ICDB Patient and Study Closeout

Definitions

Phase I:	Beginning of final follow-up (FUP) visits February 1, 1997 to April 30, 1997
Phase II:	Limited Annual Follow-Up and Data Clean-Up May 1, 1997 to November 30, 1997
Phase III:	Data Clean-up, CC & DCC Close-Out, and Data Archival December 1, 1997 to February 28, 1998
Phase IV:	Analyses March 1, 1998 to July 31, 1998

Phase I: Beginning of final follow-up (FUP) visits
February 1, 1997 to April 30, 1997

Last ICDB Study Patient Visit for Patients who are not Eligible for an Annual FUP Visit After May 1, 1997.

The RC will complete the scheduled contact as planned (telephone or clinic visit). In addition, the RC will be responsible for the following.

- Prior to completing the visit, carefully review the patient's study book to ensure that all forms and information collected to date are accounted for and submitted to the DCC for processing. Any forms or information collected but not yet submitted to the DCC, should be submitted in the next scheduled mailing to the DCC.

- Provide the patient with an ICDB Study Opinion Survey (SURVEY) form and a self-addressed, stamped (if mailed) envelope. The patient should complete this form and return it to the RC in the *sealed* envelope. The patient should be assured that the survey will be forwarded to the DCC unopened. The envelope will be marked with the patient's ICDB Study number for record keeping purposes.

- Discuss future contacts with the patient, ask if the patient is interested in being contacted for future IC studies, and, if so, collect future contact information.

- Assist the patient in establishing contact with another physician, if, at the completion of the study, the patient discontinues care with the ICDB Study physician and does not have a private physician.

- Answer any questions regarding the study and/or the study results.

- Distribute the second volume of the ICDB Newsletter.

- Thank the patient for her/his time and participation in the ICDB Study.

- Explain to the patient that the RC may need to contact the patient within the next month or two for data clarification.

- After the final visit is concluded, complete the Patient Close-Out (CLOSE) form to indicate no additional data will be collected for this patient.

- Submit the Opinion Survey (SURVEY) and the Patient Close-Out (CLOSE) forms to the DCC with the completed visit packet and checklist.

Phase II: Limited Annual Follow-Up and Data Clean-up
May 1, 1997 to November 30, 1997

Limited Annual Follow-Up Visits
Only 12, 24, 36, and 48 month visits will be completed during this phase. These visits must be completed according to the Manual of Operations for Brief (12, 36) and Extensive (24, 36) Visits, EXCEPT

- Do NOT collect Concomitant Medication (CMED) data.
- Do NOT collect Physician Treatment and Evaluation (PHYTRT) data.
- If a cystoscopy is indicated, do NOT obtain biopsies for the ICDB Study. DO collect the information on the Cystoscopy (CYST) form for Questions 1-16. Only Questions 17-19 should be blank.
- As this will be the patient's last ICDB Study Visit, refer to the instructions under Phase I: Last ICDB Study Patient Visit.

Data Clean-Up of Patients Closed Out on or Before April 30, 1997 (to be completed by August 1, 1997)

This phase will primarily include data clean-up and query resolution.

- DCC processes data forms completed prior to May 1, 1997.
- DCC generates and distributes queries.
- RCs resolve queries and return to them DCC *as soon as possible*.
- DCC processes queries and either finalizes the data or submits additional queries to the RC.
- All completed queries should be completed *as soon as possible* and returned to the DCC no later July 31, 1997.

Once all data queries are resolved, the DCC will finalize the data for these patients.

Phase III: Data Clean-up, CC & DCC Close-Out, and Data Archival
December 1, 1997 to February 28, 1998

Data Clean-Up of Patients Closed Out After April 30, 1997

This phase will primarily include data clean-up and query resolution.

- DCC processes data forms completed between May 1, 1997 and November 30, 1997.
- DCC generates and distributes queries.
- RCs resolve queries and return to them DCC *as soon as possible*.
- DCC processes queries and either finalizes the data or submits additional queries to the RC.
- All completed queries should be completed *as soon as possible* and returned to the DCC no later than February 28, 1998.

Once all data queries are resolved, the DCC will finalize the data for these patients.

Clinical Center Closeout

During this phase, the RC will be responsible for the following activities.

- Ensuring that all ICDB Study books are complete and organized.
- Responding to DCC generated queries and making any necessary corrections to the study books.
- Returning all unused biopsy kits to the APL.
- Recycling, or returning to the DCC for recycling, all unused ICDB Study forms.
- Preparing the Clinical Center ICDB Study books for archival (General NIH guidelines require investigators to retain raw study documents for a minimum of 2-3 years after expiration of study funding. It may be prudent to retain these documents much longer.)
- Developing a listing of patients who are interested in being contacted for future IC studies, including name, address, and phone numbers.

During this phase, the ICDB Study investigators will be responsible for the following activities.

- Assisting the RCs with close-out procedures and query resolution, as necessary.
- Developing a set of research questions to be answered during Phase IV: Analysis.

Phase IV: Data Analysis
March 1, 1998 to July 31, 1998

During this phase the DCC will be responsible for the following activities.

- Final edits and clean-up of the database (March 1, 1998 - March 13, 1998)
- Lock the database and begin creation of initial analysis datasets (March 18, 1998). (No changes will be made to the master database after this date.)
- Prepare DCC study forms for archival.
- Archive DCC study forms (paper storage, microfiche, optical scanning?)
- Archive DCC study documents (paper and computer storage)
- Perform analyses according to the request of the ICDB Study investigators and NIH representatives.
- Assist in the preparation of abstracts, presentations, and manuscripts.

During this phase, the ICDB Study investigators will be responsible for the following activities.

- Developing research questions for analyses.
- Developing abstracts, presentations, and manuscripts.
- Reviewing abstracts, presentations, and manuscripts.