Attachment 6-5a

PROTOCOL CHECKLIST
FOR CONTINUING REVIEWS

_____**PROTOCOL NUMBER**

☐ **NIH-1195-1 (V.9-06) with ALL ITEMS CHECKED** and **signatures** down through and including the **Clinical Director**

☐ **CLEARANCE OF NIH INVESTIGATOR PERSONAL FINANCIAL HOLDINGS BY IC ETHICS OFFICE (PFH)** Version 3/18/08 **(WITH DEC APPROVAL) (MANDATORY)**

☐ **DESIGNATION OF REIMBURSEMENT FOR TRAVEL AND SUBSISTENCE (DRTS) FORM (MANDATORY)**

☐ **COPY OF THE PRECIS/PROTOCOL**

☐ **COPY OF PREVIOUS YEAR'S 1195-1 OR 1195**

☐ **MEMORANDUM OF PROGRESS CONTAINING THESE ELEMENTS (All elements must be addressed– state n/a if they do not apply)**

- ☐ 1) Description of study progress;
- ☐ 2) List of amendments over previous year,
- ☐ 3) Past year subject accrual demographics;
- ☐ 4) Detailed cumulative information on previously enrolled subjects (e.g.. status of their current treatment on protocol, current illness status, cure rate, mortality);
- ☐ 5) Explanation of pediatric experience, if any
- ☐ 6) Discussion of any new information that may affect risk or benefit to subjects;
- ☐ 7) Additions or removal of investigators from study (including off-site);
- ☐ 8) The scientific justification for continuation of the protocol based upon the cumulative results of treatment thus far, including specific endpoints of the study;
- ☐ 9) Summary of adverse events as defined in the protocol and approved by the IRB.
- ☐ 10) Data and safety monitoring plan.
- ☐ 11) Study plans.

☐ **Completed Gender Minority Accrual Chart (PHS 398/2590 revised 5/01) REQUIRED**

☐ **Completed Targeted/ Planned Enrollment Table: Gender Minority Accrual Chart (PHS 398/2590 revised 5/01)** Required for Clinical Trials Phase 3 or 4 protocols only

☐ **Completed NIEHS IRB Accrual Data Recruitment Report (Version** 9/2004) **REQUIRED**

☐ **List Of Relevant Publications Or Abstracts.**

☐ **Current Consents (MANDATORY)**

☐ **Current Protocol with all changes since last IRB review noted**

☐ **If study involves an IND or IDE, please submit a summary of the FDA annual report.**

☐ **Current Off-site IRB Approval (Only for protocols with off-site locations.)**

☐ **List of persons authorized to obtain consent if other than the PI or AI is attached; OR**

☐ **Only principle investigators or associate investigators may obtain consent for this study**

☐ **CORRESPONDENCE WITH PI**