B. Institutional Review Board Approval Form

UNIFORMED SERVICES UNIVERSITY OF THE HEALTH SCIENCES
4301 JONES BRIDGE ROAD
BETHESDA, MARYLAND 20814-4712
www.usuhs.mil

May 25, 2006

MEMORANDUM FOR MS. CHERISE B HARRINGTON, , MEDICAL AND CLINICAL PSYCHOLOGY

SUBJECT: IRB Exemption of Study (DoD Assurance No. P60001 and FWA # 00001628)

1. Your research protocol G172HT entitled, "DoD/VA Treatment Guidelines: Impacts of Patterns of Care on Patient Satisfaction, Functional and Health Outcomes and Healthcare Costs," was reviewed and approved for execution on May 25, 2006 as an EXEMPT human use study under the provisions of 32 CFR 219.101(b)(4).

2. An exempt study signifies that you will not be required to submit renewal applications for full Board review **as long as that portion of your project involving human subjects remains unchanged.** If during the course of your project, you intend to make changes which may significantly affect the human subjects involved, you should contact the IRB office for guidance prior to implementing these changes.

3. The aim of this study is to examine the influence of treatment type on outcomes for patients with lower back pain. The information for this study will be extracted from records that were transferred from a DOD/TriCare database under a data use agreement for Dr. Michael Feuerstein's approved protocol, CO72FT. The PI is a co-investigator on Dr. Feuerstein's study. The data extracted for this protocol contains no identifying information.

4. Any unanticipated problems related to your use of human subjects in this project must be promptly reported to the full Board through this office. This is required so that the IRB can institute or update protective measures for human subjects as necessary.

5. Exemption is granted with the understanding that no further changes or additions will be made to the procedures followed or investigators involved without the knowledge and approval of the IRB.

6. You are required to keep all research-related documents in a permanent file in an area designated for that purpose that is accessible to your chain of command and inspectors of official audit agencies. Your study and its documentation are subject to inspection at any time. You must maintain your records to facilitate such inspections. **You are to notify the USU IRB Office upon completion of the study.**

7. If you have questions regarding specific issues on your protocol, or questions of a more general nature concerning human subjects protection, please contact me at 301-295-3303/9534 or rlevine@usuhs.mil

[redacted]

Richard R. Levine, Ph.D.
Assistant Vice-President for Research
and Executive Secretary, IRB

: Director, Research Administration
Chair, MPS
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