SMART-C

Simplified Monitoring – A Randomised Trial in hepatitis C

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

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Manual of Operations

Study Specific Supplement

Version 1.0| Date: 15/August/2017

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1. Communication and Contacts

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Study Email	smartc@kirby.unsw.edu.au		

For all protocol, study or site management related questions, please contact your Project Coordinator.

For laboratory specific questions please contact the Laboratory Coordinator

2. Study and Participant Identifiers

Protocol number: 1701 (used in participant ID number from baseline onwards)

Screening Number: 333 (used in screening ID at screening visit only)

At sites where regulations restrict the collection of full date of birth and/or initials, the following conventions will be used:

- Date of birth will be entered as 01/01/YYYY
- Initials will be entered as AA-AA, BB-BB, CC-CC etc.

3. Schedule of Assessments

Standard Monitoring Arm

Assessment / Procedure	Screening	Baseline	On-treatment Phase		Follow-Up Phase
Study weeks	**-6 to 0**	**0**	**4**	**8 (EoT)**	**20 (SVR12)**
Study Days	**-42 to 0**	**0**	**28**	**56**	**140**
Visit Window (Days)			***+/- 3***	***+/- 3***	***+/- 14***
Informed consent	x				
Medical history / Patient demographics	x				
Randomisation		x			
Dispense study drug		x	x		
Return study drug					x
Vital signs & physical measurements	x	x	x	x	x
HCV-RNA testing (Local Laboratory)	x			x	x
HCV genotyping (Local Laboratory)	x[a]				
Study Drug Adherence Survey			x[b]	x[b]	
Health outcomes survey (EQ-5D-3L)	x				x
Participant Satisfaction Survey	x				x
Fibroscan® / APRI	x[c]				
Liver function tests/ Full blood count/ Biochemistry	x	x	x	x	x
Clotting (INR)	x				
Urinary Drug Screen	x				
HIV & HBV serology	x				
Pregnancy Test[d]	x	x	x	x	x
Adverse events		x	x[b]	x[b]	x
Concomitant medication	x	x	x[b]	x[b]	x
Research Specimen Collection					
EDTA Whole Blood (4mL)	x				
EDTA plasma (10mL)	x[e]	x[e]	x	x	x
PBMCs[f] (60mL)	x		x		x

[a]Within 5 years prior to screening; [b]Completed by study nurses during phone contact; [c]Fibroscan within 6 months prior to screening; [d]Women of child bearing potential only; [e]20mL at Screening and Baseline; [f]At selected sub-study sites only

Simplified Monitoring Arm

Assessment / Procedure	Screening	Baseline	On-treatment Phase		Follow-Up Phase
Study weeks	**-6 to 0**	**0**	**4**	**8 (EoT)**	**20 (SVR12)**
Study Days	**-42 to 0**	**0**	**28**	**56**	**140**
Visit Window (Days)			***+/- 3***	***+/- 3***	***+/- 14***
Informed consent	x				
Medical history / Patient demographics	x				
Randomisation		x			
Dispense study drug (8 weeks)		x			
Return study drug					x
Vital signs & physical measurements	x	x			x
HCV-RNA testing (Local Laboratory)	x				x
HCV genotyping (Local Laboratory)	x[a]				
Study Drug Adherence Survey			x[b]	x[b]	
Health outcomes survey (EQ-5D-3L)	x				x
Participant Satisfaction Survey	x				x
Fibroscan® / APRI	x[c]				
Liver function tests/ Full blood count/ Biochemistry	x	x			x
Clotting (INR)	x				
Urinary Drug Screen	x				
HIV & HBV serology	x				
Pregnancy Test[e]	x	x	x[d]	x[d]	x
Adverse events		x	x[b]	x[b]	x
Concomitant medication	x	x	x[b]	x[b]	x
Research Specimen Collection					
EDTA Whole Blood (4mL)	x				
EDTA plasma (10mL)	x[f]	x[f]			x
PBMCs[g] (60mL)	x				x

[a]Within 5 years prior to screening; [b]Completed by study nurse during phone contact; [c]Fibroscan within 6 months prior to screening; [d]Self-completed by participants at home; [e]Women of child bearing potential only; [f]20mL at Screening and Baseline; [g]At selected sub-study sites only

4. Study visits windows

The following visits windows are authorised during the study:

Study Visit week	Window (Days)
Week 4	± 3
EoT (Week 8)	± 3
SVR12 (Week 20)	± 14

Contact your project coordinator for advice on how to proceed for visits outside these windows.

Telephone contact visits are conducted 1 to 2 days prior to Week 4 and EoT. A maximum of three attempts should be made by the site personnel to contact the participant over the phone. Phone contact attempts must be within the visit window allowed per protocol. All attempts must be recorded in the source documents. If a patient is unable to be contacted despite 3 documented attempts, the visit will be considered missed.

4.1. Projected Visits Worksheet

A visit calculator tool has been created as an aid for visit windows for each study visit. The projected dates are auto-populated from the dates entered on the enrolment tracker worksheet. See Appendix 3 for an example.

5. Randomisation

Participants will be randomised at Baseline into the Standard or Simplified monitoring arm using *Sealed Envelope*- an internet-based service which allows sites to randomise participants through a web browser. It requires an active internet connection during the point of randomisation and sites are immediately shown the treatment allocation after completing an on-screen form. You can access the system online at https://sealedenvelope.com/redpill/smartc/ using the individual username and password provided once the site is open for recruitment.

You will need to enter the following details for randomisation:

1. Patient ID
2. Patient initials: Entered in the format of XX-YY where XX are the first two letters of the patient's last name and YY is the first two letters of the patient's first name.
3. Date of birth (dd/mm/yyyy).
4. Date of baseline visit (dd/mm/yyyy). The date of the baseline visit must be within 3 days of randomisation date.
5. Genotype (type 1 or non-type 1)
6. Confirm eligibility status

Once you have entered all the required data, please click on the 'randomise' button and you will be asked to input your password. The website will display the monitoring arm the participant is randomised to and you will receive an email notification. Your email notification will be your source for randomisation. Please enter the participant's randomised treatment duration into the eCRF and the enrolment tracker. If you require any assistance with the randomisation system, please contact the SMART-C Project Coordinator.

6. Research Laboratory Samples

6.1. Specimen collection and documentation

The following samples are collected for research at the time points specified below.

Visit Name	EDTA Whole Blood (4mL)	EDTA Plasma (10mL)	EDTA Plasma (20mL)	PBMC* (60mL)	Visit Abbreviation	Kit Type
Screening	X		X	X	SCR	1
Baseline			X		BSL	2
Week 4		†		†	WK4	3
EoT (Week 8)		†			EoT	3
SVR12 (Week 20)		X		X	SVR12	3

Key:

X Collected from all participants (i.e. both study arms)

† Collected from standard monitoring arm only

* At selected sub-study sites only

6.2. Lab kit Descriptions

Lab kits will be provided to the Site Coordinator and will contain all materials required for specimen collection and sample storage at the local processing laboratory.

The 3 lab kit types for SMART-C are described in the following tables.

	Kit Type 1	Kit Type 2	Kit Type 3
Visits	**SCR**	**BSL**	**WK4/EoT/SVR12**
All Sites	1 x Laboratory Request Form 3 x specimen tube label 1 x spare cryovial label 1 x spare site log cryovial label *EDTA Collection* 2 x 10mL EDTA blood collection tubes 8 x 1.8mL cryovials (purple top) 8 x EDTA Plasma cryovial labels *Whole Blood Collection* 1 x 4mL EDTA whole blood collection tube 2 x 1.8mL cryovials (red top) 2 x EDTA Whole Blood cryovial labels	1 x Laboratory Request Form 2 x specimen tube label 1 x spare cryovial label 1 x spare site log cryovial label *EDTA Collection* 2 x 10mL EDTA blood collection tubes 8 x 1.8mL cryovials (purple top) 8 x EDTA Plasma cryovial labels	1 x Laboratory Request Form 1 x specimen tube label 1 x spare cryovial label 1 x spare site log cryovial label *EDTA Collection* 1 x 10mL EDTA blood collection tube 4 x 1.8mL cryovials (purple top) 4 x EDTA Plasma cryovial labels

Sub-study Sites	As above with the addition of: *PBMC Collection:* 6 x 10mL ACD blood collection tubes 6 x 1.8mL cryovials (yellow top) 6 x PBMC cryovial labels		For WK4 and SVR12 visit only, as above with the addition of: *PBMC Collection:* 6 x 10mL ACD blood collection tubes 6 x 1.8mL cryovials (yellow top) 6 x PBMC cryovial labels

Each kit (except the screening kit) is labelled for a specific participant and a specific visit.

Screening kits are labelled with a screening ID number starting with 333. These kits must only be used for screening visits. If a patient is eligible and is enrolled in the study they will be assigned a subject ID by the Site Coordinator at the Baseline visit.

Week 4 and EoT kits are labelled with "Standard Arm Only". As the kits are participant specific, if the participant is randomised to the Simplified Monitoring Arm, the Week 4 and EoT kits can be discarded.

Please contact the SMART-C Project Coordinator to request additional kits.

6.3. Transport Requirements

Samples will be sent to local laboratories for processing and storage. For details of sample delivery to the local processing laboratory and labelling of samples, please see VHCRP Manual of Operations. For sites collecting ACD PBMCs, these samples must be sent to the processing laboratory before a set time (please check your local requirements) due to the time required for processing of specimens.

These samples will be stored until shipment to the Kirby Institute as per instruction by the SMART-C Project Coordinator.

7. Phone-based Visit

All participants on-treatment are contacted by telephone at Week 4 and Week 8 regardless of the study arm. For the simplified monitoring arm, this is their only clinical contact while on-treatment. The visit window for the phone-based visit is 1 to 2 days before their scheduled Week 4 and EoT clinic visit. This visit is to be completed by the Study Nurse/Coordinator.

A maximum of 3 attempts should be made to reach the participant over the phone. Unsuccessful phone contact should be documented and can be done with the study proforma. If the participant cannot be reached despite 3 documented attempts, the visit will be considered missed.

A questionnaire has been developed to assist data collection. The questionnaire consists of 3 sections:

- Section A: Adverse Events
- Section B: Concomitant Medication

- Section C: Study Drug Adherence Survey

To standardise reporting of adverse events, concomitant medications and adherence, please ensure that the questions are administered as per the wording of the questionnaire.

Section A is for Adverse Events. For reported AEs, the following should be recorded: AE term, severity, action taken with study drug, start and end date (if applicable).

The study nurse is to grade the AE severity based on these definitions (as per protocol section 7.2.2):

- Mild: Discomfort noticed but no disruption of normal daily activity
- Moderate: Discomfort sufficient to reduce or affect normal daily activity
- Severe: Incapacitating with inability to work or perform normal daily activity
- Life Threatening: Represents an immediate threat to life

Note: For any AE classified as moderate, severe or life-threatening in severity, Section A must be reviewed by a site investigator for further assessment and action if required.

The relationship of the AE to the study drug is also recorded. Definitions of relatedness are as follows:

- Unlikely: An adverse event that is unlikely to be related to the use of the drug
- Possibly: An adverse event that might be related to the use of the drug
- Probably: An adverse event that is likely to be related to the use of the drug

Please see 11.1 for further details on adverse event reporting.

Section B is for concomitant medications to be collected as part of standard of care. Any changes to medications since last contact (i.e. last 4 weeks) should be recorded for the medication name, indication, start and end-date (if applicable). This information is NOT entered into the eCRF. Contraindicated medications reported should be conveyed to a site investigator and the study medical monitor must be made aware of the use of any contra-indicated medications as soon as possible. Contact details for the Medical Monitor are located at the cover of the study protocol.

Refer to 8.1 for details on **Section C**.

As part of the standard of care during HCV treatment, it is important to monitor for pregnancy. For the simplified monitored arm, the phone-based visit will be the only time point whilst on-treatment that this information can be obtained.

Please ask simplified monitoring arm participants at the phone-based visit if they completed the home pregnancy test.

This does not need to be entered into the eCRF. Any positive pregnancy result requires further investigation and reporting.

NOTE: It is important to note that if there are any clinical concerns, a participant in the simplified monitoring arm can be asked to attend the clinic as an unscheduled visit. The phone-based visit questionnaire serves only as a guide for data collection for the protocol aims and does not supersede or limit your clinical care. For example, if the participant is unable to be reached despite 3 documented phone calls but there are safety or wellbeing concerns, you can continue phone contact attempts as part of your clinical care.

8. Questionnaires

SMART-C uses 4 different questionnaires.

Questionnaire	Visit Name						
	Before Screening	**Screening**	**Week 4**	**EOT**	**SVR12**	**Post SVR12**	**Completed by**
Study Drug Adherence Survey (included in the Phone-based Visit Questionnaire)			**x**	**x**			Participant
Health Outcomes Survey (EQ-5D-3L)		**x**			**x**		
Participant Satisfaction Survey		**x**			**x**		
Practitioner Acceptability Questionnaire*	**x**					**x**	Principal Investigator and Primary Research Nurse

*Practitioner Acceptability Questionnaire is not completed on a per participant basis. It will only be completed by the practitioners twice during the study: before first patient first visit (FPFV) and after last patient last visit (LPLV).

Completed paper versions of the questionnaires should be filed in the Investigator Site File.

8.1. Study Drug Adherence Survey (included in the Phone-based Visit Questionnaire)

The study drug adherence survey is conducted as part of the Week 4 and EoT telephone contact visits by the Study Nurse. Please see Appendix 6 for a sample of the questionnaire.

The adherence survey is found in Section C of the telephone visit questionnaire. This questionnaire is to be completed on paper and to be entered in the eCRF by the site personnel. Any complete days of missed study drug dosage and the reason for missed dosage recorded.

8.2. Health Outcomes Survey (EQ-5D-3L)

Please see the VHCRP Manual of Operations for detailed instructions on how to complete the EQ-5D.

All participants are to complete this questionnaire at the Screening and SVR12 visits. This questionnaire is to be completed on paper and a completed copy emailed to smartc@kirby.unsw.edu.au for it to be entered

into the eCRF. The Screening questionnaire should be sent to the Kirby Institute once the patient is successfully enrolled at Baseline. The SVR12 questionnaire should be sent after completion of the visit.

This questionnaire is to be completed by the study participant. Site staff cannot administer this questionnaire and complete it on participant's behalf. Site personnel are required to review the questionnaire for completion.

8.3. Participant Satisfaction Questionnaire

Please see Appendix 7 for a sample of the Participant Satisfaction Questionnaire. There are two versions of this questionnaire to be completed at their respective visits, Screening and SVR12 (Week 20), by all participants. This questionnaire is to be completed on paper and a completed copy emailed to smartc@kirby.unsw.edu.au with the EQ-5D-3L so they can be entered into the database by the Kirby Institute staff.

This questionnaire is to be completed by the study participant. Site staff cannot administer this questionnaire and complete it on participant's behalf. Site personnel are required to review the questionnaire for completion.

8.4. Practitioner Acceptability Questionnaire

Please see Appendix 8 for a sample of the Practitioner Acceptability Questionnaire. There are two versions of this questionnaire, pre-screening and post-treatment. Pre-screening version is to be completed prior FPFV (first patient first visit) at each site; post-treatment version is to be completed after LPLV (last patient last visit) at each site.

These questionnaires are to be completed by each site Principal Investigator and the primary Research Nurse. This questionnaire is to be completed on paper and a completed copy emailed to smartc@kirby.unsw.edu.au after completion for it to be entered into OpenClinica by the Kirby Institute data entry staff.

9. Study Drug Handling

9.1. Study Drug received at site

An initial cap of 10 participants will be allocated at each site. Only one study drug shipment is planned for each site. This initial shipment will contain all drug supply for 8 weeks for the planned number of enrolled participants at each site.

Study drug re-supply is not planned. However, study drug stock for each site will be closely monitored by the Project Coordinator on an ongoing basis and a re-supply will be organized if needed.

9.2. Dispensing Procedures

Only authorized site personnel according to the SMART-C Site Signature and Study Responsibilities Log can dispense the study drug. Study staff must not open and count clinical trial supplies prior to dispensing.

At baseline (week 0), participants will be randomised into the standard monitoring or simplified monitoring group. Site personnel are responsible for the randomisation and to provide these details to the site pharmacy or the site personnel responsible for dispensing the study drug. Quantity of study product to dispense varies depending on the study arm as follows:

- **Standard monitoring** arm participants will be dispensed with 4 weeks treatment supply (3 bottles) at Baseline and Week 4 visit. This includes extra 2 days of treatment.
- **Simplified monitoring** arm participants will be dispensed with 8 weeks treatment supply (6 bottles) at Baseline. This includes extra 4 days of treatment.

9.3. Participant Instruction

Participants should be instructed with the following:

- Take the drug orally once a day (3 tablets per day) with food.
- Maintain approximately the same daily dosing interval between study drug doses.
- Swallow the study drug tablets whole.
- Only remove the tablets from the bottle immediately prior to dosing.
- If a dose of the study drug is missed, participants should take the missed dose as soon as possible during the SAME day. However, no more than the daily dose of glecaprevir/pibrentasvir should be taken on any calendar day. Participants should be cautioned never to double the next dose with a missed dose of study drug under any circumstances.
- Store the study drug packs at room temperature, not in the refrigerator.
- Keep the study drug out of the reach of children.

9.4. Study Drug Accountability and Compliance

All participants will be required to return the study drug to the site at the SVR12 visit. To provide standardised drug accountability assessment across both arms, participants in the standard arm are to be instructed to only return all study medication at SVR12. A pill count is to be conducted for all study drug returned at SVR12 and noted if any discrepancies or signs of non-compliance are found.

If for any reason the study drug bottle is returned prior to SVR12, these study drug bottles can be collected as long as they are stored in a secure location with limited access. These bottles must be stored in a clearly

designated and secure location to ensure that they are not re-used and can be collected for future product accountability purposes.

Returned study drug must not be dispensed again. Study drug may not be relabelled or reassigned for use by other participants.

Study drug accountability and compliance must be recorded in source documents. Study drug accountability must be also recorded in the Master Study Drug Accountability Log (see SMART-C Pharmacy Manual Supplement for more information).

10. Data Collection

The following electronic data capture system will be used for SMART-C:

- OpenClinica for collection of clinical data.

All study questionnaires will be completed in paper format. Questionnaire data (except for the Phone-based Visit questionnaire) is NOT to be entered into the eCRF by site personnel as defined in section 7 of this Manual supplement.

11. Safety

11.1. Adverse Events (AEs)

AEs will be collected for all participants from Baseline to SVR12 (Week 20). AEs will be collected in the clinic visits at Baseline and SVR12 (Week 20) and via phone contact at Week 4 and EoT (Week 8). AEs reported in the mentioned timepoints will be recorded using the first tab of the AE eCRF.

For AEs reported at other time points (e.g. Week 4 clinic visits – standard arm only), these AEs will be recorded in the Unscheduled Adverse Event eCRF.

11.2. Serious Adverse Events (SAE)

SAEs should be reported throughout the duration of the study, and within 24 hours of occurrence. All SAEs should be reported using the SAE form (Appendix 9, e-version or paper version available) to the Kirby Institute and AbbVie:

Kirby Institute: Email: smartc@kirby.unsw.edu.au

Fax: +61 2 9385 9214

AbbVie: Email: PPDINDPharmacovigilance@abbvie.com

A SAE is defined as any event that results in any of the following:

i. death;

ii. a life threatening adverse event experience (i.e., participant was at immediate risk of death from the event as it occurred);

iii. a persistent or significant disability/incapacity;

iv. inpatient hospitalisation

v. prolongation of existing hospitalisation;

vi. a congenital anomaly/birth defect; or

vii. an important medical event that jeopardizes the participant and requires medical/surgical intervention to prevent one of the outcomes listed in (i) through (vii) of this definition.

SAEs should also be recorded into the Adverse Event eCRF.

11.3. Product Complaints

Product complaints refer to any suspected quality defect in the study drug or its package or labelling. This may include, but is not limited to:

- Damaged/broken product or packaging issues
- Product appearance whose colour/markings do not match the labelling
- Labelling discrepancies/inadequacies in the labelling/instructions
- Missing components/product

All product complaints must be reported to the Kirby Institute and AbbVie within 24 hours.

Kirby Institute: Email: smartc@kirby.unsw.edu.au

Fax: + 61 2 9385 9214

AbbVie: Email: RD_PQC_QA@abbvie.com

A product complaint form will be provided for documentation and reports.

12. Monitoring and Quality Assurance

The sponsor's monitor will visit sites to conduct site visits (Initiation, Monitoring and Close-Out). The number of visits will vary; however, the monitor will conduct a minimum of three visits.

The study coordinator will contact the site 4 weeks prior to the proposed date to request a visit.

Two weeks prior to the confirmed monitoring visit date, the project coordinator will provide the site with a list of patients which will be monitored. The site must ensure the medical record for the patients listed are available on the visit day.

13. Participant reimbursement

If approved by the site Ethics Committee, participants will be reimbursed for their time and reasonable travel expenses for all study visits within the SMART-C study. Each participant will be reimbursed AUD30 (or local currency equivalent as outlined in site contract agreement) for each visit which equates to AUD150 over the course of the study. Payment can be in the form of cash or vouchers as decided by your clinic.

13.1. Obtaining a participant reimbursement advance

Cash

- On receipt of the signed clinical trial agreement (CTRA), which contains the participant reimbursement payment details, the Institution should submit a tax invoice for amount defined in the CTRA for participant reimbursement.
- If the Institution chooses to submit a tax invoice, they are responsible for drawing cash or cheque to be stored at the clinic site.

Voucher

- On receipt of the signed clinical trial agreement (CTRA), which contains the participant reimbursement payment details, the Institution should notify the SMART-C Project Coordinator to send the vouchers.
- Receipt of the vouchers must be acknowledged (by email, fax or phone contact) as per instructions from the SMART-C Project Coordinator.
- After the Project Coordinator has received the acknowledgement from the Institution, the vouchers will be activated. The vouchers are required to be activated prior to being given out to participants.

13.2. Storing and maintaining the money/vouchers

- The money/vouchers sent at site remain the responsibility of the study site PI or designee, who will be responsible for their tracking and acquittal.
- The money/vouchers must be kept in a safe and secure manner at the site.
- Only study staff should have access to the money/vouchers.
- To minimise risk, when participant payments are made, the study staff member should only take the required amount of money/vouchers and place it in an envelope.

13.3. When should participant reimbursement be made?

Each participant will be reimbursed a maximum of AUD150 (or local currency equivalent as outlined in site contract agreement) for completion of all study visits. Participant reimbursement will vary depending on their stratification (i.e. standard monitoring arm or simplified monitoring arm).

STANDARD MONITORING ARM		**SIMPLIFIED MONITORING ARM**	
Visit	**Amount***	**Visit**	**Amount***
Screening	$30	Screening	$30
Baseline	$30	Baseline	$30
Week 4	$30	Week 4	N/A
EOT	$30	EOT	N/A
SVR12	$30	SVR12	$90
Total	**$150**	**Total**	**$150**

*Amounts in AUD

13.4. Accounting for money/vouchers

- When the participant receives the money/voucher, for acquittal purposes, it is essential that they sign the participant reimbursement tracking log found in the Investigator Site File (ISF).
- Sites may use their own clinic/hospital receipt. If so, receipts should be kept in the ISF to allow for the acquittal of the money/vouchers as required by the Kirby Institute as per the clinical trial agreement.
- A tracking log of participant reimbursements (Appendix 10) recording all monies/vouchers paid is to be maintained and should be stored in Section 9.3 of the ISF.

13.5. Acquittal process

- As requested by the clinical project coordinator, the institution must submit a copy of the tracking log for the acquittal of the money/vouchers. The original tracking log is kept at the institution.
- Upon request by the clinical project coordinator, any unspent money/vouchers will be returned to the Kirby Institute as per the clinical trial agreement (CTRA) which contains the participant reimbursement payment details.

13.6. Re-ordering of Money/Vouchers

If more money/vouchers are required, the institution must submit a copy of the tracking log to the Kirby Institute for acquittal as described in Section 13.5 with either the participant reimbursement voucher request form (found in the Investigator Site File) for vouchers or a tax invoice for additional money as described in Section 13.1.

13.7. Monitoring of reimbursement

The storage, allocation and tracking of money/vouchers (including the signed tracking log) will be checked at the monitoring visits.

Appendix 1. SMART-C Protocol Exemption Form

SMART-C	**Sponsor:** UNSW Sydney – The Kirby Institute
	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)	☐ Eligibility criteria	☐ 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**	**□ Yes □ No**
Signature of Investigator		**Date: (dd/mm/yyyy)**	
Protocol Exemption Number:		**Faxed to site: (dd/mm/yyyy)**	

Please enter the protocol exemption number in screening e-CRF if the exemption is granted for the study eligibility criteria

Please keep this form in the Study Investigator Folder

SMART-C Protocol Exemption Form version 1.0 dated 8-Mar-2017

Appendix 2. SMART-C Master Participant Enrolment Log

ISF FILING: 9

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

Master Participant Enrolment Log – Keep at site

Do not fax to the Kirby Institute

Site name: _____ **Investigator:** _____

Patient ID Number	Patient Name	Medical Record Number	DOB	Emergency Contact Number	Enrolment Date	Study Completion Date	Comments
____-_____-___							
____-_____-___							
____-_____-___							
____-_____-___							
____-_____-___							
____-_____-___							
____-_____-___							
____-_____-___							
____-_____-___							
____-_____-___							
____-_____-___							

Appendix 3. SMART-C Study Visit Calculator Tool

Participant No.	Baseline	Week 4 Phone Call *(must occur 1-2 days before the clinic visit)*	Week 4 Clinic Visit (lower visit window)	Week 4 Clinic Visit (actual date)	Week 4 Clinic Visit (upper visit window)	EoT Phone Call *(must occur 1-2 days before the clinic visit)*	EOT Clinic Visit (lower visit window)	EOT Clinic Visit (actual date)	EOT Clinic Visit (upper visit window)	SVR12 Clinic Visit (lower visit window)	SVR12 Clinic Visit (actual date)	SVR12 Clinic Visit (upper visit window)
1701-			25-Jan-00		31-Jan-00		22-Feb-00		28-Feb-00	16-May-00		22-May-00
1701-			25-Jan-00		31-Jan-00		22-Feb-00		28-Feb-00	16-May-00		22-May-00
1701-			25-Jan-00		31-Jan-00		22-Feb-00		28-Feb-00	16-May-00		22-May-00
1701-			25-Jan-00		31-Jan-00		22-Feb-00		28-Feb-00	16-May-00		22-May-00
1701-			25-Jan-00		31-Jan-00		22-Feb-00		28-Feb-00	16-May-00		22-May-00
1701-			25-Jan-00		31-Jan-00		22-Feb-00		28-Feb-00	16-May-00		22-May-00
1701-			25-Jan-00		31-Jan-00		22-Feb-00		28-Feb-00	16-May-00		22-May-00
1701-			25-Jan-00		31-Jan-00		22-Feb-00		28-Feb-00	16-May-00		22-May-00
1701-			25-Jan-00		31-Jan-00		22-Feb-00		28-Feb-00	16-May-00		22-May-00
1701-			25-Jan-00		31-Jan-00		22-Feb-00		28-Feb-00	16-May-00		22-May-00

Appendix 4. SMART-C Lab Request Form

SMART-C

For Clinic use only

Subject Study No.: 1701 – _ _ _ _ _ _ – _ _ _ **Subject initials:** _ _ _ / _ _ _
Last name, First name

Date of Birth: (Format: 23/NOV/2009) _ _ / _ _ _ / _ _ _ _ **Collectors' name:** _____

Date of Collection: (Format: 23/NOV/2009) _ _ / _ _ _ / _ _ _ _ **Collection Time:** (Format: 24 hour time, e.g. 15:30) _ _ : _ _

Visit: (Please tick box)

☐ **BSL**	2 x 10mL EDTA
Screen ID: 3 3 3- _ _ _	
☐ **WK4** (standard arm only)	1 x 10mL EDTA
☐ **ETR (WK8)** (standard arm only)	1 x 10mL EDTA
☐ **SVR12**	1 x 10mL EDTA

Comments:

For processing site use only

Specimen received: Date: _ _ / _ _ _ / _ _ _ _ (e.g. 23/NOV/2009) **Time:** _ _ : _ _ (e.g. 15:30)

Specimen processed: Date: _ _ / _ _ _ / _ _ _ _ (e.g. 23/NOV/2009) **Time:** _ _ : _ _ (e.g. 15:30)

Samples stored: _____ x 1mL + 1 x _____ mL EDTA plasma in round bottom cryotube vials
Box #: ____ Positions: _____
Stored at -80°C ☐

(Please tick box)

Samples specific comments:

Data recorded in Labkey ☐ **Processed by:** (Name and signature)

SITE KEEP YELLOW COPY - LABORATORY KEEP PINK COPY
WHITE COPY TO BE SENT TO KIRBY LABORATORY UPON INSTRUCTIONS

STORE THIS COMPLETED FORM IN YOUR STUDY BINDER.
DO NOT SHIP SAMPLES UNTIL REQUESTED BY THE **SMART-C COORDINATOR**

Laboratory Contact:
HepBank@kirby.unsw.edu.au

SMART-C Research Assistant
+61 2 93850203, smartc@kirby.unsw.edu.au

SMART-C	**Sponsor:**	UNSW Sydney – The Kirby Institute
	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 Research Specimens Collection Log

Site Name: _____ **Site Number:** _____ **Principal Investigator:** _____

Screening ID:	333 - __ __ __	**Participant's Initials:**	__ __ - __ __	***Instructions:*** *Please complete a log for each participant who has research specimens collected.*
Participant ID:	1701 - __ __ __ __ - __ __			

Visit ID	Date of Collection	Time of Collection	Collector's Initials	Specimen Type	Date sent to Local Laboratory	Time sent to Local Laboratory	Kirby Institute bar-coded label
SCR				☐ EDTA plasma ☐ EDTA whole blood ☐ ACD PBMC			
BSL				☐ EDTA plasma			
WK4*				☐ EDTA plasma ☐ ACD PBMC			
EOT*				☐ EDTA plasma			
SVR12				☐ EDTA plasma ☐ ACD PBMC			

***Week 4 and EOT specimens are only applicable for standard arm participants.**

Appendix 6. Phone-based Visit Questionnaire

Visit date	Study subject ID	Participant initials	
☐☐/☐☐☐/☐☐☐☐ (dd/mon/yyyy)	1701-☐☐☐☐☐-☐☐	☐☐☐☐ E.g. Smith John SMJO	SMART-C
Phone-based visit questionnaire			

Name of the site personnel completing the form:		
Visit (please select the applicable visit):	☐ Week 4	☐ EoT (Week 8)

SECTION A: ADVERSE EVENTS

1. Have you experienced any side effects since last contact?

☐ No *(skip to question 2)*

☐ Yes *(If yes, please collect data)*

Participant Reported					Nurse Assessment	
AE term	Severity	Action taken with study drug	Start date	End date	Relatedness+	SAE?
	☐ Mild ☐ Moderate* ☐ Severe* ☐ Life threatening*	☐ Drug withdrawn ☐ Drug interrupted ☐ No action ☐ Not applicable	__/___/__ (dd/mon/yy)	__/___/__ (dd/mon/yy) or ☐ Ongoing	☐ Not related ☐ Unlikely ☐ Possibly ☐ Probably	☐ Yes ☐ No
	☐ Mild ☐ Moderate* ☐ Severe* ☐ Life threatening*	☐ Drug withdrawn ☐ Drug interrupted ☐ No action ☐ Not applicable	__/___/__ (dd/mon/yy)	__/___/__ (dd/mon/yy) or ☐ Ongoing	☐ Not related ☐ Unlikely ☐ Possibly ☐ Probably	☐ Yes ☐ No
	☐ Mild ☐ Moderate* ☐ Severe* ☐ Life threatening*	☐ Drug withdrawn ☐ Drug interrupted ☐ No action ☐ Not applicable	__/___/__ (dd/mon/yy)	__/___/__ (dd/mon/yy) or ☐ Ongoing	☐ Not related ☐ Unlikely ☐ Possibly ☐ Probably	☐ Yes ☐ No

+ refer to protocol section 7.2 for definitions of relatedness

*ALL MODERATE, SEVERE AND LIFE THREATENING ADVERSE EVENTS MUST BE REVIEWED BY A SITE INVESTIGATOR.

Investigator review
Date of review by an investigator: ____/____/_____ Signature of site Investigator ______________________
Action required? Yes ☐ No ☐
If yes, specify:

SMART-C Phone-based visit questionnaire_V1.0 dated 31-May-2017 Page 1 of 3

Appendix 6 (continued) Phone-based Visit Questionnaire (Page 2)

Visit date	Study subject ID	Participant initials	
□□/□□□/□□□□ (dd/mon/yyyy)	1701-□□□□□-□□	□□□□ E.g. Smith John SMJO	SMART-C
Phone-based visit questionnaire			

SECTION B: CONCOMITANT MEDICATION

2. **Have you started, stopped, or changed any medication since last contact?**

☐ No *(skip to Section B)*

☐ Yes *(If yes, please collect data)*

Medication name	Indication	Start date	End date
		__/__ __/__ __ *(dd/mon/yy)*	__/__ __/__ __ *(dd/mon/yy)* *or* ☐ Ongoing
		__/__ __/__ __ *(dd/mon/yy)*	__/__ __/__ __ *(dd/mon/yy)* *or* ☐ Ongoing
		__/__ __/__ __ *(dd/mon/yy)*	__/__ __/__ __ *(dd/mon/yy)* *or* ☐ Ongoing
		__/__ __/__ __ *(dd/mon/yy)*	__/__ __/__ __ *(dd/mon/yy)* *or* Ongoing
		__/__ __/__ __ *(dd/mon/yy)*	__/__ __/__ __ *(dd/mon/yy)* *or* Ongoing

Appendix 6 (continued) Phone-based Visit Questionnaire (Page 3)

Visit date	Study subject ID	Participant initials	
□□/□□□/□□□□ (dd/mon/yyyy)	1701-□□□□□-□□	□□□□ E.g. Smith John SMJO	SMART-C
Phone-based visit questionnaire			

SECTION C: ADHERENCE QUESTIONNAIRE

3. **Since last contact, how many DAYS did you MISS taking GLECAPREVIR/PIBRENTASVIR?**

   ☐

If participant didn't miss any dose, STOP. Otherwise, please continue with next question.

4. **Why did you miss taking GLECAPREVIR/PIBRENTASVIR?** ***Check all that apply.***

   Side effects ☐

   Forgot to take ☐

   Other reason ☐

   If other reason, briefly describe reason _____

Appendix 7. Treatment Satisfaction Questionnaire

Visit date	Study subject ID	Patient initials	
☐☐/☐☐☐/☐☐☐☐ (dd/mon/yyyy)	1701-☐☐☐☐☐-☐☐	☐☐☐☐ E.g. Smith John SMJO	SMART-C
PARTICIPANT SATISFACTION QUESTIONNAIRE - **SCREENING**			

INSTRUCTIONS

For the following questions, please tick the appropriate boxes.

1. Clinic Visits

For an hepatitis C treatment program consisting of 8 weeks of treatment and a 12 week post-treatment follow-up, which of the following visits after starting treatment do you feel are necessary to be seen in clinic?

Select all that apply:

Week 4	Week 8 (EOT - end of treatment)	Week 20 (SVR12 - 12 weeks post-treatment)	Additional visits in weeks other than those specified
☐	☐	☐	☐

2. Patient Preferences

For the following statements, please indicate your opinion by ticking 1 box per row.

Statement	1 Strongly Disagree	2 Disagree	3 No strong opinion	4 Agree	5 Strongly Agree
You expect to be seen by a doctor in clinic during the course of treatment	☐	☐	☐	☐	☐
You expect to be seen by a nurse in clinic during the course of treatment	☐	☐	☐	☐	☐
Phone contact during treatment is just as good as clinic visits	☐	☐	☐	☐	☐

SMART-C Participant satisfaction questionnaire - Screening_V1.0_31May2017 Page 1 of 1

Visit date	Study subject ID	Patient initials	
□□/□□□/□□□□ (dd/mon/yyyy)	1701-□□□□□-□□	□□□□ E.g. Smith John SMJO	SMART-C

PARTICIPANT SATISFACTION QUESTIONNAIRE – **SVR12 (Week 20)**

INSTRUCTIONS

For the following questions, please tick the appropriate boxes.

1. Clinic Visits

Having completed your hepatitis C treatment program, which of the following visits after starting treatment do you feel are necessary to be seen in clinic?

Select all that apply:

Week 4	Week 8 (EOT - end of treatment)	Week 20 (SVR12 - 12 weeks post-treatment)	Additional visits in weeks other than those specified
☐	☐	☐	☐

2. Patient Preferences

Now that you have completed treatment, if you had to repeat treatment, please indicate your opinion on the following statements by ticking 1 box per row.

Statement	1 Strongly Disagree	2 Disagree	3 No strong opinion	4 Agree	5 Strongly Agree
You expect to be seen by a doctor in clinic during the course of treatment	☐	☐	☐	☐	☐
You expect to be seen by a nurse in clinic during the course of treatment	☐	☐	☐	☐	☐
Phone contact during treatment is just as good as clinic visits	☐	☐	☐	☐	☐
Overall, you are satisfied with your treatment follow-up plan	☐	☐	☐	☐	☐

Appendix 8. Practitioner Acceptability Questionnaire

Completion date	Site Number	
□□/□□□/□□□□ (dd/mon/yyyy)	□□□□□ Site Practitioner name _____	SMART-C

PRACTITIONER ACCEPTABILITY QUESTIONNAIRE – PRE-SCREENING

INSTRUCTIONS

One questionnaire is to be completed **each by the site Principal Investigator and the primary Research Nurse** prior to the commencement of screening.

SECTION 1: YOUR DETAILS

1. Practitioner type:

- ☐ Hepatologist
- ☐ Infectious Diseases
- ☐ General Practitioner
- ☐ Other Medical Doctor, please specify _____
- ☐ Study Nurse/Study Coordinator

SECTION 2: HCV TREATMENT EXPERIENCE

2. Previous experience with treating HCV patients:

- ☐ < 2 years
- ☐ 2-4 years
- ☐ > 4 years

3. Previous experience with IFN free DAA treatment:

- ☐ < 1 years
- ☐ 1 - 2 years
- ☐ > 2 years

SECTION 3: CURRENT PRACTICE

4. For a treatment naïve, non-cirrhotic patient without a history of recent injecting drug use, please indicate when and who would typically see the patient in clinic during short course HCV DAA treatment.

Note: if a clinic visit is not routine for your practice, please tick the "No clinic visit" box for the visit type.

Select all that apply.

Visit	Screening	Baseline	Week 4	Week 8 (12-week regimens only)	EOT	SVR12	SVR24
Week	-	***0***	***4***	-	***8 or 12***	***20 or 24***	***32 or 36***
Nurse	☐	☐	☐	☐	☐	☐	☐
Doctor	☐	☐	☐	☐	☐	☐	☐
Other practitioner	☐	☐	☐	☐	☐	☐	☐
No clinic visit	☐	☐	☐	☐	☐	☐	☐

Completion date	Site Number	
□□/□□□/□□□□ (dd/mon/yyyy)	□□□□□ Site Practitioner name _____	SMART-C

PRACTITIONER ACCEPTABILITY QUESTIONNAIRE – PRE-SCREENING

SECTION 4: SIMPLIFIED TREATMENT MONITORING EXPECTATIONS

5. Please rate the protocol simplified monitoring strategy based on the following: *Do you expect…*

	Lower in the simplified group than in the standard one	Equivalent in both treatment monitoring strategies	Higher in the simplified group than in the standard one
treatment adherence will be	☐	☐	☐
SVR12 will be	☐	☐	☐
adverse Events reported rate will be	☐	☐	☐
lost to follow up rates will be	☐	☐	☐
treatment discontinuation rates will be	☐	☐	☐

6. Which monitoring strategy do you prefer for this study's patient population?
   - ☐ Standard monitoring
   - ☐ Simplified monitoring
   - ☐ Other, specify _____

Completion date	Site Number	
□□/□□□/□□□□ (dd/mon/yyyy)	□□□□ Site Practitioner name _____	SMART-C

PRACTITIONER ACCEPTABILITY QUESTIONNAIRE – POST-TREATMENT

INSTRUCTIONS

One questionnaire is to be completed **each by the site Principal Investigator and the primary Research Nurse** after all participants have completed SVR12.

SECTION 1: YOUR DETAILS

1. Practitioner type:

- ☐ Hepatologist
- ☐ Infectious Diseases
- ☐ General Practitioner
- ☐ Other Medical Doctor, please specify _____
- ☐ Study Nurse/Study Coordinator

SECTION 2: SIMPLIFIED TREATMENT MONITORING EXPERIENCE

2. Please rate the simplified monitoring strategy based on the following: *Do you expect…*

	Lower in the simplified group than in the standard one	Equivalent in both treatment monitoring strategies	Higher in the simplified group than in the standard one
treatment adherence will be	☐	☐	☐
SVR12 will be	☐	☐	☐
adverse Events reported rate will be	☐	☐	☐
lost to follow up rates will be	☐	☐	☐
treatment discontinuation rates will be	☐	☐	☐

3. Which monitoring strategy do you prefer for this study's patient population?
   - ☐ Standard monitoring
   - ☐ Simplified monitoring
   - ☐ Other, specify _____

4. Would you suggest changes to the protocol simplified monitoring strategy for this study's patient population?
   - ☐ No
   - ☐ Yes

5. If yes, please indicate which of the following you would suggest:
   - ☐ Additional clinic visit
   - ☐ Reduce the number of phone calls, i.e. one phone contact only
   - ☐ Other, specify _____

Appendix 9. Serious Adverse Event Form

KIRBY INSTITUTE SERIOUS ADVERSE EVENT (SAE) FORM

SITE INFORMATION

Kirby Protocol Number: VHCRP1701 EDURACT Number: 2017-000694-37

To: Kirby Institute, VHCRP Fax No: +61 2 9385 9214 Email: smartc@kirby.unsw.edu.au

To: AbbVie Email: PPDINDPharmacovigilance@abbvie.com

Pages:_____ ☐ Initial Report ☐ Follow-up report Date of report *(dd/mon/yyyy)*: ____/_____/_____

Principal Investigator's Name: _____ Reported By: _____

Site Phone Number: _____ Site Fax No: _____

PATIENT

Subject ID Number: 1701-__ __ __ __ __-__ __ Subject date of birth *(dd/mon/yyyy)*: ____/ _____/ _____ Initials: ____-____

Date site became aware of the SAE *(ddmonyyyy)*: _____

Patient Gender: ☐ Male Height: _____ (cms) Weight: _____ (kgs)

☐ Female

☐ Transgender

☐ Unknown

INVESTIGATOR SIGN-OFF	INVESTIGATOR SIGN-OFF: I verify that the information contained in this SAE is accurate and compatible with the source documents. Investigator Name (Please print): _____ Investigator Signature: _____ Date *(dd/mon/yyyy):* ____/ _____/ _____ Reported to IRB/REC/EC/HREC: ☐ Yes ☐ No. If no, why? _____ Note: SAE form can be submitted without the investigator signature but must be signed and resubmitted once signature is complete.

KIRBY	Received date: _____ Received By: - _____

SAE INFORMATION

SAE DETAILS:

Event name: _____

Event Onset Date *(dd/mon/yyyy)*: ____/ _____/ _____

Severity: ☐ Mild ☐ Moderate ☐ Severe ☐ Life Threatening

Investigator Narrative: describe the event , suspected causes and timing	
Include: Signs & Symptoms Investigations Course of Events Timings Treatment for SAE Suspected Causes Other Comments	

Drug: Glecaprevir/Pibrentasvir (GLE/PIB)

Causality:

- ☐ Not related
- ☐ Unlikely
- ☐ Possibly
- ☐ Probably

Action Taken:

- ☐ Drug withdrawn
- ☐ Drug interrupted
- ☐ No change to drug
- ☐ Unknown
- ☐ Not applicable

SAE INFORMATION CONTINUED

SAE Outcome:

☐ Recovered/Resolved

Recovery date (dd/mon/yyyy): ____/ _____/ _____

☐ Recovered with sequalae

☐ Recovering/Resolving

☐ Not recovered/not resolved

☐ Fatal (complete death details)

☐ Unknown

SAE Seriousness Category:

☐ Death (complete death details)

☐ Life Threatening

☐ Persistent or significant disability/incapacity

☐ Inpatient hospitalisation

☐ Prolongation of existing hospitalisation

☐ Congenital anomaly/birth defect

☐ Other medically important condition

Study Drug Dosing:

Start Date *(dd/mon/yyyy)*: ____/ _____/ _____

Stop Date*(dd/mon/yyyy)*: ____/ _____/ _____

Dose: 100/40

Unit: mg

Frequency: Once daily

Route: Oral

Batch/Lot No.: _____

DEATH	DEATH DETAILS Date of Death *(dd/mon/yyyy):* ____/ _____/ _____ Autopsy Performed?: ☐ No ☐ Yes (if yes, attach a copy of report if available)

Appendix 10. Participant Reimbursement Tracking Log

SMART-C	**Sponsor:**	UNSW Sydney – The Kirby Institute
	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

Participant Reimbursement Log

Site Name: ____________________ **Site Number:** ________ **Principal Investigator:** ____________________

Participant ID:	1701 - __ __ __ __ - __ __	**Participant's Initials:**	__ __ - __ __

Date *(dd/mm/yyyy)*	**Visit** *(tick all applicable)*	**Reimbursement type**	**Reimbursement given for visit**	**Participant Signature**	**Comments**
	☐ SCR ☐ BSL ☐ WK4 ☐ EOT ☐ SVR12	☐ Cash Amount: ☐ Voucher Number(s):	☐ Yes ☐ No		
	☐ SCR ☐ BSL ☐ WK4 ☐ EOT ☐ SVR12	☐ Cash Amount: ☐ Voucher Number(s):	☐ Yes ☐ No		
	☐ SCR ☐ BSL ☐ WK4 ☐ EOT ☐ SVR12	☐ Cash Amount: ☐ Voucher Number(s):	☐ Yes ☐ No		
	☐ SCR ☐ BSL ☐ WK4 ☐ EOT ☐ SVR12	☐ Cash Amount: ☐ Voucher Number(s):	☐ Yes ☐ No		
	☐ SCR ☐ BSL ☐ WK4 ☐ EOT ☐ SVR12	☐ Cash Amount: ☐ Voucher Number(s):	☐ Yes ☐ No		

SMART-C_Participant Reimbursement Log_v1.0_22 May 2017

Appendix 11. Participant Reimbursement Voucher Request

As outlined in the clinical trial agreement which contains the participant reimbursement payment details in Schedule 2, I would like to request that my site receive the participant reimbursement payment in the form of vouchers and a tax invoice will not be issued to The Kirby Institute for this payment.

Site Name _____

PI Name _____

Requested By _____

Amount (no. of vouchers) _____

Date _____

Please email or fax this form to your Project Coordinator:

Danny Kho

Clinical Project Coordinator
Viral Hepatitis Clinical Research program
The Kirby Institute, UNSW Sydney
Wallace Wurth Building, Sydney NSW 2052
Fax: 02 9385 9214
Email: dkho@kirby.unsw.edu.au

Gerard Estivill Mercade

Clinical Project Coordinator
Viral Hepatitis Clinical Research program
The Kirby Institute, UNSW Sydney
Wallace Wurth Building, Sydney NSW 2052
Fax: 02 9385 9214
Email: gestivill@kirby.unsw.edu.au

*please submit the tracking log together with the request form