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May 24, 1996

Memorandum: To all investigators with current active ACAM IRB reviewed study protocols.

Re: Interim Monitoring Reports

Dear Doctor:

At the Orlando meeting of the IRB, a dozen research protocols were reviewed. After reviewing the periodic monitoring reports, it became evident that clarification of IRB requirements is necessary. In particular item "4E" which requests you to "...attach a written description of the benefits obtained to date from this study" seems to have generated some confusion. This item refers to clinical benefits obtained by the study subjects/patients.

The reported benefits should specifically address the concerns that pertain to the scope of your stated protocol. Incidental or extraneous observations are not required for IRB interim reports. Please use the interim monitoring form to document and report quantitatively the changes you have observed in your study subjects. For example, descriptions such as:

> *30% of male patients reported a >25% reduction in anginal episodes. In 12 patients we were able to discontinue diuretics completely. 20 patients were able to reduce their nitroglycerine use by >50%. To date there has been a >50% increase in walking distance in 7 male and 9 female patients.*

are more meaningful to the IRB reviewers than vague descriptions such as "better memory," "less angina," "less pain," "improvement in claudication."

Unless your study is completed, final outcomes should only be reported for those subjects who are no longer involved in the research.

Please be aware of the constant need to respect patient confidentiality. **DO NOT** report patient names to the IRB unless specifically requested to do so. All study subjects should be identified by a code number only, so that names will not appear on any document outside of your establishment.

If the interim report you submitted accompanies this letter, your report is either incomplete or in need of revision in one or more of the areas discussed above. Please effect the necessary revisions and submit your amended report within 15 days.

Sincere thanks for your compliance,

Ralph A. Miranda, MD, FACAM
Chairman, ACAM IRB

RAM:nm