

UConn HEALTH

POLICY NUMBER 2004-04

June 1, 2004

**POLICY: IRB APPROVAL OF HUMAN RESEARCH CONDUCTED BY
SUBCONTRACTORS**

PURPOSE:

To ensure that all external agreements and/or sub-contractual arrangements related to grants awarded to UConn Health (also known as sub-awards) meet the requirements of Human Subject Use compliance regulations.

POLICY STATEMENT:

- 1) It is the policy of UConn Health that prior to initiation of any agreements and/or subcontracts with collaborators that are not employees of UConn Health, written assurance will be provided that all required information related to the use of Human Subjects in a UConn Health project will have been approved by the collaborator's Institutional Review Board in accordance with 45CFR46 that has the authority to approve such actions on behalf of the collaborating institution or organization.
- 2) In the event that no written assurance is on file at the time of initiating the sub-award, UConn Health reserves the right to suspend or restrict all activities related to the use of Human Subject until such time as the collaborating organization provides such information to UConn Health.
- 3) Written assurances that a collaborator or sub-awardee has been approved for use of Human Subject shall become a part of the approved project file and a copy shall be filed with UConn Health Investigator's project assurance file.

Richard D. Berlin (signed)

8/19/04

Associate Dean for Research/Planning & Coordination

Date

Peter J. Deckers, MD (signed)

8/19/04

Executive Vice President for Health Affairs

Date

NEW POLICY

Effective: June 1, 2004