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School of Medicine
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Martin B. Keller, M.D.
Mary E. Zucker Professor & Chairman

TO: Ivan W. Miller, Ph.D., Chair
Institutional Review Board

FROM: Martin B. Keller, M.D.

DATE: November 11, 1995

RE: Annual Review of Project Entitled: "A Multicenter, Double-blind, Placebo Controlled Study of Paroxetine and Imipramine in Adolescents with Unipolar Major Depression"

Enrollment: During the past project year, there had been an additional fourteen subjects enrolled into the study, for a total of eighteen subjects total. Of these eighteen, 11 completed the acute phase and entered extension; one of these completing extension. Seven subjects withdrew during the acute phase for reasons of non-compliance (the three adverse experiences reported below are considered non-compliant) or non-responding.

Personnel Changes: Project Coordinator, Eileen Small vacated this position in April, 1995. In the interim, Christiana Provencal, M.A. has been acting as coordinator/supervisor on this project. She has been overseeing the day to day operation of the study including, monitoring recruitment issues, advertising, supervising research staff, monitoring time and effort of research staff, and assisting with IRB and administrative tasks.

Procedural Changes: None

Adverse Experiences: Attached, please find documentation of three adverse experiences. A brief summary follows:

- December, 1994, Subject #00057, became pregnant.
- January, 1995, Subject #070, ingested several Tylenol and was admitted to the hospital
- September, 1995, Subject #106, hospitalized as a result of becoming combative with mother and threatening suicide

All of these subjects were terminated from the study. Please see attached documentation for more specific information.

Written Reports or Manuscripts: None

Consent Forms: Enclosed