GUIDELINES FOR SUBMITTING RESEARCH PROTOCOLS TO THE
INSTITUTIONAL REVIEW BOARD

In order to expedite the review of research protocols submitters should use the following checklist:

1. _____ A formal letter addressed to the Chairman of the Institutional Review Board requesting review of your study. Include the title of your study in this letter;

2. _____ Completed IRB application along with the listed documents;

3. _____ One (1) hard copy of protocol, summary sheet, informed consent forms, HIPAA Authorizations and Disclosures, any advertising material, including the text transcription of verbal advertisements (if applicable) and the IRB application form with an e-mail version the. E-mail version should be sent to the IRB Coordinator (halll@sjhmc.org);

4. _____ A letter of approval from the appropriate administrative individuals including the chairman of a medical department or his designee (associate chairperson, director of research, or chief of divisional service) or the vice-president of a non-medical service (nursing, clinical services, etc.);

5. _____ The CV’s of all investigators and a certification documenting completion of a training course in the ethical conduct of biomedical research, which must include information on investigators specific responsibilities Internet website: http://phrp.nihtraining.com/users/login.php (ALL PARTICIPANTS LISTED ON THE STUDY MUST COMPLETE COURSE);

6. _____ IRB fees or a letter from the investigator committing to the payment of IRB fees from the investigators research funds or actual payment.

ADDITIONAL GUIDELINES FOR SUBMITTING RESEARCH PROTOCOLS TO
THE INSTITUTIONAL REVIEW BOARD

In the case of a study of any investigational new drug device or biological or experimental research; in addition to the above:

1. _____ A copy of the sponsor’s application to the U.S.F.D.A.
2. _____ A copy of the form 1572 in the case of a drug/device trial or, in the case of a non-sponsored therapeutic or non-therapeutic study, a copy of:
3. _____ One copy of the investigator’s brochure for the IRB file.
4. _____ The CV’s of all investigators: certification documenting completion of a training course in the ethical conduct of biomedical research, which must include information on investigators specific responsibilities Internet website: http://phrp.nihtraining.com/users/login.php (ALL PARTICIPANTS LISTED ON THE STUDY MUST COMPLETE COURSE);
5. ____ A statement that “All pertinent State and Federal regulations as described in the Common Rule (45 CFR 46) and 21 CFR 50, 56 will apply.”

6. ____ A copy of the administrative contract. (Clear language in the contract wherein the sponsor agrees to pay the IRB fees or a letter from the investigator committing to the payment of IRB fees from the investigators research funds or actual payment.)

Note: If the initial protocol submission is incomplete, it will **not** be considered for review by the IRB.

The IRB office will compose the submission with the items above and, if complete, will assign the proposal a protocol number, register it and schedule it for presentation at the next available meeting. **In that protocols must be registered prior to the Board meeting, all complete protocols and IRB submissions received by the deadline will appear on the agenda for the monthly meeting scheduled for the first Thursday of the month.** Protocols receiving final IRB approval will be referred to the Medical Board/Systems Board as the proxy of the governing body (the Board of Trustees) approval. Only protocols free from contingencies will be submitted to the governing body’s proxy.

Any investigator seeking an exemption or expedited review, as described further in this document, should submit one copy of his/her proposal to the IRB office for pre-review by the IRB Chairperson, Associate Chairperson, or designee. Exempt protocols will be registered and the investigator notified that the study may begin immediately. Protocols appropriate for expedited review will be reviewed by the Chairperson, Associate Chairperson or designee and registered at the IRB office. They may be initiated after review and acceptance.

**The following fee schedule is in effect:**

- **$1,500.00** New commercially sponsored protocols;
- **$ 250.00** Renewals/Revision of commercially sponsored protocols;
- **$ 25.00** Filing fee for non-sponsored protocols and their renewals;
- **$ 250.00** Externally funded but not commercially sponsored protocols;
- **$ 100.00** Renewals/ Revision of externally funded but not commercially sponsored protocols;
- **$ 500.00** Expedited Sponsored research protocols;
- **$ 25.00** In-house/non-Sponsored Nursing and Residential Program Research Projects;

The fees that we have instituted here at the Medical Center are certainly within the scale that most institutions currently use. The mechanism for submitting this will be in the form of a check **payable to St. Joseph's Regional Medical Center IRB**, to accompany the other materials as described above. It would probably be wise to advise your sponsors that this fee schedule is in effect, as the protocols will not be processed unless they are accompanied by the signed administrative contract and appropriate fee.