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

Site Signature and Study Responsibilities Log

Site Name: _____ **Site Code:** _____ **Principal Investigator:** _____

Name of Site Personnel *(first and last names)*	**Signature** *	**Initials**	**Start Date** *(dd/mmm/yyyy)*	**End Date** *(dd/mmm/yyyy)*	**Role** *(PI, Co-PI, SC, Lab, Lead Pharmacist)*	**Responsibility Code(s)** ^ *(indicate codes using codes in attached key)*	**CV and ICH-GCP certificate filed** #	**Site PI Authorization** ** *(initials/date)*
							Yes / No	
							Yes / No	
							Yes / No	
							Yes / No	
							Yes / No	
							Yes / No	
							Yes / No	
							Yes / No	
							Yes / No	
							Yes / No	
							Yes / No	

^ Study Responsibility Codes

1. Obtaining informed consent
2. Eligibility determination
3. Adverse event interpretation
4. Prescribe study drug
5. Lab Result interpretation
6. SAE Reporting
7. Sign-off eCRF
8 Conduct study visit procedures (i.e. randomisation, physical measurements)
9. Collection of Fibroscan® data (if available)
10. Adverse event (including SAE) data collection
11. Participant visit scheduling – planning and follow-up
12. Collection of blood samples
13. Processing and storage of research samples
14. eCRF data entry and correction
15. Maintenance of Investigator Site File
16. Monitoring of investigational product (IP) receipt and storage condition
17. IP dispensation
18. IP accountability
19. IP destruction/return
20. Other (specify) _____
21. Other (specify) _____
22. Other (specify) _____

 # CV must be current within ≤3 years and a copy must be available within the Investigator Site File and sent to Kirby Institute.
** By signing the SMART-C Site Signature and Study Responsibilities Log, you agree that your contact details may be disclosed to AbbVie Inc.*
*** Each update to the Site Signature and Study Responsibilities Log must be authorised by the PI (initials and date). By authorising, the PI confirms the site personnel completed project specific training prior to performing any study procedures and will operate under the PI's oversight from the Start to End Date.*