

GENERAL INSTRUCTIONS

The Global Assessment (GA) form captures the assessor's opinion of how the patient is doing at the current time (time of the assessment) and compared to yesterday (or the prior assessment). The assessor is also asked to indicate whether or not they would accept a cadaveric liver and if so, the acceptable donor criteria.

The assessment is to be performed by a PALF study investigator or designated, trained person. Ideally, the same individual is to perform the assessment over the hospital stay. If circumstances do not allow for the same individual to perform the assessment, another designated person may complete the assessment. If the study investigator or designated person is not available to perform the daily assessment on a given day, the assessment should be reported as "Not Done".

The assessment should be performed daily according to the INR and encephalopathy criteria, close to the time of the routine blood draw when research samples are obtained, or no later than 12:00 pm (noon). If the assessment is not performed by 12:00 pm (noon) then it should be reported as "Not Done" in the Missed/Incomplete Visit Utility.

The assessment is performed **daily** when the patient meets the following INR and encephalopathy criteria:

INR ≥ 1.5 and INR < 2.0 with encephalopathy or
INR ≥ 2.0 with or without encephalopathy

One GA form is to be completed per day on the days required according to the INR/encephalopathy criteria. Refer to page 2 of the Data Collection Timeline or Flowsheet for detailed information on the INR and encephalopathy criteria.

The assessor may look at the previous assessments before completing the current assessment.

SPECIFIC INSTRUCTIONS

- Patient ID:** Record the Patient ID
- Date of Assessment:** Record the date that the assessment was performed; using a 2-digit month, day, year format.
- Time of Assessment:** Record the time that the assessment was performed in 24-hour/military time (e.g. 00:00 = midnight, 06:00 = 6 A.M., 12:00 = noon, and 20:00 = 8 P.M.). If any part of the time is unknown, enter -3 for the unknown part of the time and enter the other parts of the time that are known. If the entire time is unknown, check "Unknown".
- Assessor Initials:** Record the initials of the person performing the assessment (first, middle, and last, or just first and last). Always use the same initials for a given assessor.
- Current status:** On a scale from 1 (very sick) to 10 (not too sick), the assessor must determine how sick they believe the patient is at the time of the assessment. Only one of the boxes can be checked. *Do not* mark a spot in between two boxes.
- If the assessment cannot be done by a designated or trained assessor, mark 'Not Done'.
- Compared status:** The assessor must make a judgment as to whether the patient is worse, better or the same as he/she was yesterday. If the patient is better or worse than yesterday, the assessor must rate how much better or worse the patient is according to the scale.

If the assessor cannot determine if the patient is better, worse or the same as compared to yesterday, check “Cannot determine” and specify why the assessment was not completed.

Check “Not Done” if the assessment cannot be done by a designated or trained assessor or the assessment is being performed for the first time following enrollment into the study.

Accept organ: The assessor must determine whether or not they would accept a cadaveric donor today, if an organ was available.

If “No”, the assessor should indicate the reason they would not accept a cadaveric donor for the patient, as because the patient is “too well” or “too sick”.

If “Yes”, the assessor should indicate which donor characteristics would be acceptable or check “None of the above” to indicate that none of the characteristics listed would be acceptable.

INR performed: These questions are completed for site use only. Coordinators should use the responses provided by the investigator to complete the INR Correction question on the Comprehensive Panel (CP) form.

The assessor should indicate whether or not an INR was performed as a part of the routine morning blood draw and whether or not this INR result is considered to be corrected. The INR should be considered as “corrected” if an intervention with the potential to impact the INR result was given within 24 hours prior to the INR measurement. The intervention could be Vitamin K (parenteral), FFP, or Cryoprecipitate.