



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

Protocol Exemption Request Form

To be completed by the site			
Site Information			
Site Name:			
Principal Investigator:			
Site Fax Number		Email:	
Subject Information			
Subject Initials (e.g. FF-LL)	____ - ____	Date of Birth (dd/mm/yyyy)	
Participant Study ID: (if already enrolled)	1701 - ____ - ____		
Exemption Request (tick one only)	<input type="checkbox"/> Eligibility criteria <input type="checkbox"/> During study conduct		
Requested By (name):		Request Date: (dd/mm/yyyy)	
Description of exemption request: (include specific criteria and reason why exemption is needed)			
Fax to +61 2 9385 9214 or email to smartc@kirby.unsw.edu.au			

To be completed by the Kirby Institute			
Name of Investigator:		Granted	<input type="checkbox"/> Yes <input type="checkbox"/> No
Signature of Investigator		Date: (dd/mm/yyyy)	
Protocol Exemption Number:		Faxed to site: (dd/mm/yyyy)	

If an exemption is granted for study eligibility criteria, please enter the protocol exemption number in the screening e-CRF.

Please keep this form in the Study Investigator Folder