January 16, 2002

MEMORANDUM

TO: James W. Holsinger, Jr., M.D.
Chair, Academic Council for the Medical Center

FROM: Emery A. Wilson, M.D.
Dean and Associate Vice President for Clinical Services

RE: New Course Application(s)

The Faculty Council of the College of Medicine has approved and submits for your consideration and approval the proposed course application(s):

**SPH 664 – Design & Analysis of Clinical Trials**
**Description:** This course will introduce the fundamental concepts used in the design of Phase I-IV clinical trials and will also introduce statistical methodology associated with the analysis of data from clinical trials.
**Justification:** This course presents advanced biostatistical concepts associated with clinical research. No such course currently exists. This course is required for participants in the Graduate Certificate in Clinical Research Skills program.

**SPH 665 – Ethical Issues in Clinical Research**
**Description:** This course will present ethical and regulatory guidelines for conducting clinical research (i.e., clinical trials).
**Justification:** No other course if offered on this topic. The NIH requires ethics education for participants in federally funded K30 research programs. As an institution with a K30 award (Career Training in Therapeutics & Translational Research), we must provide such a course.

**SPH 666 – Practicum in Clinical Research**
**Description:** This course is for participants in the Graduate Certificate in Clinical Research Skills program includes a mentored research experience; monthly journal club meetings; 2 annual retreats; special seminars; completion of research reports and a summary of the participant’s experience in and evaluation of the K30 program.
**Justification:** This course will complete the course requirements of the K30 program by offering participants up to 3 credit hours for participation in nondidactic program activities.
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