HUMAN SUBJECTS PROTECTION: POLICIES AND PROCEDURES
Department of Pharmacy Practice and Science

Introduction
The Department of Pharmacy Practice and Science has designated individuals responsible for scientific review of local human subjects’ protocols. At least one of these individuals must review and approve Project Approval Forms and Periodic Reports. The Vice President for Research and Graduate Studies announced new requirements (memo dated September 27, 2000 regarding “Local Monitoring of Human Subjects Protection”) that each organizational unit must have local monitoring of human subject activities. In addition to the current scientific review, the Department will need to conduct a periodic review for compliance including auditing procedures and records. In what follows, some of the essential components of the local monitoring process will be delineated. Further information can be obtained from documents distributed by the Human Subjects Committee and the office of the Vice President for Research and Graduate Studies.

Local Review
The Head of the Department of Pharmacy Practice & Science will appoint at least one individual to serve a one-year term who will be responsible for a semi-annual local review process. Failure to implement local monitoring could have significant consequences for the department and investigators (memo dated September 27, 2000 regarding “Local Monitoring of Human Subjects Protection”). However, as mentioned throughout this document, it is ultimately the responsibility of Principal Investigator to insure the protection of human subjects by following local policies, Good Clinical Practices, and all governmental regulations.

An administrative assistant in the Department Office will maintain a current list of ongoing and/or completed projects. Projects will be identified through submission of a Project Approval Form or Periodic Review Form. Individuals charged with scientific review of these forms will notify the administrative assistant by providing a copy of the signed form. The administrative assistant will obtain the Human Research Committee approval date (if approved), whether an informed consent form is required, re-approval dates (if applicable), and termination date. This database will serve as a master list for the local review individual or group.

The individual(s) assigned for local review shall review documents in the Administrative Office and ensure that the documents are complete and appropriately executed. If any deficiencies are noted, these will be reported to the Department Head. The Department Head may instruct the local review designate or appoint additional individuals to inspect the records in the Administrative Office as outlined below as well as additional records possessed by the investigator(s). Depending on the findings of this audit, deficiencies may be reported to the
Human Subjects Committee and the Office of the Vice President for Research. The Department Head is responsible for any corrective action in conjunction with other University Officials if serious deficiencies are noted.

**Use of Approved, Updated, and Secured Consent Forms**
The Project Approval Form that must be completed by investigators proposing studies involving human subjects asks, “Where will the signed subject consent forms be stored so that they will be easily accessible in the event of on-site visits from authorities (include administrative office and room number).” The Project Approval Form also states that “the signed consent forms will be filed in the Departmental file and retained for a period of six years.” In addition to these requirements, there is a Periodic Review Form that is distributed by the Human Subjects Committee that will assess the status of approved projects. Among other things, this form specifically asks, “Is the consent form as approved by the Human Subjects Committee still being used.” All consent forms must bear a stamp that lists when the consent form was approved and when the consent form expires. In addition to compliance with these items, **it is the responsibility of the Principal Investigator to ensure that the consent forms are stored in the designated area of the Department (room 313)** and that the forms are readily available during audits by local reviewers.

**Consent in Accordance with Established Policies**
Since the individuals performing the local review will not usually be present when informed consent is obtained from the subject, it is incumbent upon the investigators to ensure that that established policies of the Human Subjects Committee are adhered to. The individuals performing the periodic local reviews will check to make sure that the subjects (or appropriate representatives) and an approved study investigator have signed and dated the approved consent forms.

**Reporting of Adverse Events**
It is the responsibility of the investigator to report all “unanticipated” and “serious or fatal anticipated events” to the Human Subjects Committee within five days of occurrence. Additionally, it is expected that such adverse events involving pharmaceuticals or medical devices will be reported to the sponsor (if applicable) and FDA. The investigators should file copies of such reports in the same designated area that contains signed consent forms; the reports will be reviewed during the local review process.

**Personnel Involved in Research**

It is the responsibility of the investigator to obtain the appropriate training and education necessary to follow established policies. There are educational program manuals placed on
The Vice President for Research and Graduate Studies has stated that “All individuals participating in research on human subjects (with any sponsoring organization or agency, or even if not funded) must complete this education program and be certified with a passing test score.” The examination form covering the educational material can be accessed through the Vice President for Research and Graduate Studies’ website. The “original completed forms bearing the signature of the test taker” must be mailed to the Vice President for Research and Graduate Studies, Room 601, Administration Building. Documentation of acceptable completion of the training program should be filed in the same designated area of the department that contains the signed consent forms (i.e., room 313 in the College).

**Administrative Office Records Area (Room 313)**

A designated area will be utilized for storage of records involving human subject research. Records maintained will include a master list of all studies for which a Project Approval Form or Periodic Review Form is initiated after April 30, 2001. A file will be created for each project and will contain:

- a copy of the Project Approval Form,
- copies of any Periodic Review Form’s,
- a copy of the Human Subjects Committee approval letter,
- copies of re-approval letter (s) (if applicable),
- the original signed consent forms for all subjects who provide consent (if applicable),
- a list of all personnel involved in the research project,
- documentation of acceptable completion of human subjects training for the listed personnel, and
- reports of any serious or unexpected adverse events.