University of Nebraska Medical Center

NEBRASKA'S HEALTH SCIENCE CENTER
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Institutional Review Board (IRB)
Office of Regulatory Affairs (ORA)

July 15, 2002

Tien M.H. Ng, Pharm.D., RP
Pharmacy Practice
UNMC - 6045

IRB # 226-02-EP

TITLE OF PROPOSAL: Characterization Of Sympathetic Regulation Of Cytokines

SECONDARY INVESTIGATORS: Richard Rigmaiden, III MD; Thomas Sears, MD

DATE OF FULL BOARD REVIEW _____ DATE OF EXPEDITED REVIEW 07-10-02

DATE OF FINAL APPROVAL 07-15-02 VALID UNTIL 07-10-03

EXPEDITED CATEGORY OF REVIEW: 45CFR46.110; 21CFR56.110, Category 2

The Institutional Review Board (IRB) for the Protection of Human Subjects has completed its review of the above-titled protocol and informed consent document(s), including any revised material submitted in response to the IRB's review. The Board has expressed it as their opinion that you are in compliance with HHS Regulations (45 CFR 46) and applicable FDA Regulations (21 CFR 50.56) and you have provided adequate safeguards for protecting the rights and welfare of the subjects to be involved in this study. The IRB has, therefore, granted unconditional approval of your research project. This letter constitutes official notification of the final approval and release of your project by the IRB, and you are authorized to implement this study as of the above date of final approval.

Please be advised that only the IRB approved and stamped consent/assent form can be used to make copies to enroll subjects. Also, at the time of consent all subjects/representatives must be given a copy of the rights of research participants. The IRB wishes to remind you that the PI or Co-PI, is responsible for ensuring that ethically and legally effective informed consent has been obtained from all research subjects.

Finally, under the provisions of this institution's Multiple Project Assurance (MPA #1509), the PI/Co-PI is directly responsible for submitting to the IRB any proposed change in the research or the consent document(s). In addition, any unanticipated adverse events involving risk to the subject or others must be promptly reported to the IRB. This project is subject to periodic review and surveillance by the IRB and, as part of their surveillance, the IRB may request periodic reports of progress and results. For projects which continue beyond one year, it is the responsibility of the principal investigator to initiate a request to the IRB for continuing review and update of the research project.

Sincerely,

Ernest D. Prentice by MJE

Ernest D. Prentice, Ph.D.
Co-Chair, IRB

EDP/kje