

**NIDDK Liver Transplantation Database  
MANUAL OF OPERATIONS (MOOP) DEFINITION**

**FORM: RU (REJECTION UPDATE)**

**Page 1 of 4**

Purpose: To document the outcome of a rejection episode that was documented as “continuing” or “resolving” at a previous timepoint.

Person(s) Responsible: LTD Clinical Coordinator.

Source(s) of Information: Medical record, physician(s) caring for the patient, Pathology Forms (PP), previous Rejection Forms (MR or RU).

General Instructions: This form should be completed whenever there is no prior documentation indicating that a rejection episode has been “resolved” {i.e. a previous Rejection Form (MR or RU) that has an overall outcome of “resolving rejection” or “continued rejection”, and there is no further documentation that this episode has been resolved.} If the overall outcome on the previous form shows disagreement among the histologic, biochemical and clinical results, the outcome that determines whether to trigger the RU Form should be in the order of precedence of histologic, then biochemical and lastly clinical.

The time point at which this form is to be completed should be one month after the overall outcome date on the most recent MR or RU Form for this episode. A list of all RU Forms due will be generated by the Coordinating Center. If the overall outcome documented on the previous RU Form was “other”, (i.e. other than cellular rejection) then no additional RU Form should be completed for this rejection episode. If the overall outcome documented on the previous RU form was “chronic” rejection, then no additional RU form should be completed until the rejection episode resolves.

**NIDDK Liver Transplantation Database  
MANUAL OF OPERATIONS (MOOP) DEFINITION**

**FORM: RU (REJECTION UPDATE)**

**Page 2 of 4**

**I. EPISODE NO., UPDATE NO.**

The episode no. is the same as that of the rejection episode which was not previously resolved. The update no. is the number of times the RU Form has been completed for this rejection episode.

Completing Form: Record the episode number from the MR or RU Form for this previously unresolved rejection. Record the update number for this form (as reported on the RU report): "1" if this is the first RU Form, "2" if it is the second RU Form, etc. for this episode of rejection.

**I.1 PATIENT'S IMMUNOSUPPRESSIVE THERAPY AT TIME OF THIS UPDATE**

Document the immunosuppressive therapy given to the patient at the time of updating the outcome of this rejection episode.

Completing Form: Check whether the immunosuppressive therapy given to the patient at this time was protocol, reduced or none. If "protocol" or "reduced", check from the provided list all that apply. If the given therapy is not on the list, check "other" and specify in the space provided. If there are more than one "other", record the remainder under "COMMENTS" (section VI) starting with section no. and item no. (e.g. "I.1.10 Other...").

**I.2 OTHER ASSOCIATED CONDITIONS DURING THIS TIME PERIOD**

These include any other liver-related complications or infections that may have occurred since the time of the last documentation for this rejection episode.

Completing Form: Check whether there were any liver-related complications or infections that occurred during this time period. If "yes", check all that apply from the provided list. If there were infections other than those listed, check "other infections" and specify the type in the space provided. If there were more than one "other infection", record under "COMMENTS" (section VI) starting with section no. and item no. (e.g. "I.2.8 Other infections...").

**II. TREATMENT GIVEN (OR CONTINUED) SINCE MR OR LAST UPDATE FOR THIS EPISODE OF REJECTION?**

This is the treatment given for the unresolved episode of rejection. It may be continuing since the time of the last documentation, or it may be a new round of treatment. This is not the usual immunosuppressive therapy for the patient.

Completing Form: Check whether there was treatment given since the last documentation of this rejection episode. If no treatment was given, specify reason in the space provided. If treatment was given, list all the treatments given as coded on the opposite page of the form, the dates that each of the treatments were given, and the total dose if a bolus corticosteroid or FK506 was given, and the recycle dose for recycled corticosteroids. If the treatment given is not on the list provided, code as "other" and specify the type in the space provided. Also check whether treatment was ended. If "yes", record the

**NIDDK Liver Transplantation Database  
MANUAL OF OPERATIONS (MOOP) DEFINITION**

**FORM: RU (REJECTION UPDATE)**

**Page 3 of 4**

results of the lab tests done at the end of the treatment in the specified units. If "no", record the labs done most recently prior to this update. Record the date of the blood draw, and whether the labs were done at the LTD center. If the units used for the tests are different than those specified, convert to the correct units before recording.

**III. LIVER BIOPSY**

This is a biopsy that could be 1) done as a follow-up biopsy for the unresolved rejection episode; 2) a protocol biopsy that is scheduled to be done during this time period (since the date of the last documentation of the rejection episode to the date of this update).

Completing Form: Check whether a biopsy has been performed since the last documentation of this rejection episode. If "no", skip to IV. Overall Outcome. If "yes", provide the answers for the following:

- 1) Date of the biopsy showing resolution of rejection; or if not resolved, the date of the most recent biopsy. Record the date as month, day, year.
- 2) Biopsy results - check the outcome that reflects the diagnosis given on the PP Form.
- 3) Biochemical tests done at the time of this biopsy - check whether tests were done prior to the time of this biopsy. If "yes", record the date of the blood draw closest in time prior to the date of the biopsy, check whether the tests were done at the LTD center, and record the results of the tests in the units specified. If the units used at the LTD center are different from those specified, convert to the correct units before recording.

**IV. OVERALL OUTCOME OF REJECTION EPISODE**

This is the outcome at the time of this update for the previously unresolved rejection episode. The outcome may be determined by histologic, biochemical or clinical evidence. It may also be some other reason such as failure of immunosuppression, chronic rejection, hepatitis, etc. The rejection may or may not be resolved at this timepoint.

Completing Form: Record the date of updating this rejection episode as month, day and year. Check whether the overall outcome was determined by histologic, biochemical or clinical evidence, and check the appropriate outcome for each. Record also the date that the result was determined. If the outcome is other than the above three, check "other" and indicate all that are applicable as listed. If other than the listed reasons, check "other" and specify in the space provided.

**V. PATIENT/GRAFT STATUS**

Document the status of the patient and/or graft at the time of this update. If death or retransplantation took place, the date of the event should be determined.

Completed Form: Check from the list provided the status of the patient and/or graft, and record the date of death or retransplantation if it occurred.

**NIDDK Liver Transplantation Database  
MANUAL OF OPERATIONS (MOOP) DEFINITION**

**FORM: RU (REJECTION UPDATE)**

**Page 4 of 4**

**VI. COMMENTS**

Use this space for any other information that is pertinent to this evaluation that has not been recorded elsewhere in this form.

Completed Form: Check whether there are any comments to be made. If "yes", write in the comments that are pertinent to this evaluation.