

IACUC POLICY AND PROCEDURE STATEMENT

Policy/Procedure: “Not Yet Approved” Protocol Retention

Policy/Procedure ID: 04-06-001

Effective: June 17, 2004

A. Background

When a new protocol submission is reviewed by the IACUC it may not be approved at the meeting (the IACUC may require clarifications or modifications, approval may be withheld or a decision on the protocol deferred). Normally the PI will submit responses to the conditions for review at the next IACUC meeting, but there are times that the PI does not respond to the conditions in a timely manner. There is the need to have a time limit within which PIs can respond to conditions and for the Office of Research Compliance to retain the “not yet approved” protocols.

B. Policy

When a new protocol is not approved at the IACUC meeting at which it is initially reviewed, the PI has 90 days to submit responses to conditions, comments or concerns. If responses are not received within 90 days a new protocol will need to be submitted to the IACUC for review, even if the research objectives have not changed. The initial review outcome notification sent to the PI by the Office of Research Compliance will indicate the date by which responses are due.