

Date: February 22, 2008
To: NAME, Principal Investigator
Subject: Study # U05040: Approval Study:

SAMPLE

On February 22, 2008, the Institutional Review Board Chair of California State Channel Islands (CSUCI) approved your research study. According to the policies and procedures of the Institutional Review Board (IRB) you may begin your investigation upon receipt of this notification. Approval is granted for one year. At the end of this period, as the principal investigator you will be asked to submit a status report which the IRB will review at its next scheduled meeting. At that time, the IRB will decide if the research should be amended, terminated, or allowed to continue as originally approved.

As principal investigator you will need to:

1. Notify the IRB within 60 days whenever research is completed or otherwise terminated;
2. Promptly report to the IRB any changes in a research activity, proposed amendments, or unexpected reactions;
3. Promptly report to the IRB any unanticipated problems involving risks to subjects or others; and,
4. Notify the IRB Chair within five (5) days immediately after any adverse reactions are experienced by participants of the investigational study or as reported to you by the sponsor/manufacturer/co-principal investigators.

You may not initiate changes in approved research protocol without IRB review and approval, except where necessary to eliminate apparent immediate hazards to the human subjects. Should you have any questions please contact Amanda Quintero, Director for Research and Sponsored programs (805) 437-3285.

Sincerely,



Don Rodriguez, Institutional Review Board Chair

CC: Amanda Quintero, Director for Research and Sponsored Programs