

Northwest Labs

Assay Tests and Validation: Biochemical Pharmacology Testing

Protocol No. 7

Tests investigating the reactivity of certain pharmaceutical compounds

Study Title: A study investigating the activity of pharmaceutical compounds to determine which compounds need to undergo further tests to ensure the safety of the various compounds.

#### Study Information:

- 1) Background: Many drugs have unexpected side effects that can induce injury to human organs and other body parts, some of which could be life-threatening. These compounds must be thoroughly tested to ensure that they are safe for human use.

Certain tests can be performed to determine the activity level of these compounds when exposed to other compounds, etc. These tests are part of the adoption process of new pharmaceutical companies, and must be performed in accordance to laws in the country which the test is performed. The results of the prescribed tests must be examined by professionals who then make sure it passes the regulatory standards in the country in which the drug will be marketed.

The aim of this study is to collect data about the activity of the compounds sent by various customers. These compounds are tested and investigated thoroughly, which leads to determining the effects of the compound.

- 2) Data Collection

The following data will be collected as part of the study:

Molecular Weight, Amount of Compound, Activity Status, Compound Properties, etc.

- 3) Access to the data

Data will be accessed by those conducting the study, as listed above. Customers also have unlimited access to their data, as well as access to anonymous data that deals specifically with similar compounds that have been tested previously.

- 4) Data Privacy

Customers wishing to grant others the privilege of viewing the data must sign a consent form. This form gives the said person unlimited viewing privileges as if they were the customer. These persons accessing the data agree to use the data as listed in the Privacy Policy.

5) Ethical considerations

Animal testing is performed in accordance with the guidelines of the Pharmacology Bureau of Singapore. Animals are studied and must pass certain health tests in order to be subjects in the various compound tests. Veterinarians and scientists collaborate to determine the Maximum Tolerable Dose for each animal and data is collected to ensure that no animals are subject to doses that would cause them harm and/or pain. Animals are not subjected to multiple tests within a six month time period. Animals' health is monitored constantly, and any signs of decreased health results in halting tests on that particular animal.

6) Documentation

Various documentation is provided with each test. These documents comprise of various reports and protocols, as well as work orders, which all may contain data used in testing. These documents follow the same protocol as the data.

7) Study Site

Northwest Labs Pharmaceutical Laboratories  
Singapore Post Pte Ltd  
10 Eunos Road 8  
#05-33 Singapore Post Centre  
Singapore 408600

I have read this protocol including the administrative and related instructions and agree to conduct this trial in accordance with all stipulations of the protocol and in accordance with the Government of Singapore and any applicable local laws and regulations.

Study Leader:\_\_\_\_\_

Biostatistician:\_\_\_\_\_

Investigator's signature:\_\_\_\_\_