OLOLRMC INSTITUTIONAL REVIEW BOARD
ANNUAL REPORT

Federal regulations require a protocol review within one year of previous approval/review (unless a more frequent review has be designated) to permit continued human subject involvement. **Although actual study approval is for one year from the date of the initial review, you must return this completed form by the last working day of the month prior to the approval expiration date to ensure compliance with the regulations.** If the form is not returned, the IRB will conclude the project is terminated and approval will **expire**.

The following question address required federal review criteria.
PROTOCOL # _____ **PRINCIPAL INVESTIGATOR(S)** _____
_____

PROJECT TITLE: _____
PROJECT STATUS: Active _____Complete _____ (Start *and* end date _____)
FUNDED BY: _____

PROTOCOL/CONSENT: (Check One)
_____Protocol and consent form use continues as previously approved.
_____Changes are requested at this time (attach request)*

**Attach a report of any significant deviations.*

ENROLLMENT (Number of subjects currently authorized _____)
subjects enrolled since: Inception: _____Last Review: _____

ADVERSE/UNEXPECTED EVENTS
How many such events have occurred since study inception _____
Since last report: _____

Have there been any previously unreported events? _____ (if YES, attach report describing event and any corrective action taken).

RISK/BENEFIT RATIO
Does new knowledge or do adverse events change the risk/benefit ratio? Y/N _____;
Is/was a corresponding change in the consent form needed. Y/N _____;
YOU MUST ATTACH A BRIEF SUMMARY of project progress/results. *Include: number enrolled, number who have completed the study, number actively participating and number who have dropped out of the study and why. Of those still participating, at what stage are they?*
IF STUDY INVOLVES AN INVESTIGATIONAL NEW DRUG/DEVICE, an annual report must be submitted to the FDA. Has an annual report been submitted to FDA? Y/N _____

Principal Investigator: _____ **Date:** _____

(Please attach copy of certificate of completion from education program at OHRP & NIH site — **http://ohrp-ed.nih.gov** ***& http://cme.nci.nih.gov/.)***

IRB ACTION:

Continuation approved _____ **Disapproved** _____ **Other** _____

Return to IRB Office, OLOLRMC 5000 Hennessy Blvd., Department of Pharmacy (225) 765-8612.

Source: Our Lady of the Lake Regional Medical Center, Baton Rouge, LA.

Sample Renewal Letter

October 22, 2001

To: Principal Investigator/Research Coordinator

Protocol Title:

Protocol Number:

IRB Meeting Date:

Approval Date:

Expiration Date:

The records of our Institutional Review Board indicate that the above-referenced study is due for renewal (or closure, if applicable) on Nov. 9, 2001.

Please complete the Annual Report Form and/or Final Report for the Institutional Review Board (please include 15 copies of the informed consent, annual report form and an abstract/summary of the protocol). As a reminder, a Protocol must remain open for IRB review as long as any enrolled patients remain in follow-up.

The continuing review or final report of this study must be presented at the next scheduled meeting of the Institutional Review Board. The IRB meeting is scheduled for **Thursday, Nov. 8, 2001** at 7 a.m. in the Chapel Boardroom of Our Lady of the Lake RMC. Information to be reported at this meeting must be submitted no later than, **Friday, Oct. 26, 2001**. If you have any questions or need additional information, please contact me at 765-8612.

Sincerely,

Cynthia A. Harper, IRB Coordinator
Institutional Review Board

/cah

Attachment

Source: Our Lady of the Lake Regional Medical Center, Baton Rouge, LA.