



AUG 5 2004

National Institutes of Health  
National Institute of Mental Health  
6001 Executive Blvd.  
Bethesda, Maryland 20892

Mrs. Vera Hassner Sharav  
President  
Alliance for Human Research Protection  
142 West End Avenue, Suite 28P  
New York, New York 10023

Dear Mrs. Sharav:

Thank you for your letter, which raises several concerns about a National Institute of Mental Health (NIMH)-supported clinical trial published in the *Archives of General Psychiatry* (Emslie et al., 1997). Among them is the possibility that two suicide attempts were not reported in the published reports of the study.

NIMH supported the study through an investigator-initiated research grant, and funding was roughly \$1.6 million (total costs for 1991 through 1995). Please be advised that we have no record of how Eli Lilly may have obtained the primary data from this study. Nor do we have any records concerning other funding that Eli Lilly may have provided to the grantee in connection with this research during the time of this grant or thereafter.

Regarding what you have described as inconsistencies in reporting through publications and to regulatory agencies, these may be explained by differences in the criteria used to define particular clinical events. You may wish to follow up with the paper's authors, or Eli Lilly, to ascertain if they can resolve your concerns. I have forwarded a copy of your letter to the study's Principal Investigator, Dr. Graham Emslie.

Again, thank you very much for bringing your concerns to my attention. I hope that the information provided above will be helpful to you.

Sincerely yours,

Thomas R. Insel, M.D.  
Director

**NIMH**  
National Institute  
of Mental Health