

## D2d MOP 7 – Appendix 1

VA COOPERATIVE STUDIES PROGRAM  
CLINICAL RESEARCH PHARMACY COORDINATING CENTER (151-I)  
2401 Centre Avenue, SE  
Albuquerque, NM 87106-4180

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501/151-I  
CSP #95/P319

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Dear Patty:

The Pharmacy Coordinating Center excludes expiration dates and lot numbers on all blinded study medication (including that for the D2d trial) for the following reasons:

- In clinical trials the expiration (or re-test) dates, and lot numbers for active medications and matching placebos are rarely the same. Therefore, making these dates and lot numbers available to a site could lead to the un-blinding of treatment assignment. It is the policy of the Center to centrally monitor all expiration (or re-test) dates for blinded active medications/placebos used in clinical trials. We then notify the site to destroy expiring medication, and provide replacement medication as needed.
- Our Center places the safety of individuals participating in clinical trials above all other concerns in the conduct of such trials. To assure that patient safety and study integrity are always maintained, our facility conducts all studies in accordance with all applicable Federal standards including Good Clinical Practices (GCP) and current Good Manufacturing Practices (cGMP).

I trust that this explanation will address any issues within your facility concerning the appropriate monitoring of dating and lot numbers of study medications for the D2d trial.  
Should you have any further questions, please call (505) 248-3203.

Sincerely yours,



ROBERT J. RINGER, PHARM.D., BCNP  
Assistant Center Director