EMORY UNIVERSITY

Institutional Review Board

FAXED
2-0423

CONFIDENTIAL

Charles B. Nemeroff MD/PhD
Psychiatry
WMB, Suite [redacted]
Interoffice Mail

RE: **NOTIFICATION OF RENEWAL PENDING**
PI: Charles B. Nemeroff MD/PhD
IRB: 488-97
TITLE: Does Fluoxetine Reverse the Effects of Early Life Stress on the CNS CRF System and Improve Psychological and Neuroendocrine Function? A Therapy Study in Women with Childhood Abuse Experiences

DATE: November 07, 2003
THIS RENEWAL WAS REVIEWED ON: 11/5/2003

Renewal Review Type: Full

Your renewal request referenced above and the associated informed consent process was reviewed by the Institutional Review Board. This renewal was not approved.

The following issue(s) must be satisfactorily addressed before approval is given.

1. Conflict of Interest Committee approval is required before the renewal may be approved.
2. What is the need for adding new subjects inasmuch as the protocol has been running for more than 5 years?
3. Why was there no response at Item J4 of the Renewal Form regarding abstracts or publications?
4. Please supply the IRB with the patient authorization form or incorporate HIPAA language into the consent.

Submit the requested changes as follows: 1) in letter format referencing individual comment/question by corresponding number 2) highlight any changes and date the revised protocol and/or consent form(s) 3) submit two copies of revised protocol and/or consent form(s), one with revisions highlighted and one without highlights 4) include a reference line: RESPONSE TO RENEWAL PENDING LTR. When requested changes have been received and approved, we will forward your final letter of approval.

Please respond to this letter at your earliest convenience. If the protocol is not approved by the expiration date of your protocol, enrollment must cease and research activities should stop. The continuation of research after expiration of IRB approval is a violation of the regulations [21 CFR 56.103(a)].

If a response is not received in 60 days form the date of this letter, the protocol will be withdrawn from the approval process and labeled inactive, unless notified otherwise. You will not be able to reactivate this protocol once it is withdrawn.

If you have any questions or concerns, please contact the IRB office at 404-727-5646 or at email address irb@emory.edu. Our web address is http://www.emory.edu/IRB. Thank you.

Sincerely,

James W. Keller, MD
Chairman, Institutional Review Board

cc: [redacted] PhD

Emory University
1256 Briarcliff Road
4th Floor, South Wing
Atlanta, Georgia 30306

Tel [redacted]
Fax [redacted]
Email [redacted]@emory.edu

INSTITUTIONAL REVIEW BOARD RENEWAL FORM

1256 Briarcliff Rd., Room 426-S, Atlanta, GA 30306
phone: (404) 727-5646 fax:(404) 727-1358
http://www.emory.edu/IRB

PLEASE TYPE

RECEIVED
OCT 22 2002
IRB

OFFICE USE ONLY
Review Type:
Full ☑ High Risk ☐
Expedited ☐ Exempt ☐
Committee/Reviewer: CMT II
Specialist: Mar

If you plan to continue conducting research beyond your current expiration date, you must complete this form and return it to the IRB Office at least 45 days prior to expiration date. Research protocols must have continuation approval until data analysis has been completed and closing reports are finished.

A. BASIC PROTOCOL INFORMATION	
1. IRB Number	488-97
2. Title of Proposal	Does Fluoxetine Reverse the Effects of Early Life Stress on the CNS CRF System and Improve Psychological and Neuroendocrine Function? A Therapy Study in Women with Childhood Abuse Experiences
3. PI	Charles B. Nemeroff MD/PhD
4. Department	Department of Psychiatry and Behavioral Sciences
5. Protocol Expiration	18 November 2002
6. If this protocol is μ 5 years old and active, please explain the reason:	**The treatment study study involves an 8-week-treatment-course and the planned enrollment is 80 subjects.**

B. STUDY STAFF
☒ There has been no change in the investigational team.
☐ The staff remains the same, but address/phone/fax/e-mail has changed; corrections attached.
☐ Team has changed (please attach a brief description and explanation. Be sure to include the WebCt ID assigned to you from the Human Subjects Testing program.

C. ENROLLMENT STATUS		
1. Are you requesting to continue enrolling new subjects?		
☐	N/A; chart review, study of existing data/specimens	
☒	Yes.	
☐	Yes, but no subjects have been enrolled to date.	
☐	No, the research is permanently closed to the enrollment of new subjects; all subjects have completed all research-related interventions *and* the research remains active only for long-term follow-up of subjects.	Date enrollment closed: _____
☐	No, enrollment closed, but not all subjects have completed all research-related interventions.	
☐	No, the remaining research activities are limited to data analysis.	
☐	No, the study has been completed. Please terminate this protocol.	

D. INFORMED CONSENT/ASSENT	
1. Is written consent/assent required?	☐ No ☒ Yes
2. Number of *different* consent/assent forms used?	2 (forms A & B) ✓
3. What is the title and current, approved version date of the each of the forms?	Does Fluoxetine reverse the effects of early life stress on the cns corticotropin-releasing factor system and improves psychological and neuroendocrine function?: a therapy outcome study in women with childhood abuse experiences Version A: 07/06/2001 Version B: 09/14/2001
4. Has a revised version of the informed consent /assent form(s) been approved since the last subject was enrolled?	☒ No ☐ Yes
5. The consent form has changed and requires re-evaluation and approval at this time (attach highlighted and clean copy, along with justification for the revision.	☒
6. An assent form has been added and requires review and approval at this time.	☐
Attach a copy of the most recently approved consent form **(required, if still enrolling subjects).**	
Attach a copy of the consent form signed by the last participant enrolled **(required unless no subjects have been enrolled or if enrollment was closed prior to your last approval).**	

E. SUBJECTS (pertains to subjects enrolled at Emory-affiliated sites or by Emory PI's)			
1. Live subjects not used (i.e., chart review, archived tissue or blood specimens).	☒		
2. How many new subjects gave informed consent for participation in the past approval period?	11		
3. What is the total number of subjects who have given informed consent to date?	61		
4. How many subjects completed required screening and began treatment/intervention?	47		
5. How many subjects has the IRB approved?	80 ✓		
6. If the number of subjects listed for No. 4 is greater than the number of subjects listed for No. 5, please attach an explanation.			
7. How many subjects were withdrawn from the study during the past year? Attach a brief explanation for each.	1		
8. Gender	☐ Male ☒ Female ☐ Both		
9. Age Groups	☐ <6 years ☐ 6-10 years ☐ 11-17 years ☒ ≥18 years		
10. Is this study geared toward a specific ethnic group(s)? If yes, which?	☒ No ☐ Yes		
11. Indicate which of the following populations are the focus of the research:			
☐ Intellectually or emotionally impaired	☐ Patients	☐ Pregnant subjects or fetuses	
☐ Prisoners, parolees, incarcerated subjects	☐ Students or trainees	☐ Employees of study sites	
☐ Subjects whose 1st language is not English	☒ Normal Volunteers	☐ Employees or subordinates of investigators	

F. RADIATION	
1. Is radiation used in this project?	☒ No ☐ Yes
2. If yes, what forms of radiation?	☐ Diagnostic x-rays ☐ Radiation therapy ☐ Radioisotopes
3. Is it beyond standard of care?	☐ No ☐ Yes
4. Radiation Safety Committee (RSC) approval:	Authorization #
5. Name of person who holds the RSC approval?	

G. DRUGS/DEVICES	
1. Are investigational drugs used in this study?	☒ No ☐ Yes, IND #
2. Are investigational devices used in this study?	☒ No ☐ Yes IDE #

H. SERIOUS ADVERSE EVENTS (SAEs)		
1. Were there any internal SAE's (involving subjects enrolled by Emory PI) **during the past approval period?**	☒ No ☐ Yes ☐ N/A	**If yes**, how many
2. Were the SAE's reported to the IRB?	☐ No ☐ Yes ☐ N/A	**If No**, attach an internal SAE form(s) and provide justification as to why they were not previously reported.
3. Were there any external SAE's **during the past approval period?**	☐ No ☐ Yes ☐ N/A	**If yes**, how many (Please attach a summary of the types of events that occurred and the relationship to the study.)
4. If any SAE's occurred, did they pose any additional risk?	☐ No ☐ Yes ☐ N/A	**If yes**, was the risk included in the informed consent form ? ☐ No ☐ Yes

I. DATA SAFETY MONITORING
☒ This study does not have/require a data safety monitoring board
☐ The study has a data safety monitoring board – reports attached
☐ The study has a data safety monitoring board, but no reports attached (attach a brief explanation)

J. OTHER	
1. Were any modifications submitted to the IRB during the last approval period?	☐ No ☒ Yes If yes, give dates:2-14-02 & 9-18-02
2. Has the FDA audited this protocol during the past year?	☒ No ☐ Yes (attach copy of Form 483)
3. Has additional or new data been collected that might affect a subject's willingness to participate in the study or that might change the risk/benefit ratio as originally proposed?	☒ No ☐ Yes (Please attach a description)
4. Have any abstracts or publications resulted from this study?	☒ No ☐ Yes (Please attach list)
5. Is the project funded? ☐ No ☒ Yes	If yes, name the sponsor. Eli Lilly & Co.

K. FACILITIES WHERE STUDY WILL BE CONDUCTED (mark all that apply):	
☐ Emory University Hospital	☐ The Atlanta Veterans Affairs Medical Center (VA R&D Committee approval is required)
☒ The Emory Clinic, Inc.	☐ Crawford W. Long Hospital
☐ Emory West	☐ Grady Memorial Hospital (Grady Research Oversight Committee approval is required)
☐ Children's Healthcare of Atlanta	☐ Wesley Woods Geriatric Center and Hospital
☒ Emory General Clinical Research Center	☐ Grady General Clinical Research Center
☐ Emory Children's Center	☐ Other: ____

L. CONFLICT OF INTEREST STATEMENT:	
1. Does any participating member, staff, students (or his/her spouse or dependent children) have any financial interest such as royalty, equity or any other payments (e.g., consulting, salary, etc...) in the sponsor or other entities having a financial interest in intellectual property, product, or service which is the subject of the proposed research?	☒No ☐Yes
Please review the following information concerning Emory University's Conflict of Interest and Disclosure guidelines: http://www.emory.edu/IRB/COI.htm	
2. Does/will any equity interest exceed $10,000 in current value or exceed 1% of ownership interest?	☒No ☐Yes
3. Does/will aggregate annual payments for royalty and other payments exceed $10,000?	☒No ☐Yes
4. If yes, indicate whether your potential conflict of interest has been disclosed to the Dean's Office.	☒No ☐Yes

M. SIGNATURE (Must be signed by PI)			
As Principal Investigator, I acknowledge responsibility for this project and assure that the faculty and staff who participate in it are qualified (or will be adequately trained) to conduct it.			
Principal Investigator:		Date:	10/21/02

Faculty Advisor (if applicable)	**Print:**		
Signature:		Date:	

EMORY UNIVERSITY SCHOOL OF MEDICINE
WOODRUFF HEALTH SCIENCES CENTER ADMINISTRATION BUILDING
1440 Clifton Road, N.E. Atlanta, Georgia 30322-4510

OFFICE OF THE DEAN

CONFIDENTIAL

FAX: [redacted]

May 15, 2000

Nemeroff faculty file — in the subfolder Nemeroff letter (Merilla Hilder)

Charles B. Nemeroff, M.D., Ph.D.
Professor and Chair
Psychiatry & Behavioral Sciences
[redacted]
CAMPUS

Dear Charlie:

At my request, the Departmental Chairs and Center Directors in the School of Medicine were asked to provide information on their consulting and similar activities. [redacted] prepared a summary spreadsheet of the responses I received. I must say, I was astonished to note that you have external involvement with more than twenty non-Emory entities. First, I would like you to provide to Ms. Seiton a copy of all consulting agreements or letters of understanding, including start and end dates and the compensation you receive. This does not include agreements that have already been provided for review, unless the current agreement is different from the one you previously sent over.

Charlie, I believe the extent of your external activity and your time away from Emory is inappropriate for a full-time Chairman in the School of Medicine and I feel I cannot defend it as Dean of the School of Medicine. Therefore, I am also asking you to come to me with a plan for a dramatic decrease in the number of consulting activities in which you engage. I want you to know that there is no comparison between your level of external activity and that of the next highest reported external activity.

I deeply appreciate your outstanding accomplishments in the growth and development of scholarly activity in your Department. It is not my intent to be hard on you, and I want you to understand that in today's climate, I am protecting the Chairs when I insist on moderation and careful monitoring of personal external activities. Your faculty and I need you here to manage and mentor them in their research, teaching, and clinical activities. You are a star in these areas, and this is a time when the School of Medicine needs you to shine.

Sincerely,

Thomas J. Lawley, M.D.
Dean

TJL/kfs