



Protocol Title: A phase IIIb, open-label, multicentre, international randomised controlled trial of simplified treatment monitoring for 8 weeks glecaprevir (300mg)/pibrentasvir (120mg) in chronic HCV treatment naïve patients without cirrhosis

Protocol No: VHCRP1701

INVESTIGATIONAL PRODUCT STORAGE TEMPERATURE DEVIATION FORM

Please **EMAIL** this notification to smartc@kirby.unsw.edu.au OR **FAX** to +61 2 93859214

Site: _____ **Site Number:** _____ **Investigator** _____

Product affected by temperature deviation	Glecaprevir (100mg)/Pibrentasvir (40mg) tablets
Date of start of temperature deviation	___ / ___ / ___ (dd/mon/yyyy)
Temperature Excursion <i>[Temperature excursion defined as storage temperature outside 15°C (59°F) - 25°C (77°F)]</i>	
Duration of Temperature Excursion	
Quantity Affected <i>(i.e. number of bottles)</i>	
Description of Event <i>(Including action taken/quarantine details)</i>	

PLEASE ATTACH AN UP-TO-DATE STORAGE TEMPERATURE LOG

Name of person reporting deviation

Signature

Date

KIRBY INSTITUTE TO COMPLETE	
Outcome	<input type="checkbox"/> Acceptable temperature excursion - <i>Investigational product considered to be safe to use.</i>
	<input type="checkbox"/> Unacceptable temperature excursion - <i>Investigational product to be destroyed as per Kirby Institute instructions.</i>
Name	Signature
	Date