

The Draft Interim Guidance on Financial Relationships was reviewed at the February 15, 2001 Grant Medical Center Institutional Review Board meeting.

1) One of the members noted that he concurs that patients should be made aware of the financial relationship and that it should be part of the informed consent. He believes it will enhance the integrity of the process. It also appears to him that the guidelines listed appropriate, assuming that staffing and time is available to support the protocol. Possibly, this document could once again emphasize the importance of adequate staffing.

2) In discussing item 2.1, one of our members that the information listed regarding relationships should be reported to the IRB with the proposal. Also, the information regarding financial arrangements should either be incorporated into the consent form or as a separate form which would include this information. Using a separate form attached to the consent which itemizes this information would probably be easier for the patient to follow since the consent itself contains the necessary medical information the patient is concerned with.

3) It was felt this is an important issue and agreed it should be addressed. But it should be done in such a way that the patient is given the pertinent information in the easiest way for them to understand and that all necessary information should be documented appropriately as discussed in your draft interim guidance proposal.

4) Members agreed that these issues are appropriate for the documentation requirements as they are stated.

If you have any questions, please contact me. My name is Ruth Hilderbrand and I am the IRB Coordinator at this facility. Thank you.