MRC Clinical Trials Unit | UCL

STOP-HCV Stratified Medicine for HepC

Attach Participant ID label

Form 01 - Screening
Version 4.0 01-Nov-2017

Visit Date: d d m m m y y y y

☞ **To be completed for everyone screened for STOP-HCV-1.**

☞ **Return completed CRFs by secure email to mrcctu.stophcv1@ucl.ac.uk or by fax 0207 670 4817.**

A. DEMOGRAPHICS

1. Participant's initials: ☐☐☐ *(fill in left 2 boxes if only two initials)*

2. Participant's date of birth: d d m m m y y y y

3. Participant's sex at birth: ☐ Male ☐ Female

4a. With what ethnicity does the participant identify?

☐ White ☐ South Asian
☐ South East Asian ☐ Hispanic/Latino
☐ Black Caribbean/American ☐ Black African
☐ Mixed ethnic group b. please specify:_____
☐ Other c. please specify:_____

B. CLINICAL INFORMATION

1. Weight: ☐☐☐ • ☐ kg

2. Height: ☐☐☐ cm

3. BMI: ☐☐ • ☐ kg/m^2

C. HEPATITIS HISTORY

Hepatitis C History

1. What is/are the likely mode(s) of HCV infection?

(Please indicate all risk factors and answer all questions either Yes or No)

a. No known risk factor	☐ Yes	☐ No
b. Injecting drug use	☐ Yes	☐ No
c. Blood/blood products	☐ Yes	☐ No
d. Perinatal exposure	☐ Yes	☐ No
e. Known Hep C positive sexual partner	☐ Yes	☐ No
f. Born abroad	☐ Yes	☐ No
g. High risk sexual partner	☐ Yes	☐ No
h. Tattoo	☐ Yes	☐ No
i. Healthcare exposure	☐ Yes	☐ No
j. Other:	☐ Yes	☐ No

k. If other please specify:_____

2. Date of first HCV positive test: d d m m m y y y y

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C. HEPATITIS HISTORY continued

Two most recent HCV viral load results taken prior to screening:

	Date specimen obtained	Absolute result (IU/mL)	Type of assay used
3.	a. d d m m m y y y y	b. , ,	c. ☐ Cobas Amplicor v2 (Roche) ☐ Realtime HCV (Abbott) ☐ Aptima QuantDX (Hologic) ☐ Versant HCV assay v2 (siemens) ☐ Other d. Please specify _____
4.	a. d d m m m y y y y	b. , ,	c. ☐ Cobas Amplicor v2 (Roche) ☐ Realtime HCV (Abbott) ☐ Aptima QuantDX (Hologic) ☐ Versant HCV assay v2 (siemens) ☐ Other d. Please specify _____

	Date specimen obtained	Genotype/subgenotype
5. HCV genotype/subgenotype result:	a. d d m m m y y y y	b. ☐ 1a ☐ 1b ☐ 4

Hepatitis B History

6. Is the participant Hep B eAg positive? ☐ Yes ☐ No

7. Is the participant Hep B sAg positive? ☐ Yes ☐ No **If C.6 and C.7 are no, go to section D**

8. If yes to C.6 or C.7, is the participant's latest HBV viral load undetectable ☐ Yes ☐ No

9. Date of last undetectable HBV viral load: d d m m m y y y y

D. HIV HISTORY

1. Is the participant HIV infected? ☐ Yes ☐ No **If no, move to section E**

If yes:

2. Date participant first diagnosed with HIV: d d m m m y y y y

3. Record the participant's HIV CDC category:
☐ A
☐ B
☐ C

4. Most recent HIV viral load result taken prior to screening:

Date specimen obtained	Absolute result or limit of quantification (copies/mL)	Mark which is recorded	Type of assay used
a. d d m m m y y y y	b.	c. ☐ Absolute result ☐ Assay lower limit	d. ☐ TaqMan® 2.0 ☐ Aptima QuantDX (Hologic) ☐ Other e. Please specify _____

D. HIV HISTORY continued

5. Last detectable HIV viral load result >1000 copies/mL (if available):

	Date specimen obtained	Absolute result or limit of quantification (copies/mL)	Mark which is recorded	Type of assay used
a.	d d m m m y y y y	b. , ,	c. ☐ Absolute result ☐ Assay upper limit	d. ☐ TaqMan® 2.0 ☐ Aptima QuantDX (Hologic) ☐ Other e. Please specify _____

	Date specimen obtained	Cells/mm³
6. Most recent CD4+ cell count:	a. d d m m m y y y y	b.

E. LIVER FIBROSIS

1. Has the participant ever had a fibroscan? ☐ Yes ☐ No **If no, go to question E.3**

	Date scan obtained	Result
2. If yes, what was the result of their last fibroscan:	a. d d m m m y y y y	b. • kPa

3. Has the participant had a liver biopsy? ☐ Yes ☐ No **If no, go to section F**

	Date biopsy obtained	Score
4. If yes, what was the Ishak score?	a. d d m m m y y y y	b. /6

F. ROUTINE BLOODS

☞ **Please ensure the required blood test results are recorded on Form 02 - Laboratory Results**

(refer to the Trial Assessment Schedule in the STOP-HCV-1 Protocol)

G. RANDOMISATION

1. What is the planned date of randomisation? d d m m m y y y y

Signature:	Printed Name:	Date Completed: d d m m m y y y y

☞ *Please return by secure email to: mrcctu.stophcv1@ucl.ac.uk or by fax 0207 670 4817.*

For office use only:

Date form received at CTU: dd - mmm - yyyy

Date form entered onto database : dd - mmm - yyyy

Initials of data enterer: