MODEL MOU

_____ HEALTH SYSTEM

MEMORANDUM OF UNDERSTANDING REGARDING COOPERATIVE INSTITUTIONAL REVIEW COMMITTEE ACTIVITIES

WHEREAS, ABC Medical Center ("ABC") and XYZ Medical Center ("XYZ") each maintain an Institutional Review Committee ("IRC"), which is a Medical Staff Committee designed to protect the rights and welfare of individuals participating in research;

WHEREAS, ABC and XYZ are components of the same Health System, and operate in the same geographic region with substantial Medical Staff overlap and common interests in multiple research projects;

WHEREAS, ABC and XYZ wish to avoid unnecessary duplication of effort in the oversight of research under their respective jurisdictions;

WHEREAS, the Food and Drug Administration ("FDA") and Department of Health and Human Services ("DHHS") permit institutions involved in multi-institutional studies to use reasonable methods of joint or cooperative review (21 CFR Section 56.114 and 45 CFR Section 46.114, respectively); and

WHEREAS, the IRCs at ABC and XYZ both operate pursuant to a standardized Procedural Manual which expressly allows for cooperative review arrangements (Section __) consistent with federal regulations;

NOW THEREFORE, it is mutually agreed and understood that:

1. A practitioner who is a member of the Medical Staffs of both ABC and XYZ, and wishes to serve as a clinical investigator in research involving patients at both facilities, may present the proposed research to the Chair of the IRC at either facility, with a written request that the research be approved by that IRC (as the "Primary IRC") for implementation at both facilities. The submission shall include attestations that:

   (a) the clinical investigator and any affiliate investigators have the requisite clinical privileges to provide the proposed research-related physician services at the site(s) where they will be participating;

   (b) both sites have adequate facilities and support personnel to assure that the study will be properly conducted there.

   A copy of the complete submission shall be provided to the Chair of the other IRC (as the "Affiliate IRC").

2. The Chair of the proposed Primary IRC shall contact the Chair of the proposed Affiliate IRC to determine whether he or she has any objection to cooperative review of the research at issue, as contemplated by this Memorandum of Understanding. If the Chairs of both IRCs agree that cooperative review would be appropriate, the research shall be presented for consideration by the Primary IRC at its next regularly scheduled meeting.

3. The Primary IRC shall consider the proposed research in accordance with its normal standards and procedures, taking into account the fact that the research is intended for implementation at both facilities. The review shall include, at a minimum, consideration of whether the

proposed consent form contains all appropriate elements, such as contact information for purposes of communicating complaints or questions about the research at each site.

4. The Primary IRC may, upon consideration, decline to serve in that capacity for any reason it deems appropriate, including but not necessarily limited to uncertainties about whether a relevant medical staff department, committee, or official at the Affiliate facility would approve of the research at that site. The Primary IRC shall also have the option to approve the research for both facilities subject to specified conditions, such as the submission of documentation or additional information regarding relevant matters.

5. The Chair of the Primary IRC shall inform the Chair of the Affiliate IRC of the results of the review, and send him or her a copy of the written notice to the clinical investigator. Denial of approval by the Primary IRC shall not preclude the clinical investigator from submitting the research for independent review and approval by the Affiliate IRC.

6. Each IRC may freely exchange with the other IRC any and all information it has regarding research which is proposed for cooperative review, regardless of the outcome of the process.

7. If the Primary IRC has accepted responsibility for serving in that capacity and has approved the research, it shall also assume primary responsibility for monitoring the research, including:

   (a) review and approval of proposed modifications in the protocol or consent form;

   (b) receipt of and responses to adverse action reports; and

   (c) periodic reviews and renewals of approval at prescribed

intervals.

8. The Chair of the Primary IRC shall be informed of significant developments regarding the research as conducted at both sites, including but necessarily limited to deviations from the approved research protocol or IRC requirements. Should controversies arise, the Primary IRC shall have the prerogatives described in the Procedural Manual and applicable regulations. The Chair of the Affiliate IRC shall be sent a copy of all correspondence with the clinical investigator regarding such matters.

9. The Chair of either IRC may, at his or her discretion, terminate the cooperative review arrangement for a given study at any time. In that event, he or she shall notify the Chair of the other IRC and the clinical investigator immediately, and proceed as warranted by the circumstances.

10. This Memorandum of Understanding shall become effective upon approval by the _____ Health System Board of Trustees, and shall remain in effect indefinitely.

Date:_____ _____
_____, M.D.
Chair, IRC
ABC Medical Center

Date:_____ _____
_____, M.D.
Chair, IRC
XYZ Medical Center

Date:_____ _____
_____, M.D.
Chief of Medical Staff
ABC Medical Center

Date:_____ _____
_____, M.D.
Chief of Medical Staff
XYZ Medical Center

Date:_____ _____
_____
President/CAO
ABC Medical Center

Date:_____ _____
_____
President/CAO
XYZ Medical Center

Date:_____ _____
_____
President/CEO
_____ Health System

Date:_____ _____
_____
Chair, Board of Trustees
_____ Health System