DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
250 Marquette Ave, Ste. 600 Minneapolis, MN 55401 (612)334-4100 Fax:(612)334-4134	8/7/2018-8/23/2018* FEI NUMBER 2127118

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Craig J. Peine, M.D., IRB Chair	
FIRM NAME	**STREET ADDRESS**
Human Subjects Research Committee	Hennepin County Medical Center, , Hennepin Healthcare System, Inc.;914 S 8
CITY, STATE, ZIP CODE, COUNTRY	**TYPE ESTABLISHMENT INSPECTED**
Minneapolis, MN 55404-1204	Institutional Review Board

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

The IRB approved the conduct of research, but did not determine that informed consent would be sought from each prospective subject or the subject's legally authorized representative, to the extent required by 21 CFR 50.

Specifically, the IRB approved studies for waiver of consent under 45 CFR 46.116 without determining the informed consent requirements of 21 CFR 50; and, that do not appear to meet the criteria for exception from informed consent (21 CFR 50.23) nor emergency research (21 CFR 50.24). Examples:

IRB#	Study title	Approval date	Review type	Study status
14-3841	Ketamine vs. Haloperidol for Severe Agitation in the Prehospital Setting	7/10/2014	Expedited	Closed 7/1/2016
17-4306	Ketamine versus Midazolam for Prehospital Agitation	5/11/2017	Expedited	Paused 6/25/2018
17-4345	Prospective Observational Investigation of Olanzapine versus Haloperidol versus Ziprasidone versus Midazolam for the Treatment of Acute Undifferentiated Agitation in the Emergency Department	5/22/2017	Expedited	Closed 5/1/2018
(b) (4)	(b) (4)	5/29/2018	Expedited	Paused 7/16/2018

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Sharon L Matson, Investigator Kellie L Thommes, Investigator	X Sharon L Matson Investigator Signed By: Sharon L. Matson -S Date Signed: 08-23-2018 10:40:44	8/23/2018

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	(b) (4)			

OBSERVATION 2

The IRB approved the conduct of research in a situation where some or all of the subjects were likely to be vulnerable to coercion or undue influence, but did not determine that additional safeguards had been included in the study to protect the rights and welfare of those subjects.

Specifically, the IRB has approved studies that are identified as including a Vulnerable Subjects category "impaired ability to give informed consent" without evidence of determining additional safeguards had been included in the study to protect the rights and welfare of those subjects. Examples are noted above under Observation 1.

OBSERVATION 3

The IRB used an expedited review procedure for research which did not appear in an FDA list of categories eligible for expedited review, and which had not previously been approved by the IRB.

Specifically, requests that do not meet the criteria for expedited review have been given expedited approval. Examples:

A. Requests for emergency use (EU) of experimental or investigational products:

IRB#	Product requested	FDA#	EU request date	Approval date	Date of use	Report date
(b) (4)	(b) (4)	(b) (4)	6/2/2017	6/2/2017	Not used	6/9/2017
(b) (4)	(b) (4)	(b) (4)	9/1/2017	9/1/2017	(b) (6)	9/12/2017
(b) (4)	(b) (4)	(b) (4)	11/6/2017	11/6/2017	(b) (6)	12/1/2017

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	Sharon L Matson, Investigator Kellie L Thommes, Investigator	X Sharon L Matson Investigator Signed By: Sharon L Matson -S Date Signed: 08-23-2018 10:48:44	8/23/2018

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(b) (4)	(b) (4)	(b) (4)	2/17/2018	2/17-18/2018	(b) (6)	2/19/2018
(b) (4)	(b) (4)	(b) (4)	7/12/2018	7/12/2018	(b) (6)	7/12/2018

B. IRB study # (b) (4) "(b) (4)" using a new unapproved non-invasive (b) (4), presented by the sponsor and clinical investigator as nonsignificant risk (NSR), and requesting waiver of signed consent, approved via expedited review 11/18/2016.

OBSERVATION 4
The IRB has no written procedure for conducting its initial and continuing review of research.

Specifically, there are no written procedures governing:
A. Determination of additional safeguards for the IRBs Vulnerable Subjects category "impaired ability to give informed consent".
B. Creation, maintenance, or use of the database utilized for tracking all studies and activities of the IRB.

***DATES OF INSPECTION**
8/07/2018(Tue), 8/08/2018(Wed), 8/10/2018(Fri), 8/15/2018(Wed), 8/16/2018(Thu), 8/21/2018(Tue), 8/22/2018(Wed), 8/23/2018(Thu)

X Kellie L Thommes
Investigator
Signed By: Kellie L Thommes -S
Date Signed: 08-23-2018 10:48:18

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Sharon L Matson, Investigator Kellie L Thommes, Investigator	X Sharon L Matson Investigator Signed By: Sharon L Matson -S Date Signed: 08-23-2018 10:48:44	8/23/2018

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."