Pregnancy Follow-up (Adult)

General Instructions

Post-delivery visits are to occur at weeks 12 (post-delivery visit 1), 24 (post-delivery visit 2), and 72 (post-delivery visit 3) following delivery. When possible, pregnancy post-delivery visits should be scheduled in conjunction with the routine cohort protocol visits.

If the pregnancy post-delivery evaluation is performed in conjunction with a routine cohort protocol visit, the Pregnancy Follow-up form is completed along with the routine Follow-up Form.

If the pregnancy post-delivery evaluation is not performed in conjunction with a routine cohort protocol visit, the Pregnancy Follow-up form should be completed along with the Special Visit form, indicating that the primary reason for the special visit is for pregnancy, post-delivery.

This form captures information on the birth and delivery, immunization, breastfeeding, hepatitis B testing outcomes, and baby development. The information is obtained from patient interview and patient's (mother) medical record. When information in the medical record conflicts with information provided by the patient, the medical record is normally considered to be the accurate source, although there may be instances when the information provided by the patient is more up to date or accurate. In this instance, the information provided by the patient may be used.

The coordinator is responsible for obtaining the information captured on this form. In non-English speaking patients, the interview may be performed through a certified interpreter. While a trained translator is preferred, a family member or friend of the patient (who speaks fluent English and the native language of the patient) may be acceptable for this role, as determined on an individual basis.

If the patient is enrolled into one of the HBRN treatment trials before all of the post-delivery visits are completed, any remaining post-delivery visits should be completed at the time of a protocol visit for the trial. The post-delivery evaluation should be performed at the treatment trial visit that falls closest to, but is after, the scheduled date for the 12, 24, or 72 week post-delivery visit.

Specific Instructions

Patient ID**:**	Record the Patient ID in the top right hand corner.
Date of Evaluation:	Record the date (month/day/year) that corresponds to the protocol visit.
Protocol timepoint:	Record the protocol timepoint that corresponds to the visit.
Pregnancy/baby:	Record the pregnancy/baby number. This is the unique identifier for the pregnancy/baby for each post-delivery visit for the pregnancy/baby. The first pregnancy/baby is assigned to number 1, and subsequent pregnancies/babies are assigned sequentially. If the outcome of the pregnancy is twins assign one baby as "1" and the sibling as "2" (or next sequential numbers as appropriate).

Section I: Birth and Delivery

This section is to be completed at Post-delivery visit 1 only.

Viable: Check "Yes" or "No" to indicate if the pregnancy resulted in a live birth.

If no, record the following and then skip to Section IV on the form:

a) Outcome
   i. Miscarriage: loss of an embryo or fetus prior to 20th week of pregnancy.
   ii. Stillborn: fetus dies during birth or ≥ 20 weeks of pregnancy.
   iii. Terminated: medically induced termination of pregnancy.
   iv. Unknown: outcome status in not known.
b) Date of outcome (month, day, year) of the outcome. If any piece of the date is not known, record "Unk" in that field and complete the remaining fields.

Date of birth: Record the date (month/day/year) of the baby's birth. If any part of the birth date is unknown, record "Unk" in that field and complete the remaining fields.

Gender: Check "Male" or "Female" to indicate the baby's gender.

Delivery method: Check "Vaginal", "Cesarean", or "Unknown" to indicate the method of delivery of the baby.

HBIG: Check "Yes" or "No" to indicate if the baby received hepatitis B immune globulin (HBIG) within 12 hours after delivery.

Section II: Immunization and Status Update

Hepatitis B vaccine: Check "Yes", "No", or "Unknown" to indicate if the baby received the hepatitis B vaccine.

If yes, record the number of doses the baby received since birth. If the number of doses is not known, check "Unknown".

Breastfeeding: Check "Yes" or "No" to indicate if the patient breastfed the baby for more than 7 days.

If yes, check "Yes" or "No" to indicate if the patient is currently breastfeeding.

If not currently breastfeeding, record the number of weeks the patient breastfed. If the number of weeks is not known, check "Unknown".

Section III: Post-delivery Events

This section is to be completed at post-delivery visit 3 only (72 weeks post delivery).

Hepatitis B testing: Check "Yes", "No", or "Unknown" to indicate if the baby has had any testing completed for hepatitis B.

If yes,

i. Check "Yes", "No", or "Unknown" to indicate if the baby has had a positive hepatitis B surface antigen (HBsAg) test result.

ii. Check "Yes", "No", or "Unknown" to indicate if the baby is known to be immune to hepatitis B or has had a positive hepatitis B surface antibody (anti-HBs) test result.

Baby development: Check "Yes", "No", or "Unknown" to indicate if the patient has been told by the baby's pediatrician that the baby is developing normally.

Section IV: Treatment

Timepoint: Check "Yes" or "No" to indicate if this form is being completed at the time of a routine cohort protocol visit.

If yes, do not record the hepatitis B treatment information on this form as this information will be captured on the cohort Follow-up form.

HBV/HIV co-infected participants: check "N/A" and capture all HBV and HIV therapyon the AH Log.

If no, record the following:

Treatment: Check "Yes" or "No" to indicate if the patient has received treatment for hepatitis B since the last protocol visit, either interferon or an antiviral oral agent.

If yes, record each treatment the patient received with the following information.

Antiviral therapy: Record the appropriate code for the treatment.

Note: Tenofovir (TDF) = Tenofovir disoproxil fumarate
Tenofovir (TAF) = tenofovir alafenamide fumarate

Date started: Record the month, day, and two digit year that the treatment was started. If any piece of the date is not known, record "Unk".

Date stopped: Record the month, day, and two digit year that the treatment was stopped. If any piece of the date is not known, record "Unk". If the patient is currently on this treatment, do not complete the date stopped fields and check "Currently on Therapy".