

Drug Enforcement Administration
Diversion Control Division
Researcher Guidance Document

Title: Q&A 222 Blind Study Procedures

Question: How should a Researcher registrant complete a DEA Form 222 when participating in double-blind studies in which the exact quantity of schedule I or II controlled substances received is unknown?

DEA registrants participating in double-blind studies should indicate the total quantity of each test material **requested** on the DEA Form 222 when submitting it to the controlled substance supplier. The controlled substance and exact amount received will be recorded by the researcher at the completion of the study. Researchers using either the existing triplicate DEA Form 222 or the new single-sheet version should submit them to their supplier in accordance with 21 CFR Part 1305.

The controlled substance supplier will note the actual quantity of controlled substance(s) (active dosage units) distributed on the received DEA Form 222. The supplier will also report the completed shipments to DEA's Automation of Reports and Consolidated Orders System (ARCOS) unit.

Upon receipt of the test material, researchers will record the date of receipt on their copy of DEA Form 222, or attach the documentation to their retained Copy 3, but they will not fill in the true name of the controlled substance or the amount received until after the completion of the blind clinical study.

Upon completion of the study, the supplier will notify the researcher of the actual name and quantity of the controlled substance(s) provided. The researcher will record that information on their copy of DEA Form 222, or attach that documentation to their retained Copy 3.

This guidance is not an exception to regulations, but an application of DEA's existing policy regarding blind clinical studies.

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