HSSC IRB COOPERATIVE REVIEW
STANDARD OPERATING PROCEDURES
(Clemson University Version 4.1.2008)

Pursuant to the “Cooperative Agreement – Institutional Review Boards” signed September 2006 by the HSSC ‘Collaborating Institutions’, the following procedures will be utilized by the accepting institution for concurrence with the lead institution’s applicable IRB approval/findings.

1. Before completing protocol forms, the PI should initiate a consultation between the IRBs of the collaborating institutions. Once it has been determined who will be the approving IRB, the PI should submit appropriate paperwork to that IRB.

2. After approval, the Principal Investigator will forward to the HSSC collaborating institution’s IRB the following:

- Lead institution’s IRB approval letter
- Study protocol
- Approved consent form (and addendum, if appropriate)
- Approval letter from Scientific Review Committee (if applicable)
- HSSC IRB Request for Cooperative Review

OR

- HSSC IRB Request for Cooperative Review of Continuing Review/Amendment-Revisions/ Reportable Events

3. Upon receipt of the above, the collaborating institution’s IRB will decide whether to accept the prior IRB approval or conduct its own review. This decision will be made within 10 business days of receipt of the HSSC Request for Cooperative Review. The collaborating IRB may require administrative changes to the consent document to reflect local requirements. These changes will be communicated to the PI who is responsible for informing the approving IRB of the changes. The approving IRB will document acceptance of the required changes.

4. The ‘Collaborating Institution’ reserves the right to its own IRB review.