

F. Selters

June 12, 1977

Hatem Al-Chalabi, M.D.
Suffolk Developmental Center
Box 788
Melville, New York

Dear Dr. Al-Chalabi,

I have read your proposal, to study the effects of lithium therapy on aggressive, disruptive and self-mutilating behavior in patients with mental deficiency (severe). In the main, the intent is clear, the issues well thought out, the mission important, and the safety well within the margins ordinarily set by our community. Indeed, I can find only two questions of merit.

Selecting dosages of lithium that will yield plasma levels of 1.5 mEq/l is a goal that is set in the study. While these levels may be necessary, I think that the conservative approach within a new setting is to set a lower level as the goal, one within the therapeutic range, but surely not associated with side effects, such as 1.0 mEq/l. If there is no therapeutic efficacy or toxicity at these levels in 3 to 6 subjects, then the higher level can be set for the remainder of the sample. If you already have experience at these lower levels, then this conservative step may not be necessary.

The second issue is that of consent. The protocol does not discuss this issue; one that is a problem since the population is made up of minors with mental deficiency. A consent form should be prepared for the relatives, describing the goal and methods of the study.

These comments are my own. Should you wish to have ~~the~~ advice of the Research Committee of the Department of Psychiatry and the Long Island Research Institute, I would suggest you send a revised copy of the protocol, with your curriculum vitae and the consent form to the Chairman of the Department, Stanley Yolles, M.D., and he may refer it to the appropriate committee.

Good luck in your study.

Sincerely yours,

Max Fink, M.D.
Professor of Psychiatry