

Steroid free. works on contact Actual Product Size on Top Panel NET WT 1.75 OZ (49 q)



In Scenario 2, there are two options for Lidocaine that require recordkeeping.

The first image requires records because even though it is below the 2.5% exclusion for Lidocaine it is available by prescription only. If a Researcher uses a GBP license to obtain a drug of any kind the receipt, dispensing, and destruction must be documented.



In the second image, the Lidocaine was available for purchase without a GBP license however, the drug must still be tracked because it is above the 4% threshold. Just because you can purchase it without a licenses does not mean it should not be logged. The Supplier of this Lidocaine cream would be in trouble with Georgia Drug and Narcotics for selling Lidocaine above 4%.

Scenario 2- explanation



This over-the-counter (OTC) Lidocaine from CVS is the only Lidocaine cream that does not meet the Georgia definition of a dangerous drug as it is below the 4% threshold and does not require a prescription to obtain it.

Scenario 2- explanation

References

- Emory Policy 7.8: <u>Policy</u>.
- Preventing Research Misconduct at Emory: <u>Website</u>
- Research Misconduct and Detrimental Research Practices Presentation: <u>ORI Presentation</u>
- Research with Controlled Substances and Dangerous Drugs at Emory: <u>Website</u>

