NIDDK Liver Transplantation Database MANUAL OF OPERATIONS (MOOP) DEFINITION

FORM: PO (PATHOLOGY FOR NATIVE LIVER)

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<u>Purpose</u>: To document:

1) The pathologic diagnosis of the native liver based on examination of liver specimen (biopsy or excised liver).

2) The final diagnosis of the patient's liver disease as suggested by the clinical, serum biochemical, serologic, and histologic evaluation.

<u>Person(s) Responsible</u>: LTD pathologist, LTD physician.

Source(s) of Information: Pathology report, medical record, laboratory and other test results.

General Instructions: This form is to be completed by the pathologist after the clinical evaluation

of the patient is complete and tissue specimen evaluation of the excised liver

is concluded.

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SURGICAL#

The surgical number is the number assigned to the tissue specimen at the transplant center. This number is not entered in the computer.

<u>Completing Form</u>: Enter the clinical center code (01, 02, etc.) before the hyphen, and the surgical number after the hyphen.

PATIENT ID

This is the number assigned to the patient upon entry in the LTD, and may not be changed.

<u>Completing Form</u>: Enter the clinical center code (01, 02, etc.) before the hyphen, and the assigned patient number after the hyphen. This information should be provided on the form by the clinical coordinator before the pathologist fills out the form.

DATE OF SPECIMEN

This is the date the specimen was obtained, not the date it was sent to pathology.

Completing Form: Enter the date the specimen was obtained as month, day and year.

I. SOURCE OF SPECIMEN

The specimen may be a biopsy of the native liver or the excised liver.

Completing Form: Check whether the specimen was a biopsy/slide or the excised liver.

II. PATHOLOGIC DIAGNOSIS(ES)

This is the diagnosis(es) of the pathologist as a result of examining the specimen. If more than one diagnosis is appropriate they should be ranked in the perceived order of importance.

Completing Form: Under each main category, rank as appropriate the specific subcategory(ies) in the perceived order of importance by placing 1, 2, 3, ... by the appropriate subcategories, with 1 being the most important. Specify type in 30 characters or less in the space provided whenever appropriate. If the subcategory is not listed, check "Other" and specify in the space provided for the appropriate main category.

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The following questions were added to the form on February 12, 1991:

- II.1.10 Acute hepatic necrosis probably viral
- II.1.11 Acute hepatic necrosis unknown
- II.6.11 Other amyloidosis

Records prior to this date may have missing data for these questions.

III. IS TISSUE AVAILABLE FOR FURTHER STUDY?

Additional tissue may be available for storage for further study. In this case the information for type of storage should be available. Bulk formalin fixed tissue storage (III.5) was added to the form on February 12, 1991. Records prior to this date may have missing data for these questions.

<u>Completing Form</u>: Check whether tissue is available for further study. If "yes", check the form(s) of storage from the selections provided and specify type if the information is requested. If the form of storage is not listed, check "Other" and specify in the space provided.

IV. FINAL DIAGNOSIS

This diagnosis should be the final diagnosis based on clinical, serum biochemical, serologic and histologic evidence, and on a consensus of opinion on the part of the clinician and the pathologist. The primary liver disease diagnosis should be the reason for transplantation.

Radiology (IV.2.3) was added to the form on February 21, 1991. Records prior to this date may have missing data for this question.

Completing Form:

- 1. Primary diagnosis enter the code from the list of Liver Disease Diagnoses provided on the opposite page of the form. Provide the specification for that diagnosis when appropriate, in the space provided.
- 2. Basis for diagnosis check the appropriate categories that served as the basis for diagnosis. If the category is not listed, check "Other" and specify in the space provided.
- 3. Secondary diagnosis enter the code(s) for the secondary diagnosis(es) when appropriate, in the perceived order of importance. Use the list of Liver Disease Diagnoses provided on the opposite page of the form and specify the type when appropriate in the space provided. Do not record the code for the primary diagnosis here.
- 4. Check whether a malignancy was known to be present in the liver prior to surgery. If there is no malignancy, check "NA".

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V. COMMENTS

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

<u>Completing Form</u>: Check whether there are any comments to be made. If "yes", write in the comments that are pertinent to this evaluation process.