NIDDK Liver Transplantation Database
MANUAL OF OPERATIONS (MOOP) DEFINITION

Purpose: To document any study drug dosage change for patients participating in the FK506 study.

Person(s) Responsible: LTD Clinical Coordinator.

Sources of Information: Hospital charts/medical records, physician caring for the patient, and patient.

General Instructions: The date for this evaluation should be 4 months after the initial transplant. Record any study drug dosage change(s) that may have occurred in the post-transplant period Week 6 through Month 4 for patients participating in the FK506 study. The reason for the change should be recorded as appropriate. Death or retransplantation should be included under "other reason." Patients receiving retransplantation are no longer in the study, and this form should not be filled out in this case.

TRANSPLANT NO.

This is the initial of liver transplant for the patient. Do not include any other organ transplant.

Completing Form: Enter the number "1". No other transplant number should be entered here.

DATE OF EVALUATION

This is the date that the patient was seen by a physician or contacted by an LTD coordinator for postoperative follow-up. The date of evaluation should occur 4 months from the date of transplant recorded on the IO form. This evaluation period covers post-transplant follow-up from Week 6 through Month 4.

Completing Form: Enter the month, day and year of the evaluation.

I. STUDY DRUG USED

This is the immunosuppressive study drug, either Cyclosporine or FK506, to which the patient is randomized.

Completing Form: Check only one study drug.

II.1 WERE THERE ANY DOSAGE CHANGES SINCE THE LAST EVALUATION TIMEPOINT

This is to document any dosage changes that may have occurred between Week 6 and Month 4.

Completing Form: If there were any changes in study drug dosage since the patient's 6 week evaluation, check "yes" and answer questions in the box, recording all changes. Death or retransplantation is considered a dosage change.

A. Date of Change - Enter date of dosage change as month, day and year. Enter date of death or retransplantation if applicable.

B. Reason for Change - Record as appropriate from the "Reason for Change" codes listed on the back of the cover page.

C. Specify: Enter specification only if reason for change was "8. Other Toxicity" or "9. Other Reason". Death or retransplantation would fall in this category.

D. Total Daily Dose: For each dosage change, enter the total daily dose (in milligrams) given on the date of change. In the case of death or retransplantation, enter zero.

E. Route: Enter route of study drug (IV or PO) as coded on the back of the cover page. In the case of death or retransplantation, enter NA.

III. COMMENTS

Use this space for any other information pertaining to the immunosuppressive study drug and dosage change for this evaluation period.

Completing Form: Check whether there are any comments to be made. If "yes" write in the comments that are pertinent to this dosage change.