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1. Interviewing will be directed primarily to the issue of disclosure to patients or informed consent. Since disclosure may have been provided by persons involved in the injections, usually attending physicians, it may be necessary to seek identification of such persons during interviews.
2. General background information will be acquired when possible during conversations with persons interviewed but <sup>such background information</sup> will not be actively solicited on matters unrelated to disclosure to patients <sup>is not the primary purpose of the interview.</sup>
3. During interviews, every effort will be made to avoid causing distress to the persons interviewed although it is recognized that some distress may inevitably result from discussions centering around the issue of informed consent.
4. Reports of interviews will be based on handwritten notes of the interviewers.
5. Additional recollections of information obtained during interviews but unrelated to patient disclosure may be recorded by the interviewers subsequent to the interviews. However, such information will be considered unquotable and will be subject to use only as general background information.

#### C. Report

Upon the conclusion of the inquiry, a report will be prepared for Commission <sup>information</sup> use that will concern itself primarily with <sup>the primary focus of the report</sup> the matter of disclosure to patients or informed consent and, secondarily, to other aspects of the initial and followup studies.