MRC Clinical Trials Unit | UCL

STOP-HCV Stratified Medicine for HepC

Attach Participant ID label

**Form 04 - Enrolment**
**Version 2.0 02-Dec-2016**

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

**Day:** 0 0

☞ **Enrolment must take place within 180 days of a Fibroscan or biopsy indicating mild disease and within 60 days of blood test results (except CD4+ cell count which must be within 1 year if HIV infected).**

☞ **Do not complete this form unless Form 03 - Randomisation has been completed, the participant is eligible and will be randomised TODAY.**

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

## A. MEDICAL HISTORY

Has the participant ever had any of the following diagnoses?

If Yes, please indicate if the diagnosis is Current, Recent or Historic.

**Current** = ongoing **Recent** = resolved within the last 12 months **Historic** = resolved more than 12 months ago

| | | b. **Current** | **Recent** | **Historic** |
|---|---|---|---|---|
| 1a. Alcoholism/alcohol abuse | ☐ Yes ☐ No | ☐ | ☐ | ☐ |
| 2a. Illicit substance use | ☐ Yes ☐ No | ☐ | ☐ | ☐ |
| 3a. Depression | ☐ Yes ☐ No | ☐ | ☐ | ☐ |
| 4a. Cerebrovascular accident | ☐ Yes ☐ No | ☐ | ☐ | ☐ |
| 5a. Malignancy | ☐ Yes ☐ No | ☐ | ☐ | ☐ |
| 6a. Peripheral neuropathy | ☐ Yes ☐ No | ☐ | ☐ | ☐ |
| 7a. Cryoglobulinemic vasculitis | ☐ Yes ☐ No | ☐ | ☐ | ☐ |
| 8a. Renal insufficiency | ☐ Yes ☐ No | ☐ | ☐ | ☐ |
| 9a. HCV immune complex-related nephropathy | ☐ Yes ☐ No | ☐ | ☐ | ☐ |
| 10a. Diabetes mellitus | ☐ Yes ☐ No | ☐ | ☐ | ☐ |
| 11a. Hypercholesterlaemia | ☐ Yes ☐ No | ☐ | ☐ | ☐ |
| 12a. Syncope | ☐ Yes ☐ No | ☐ | ☐ | ☐ |
| 13a. Hypertension | ☐ Yes ☐ No | ☐ | ☐ | ☐ |
| 14a. Heart failure | ☐ Yes ☐ No | ☐ | ☐ | ☐ |
| 15a. Angina | ☐ Yes ☐ No | ☐ | ☐ | ☐ |
| 16a. Myocardial infarction | ☐ Yes ☐ No | ☐ | ☐ | ☐ |
| 17a. Coronary artery bypass graft | ☐ Yes ☐ No | ☐ | ☐ | ☐ |

18. What is the participant's cigarette smoking status?

☐ Non-smoker (never smoked)
☐ Past smoker (not currently)
☐ Current smoker

## B. PREVIOUS HCV TREATMENT

1. Has the participant ever spontaneously cleared infection and then become re-infected? ☐ Yes ☐ No
2. Has the participant ever previously been **successfully** treated and then become re-infected? ☐ Yes ☐ No
3. Has the participant previously been treated **unsuccessfully** with interferon and/or ribavirin? ☐ Yes ☐ No
4. If 3. is yes, was the participant
   - an intolerant relapser ☐
   - a relapser after full treatment ☐
   - a non-responder ☐
   - breakthrough on treatment ☐

☞ **If the participant has been successfully or unsuccessfully treated please continue below, if not please move to section C**

Record dates of most recent treatment:

5. **Interferon:** from a. d d m m m y y y y to b. d d m m m y y y y
6. **Ribavirin:** from a. d d m m m y y y y to b. d d m m m y y y y
7. **DAA:** from a. d d m m m y y y y to b. d d m m m y y y y
   c. Please specify which DAAs: _____

## C. STORED SAMPLES

**Required storage**

1. 20 ml whole blood for EDTA plasma

| | **Size of collection tubes** | **Number of tubes collected** | **Date specimen obtained** | **Time of collection** (use 24 hour clock) |
|---|---|---|---|---|
| | a. ☐☐ • ☐ ml | b. ☐☐ | c. d d m m m y y y y | d. h h : m m |

**Optional storage**

2. 2.5 ml whole blood for PAXgene RNA (If genetics consent provided must be taken at Day 0)

a. ☐☐ • ☐ ml b. ☐☐ c. d d m m m y y y y d. h h : m m

3. 2.5 ml whole blood for EDTA DNA (If genetics consent provided can be taken either at day 0 (record below) or at a later date (record on Form 02 - Laboratory Results)

a. ☐☐ • ☐ ml b. ☐☐ c. d d m m m y y y y d. h h : m m

4. 20 ml whole blood for PBMC (Specific sites only)

a. ☐☐ • ☐ ml b. ☐☐ c. d d m m m y y y y d. h h : m m

## D. CONCOMITANT MEDICATIONS

1. Is the participant currently prescribed, or taking regularly without prescription, any medication? (including ARVs if HIV infected) ☐ Yes ☐ No

☞ **If Yes, complete Form 08 – Concomitant Medication and submit by secure email.**

## E. PREGNANCY

1. Is the participant a woman of childbearing potential? ☐ Yes ☐ No **If no, go to Section F**

| | | Date specimen obtained | Result |
|---|---|---|---|
| 2. If yes, record result of urine pregnancy test: | a. | d d m m m y y y y | b. ☐ Positive ☐ Negative |

☞ **For all women of childbearing potential, a negative urine pregnancy test is required at day 0 prior to randomisation.**

## F. POC IL28 (EPISTEM) TEST

1. Was a POC IL28 test performed in clinic today? ☐ Yes ☐ No

2. If yes, what was the result: ☐ IL28 CC ☐ IL28 CT ☐ IL28 TT ☐ No result

3a. If no, why? ☐ No machine at this site ☐ Participant did not consent to this test

☐ Other b. Please specify: _____

☞ **If the participant has consented to POC IL28 test but it was not done, please ensure this is done at a later date and the results are recorded on Form 02 - Laboratory Results.**

## G. QUESTIONNAIRES

☞ **Please ensure Form 05 - EQ-5D, Form 06 - MOSCOG and Form 07 - SF-12 have been completed by the participant.**

## H. ROUTINE BLOODS

☞ **Please ensure blood is taken for haematology, biochemistry and HCV viral load. Record results on Form 02 - Laboratory Results.**

## I. NEXT VISIT

1. Record the dates of the next 3 visits:

a. Day 3 d d m m m y y y y

b. Day 7 d d m m m y y y y

c. Day 14 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: ☐☐☐☐