

January 13, 1973

Jonathan O. Cole, M.D.
Chairman, CRB Research Committee
National Institute of Mental Health
Rockville, Maryland 20852

Re:MI 24323-01
Site Visit, 1/12/73

Dear Dr. Cole,

In response to the questions regarding the use of EEG measures as predictors and criteria for change in the proposed study, *Activated EEG and DPH Response of Female Delinquents*, I participated in the site visit on January 12. Prior to the visit, we had the opinion of Dr. Joyce Small to supplement our questions.

1. The quantitative EEG methods for the evaluation of the alpha-chloralose response are not yet available; nor are they likely to be available in the foreseeable future, thus allowing the additional funds in the second year (pg 4) to be deleted.

2. The technique was described, and the evaluation of the records by members of the clinical staff at the University of Maryland will provide, using simple descriptive criteria, reasonable estimates of the changes induced by the drug. While the test is to be repeated, neither the investigators nor the superintendent know whether the patients will cooperate. In response to the question of test-retest reliability, Dr. Monroe indicated that these data are not available.

While the test may have some merit, Dr. Monroe did not make clear what was the basis for the choice of this test, leaving us with the distinct impression that the inclusion was in the nature of a 'fishing' expedition.

3. There is much confusion among the participants as to the dosage of DPH, the relation to blood levels, and the symptoms that are the targets (and the evaluation criteria) of this therapy. In contrast to the specific nature of the EEG test and its evaluation, the psychiatric-psychopharmacologic aspects of the study seemed so poorly documented, that the recommendation of the site visit team, arrived at unanimously, was *Deferral, with advice*. The advice is to include some pilot work to define drug dosage, acceptance of blood sampling, criteria and ratings; and also, attempts to test and repeat testing in a small group of subjects to determine if the patients' cooperation can be assured: ^{for the EEG.}

Sincerely yours,

Max Fink, M.D.