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Wed 7/25/2018 11:09 AM




 Lees, Paul (HHS/OASH) <Paul.Lees@hhs.gov>

FW: Complaint letter about two unethical prospective clinical trials that tested ketamine for agitation

To: Michael Carome

Cc: Buchanan, Lisa (HHS/OASH); Menikoff, Jerry (HHS/OASH); Kaneshiro, Julie A (HHS/OASH)

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This message was sent with High importance.

-  180725_Letter to FDA-OHRP RE Ketamine Trials_FINAL+ENCL.pdf (959 KB)
-  Ketamine Versus Midazolam for Prehospital Agitation - Full Text View - ClinicalTrials.gov.pdf (187 KB)
-  Hennepin County Med Ctr_FAQs about Ketamine Trial-2018-6-262.pdf (293 KB)
-  Cole_Ketamine vs Haloperidol for Prehospital Agitation_Clin Toxicol_2016.pdf (958 KB)
-  Ho_Ketamine for Excited Delirium Syndrome-Two Cases_Prehosp Emerg Care_2013.pdf (344 KB)

Dr. Carome,

Thank-you for the information you provided about the research studies that were using ketamine for management of agitation along with the supporting information about possible non-compliance to human subject protections under federal regulations. OHRP takes allegations of non-compliance very seriously. In carrying out this responsibility, OHRP reviews allegations of noncompliance involving human subject research projects conducted or supported by HHS or that are otherwise subject to the regulations, and determines whether to conduct a for-cause compliance evaluation. We will be reviewing the information your organization provided to determine if an evaluation is required.

If you have any question please contact me.

Thank-you.

Sincerely,

Paul E. Lees, MPH, MS
Lieutenant Commander, U.S. Public Health Service
Public Health Analyst

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