NIDDK Liver Transplantation Database
MANUAL OF OPERATIONS (MOOP) DEFINITION

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

Person(s) Responsible: LTD Clinical Coordinator.

Source(s) of Information: Hospital charts/medical records, physician caring for the patient, and patient.

General Instructions: The evaluation periods are within the first 4 months after the initial transplant. Record any dosage change(s) that may have occurred in the post-transplant period since the initial transplant for patients enrolled in the CMV 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 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.

I. EVALUATION PERIOD

1. 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 fall 2 weeks, 4 weeks, 6 weeks, or 4 months from the date of transplant recorded on the IO form.

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

2. EVALUATION TIMEPOINT

   The evaluation timepoint defines the end of the time period covered by this evaluation:

   1. Week 2 - includes dosage changes in weeks 1 and 2.
   2. Week 4 - includes dosage changes in weeks 3 and 4.
   3. Week 6 - includes dosage changes in weeks 5 and 6.
   4. Month 4 - includes dosage changes in week 7 through month 4.

   Completing Form: Record appropriate evaluation timepoint.

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

This is to document any dosage changes that may have occurred between this evaluation and the previous evaluation.

Completing Form: If there were any changes in study drug dosage since the patient's last evaluation, check "yes" and record all dosage change information in the box provided. Death or retransplantation is considered a dosage change.

III. 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, specify". 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.

IV. COMMENTS

Use this space for any comments pertaining to the dosage change that have not been documented elsewhere on the form.

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