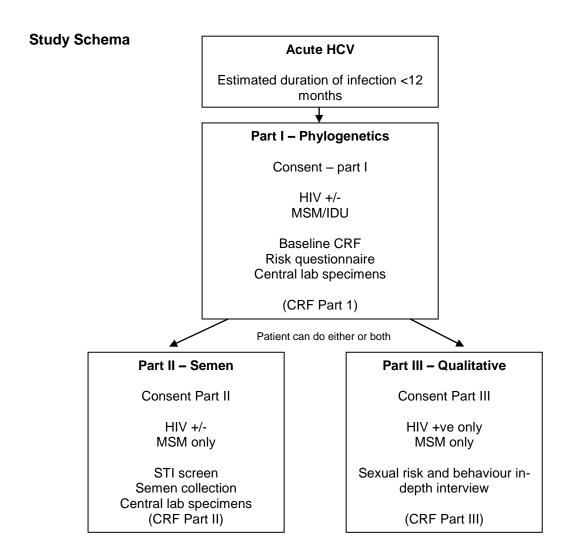
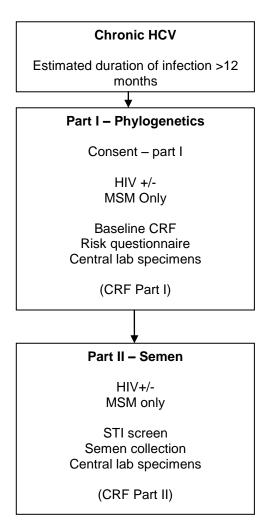




# Defining <u>risk and mechanisms of permucosal</u> transmission for acute HCV infection within high-risk populations

# **COMPLETION INSTRUCTIONS** ☐ Ensure the patient information sheet and consent form has been correctly completed ☐ Ensure the visit date, study identifier are completed on each page of this form ☐ Complete all questions (unless otherwise specified) ☐ Except where specified, all questions are single response only □ Please write legibly ☐ All text and explanatory comments should be brief ☐ If the answer is zero, do not leave the field blank write '0' ☐ If the answer to the question is unknown, write 'not known' or 'NK' ☐ If a question is not applicable, write 'not applicable' or 'NA' □ Date format is dd/mm/yyyy ☐ If a date is partially known, enter that part of the date known and 'NK' for that not known part e.g. NK / 04 / 08 ☐ When making a correction, draw a single line through the text to be changed so that the original entry is still legible. Initial and date the correction □ DO NOT use correction fluid or write over information as this will invalidate the data and create query





#### Schedule of Asessment - Baseline Visit

Schedule of Assessment	Part I only	Part I & II	Part I & III	Part I, II & III
Written Informed Consent	Х	Х	X	Х
Central Lab – AMR				
Stored Study Plasma Sample	X	X	X	Χ
Local Lab – standard of care				
Anti-HCV antibody	Х	X	Х	Х
HCV RNA quantitative	Х	X	Х	Х
HCV genotype				
BBV serology (HBsAG, HIV Ab)	X	X	X	Х
HIV RNA & T-cell subsets <sup>a</sup>	X	X	Х	Х
SOC – LFT, platelets	X	X	Х	Х
Baseline Interview (includes Incident case interview & Sexual behavior and practices interview <sup>b</sup> )	Х	Х	X	X
Central Lab – AMR				
Stored Study Plasma Sample		X		X
Stored Semen Sample		X		X
Local Lab - STI Screen				
<ul> <li>Syphilis serology - SST tube</li> </ul>		X		X
<ul> <li>Chlamydia, Gonorrhea, LGV - Urine, throat &amp; rectal swabs</li> </ul>		Х		X
HSV swab <sup>c</sup>		Х		Х
HAV serology - SST tube		Х		Х
Behavioural Mechanisms Interview			Х	Х

<sup>&</sup>lt;sup>a</sup> If HIV serology positive <sup>b</sup> Complete by acute MSM patients only <sup>c</sup> Perform in the presence of ulcerative lesions only

RAMPT-C	BASELIN	BASELINE VISIT		
Visit date	Study number	Patient initials		
	0902			
(dd/mm/yyyy)		E.g. <u>Smith</u> John SMJO		

# **INCLUSION & EXCLUSION CRITERIA CHECKLISTS**

Part I – Phylogenetics Component – ALL PATIENTS
All patients
Inclusion Criteria:  a) Is the male patient >= 16 years of age?  Yes
If any no box have been ticked the patient is <b>not eligible</b> to enter Part I of the Study
Exclusion criteria a) Does the investigator consider the patient to be unlikely to participate in follow-up and/or unwilling to provide extra blood samples?  Yes   No

If the yes box have been ticked the patient is **not eligible** to enter Part I of the Study

RAMPT-C	BASELINE VISIT		
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Inclusion Criteria: a) Is the male patient >= 16 years of age? Yes	PART II – Semen Component
a) Is the male patient >= 16 years of age? Yes	N/A □ (please tick the box if patient is not enrolled into this Component)
b) Has the patient provided written informed consent?  Yes	a) Is the male patient >= 16 years of age?
c) Is the patient HCV RNA positive?  Yes	b) Has the patient provided written informed consent? Yes □
d) Does the patient have a first positive HCV antibody or HCV RNA positive within the previous 6 months and documented HCV antibody negative or HCV RNA negative within the 12 months? OR  Does the patient have a first positive HCV antibody or HCV RNA positive within the previous 6 months and documented acute clinical hepatitis (jaundice or ALT> 10x ULN)  OR  Has the patient been HCV RNA positive > 12 months (Chronic HCV)?  Yes	c) Is the patient HCV RNA positive? Yes
months and documented acute clinical hepatitis (jaundice or ALT> 10x ULN) OR Has the patient been HCV RNA positive > 12 months (Chronic HCV)? Yes	d) Does the patient have a first positive HCV antibody or HCV RNA positive within the previous 6 months and documented HCV antibody negative or HCV RNA negative within the 12 months?
Yes	months and documented acute clinical hepatitis (jaundice or ALT> 10x ULN) OR
reliable responses to the study interview? Yes	Yes □ No □
Exclusion criteria:  a) Does the investigator consider the patient to be unlikely to participate in follow-up and/or unwilling to provide extra blood samples?  Yes   No   b) Is the patient currently on HCV treatment or had prior HCV treatment?  Yes   No	reliable responses to the study interview?
Exclusion criteria:  a) Does the investigator consider the patient to be unlikely to participate in follow-up and/or unwilling to provide extra blood samples?  Yes	No
a) Does the investigator consider the patient to be unlikely to participate in follow-up and/or unwilling to provide extra blood samples?  Yes □  No □  b) Is the patient currently on HCV treatment or had prior HCV treatment?  Yes □  No □	If any no box have been ticked the patient is <b>not eligible</b> to enter Part II of the Study
b) Is the patient currently on HCV treatment or had prior HCV treatment?  Yes   No	a) Does the investigator consider the patient to be unlikely to participate in follow-up and/or unwilling to provide extra blood samples? Yes $\ \ \Box$
	b) Is the patient currently on HCV treatment or had prior HCV treatment? Yes □

RAMPT-C	BASELIN	IE VISIT
Visit date	Study number	Patient initials
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PART III – Behavioural Interview Component				
$N/A \square$ (please tick the box if patient is not enrolled into this Component)				
Inclusion Criteria: a) Is the male patient >= 16 years of age? Yes □				
No □ b) Does the patient identify as MSM? Yes □				
No □ c) Is the patient co-infected with HIV? Yes □ No □				
d) Is the patient HCV RNA positive?  Yes  No				
e) Does the patient have a first positive HCV antibody or HCV RNA positive within the previous 6 months and documented HCV antibody negative or HCV RNA negative within the 12 months? OR				
Does the patient has a first positive HCV antibody or HCV RNA positive within the previous 6 months and documented acute clinical hepatitis (jaundice or ALT> 10x ULN)  Yes   No				
f) Does the patient have adequate English to provide written, informed consent and to provide reliable responses to the study interview?  Yes				
No 🗆				
If any no box have been ticked the patient is <b>not eligible</b> to enter Part III of the Study				
Exclusion criteria  a) Does the investigator consider the patient to be unlikely to participate in follow-up and/or unwilling to provide extra blood samples?				
Yes Don Don Don House have tighted the potient is not alimitate and a Port III of the Cturb.				
If the yes box has been ticked the patient is <b>not eligible</b> to enter Part III of the Study				

RAMPT-C		BASELINE VISIT
Visit date	Study number	
	0902-	
(dd/mm/yyyy)		E.g. <u>Smith</u> John SMJO
Interviewer's Name:		
PART I –	Phylogenetics Co	omponent (All patients)
Has subject been enre	olled into the following co	hort? Yes No
HITS-i		
ATAHC		
pH		
HIM		
	HEPATITIS C D	PIAGNOSIS
Date first document	red to be HCV antibody posi	itive//_ dd/mm/yyyy
		dd/mm/yyyy
		not positive
Date first document	ed to be HCV RNA positive	/ /
	·	dd/mm/yyyy
3 Date of most recent	t negative HCV antibody tes	.t / /
	ent is chronic HCV)	dd/mm/yyyy
		☐ Never done
		☐ No record of result
4. Documented HCV s	seroconversion illness?	
(Tick N/A 🗌 if pation	ent is chronic HCV)	
4a. If yes, which of	the following symptoms hav	re been experienced?
	Yes No Unclea	ar/specify
Jaundice		
Nausea/vomitin		
Abdominal pain		
Fever		
4b. Date of initial or		
	dd/mi	m/yyyy

RAMPT-C	BASELINE VISIT			
Visit date	Study number	Patient initials		
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(dd/mm/yyyy)		E.g. <u>Smith</u> John SMJO		

5. Consent form signed	// dd/mm/yyyy
Components Phylogenetics Study (Part I)	Yes No
Semen Study (Part II)	
Behavioural Interview (Part III)	

RAMPT-C	BASELINE VISIT		
Visit date	Study number	Patient initials	
	0902-		
(dd/mm/yyyy)		E.g. <u>Smith</u> John SMJO	

### **VIROLOGICAL SCREENING**

6.	HCV Antibody		Sample	e collection dat	e// dd/mm/yyyy	
6a.	HCV Antibody result	Desitive		Negative	Equivocal	Not done
7.	HCV RNA - Quantitative		Sample	e collection dat	e// dd/mm/yyyy	
7a.	HCV RNA		Сорі	es/ml 🔲 IU/ı	ml	
8.	HCV Genotype		Sample	e collection dat	e// dd/mm/yyyy	
8a.	Genotype		Subtyp	oe		
9.	HIV Antibody		Sample	e collection dat	e// dd/mm/yyyy	
9a.	Anti-HIV result	Desitive		☐ Negative	☐ Equivocal	Not done
10.	HIV-1 RNA/CD4/CD8		Sample	e collection dat	e// dd/mm/yyyy	Not required
10a	a. HIV RNA		Сорі	es/ml	□ N/A	
10k	o. CD4 total	_ □cel	ls/mm <sup>3</sup>	CD8 total _	□	cells/mm³
11.	Hepatitis B Serology		Sampl	e collection da	te// dd/mm/yyyy	
11a	a. HBsAg	Desitive		Negative	Equivocal	Not done

RAMPT-C	BASELINE VISIT		
Visit date	Study number	Patient initials	
(dd/mm/yyyy)	0902-	E.g. <u>Smith</u> John SMJO	
(33,1111,17,7,7,7)			

# 12. SOC Bloods

Sample collection date	
•	dd/mm/yyyy

<b>Liver Function Test</b>	Result	Unit
Albumin		g/L
Total bilirubin		U/L
ALT		U/L
AST		U/L
Alkaline phosphatase		U/L
GGT		U/L

Full Blood Count	Result	Unit (please tick box)
Platelets		10^9/L

# **CENTRAL LABORATORY COLLECTION**

13. Sample collection date	// dd/mm/yyyy		
Collected	Yes	No	Comments
Stored Plasma			

RAMPT-C	BASELINE VISIT		
Visit date	Study number	Patient initials	
(dd/mm/yyyy)	0902	E.g. <u>Smith</u> John SMJO	

# **DEMOGRAPHICS**

I'd like to ask you a few questions about yourself

14.	Do you consider yourself to be male, female or transgender?
	Male       1         Female       2         Transgender       3         Not stated/inadequately described       9
15.	Do you identify as? Heterosexual/Straight
16.	What is your year of birth?
17.	(yyyy)  Are you of Aboriginal or Torres Strait Islander origin?
	No response1Non-indigenous2Aboriginal3Torres Strait Islander4Both Aboriginal and Torres Strait Islander5Indigenous non-specified6
18.	What is the main language you speak at home?  English
19.	What is your country of birth?

RAMPT-C	BASELINE VISIT		
Visit date	Study number	Patient initials	
	0902		
(dd/mm/yyyy)		E.g. <u>Smith</u> John SMJO	

20.	If not Australian born, in what year did you first come to Australia?
21.	Have you ever been in prison/ Juvenile justice centre?
	Yes
22.	If yes, have you been in prison or juvenile justice centre within the last 2 years?
	Yes
	Ινο

#### DRUG USAGE AND INJECTING BEHAVIOURS

We now need to ask you some questions about your drug use – when you first used drugs and how often and how you use drugs and alcohol now. I'll also be asking you about practices such as sharing needles and syringes and other injecting equipment. One of the aims of this study is to examine how people become infected with hepatitis C. Remember all of this information is confidential. Your answers will not affect the treatment you receive.

23.	Have you ever	· injected	any drug?
-----	---------------	------------	-----------

No0	(If no, go to Question 27)
Yes1	(If yes, go to Question 24)

24. How old were you when you first injected any drug?

•	VASTO
	years

25. When was the last time you injected?

Within the last month1	
Between 1 and 6 months ago2	
Between 6 and 12 months ago	(go to question 27
Between 1-2 years ago4	(go to question 27
More than 2 years ago5	(go to question 27

RAMPT-C		BASELINE VISIT			
Visit	date		Study number	Р	atient initials
		0902			
(dd/mr	n/yyyy)			E.g. <u>S</u>	Smith John SMJO
		<u>I</u>			
26.	If you injected in	n the las	st 6 months, how often did you inje	ect?	
	, ,		•		
	More than three	times	most days		1
2-3 times most of		days2			
Once a day					3
More than week		dy, not	daily (uses between 1-6 days per v	week)	4
Less than week		kly			5
Have not injecte		ed in the	e last 6 months		6
27.	What do you co infected with he		the most likely way and other poss C?	ible ways i	n which you became
	Most likely way				Other possible ways
	(Circle one resp	onse o	nly)		(circle all that apply)
	1		Injecting drug use		1
	2		Transfusion of blood products		2
	3		Occupational (needle stick or oth exposure)		3
	4		Sexual exposure to a known HC' person of the same sex	√ positive	4

28. Have you injected in the last month?

5 .....

6.....

7 .....

8 .....

9 .....

10 .....

11 ......

(.....)

Sexual exposure to a known HCV positive

Sexual exposure to persons of unknown

Sexual exposure to persons of unknown

person of the opposite sex

HCV status of the same sex

HCV status of the opposite sex

Use of other recreational drugs

29. How often did you use a NEW sterile needle and syringe last month?

Body piercing

Other, specify

(snorting/inhaling)

**Tattoos** 

.....5

.....6

.....7

.....8

.....9

.....10

.....11

(.....)

RAMPT-C BASEI		BASELIN	NE VISIT
Visit	date	Study number	Patient initials
		0902-	
	/	0902	
(dd/mn	1/yyyy)		E.g. <u>Smith</u> John SMJO
	All initiations		4
	•		
		e	
		onth	
	Not in the last in	OHUI	3
30.		s in the last month have you used a need	dle and/ or syringe after
someo	ne else had alrea	ady used it?	
	None		0
	More than 10 tin	nes	5
31.	What was the <i>la</i> months? <b>LAST DRUG</b>	st drug you ever injected and the drug yo	ou injected <i>most often</i> in last 6  MOST OFTEN LAST 6 MONTHS
	DIGO		LAGI O MONTHO
	1	Heroin	1
	2	Methadone	2
		Other opiates	
		Methamphetamine	
		Amphetamine	
		Cocaine	
		Cocaine +heroin	
		Benzodiazepines	
		Buprenorphine	
	10		
		(	)
		Never injected	99
32. In 1	the last six month	ns have you taken drugs in other wavs ot	her than injecting?
32. In	the last six month	ns have you taken drugs in other ways ot Yes No Time	
32. In	the last six month	· · · · · · · · · · · · · · · · · · ·	es

RAMPT-C	BASELINE VISIT		
Visit date	Study number	Patient initials	
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(dd/mm/yyyy)		E.g. <u>Smith</u> John SMJO	

# TO BE COMPLETED BY ACUTE HCV MSM ONLY

#### **SEXUAL BEHAVIOUR AND PRACTICES**

These questions are about your sexual practices over the last six months. You will be asked about your sexual practices including information about number of partners, HIV status and specific practices that could contribute to sexual transmission of HCV. Remember all of this information is confidential. Your answers will not affect the treatment you receive.

33.	In the past six months, how many different men have you had sex with?
	None0
	One1
	2-5 men 2
	6-10 men 3
	11-50 men 4
	More than 50 men5
34.	In the <u>past six months</u> , how many men of the men you had sex with were men whose HIV status you did not know?
	men
35.	In the <u>past six months</u> , how many of the men had sex with were men you knew were HIV positive?
	men
36.	In the <u>past six months</u> , how many of the men you had sex with, were men you knew were HIV negative?
	men
37.	In the past six months have you been involved in group sex (sex involving more than two individuals)? If so how many times?
	No
	times

RAMPT-C	BASELINE VISIT		
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38. In the last <u>six months</u> how many men have you been involved with the following sexual practice?

Sexual behaviour*	Number of men whose HIV status you did not know	17	Number of men you knew were HIV-negative
Oral sex – you sucked his cock			
•Oral sex – he sucked your cock			
Anal sex – he fucked you with a condom			
Anal sex – you fucked him with a condom			
Anal sex – he fucked you without a condom			
•Anal sex – you fucked him without a condom			
<ul> <li>Fisting – you fisted him while wearing a glove</li> </ul>			
•Fisting – you fisted him without wearing a glove			
•Fisting – he fisted you while wearing a glove			
•Fisting – he fisted you without wearing a glove			
•S/M or bondage without blood			
•S/M or bondage with blood			
<ul> <li>Injected drugs before or during sex</li> </ul>			

RAMPT-C	BASELINE VISIT		
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Thank you for participating and answering these questions.

Do you have any comments you would like to make?				

End of Part I

RAMPT-C	BASELINE VISIT		
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# **PART II – Semen Component**

### **CENTRAL LABORATORY COLLECTION**

Sample collection date	//_ dd/mm/yyyy			
Collected	Yes	No	Comments	
Stored Plasma				
Collected	Yes	No	Comments	
Stored Semen				

# LOCAL LABORATORY COLLECTION

# STI SCREEN

Sample collection date	//
·	dd/mm/yyyy

# Syphilis serology

	Reactive	Non-reactive	Not done	
Syphilis antibody				
Con	firmatory test	s if syphilis antibo	ody reactive	
	Reactive	Non-reactive	Not done	N/A
TPPA				
FTA-ABS				
Non treponemal tests	Titre	Not done	N/A	
RPR				
VDRL				1

RAMPT-C	BASELINE VISIT			
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(dd/mm/yyyy)	0902	E.g. <u>Smith</u> John SMJO		

#### STI SCREEN continued.......

# Chlamydia urine, throat & rectal swab

	Detected	Not detected	Not done
Chlamydia urine			
PCR			
Chlamydia throat swab			
PCR			
Chlamydia rectal swab			
PCR			

# Lymphogranuloma venereum (LGV) rectal swab – only perform if Chlamydia PCR was detected

	Detected	Not detected	Not done	N/A
LGV rectal swab				
PCR				

# Gonorrhoea urine, throat & rectal swab

	Detected	Not detected	Not done
Gonorrhoea urine PCR			
Gonorrhoea throat swab PCR			
Gonorrhoea throat swab	□ 1+		
Culture	□ 2+		
(if detected, indicate 1+, 2+, 3+ or 4+	□ 3+		
by ticking the box)	□ 4+		
Gonorrhoea rectal swab PCR			
Gonorrhoea rectal swab Culture	□ 1+		
(if detected, indicate 1+, 2+, 3+ or 4+	□ 2+		
by ticking the box)	□ 3+		
	□ 4+		

# HSV swab – only perform in the presence of an ulcerative lesion

	Detected	Not detected	Not done	N/A
HSV-1 DNA PCR				
HSV-2 DNA PCR				

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(dd/mm/yyyy)		E.g. <u>Smith</u> John SMJO		

# STI SCREEN continued......

# **HAV** serology

	Detected	Not detected	Equivocal	Not done
HAV total antibody				

### **End of Part II**

RAMPT-C	BASELINE VISIT			
Visit date	Study number	Patient initials		
(dd/mm/yyyy)	0902	E.g. <u>Smith</u> John SMJO		

# **PART III – Behavioural Interview Component**

Has the patien	t been referred to	Dr Garrett Prestag	e for the Behaviour	al mechanisms into	erview?
Referral date _	// dd/mm/yyyy				

**End of Part III**