

3. Consent form for patient [REDACTED] was not signed. There was no way to determining whether consent was obtained before or after [REDACTED] to the right eye on 12/4/97, due to lack of a date next to patients' signature.

Dr. Nevyas assured me this was merely a mistake and that all patients read and sign consent forms before surgery. He stated he would remind his staff to be more careful when filling out consent forms. There were no incidences of this type observed during the current inspection.

4. Consent forms for patient [REDACTED] were signed and dated (2/20/98) one day after [REDACTED] to the right eye was performed (2/19/98).

Dr. Nevyas stated it may appear that patients signed the consent forms one day after surgery however, this is certainly not the case and is not the way things are normally done. He indicated this was a mistake made by someone on his staff. There were no incidences of this type observed during the current inspection.

5. Patient [REDACTED] had B [REDACTED] for [REDACTED] on 8/13/98. However, the patient information and consent form which was approved for use by the IRB on 7/17/98, was not present in the patient file or made available upon request.

Dr. Nevyas indicated this was a mistake and they would have to be more careful in the future. The person who is responsible was new and not aware of the IRB approved consent form to be used. There were no incidences of this type observed during the current inspection.

6. IDE patients, [REDACTED] had [REDACTED] performed which is a condition not indicated in the Protocol [REDACTED]. Additionally, the procedures were performed with a laser that is not indicated in the study and the surgery was performed at a location that