

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

FORM: NR (NO REJECTION CLINICALLY DIAGNOSED)

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Purpose: To document that a histologic diagnosis of rejection was made on the Pathology Form (PP) and is not clinically diagnosed as a rejection episode and is not treated.

Person(s) Responsible: LTD Clinical Coordinator.

Source(s) of Information: Pathology Form (PP) that shows documentation of diagnosis of rejection; medical record or other source of information to indicate that clinically there is no diagnosis of rejection.

General Instructions: This form should be completed only in the event that a PP Form documents a diagnosis of rejection (section III.4.1 - III.4.6) but there is no clinical diagnosis of rejection or treatment for rejection. This form should not be filled out at the time that an MR Form has been triggered for documenting rejection.

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I.1 BIOPSY DATE

This is the date of the biopsy for which there is a PP Form showing diagnosis of rejection.

Completing Form: Record the date of the biopsy as month, day and year.

I.2 BIOPSY RESULTS

These are the results for the diagnosis of rejection as recorded on the PP Form (section III.4.1 - III.4.6).

Completing Form: Check the category that matches the result recorded on the PP Form for diagnosis of rejection.

I.3 OTHER EVIDENCE OR SYMPTOMS OF REJECTION AT THIS TIME?

Document any clinical symptoms, increased LFT's or other evidence of rejection that has occurred at the time of this biopsy.

Completing Form: Check whether there were symptoms or other evidence of rejection at this time. If "yes", check whether they were clinical symptoms, increased LFT's or "other". If "other" is checked, specify in the space provided. If there are more than one "other", record under "COMMENTS" (section II) starting with the section no. and item no. (e.g."I.3.4 Other...").

I.4 IS VIRAL HEPATITIS SUSPECTED?

This allows for documentation of a situation in which viral hepatitis may be suspected of confusing the picture of rejection diagnosis at this time.

Completing Form: Check whether viral hepatitis is suspected at this time. If "yes", check all the types that apply. If "other" is checked, specify in the space provided. If there are more than one "other", record under "COMMENTS" (section II) starting with the section no. and item no. (e.g. "I.4.8 Other...").

I.5 OTHER SUSPECTED PROBLEMS

Document any other problems that may contribute to the diagnosis of rejection as recorded on the PP Form.

Completing Form: If there are other suspected problems, specify in the space provided, continuing in the "COMMENTS" section if necessary, starting with the section no. and item no. (e.g. "I.5 Other suspected problems..."). If there are no other suspected problems, enter "-2" in the space provided.

I.6 BIOCHEMICAL PARAMETERS

Document the results of any liver function tests that may have been done before the time of the biopsy.

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Completing Form: 1) Record the date of the blood sample as month, day and year; 2) Check whether the tests were done at the LTD Center; 3) Record the results of the tests in the units specified. If the units are different for the test results, convert to the specified units before recording.

I.7 ACTION TAKEN?

Document whether any action was taken in response to the biopsy finding of rejection or other complication that is suspected. Examples include increasing immunosuppressive medications, administering antiviral medication, etc.

Completing Form: Check whether any action was taken in response to this diagnosis of rejection on the PP Form. If "yes", check all that apply on the given list. If "other" is checked, specify in the space provided. If there are more than one "other", record under "COMMENTS" (section II) starting with the section no. and item no. (e.g. "I.7.4 Other...").

II. COMMENTS

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

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