

RR 403-D

01/01/07

**IRB #:** \_\_\_\_\_ **Date of Audit:** \_\_\_\_\_

**Reliance Study:**  Yes  No If yes, indicate which one & list that site's IRB #  
 BIRB \_\_\_\_\_  CRIRB \_\_\_\_\_  OCIRB \_\_\_\_\_

**Protocol:** \_\_\_\_\_

**Investigator:** \_\_\_\_\_

**Contact:** \_\_\_\_\_

**Site of Audit:** \_\_\_\_\_

**Review Level:**  Exempt  Expedited  Full Board Review

**Status:**  Active  Completed  Terminated  Other

**This audit is based on information in IRB file as of the last submission, dated:** \_\_\_\_\_

**Ask PI who are the co-investigators and key personnel on the project (prior to audit complete list from IRB records).**

- |          |   |              |                                  |                                      |
|----------|---|--------------|----------------------------------|--------------------------------------|
| 1. _____ | <input type="checkbox"/> Listed on record | HS Training: | <input type="checkbox"/> Current | <input type="checkbox"/> Not Current |
| 2. _____ | <input type="checkbox"/> Listed on record | HS Training: | <input type="checkbox"/> Current | <input type="checkbox"/> Not Current |
| 3. _____ | <input type="checkbox"/> Listed on record | HS Training: | <input type="checkbox"/> Current | <input type="checkbox"/> Not Current |
| 4. _____ | <input type="checkbox"/> Listed on record | HS Training: | <input type="checkbox"/> Current | <input type="checkbox"/> Not Current |
| 5. _____ | <input type="checkbox"/> Listed on record | HS Training: | <input type="checkbox"/> Current | <input type="checkbox"/> Not Current |
| 6. _____ | <input type="checkbox"/> Listed on record | HS Training: | <input type="checkbox"/> Current | <input type="checkbox"/> Not Current |

**Number of subjects recruited in the last approval period:** \_\_\_\_\_

**1. Patient Population:**  
Population from which subjects are selected:

Who selects subjects for the study? \_\_\_\_\_

How are subjects identified for the study?

# Males: \_\_\_\_\_ # Females: \_\_\_\_\_ # Enrolled: \_\_\_\_\_  
 Age Range: \_\_\_\_\_ Race and Ethnicity: \_\_\_\_\_

Are there any vulnerable subjects enrolled? If so, describe safeguards?  No  Yes

Are subjects currently being enrolled?  No  Yes

Comments on Patient Population:

**2. Informed Consent:**

Who explains the study to potential subjects?

Is everyone who is explaining the study, qualified? If no, explain.  No  Yes

Is approved version of Informed Consent Form being used? If no, explain.  No  Yes

Are Informed Consent forms signed and dated? If no, explain.  No  Yes

Has each subject been given a copy of the consent form? If no, explain.  No  Yes

Are all consent forms accounted for? If no, explain.  No  Yes

Is there any advertising / recruitment flyers?  No  Yes

If yes, had it been approved by the IRB?  No  Yes

Comments on consent forms:

**3. Data Collection Instruments**

All data collection instruments were approved version. If no, explain.  No  Yes

All hard data was kept in secure location as per application. If no, explain.  No  Yes

Comments on data collection instruments:

#### 4. Electronic Data

Electronic data was stored securely, as per application. If no, explain.  No  Yes

Electronic data contains approved variables. If no, explain.  No  Yes

Comments on electronic data:

#### 5. Patient Safety

Were reportable SAE's reported appropriately? If no, explain.  No  Yes

Has the study been recently monitored /audited? (If yes, attach available report).  No  Yes

Comments on patient safety:

#### 6. Administrative

Have all amendments/revisions been submitted to the IRB? If no, explain.  No  Yes

Are records kept confidential?  No  Yes

Who has access to research records?

Where are research records stored and in what format?

Comments on administrative documentation:

**7. Reviewer Comments**

Do research staff members need additional training in any aspect of conducting clinical trials?

No  Yes

Do you feel that there is a need for additional monitoring?

No  Yes

Comments:

\_\_\_\_\_  
Reviewer  
\_\_\_\_\_  
Reviewer  
\_\_\_\_\_  
Reviewer  
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Date of Visit  
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