PART VI: ANNUAL RENEWAL/FINAL REPORT

A. General Information
The Department of Health and Human Services (DHHS), The Food and Drug Administration (FDA) and the University of South Alabama (USA) require at least annual review of all projects involving human subjects. As a courtesy, the IRB office sends out renewal reminders six to eight weeks before the studies expire. However, it is ultimately the investigator’s responsibility to initiate a renewal application, allowing sufficient time for the review and re-approval process to be completed before the current approval expires. If any project activity occurs or continues after the expiration date, the investigator is out of compliance with both federal and university policy.

The Guidance on Continuing Review (7/11/02), the Dept. of Health and Human Services (DHHS) notes that:
Continuing review of research must be substantive and meaningful.
In conducting continuing review of research not eligible for expedited review, all IRB members should at least receive and review a protocol summary and a status report on the progress of the research, including:
• The number of subjects accrued;
• A summary of adverse events and any unanticipated problems involving risks to subjects or others and any withdrawal of subjects from the research or complaints about the research since the last IRB review;
• A summary of any relevant recent literature, interim findings, and amendments or modifications to the research since the last review;
• Any relevant multi-center trial reports;
• Any other relevant information, especially information about risks associated with the research; and
• A copy of the current informed consent document and any newly proposed consent document. Previously approved questionnaires or survey instruments should be submitted only if they have been revised in the previous year or modifications are being proposed for the coming year. Any new questionnaires should be submitted.

Generally, if research did not qualify for expedited review at the time of initial review, it does not qualify for expedited review at the time of continuing review, except in limited circumstances described by expedited review categories (8) and (9) at 63FR60364-60367. Under Category (8), an expedited review procedure may be used for the continuing review of research previously approved by the IRB as follows:
(a) Where: the research is permanently closed to the enrollment of new subjects; all subjects have completed all research-related interventions; and the research remains active only for long-term follow-up of subjects; OR
(b) Where no subjects have been enrolled and no additional risks have been identified; OR
(c) Where the remaining research activities are limited to data analysis.

Under Category (9), an expedited review procedure may be used for continuing review of research not conducted under an investigational new drug application or investigational device exemption where categories (2) through
(8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

B. Specific Submission Requirements for IRB Annual Renewal and Final Reports (see sample form, Appendix I)

Submit two copies of the Annual Renewal/Final Report Form, two copies of the most recent version of the stamped approved consent and two copies of the current protocol and investigator brochure (if applicable).

Submit thirty copies of the Annual Renewal/Final Report Form, thirty copies of the most recent version of the stamped approved consent, and three copies of the most current protocol and investigator’s brochure (if applicable).

NOTE: Only the above information should be included. Previous approval letters and correspondence and other extraneous materials should not be attached as they needlessly increase the volume of paperwork and the amount of time required to approve an application. A final report should be submitted when the study is officially closed to new patient enrollment and follow up. If patients continue to be actively followed the study is not considered closed and requires annual renewal.

The IRB office is required by Federal regulations to maintain records for three years following the closure of a study.