Liver Biopsy (Adult)

General Instructions

The Liver Biopsy form is completed each time a liver biopsy is performed for diagnostic or clinical purposes. The form captures information related to the biopsy procedure, pre-procedure lab tests, and post-procedure complications. The form is to be completed a minimum of 24 hours after the liver biopsy procedure is performed so that post biopsy information is available.

When a biopsy is performed during the course of the study, every effort should be made to obtain unstained slides for the central reading. If possible, obtain slides that do not have to be returned to the local institution. If this is not possible, slides will be returned to the local institution after being read by the HBRN central pathologists.

For biopsies performed prior to enrollment into the Cohort Study, this form is not required.

Specific Instructions

Patient ID**:**	Record the Patient ID in the top right hand corner.
Date of biopsy:	Record the date (month/day/year) the liver biopsy was completed.
Reason for biopsy:	Check the appropriate reason the biopsy was performed. If the reason is not listed, check “Other” and record the reason in the specify field.
Operator:	Check “Hepatologist/Gastro”, “Radiologist”, or “Fellow” to indicate the type of operator who performed the biopsy procedure. If the type of operator is not listed, check “Other” and record the operator’s discipline in the specify field. If the type of operator is not known, check “Unknown”.
Coagulation parameters:	For each lab test record the most recent result available within one month of the biopsy. If a test was not done or the result is not available, check “Not done”.
Image-guided:	Check “Yes”, “No”, or “Unknown” to indicate if the biopsy procedure was guided by any type of imaging modality, such as ultrasound or MRI.
Needle type:	Check “Aspiration” or “Cutting” to indicate the type of needle used for the biopsy procedure. If a different type of needle was used, check “Other” and record the type of needle in the specify field. If the type of needle is unknown, check “Unknown”.
Needle diameter:	Record the gauge of needle used for the biopsy procedure. The gauge is a numerical value, including but not limited to 14, 16, or 18. If the needle diameter is not known, check “Unknown”.
Number of passes:	Record the number of passes made during the biopsy procedure. If the number of passes is not known, check “Unknown”.
Liver tissue:	Check “Yes”, “No”, or “Unknown” to indicate if liver tissue was obtained, regardless of the size of the sample.
Fragmented:	Check “Yes”, “No”, or “Unknown” to indicate if biopsy was fragmented.
Sedation:	Check ”No”, “Conscious”, “General”, or “Unknown” to indicate if conscious sedation was used for the procedure.

Complications: Check “Yes”, “No”, or “Unknown” to indicate if the patient had any complications related to the biopsy procedure.

If yes, record the following:

i. Pain: check “Yes”, “No”, or “Unknown” to indicate if the patient reported any **unexpected** pain as a result of the procedure.

If yes,

a. Check “Immediate”, “Delayed” or “Unknown” to indicate the onset of pain.

Immediate: pain occurred at the time of the procedure or immediately after the procedure, within 60 minutes of the procedure.

Delayed: pain occurred more than 60 minutes post procedure.

Unknown: the time of onset of pain cannot be determined or is not known.

b. Check the appropriate category to indicate the approximate duration of pain, in hours. If the duration cannot be determined or is not known, check “Unknown”. Record duration according to the following categories:

<1 = less than 60 minutes

1-4 = at least 1 hour and less than 5 hours

5-24 = at least 5 hours and up to 24 hours

>24 = more than 24 hours

c. Check “Mild”, “Moderate”, “Severe”, or “Unknown” to indicate the severity of the pain.

Mild: not requiring analgesia.

Moderate: use of an oral analgesic only.

Severe: use of a parenteral, IV or intramuscular injection, analgesic.

Unknown: use of analgesics not known or severity of pain cannot be determined.

ii. Bile leak: check “Yes”, “No”, or “Unknown” to indicate if a bile leak occurred as a result of the biopsy procedure.

If yes, check the appropriate category to indicate how the leak was managed.

Conservative: bile leak was managed without ERCP or surgery.

ERCP: Endoscopic retrograde cholangiopancreatography.

Surgery: a surgical procedure was performed to repair or manage the bile leak.

Other: management other than those listed. Check "Other" and record the management used in the specify field.

Unknown: the management used is not available or unknown.

iii. Bleeding: check "Yes", "No", or "Unknown" to indicate if **unexpected** bleeding occurred as a result of the biopsy procedure.

If yes, check all that apply to indicate the severity of any unexpected bleeding. If the severity is not known, check "Unknown".

iv. Vasovagal episode: check "Yes", "No", or "Unknown" to indicate if the patient experienced a vasovagal episode - fainting or temporary loss of consciousness as a result of the biopsy procedure.

v. Other: Check "Yes", "No" or "Unknown" if the patient experienced a complication as a result of the liver biopsy procedure other than pain, bile leak, bleeding, or a vasovagal episode. If unknown, check "Unknown". If yes, record the complication in the specify field.

vi. ER visit: check "Yes", "No", or "Unknown" to indicate if any complication related to the biopsy procedure resulted in an emergency room visit.

vii. Hospital admission: check "Yes", "No", or "Unknown" to indicate if any complication related to the biopsy procedure resulted in a hospital admission or prolonged a hospital stay.

viii. Outcomes: Check "Permanent injury", "Disability", or "Death" to indicate if any of the complication related to the biopsy lead to one or more of these events or outcomes.