Drug #1: _____
please print name

Prospective Study RUCAM

Site Number: ___ ___ ___ Participant ID Number: ___ ___ ___ ___

Date completed: ___ ___ /___ ___ ___ /___ ___ ___ ___ (*day* / *month* / *year*) Reviewer Code: _____ ☐ Site investigator ☐ Reviewer A ☐ Reviewer B

RUCAM Causality Assessment of a Drug in a Case of Acute Liver Injury

	Hepatocellular Type		Cholestatic or Mixed Type		Assessment
1 Time to onset:					
Incompatible	Reaction occurred before starting the drug or more than 15 days after stopping the drug (except for slowly metabolized drugs)		Reaction occurred before starting the drug or more than 30 days after stopping the drug (except for slowly metabolized drugs)		**Unrelated**
Unknown	When information is not available to calculate time to onset, then case is:				**Insufficiently documented**
	Initial Treatment	**Subsequent Treatment**	**Initial Treatment**	**Subsequent Treatment**	**Score** *(check the results)*
1a From the beginning of the drug:					
Suggestive	5–90 days	1–15 days	5–90 days	1–90 days	☐ +2
Compatible	< 5 or > 90 days	> 15 days	< 5 or > 90 days	> 90 days	☐ +1
1b From the cessation of the drug:					
Compatible	≤ 15 days	≤ 15 days	≤ 30 days	≤ 30 days	☐ +1
2 Course:	**Difference between the Peak of ALT** *(SGPT)* **and Upper Limit of Normal Values**		**Difference between the Peak of A.P.** *(or TB)* **and Upper Limit of Normal Values**		
2a After cessation of the drug:					
Highly suggestive	Decrease ≥ 50% within 8 days		Not applicable		☐ +3
Suggestive	Decrease ≥ 50% within 30 days		Decrease ≥ 50% within 180 days		☐ +2
Compatible	Not applicable		Decrease < 50% within 180 days		☐ +1
Inconclusive	No information **OR** Decrease ≥ 50%, after the 30th day		Persistence or increase or no information No situation		☐ 0
Against the role of the drug **OR**	Decrease < 50%, after the 30th day **OR** Recurrent increase		Not applicable		☐ –2
2b If the drug is continued:					
Inconclusive	All situations		All situations		☐ 0
3 Risk factors:	**Ethanol**		**Ethanol or Pregnancy**		
Presence					☐ +1
Absence					☐ 0
Age of the patient ≥ 55 years					☐ +1
Age of the patient < 55 years					☐ 0

Fax completed form to
Duke Clinical Research Institute
(919) 668-7100

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RUCAM Causality Assessment of a Drug in a Case of Acute Liver Injury (continued)

				Score
4	**Concomitant drug(s):**			
	None or no information or concomitant drug with incompatible time to onset			☐ 0
	Concomitant drug with compatible or suggestive time to onset			☐ –1
	Concomitant drug known as hepatotoxin and with compatible or suggestive time to onset			☐ –2
	Concomitant drug with evidence for its role in this case *(positive rechallenge or validated test)*			☐ –3
5	**Search for nondrug causes:**			
	Group I *(6 causes)*: **Recent viral infection with HAV** *(IgM anti-HAV antibody)* or **HBV** *(IgM anti-HBc antibody)* or **HCV** *(anti-HCV antibody and circumstantial arguments for non-A, non-B hepatitis)*; **Biliary obstruction** *(ultrasonography)*; **Alcoholism** *(AST/ALT ≥2)*; **Acute recent hypotension history** *(particularly if underlying heart disease)*. **Group II:** Complications of underlying disease(s); clinical and/or biological context suggesting CMV, EBV or herpes virus infection.		• All causes–groups I and II–reasonably ruled out	☐ +2
			• The 6 causes of group I ruled out	☐ +1
			• Five or 4 causes of group I ruled out	☐ 0
			• Less than 4 causes of group I ruled out	☐ –2
			• Non drug cause highly probable	☐ –3
6	**Previous information on hepatotoxicity of the drug:**			
	Reaction labeled in the product characteristics			☐ +2
	Reaction published but unlabeled			☐ +1
	Reaction unknown			☐ 0
7	**Response to readministration:**			
	Positive	Doubling of ALT with the drug alone	Doubling of AP *(or TB)* with the drug alone	☐ +3
	Compatible	Doubling of ALT with the drugs already given at at the time of the first reaction	Doubling of AP *(or TB)* with the drugs already given at the time of the first reaction	☐ +1
	Negative	Increase of ALT but less than N in the same conditions as for the first administration	Increase of AP *(or TB)* but less than N in the same conditions as for the first administration	☐ –2
	Not done or not interpretable	Other situations	Other situations	☐ 0

Investigator Signature

Investigator's signature: _____ **Date signed:** ___ ___ / ___ ___ ___ / ___ ___ ___ ___
day *month* *year*