



State of Utah  
Department of Commerce

Division of Occupational and Professional Licensing

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CLASS E  
Human Clinical Investigational  
Drug Research Facility

INSPECTION

New Opening  Regular

INFORMATION

(Please print clearly or type information)

Facility Name: \_\_\_\_\_ Date: \_\_\_\_\_

Facility Email: \_\_\_\_\_ Facility Telephone: \_\_\_\_\_

License Number: \_\_\_\_\_

Facility Hours (Monday-Friday): \_\_\_\_\_ (Saturday): \_\_\_\_\_ (Sunday): \_\_\_\_\_

Facility Street Address: \_\_\_\_\_

City: \_\_\_\_\_ State: \_\_\_\_\_ Zip: \_\_\_\_\_

Responsible Person: \_\_\_\_\_ Phone Number: \_\_\_\_\_

INSPECTION

- |    | Yes                      | No                       |   |
|----|--------------------------|--------------------------|---|
| 1. | <input type="checkbox"/> | <input type="checkbox"/> | The facility will/does have a written pharmacy care protocol which includes: [R156-17b-617a (1)]<br><input type="checkbox"/> the identity of the supervisor or director;<br><input type="checkbox"/> a detailed plan of care;<br><input type="checkbox"/> the identity of the drugs that will be purchased, stored, used and accounted for; and<br><input type="checkbox"/> the identity of any licensed healthcare provider associated with the operation. |
| 2. | <input type="checkbox"/> | <input type="checkbox"/> | When preparing sterile compounds, the facility will/does follow the USP-NF Chapter 797 Compounding for sterile preparations. [R156-17b-617a (2)]  |
| 3. | <input type="checkbox"/> | <input type="checkbox"/> | The facility will/does conduct operations in accordance with the operating standards set forth in 21 CFR Part 312, April 1, 2012 edition; [R156-17b-617e (1)]   |
| 4. | <input type="checkbox"/> | <input type="checkbox"/> | Any facility who experiences a shortage or theft of controlled substances shall immediately file the appropriate forms with the Drug Enforcement Administration, with a copy to the Division directed to the attention of the Investigation Bureau... [UAC R156-37-602 (2)]   |
| 5. | <input type="checkbox"/> | <input type="checkbox"/> | The facility will/does have a separate license at each principal place of business or professional practice where the facility manufactures, produces, distributes, dispenses, conducts research with, or performs laboratory analysis upon controlled substances.  |

COMMENTS



CLASS E

# INSPECTION

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Signature of Responsible Person: \_\_\_\_\_ Date of Signature: \_\_\_\_/\_\_\_\_/\_\_\_\_  
Signature of Division Investigator: \_\_\_\_\_ Date of Signature: \_\_\_\_/\_\_\_\_/\_\_\_\_