UCONN HEALTH

POLICY NUMBER 2002-31

February 25, 2002

POLICY: ADMINISTRATION OF CLINICAL TRIALS (RESEARCH/SPONSORED PROGRAMS)

PURPOSE:

To ensure that funds received for the clinical testing of pharmaceuticals and medical devices ("clinical trials") are administered in accordance with University policies, sponsor requirements and federal regulations.

POLICY STATEMENT:

1. All externally funded clinical trials must be approved in accordance with Policy #2002-30 Approval of Proposals, as referenced in this manual, as well as by the University's Institutional Review Board, and performed under the terms of a formal clinical trial agreement, grant award or consortium agreement, which has been negotiated and executed on behalf of the University by the Office Clinical Trials ("OCT"), or the Office of Research and Sponsored Programs.

2. All externally funded clinical trials will be accounted for in a sponsored project account established by ORSP upon receipt of payment from the sponsor.

3. The Principal Investigator is responsible for managing the clinical trial in accordance with the terms of the clinical trial agreement, University policies, including IRB Regulations, and applicable State and Federal regulations.

4. The Principal Investigator will complete case report forms in a manner consistent with the sponsor's specifications. Case report forms will be completed in a timely manner to ensure prompt and appropriate sponsor payment.

5. The Principal Investigator and the General Clinical Research Center (GCRC), where appropriate, will participate in all appropriately sanctioned audits and investigations conducted to monitor fiscal and research compliance.

6. If funds remain at the end of a clinical trial, after all appropriate expenses have been charged to the clinical trial account, they may be transferred to an operating account, for use by the Principal Investigator or his/her department or school for research and/or educational purposes. If the account is in a deficit position, the balance will be transferred to the appropriate operating account designated by the Principal Investigator. If none is designated within 90 days of the end of the trial, the Finance Officers of the School of Medicine and School of Dental Medicine will designate the appropriate account.

7. Billing for patient services (deemed to be standard of care) either to the patient who is enrolled in a clinical trial or to his/her third party payer shall be governed by the procedures set forth by the "GCRC" and coordinated through the patient billing office. Such billing shall be governed by clinical standards, sponsor requirements and the Center for Medicare and Medicaid Services ("CMS") regulations where applicable.

Dan Upton (signed) — 4/10/02
Chief Financial Officer — **Date**

Richard Berlin, MD (signed) — 4/8/02
Associate Dean for Research/Planning & Coordination — **Date**

Peter Deckers, MD (signed) — 4/10/02
Executive Vice President for Health Affairs — **Date**

Replaces: NEW POLICY