CONSENT

PID#_____ **Date of Visit** _____

Consent form
All essential parts of the consent form are initialled : Y ☐ N ☐

Optional consent items:
GP to be notified? Y ☐ N ☐
IL-28 gene clinic test Y ☐ N ☐ N/A ☐
Human genetic testing Y ☐ N ☐

Any question asked by the participant and answers should be noted in the participants medical notes

Date Participant signed consent: ☐☐-☐☐☐-☐☐☐☐

Date Investigator signed consent: ☐☐-☐☐☐-☐☐☐☐

SCREENING (1)

PID#_____ **Date of Visit** _____

Demographics
Participant's initials ☐☐☐ DOB ☐☐-☐☐☐-☐☐☐☐
Sex at birth Male☐ Female☐ Ethnicity_____

Clinical Information
Weight _____kg Height _____cm BMI _____kg/m²

Hepatitis C History
Likely mode of HCV infection _____
Date of first positive test ☐☐-☐☐☐-☐☐☐☐
HCV genotype 1a ☐ 1b ☐ 4 ☐
Date of genotype test ☐☐-☐☐☐-☐☐☐☐

Hepatitis B History
Hep B eAg positive Y ☐ N ☐ Hep B sAg positive Y ☐ N ☐
(if Hep B infected) Latest HBV VL is undetectable? Y ☐ N ☐
Date of last undetectable HBV VL ☐☐-☐☐☐-☐☐☐☐

HIV History
HIV Infected Y ☐ N ☐
(if HIV infected) Date of HIV diagnosis ☐☐-☐☐☐-☐☐☐☐
(if HIV infected) HIV CDC category A ☐ B ☐ C ☐

Liver Fibrosis
Fibroscan? Y ☐ N ☐ Result _____kPa
Date of Fibroscan ☐☐-☐☐☐-☐☐☐☐
Liver Biopsy? Y ☐ N ☐ Score: ____/6
Date of Biopsy ☐☐-☐☐☐-☐☐☐☐

Lab results required – tick if collected or previous results are available (within 60 days of randomisation)
Haematology ☐ HCV VL ☐ Coagulation markers ☐
Biochemistry ☐ If HIV infected: HIV VL ☐ CD4+ cell(within 1 year) ☐
Planned date of randomisation: ☐☐-☐☐☐-☐☐☐☐
Sign:_____ Date: _____

RANDOMISATION (1)

PID#_____ **Date of Visit** _____

Inclusion Criteria
Aged ≥ 18 Y ☐ N ☐
HCV genotype 1a, 1b or 4 with access to FL treatment appropriate for their genotype, with at least one detectable viremia 6 months prior to randomisation with no intervening results showing undetectable virema Y ☐ N ☐
HCV RNA>LLOQ at screening Y ☐ N ☐
No sig. evidence of liver fibrosis (within 180 days)
Fibroscan ≤7.1kPa or Ishak score ≤2/6 Y ☐ N ☐
BMI ≥ 18kg/m^2 Y ☐ N ☐
Platelets≥60x10^9/L Y ☐ N ☐
Haemaglobin >12g/dL male or >11 g/dL female Y ☐ N ☐
Creatinine clearance ≥60mL/min Y ☐ N ☐
INR<1.5 Y ☐ N ☐
Screening HCV VL <10,000,000 IU/ml Y ☐ N ☐
Date of HCV VL ☐☐-☐☐☐-☐☐☐☐
HCV VL result ☐☐☐☐☐☐☐
Weight ≥50kg Y ☐ N ☐
If HIV infected: On ART and HIV VL<50copies/mL for >24 weeks N/A ☐ Y ☐ N ☐

Exclusion Criteria
Previous DAA exposure for this infection Y ☐ N ☐
Female lactating pregnant or planning on becoming pregnant, or not willing to use effective contraception during the study and for 4 months after last dose of study medication Y ☐ N ☐
Woman taking eithinyl-oestradiol product Y ☐ N ☐
Male planning pregnancy with partner or not willing to use effective contraception during the study and for 7 months after the last dose of study medication Y ☐ N ☐

RANDOMISATION (2)

PID#_____ **Date of Visit** _____

Exclusion Criteria cont.
Malignancy within 5 years prior to screening Y ☐ N ☐
Any condition that might limit life expectancy Y ☐ N ☐
Taking meds known to interact with study meds Y ☐ N ☐
Disorder which may cause ongoing liver disease Y ☐ N ☐
Disorder which may affect adherence to trial drug Y ☐ N ☐
Investigational products within 60 days Y ☐ N ☐
Hypersensitivity to any active ingredient and/or excipients of study meds Y ☐ N ☐
Severe pre-existing cardiac disease in the previous 6 months Y ☐ N ☐
Haemoglobinopathies Y ☐ N ☐
Record method of contraception_____

Eligiblity outcome
Is the Participant eligible Y ☐ N ☐
Will eligible participant be enrolled Y ☐ N ☐
If No provide reason why _____
Date first dose intended to be taken: ☐☐-☐☐☐-☐☐☐☐
Time ☐☐:☐☐
What first-line treatment will the participant be prescribed
(Mark one box that applies)
VIK and EXV with or without RBV (Genotype 1a/1b only) ☐
VIK with or without RBV (Genotype 4 only) ☐
MVT with or without RBV (Genotype 1a, 1b and 4) ☐

Group Participant randomised to _____days
With Ribavirin ☐ Without Ribavirin ☐
Enrollment number ☐☐☐
Sign:_____ Date: _____