SHARP-C SOURCE DATA PROFORMA

Purpose of This Document:
This proforma is an optional tool you may use to assist in recording SHARP-C study source data. It may be used, in full or part, to record source data or adapted to suit the needs and preferences of your site. If you choose to use this, it can form part of the source documentation for an enrolled patient.

What is Source Data and why is it needed?
All sites participating in this study must maintain source data for all study patients. All of the data entered into the study database (eCRF) need to be verifiable from source – this "Source Data Verification" will be performed during on-site monitoring visits throughout the study.

Source data is defined in (ICH) GCP (1.51) as "all information in original records (and certified copies of original records) of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial". In other words, it is the *first place that data are recorded* and provides evidence for data entered into the database.

Source data are documented in source documents which may be both electronic and paper. Examples of source documents where source data may be located include:
- medical records
- laboratory reports
- nurses', doctors' and allied health progress notes
- dispensing logs
- study questionnaires
- electrocardiogram (ECG) print-outs, etc

How to Use This Proforma:
All of the data entered into the database and listed in this proforma **must** be recorded in source documents. If you wish, you may use this document to record source data for SHARP-C patients. Once completed it will form part of the source documentation for that patient, along with the patient file or medical record, laboratory reports, and other types of source documents such as the examples listed above.

Proforma Document Instructions:
1. Record the patient initials and subject ID at the top of each page.
2. Each visit includes a checklist of the assessments to be completed at that visit. You can use this to tick off the assessments when they are completed.
3. Record the date of each visit.
4. Record the data for each section. Null statements should also be recorded
5. All data recorded should match the data entered into the study database.
6. All corrections and additions must be initialled and dated.

Study number	Patient initials	
1605-□□□□□-□□	□□□□ E.g. <u>Smith</u> John SMJO	SHARP-C

BASELINE VISIT CHECKLIST

Assessment	Complete
1. Eligibility – inclusion/exclusion criteria	□
2. Informed consent	□
3. Demographics	□
4. Recent injecting drug use history	□
5. Current and past opioid substitution therapy (OST) treatment	□
6. Study questionnaire: – Behavioural and health outcomes (EQ-5D-5L) survey	□
7. Hepatitis C testing – HCV RNA – finger-stick point of care testing	□
8. Research specimen collection – EDTA plasma (20mL) and whole blood (4mL)	□

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BASELINE VISIT (week 0)

Date of visit: □□-□□□-□□□□ (DD – MMM – YYYY)

ELIGIBILITY – INCLUSION/EXCLUSION CRITERIA

	YES	NO
• *Eligibility checklist completed and attached*	☐	☐
• *All eligibility criteria satisfied*	☐	☐

If no (and waiver granted) eligibility criteria not met:
_____

Protocol exemption number:
_____

INFORMED CONSENT CONFIRMATION

Version number and date: _____

Date of signature (dd-mmm-yyyy): _____

Staff member who performed consenting with the patient: _____

A copy of the signed Participant Information Sheet and Consent Form provided to the participant? ☐ Yes ☐ No

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DEMOGRAPHICS

Subject date of birth (dd-mmm-yyyy):

_____

Gender:

☐ *Male*

☐ *Female*

☐ *Transgender*

☐ *Other, not specified*

CURRENT INJECTING DRUG USE HISTORY

Record details of current injecting drug use

CURRENT AND PAST OPIOID SUBSTITUTION THERAPY (OST) TREATMENT HISTORY

Record details of current and past OST use.

STUDY QUESTIONNAIRES

Was the baseline behavioural and health outcomes (EQ-5D-5L) survey completed? ☐ *Yes* ☐ *No*

RESEARCH SPECIMEN COLLECTION

Date of collection and sample(s) stored. ***Make sure to complete the research specimen collection log.***

Date of collection (dd-mmm-yyyy), if different from visit date: _____

Research samples:

EDTA plasma (20ml): ☐ *Yes* ☐ *No* *If no result, please specify:_____*	*Whole blood (4ml):* ☐ *Yes* ☐ *No* *If no result, please specify:_____*

Finger-stick GeneXpert HCV RNA point of care test

Sample collected: ☐ *Yes*   ☐ *No*

If yes, result: ☐ *Detected Viral load:* _____ *IU/mL* ☐ *Not detected*

☐ *Invalid*   ☐ *Error Error code:* _____

If no result, specify: _____

Recommended assessments

The study physician is responsible for the treatment and monitoring of participants and their care. It is recommended that the following assessment are conducted as part of standard treatment monitoring. Any results that are generated from these assessments must be collected as part of the study data.

Assessment	Complete
1. Fibroscan® **OR** APRI score	☐

LIVER STAGING (Please record either the Fibroscan OR the APRI score, not both)

Fibroscan

Fibroscan results in past 2 years are available? ☐ *Yes, complete details below:*   ☐ *No*

Date of fibroscan (dd-mmm-yyyy): _____

Median stiffness (Kpa): _____

Interquartile range (Kpa): _____

Total readings: Valid readings: _____

Make sure to keep the fibroscan report in the patients notes.

OR

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APRI score

Date of APRI score calculation (dd-mmm-yyyy): _____

AST level (IU/L): _____

Platelet count (10^9/L): _____

APRI Score: _____

Visit	Study questionnaires	Hepatitis C testing *HCV RNA – Finger-stick point of care testing*	Research specimen collection *If the HCV RNA point of care test is **positive** or returns and **error OR invalid** result.*	HCV RNA testing (Local Laboratory)
ETR (variable week dependant on treatment regimen) Visit date: ☐ Not attended Why?_____ _____	☐ Follow up behavioural and health outcomes (EQ-5D-5L) survey	Sample collected: ☐ Yes　　☐ No If yes, result:　If no, why?_____ ☐ Not detected ☐ Detected　*Viral Load ___IU/mL* ☐ Invalid ☐ Error　*Error Code:_____* **NOTE** *if the HCV RNA POC is **positive (detected)** or displays and **error** OR **invalid** result a research sample and local lab sample will need to be collected.*	Date of collection (dd-mmm-yyyy), if different from visit date: _____ Research samples collected: EDTA plasma (10mL): Yes ☐ 　　　　　　　　　**PLUS** No ☐ *Make sure to complete the research specimen log* ☐ Not applicable	Specimen for HCV RNA collected: ☐ Yes　　☐ No Date of collection (dd-mmm-yyyy), if different from visit date: _____ HCV RNA quantitation result: ☐ *Non-quantifiable and undetected* ☐ *No quantifiable and detected* ☐ *Quantifiable Result:* _____IU/mL ☐ Not applicable
SVR12 (week 12) Visit date: ☐ Not attended Why?_____ _____	☐ Follow up behavioural and health outcomes (EQ-5D-5L) survey	Sample collected: ☐ Yes　　☐ No If yes, result:　If no, why?_____ ☐ Not detected ☐ Detected　*Viral Load ___IU/mL* ☐ Invalid ☐ Error　*Error Code:_____* **NOTE** *if the HCV RNA POC is **positive (detected)** or displays and **error** OR **invalid** result a research sample and local lab sample will need to be collected.*	Date of collection (dd-mmm-yyyy), if different from visit date: _____ Research samples collected: EDTA plasma (10mL): Yes ☐ 　　　　　　　　　**PLUS** No ☐ *Make sure to complete the research specimen log* ☐ Not applicable	Specimen for HCV RNA collected: ☐ Yes　　☐ No Date of collection (dd-mmm-yyyy), if different from visit date: _____ HCV RNA quantitation result: ☐ *Non-quantifiable and undetected* ☐ *No quantifiable and detected* ☐ *Quantifiable Result:* _____IU/mL ☐ Not applicable

			Study number	Patient initials	SHARP-C

Study number

1605-☐☐☐☐☐-☐☐

Patient initials

☐☐☐☐

E.g. Smith John SMJO

Visit	Study questionnaires	Hepatitis C testing *HCV RNA – Finger-stick point of care testing*	Research specimen collection *If the HCV RNA point of care test is* ***positive*** *or returns and* ***error OR invalid*** *result.*	HCV RNA testing (Local Laboratory)
SVR 24 (week 24) Visit date: ☐ Not attended Why?_____ _____	☐ Follow up behavioural and health outcomes (EQ-5D-5L) survey	Sample collected: ☐ Yes ☐ No If yes, result: If no, why?_____ ☐ Not detected ☐ Detected *Viral Load ___IU/mL* ☐ Invalid ☐ Error *Error Code:_____* ***NOTE*** *if the HCV RNA POC is* ***positive (detected)*** *or displays and* ***error*** *OR* ***invalid*** *result a research sample and local lab sample will need to be collected.*	Date of collection (dd-mmm-yyyy), if different from visit date: _____ Research samples collected: EDTA plasma (10mL): **PLUS** Yes ☐ No ☐ *Make sure to complete the research specimen log* ☐ Not applicable	Specimen for HCV RNA collected: ☐ Yes ☐ No Date of collection (dd-mmm-yyyy), if different from visit date: _____ HCV RNA quantitation result: ☐ *Non-quantifiable and undetected* ☐ *No quantifiable and detected* ☐ *Quantifiable Result:* _____IU/mL ☐ Not applicable
FU1 (week 36) Visit date: ☐ Not attended Why?_____ _____	☐ Follow up behavioural and health outcomes (EQ-5D-5L) survey	Sample collected: ☐ Yes ☐ No If yes, result: If no, why?_____ ☐ Not detected ☐ Detected *Viral Load ___IU/mL* ☐ Invalid ☐ Error *Error Code:_____* ***NOTE*** *if the HCV RNA POC is* ***positive (detected)*** *or displays and* ***error*** *OR* ***invalid*** *result a research sample and local lab sample will need to be collected.*	Date of collection (dd-mmm-yyyy), if different from visit date: _____ Research samples collected: EDTA plasma (10mL): **PLUS** Yes ☐ No ☐ *Make sure to complete the research specimen log* ☐ Not applicable	Specimen for HCV RNA collected: ☐ Yes ☐ No Date of collection (dd-mmm-yyyy), if different from visit date: _____ HCV RNA quantitation result: ☐ *Non-quantifiable and undetected* ☐ *No quantifiable and detected* ☐ *Quantifiable Result:* _____IU/mL ☐ Not applicable

Study number

1605-☐☐☐☐☐-☐☐

Patient initials

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E.g. Smith John SMJO

SHARP-C

Visit	Study questionnaires	Hepatitis C testing *HCV RNA – Finger-stick point of care testing*	Research specimen collection *If the HCV RNA point of care test is **positive** or returns and **error OR invalid** result.*	HCV RNA testing (Local Laboratory)
FU2 (week 48) Visit date: ☐ Not attended Why?_____ _____	☐ Follow up behavioural and health outcomes (EQ-5D-5L) survey	Sample collected: ☐ Yes ☐ No If yes, result: If no, why?_____ ☐ Not detected ☐ Detected *Viral Load ___IU/mL* ☐ Invalid ☐ Error *Error Code:_____* ***NOTE** if the HCV RNA POC is **positive (detected)** or displays and **error** OR **invalid** result a research sample and local lab sample will need to be collected.*	Date of collection (dd-mmm-yyyy), if different from visit date: _____ Research samples collected: EDTA plasma (10mL): **PLUS** Yes ☐ No ☐ *Make sure to complete the research specimen log* ☐ Not applicable	Specimen for HCV RNA collected: ☐ Yes ☐ No Date of collection (dd-mmm-yyyy), if different from visit date: _____ HCV RNA quantitation result: ☐ *Non-quantifiable and undetected* ☐ *No quantifiable and detected* ☐ *Quantifiable Result:* _____IU/mL ☐ Not applicable
FU3 (week 60) Visit date: ☐ Not attended Why?_____ _____	☐ Follow up behavioural and health outcomes (EQ-5D-5L) survey	Sample collected: ☐ Yes ☐ No If yes, result: If no, why?_____ ☐ Not detected ☐ Detected *Viral Load ___IU/mL* ☐ Invalid ☐ Error *Error Code:_____* ***NOTE** if the HCV RNA POC is **positive (detected)** or displays and **error** OR **invalid** result a research sample and local lab sample will need to be collected.*	Date of collection (dd-mmm-yyyy), if different from visit date: _____ Research samples collected: EDTA plasma (10mL): **PLUS** Yes ☐ No ☐ *Make sure to complete the research specimen log* ☐ Not applicable	Specimen for HCV RNA collected: ☐ Yes ☐ No Date of collection (dd-mmm-yyyy), if different from visit date: _____ HCV RNA quantitation result: ☐ *Non-quantifiable and undetected* ☐ *No quantifiable and detected* ☐ *Quantifiable Result:* _____IU/mL ☐ Not applicable

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Visit	Study questionnaires	Hepatitis C testing *HCV RNA – Finger-stick point of care testing*	Research specimen collection *If the HCV RNA point of care test is* ***positive*** *or returns and* ***error OR invalid result.***	HCV RNA testing (Local Laboratory)
FU4 (week 72) Visit date: ☐ Not attended Why?_____ _____	☐ Follow up behavioural and health outcomes (EQ-5D-5L) survey	Sample collected: ☐ Yes ☐ No If yes, result: If no, why?_____ ☐ Not detected ☐ Detected *Viral Load ___IU/mL* ☐ Invalid ☐ Error *Error Code:_____* ***NOTE*** *if the HCV RNA POC is* ***positive (detected)*** *or displays and* ***error*** *OR* ***invalid*** *result a research sample and local lab sample will need to be collected.*	Date of collection (dd-mmm-yyyy), if different from visit date: _____ Research samples collected: EDTA plasma (10mL): Yes ☐ **PLUS** No ☐ *Make sure to complete the research specimen log* ☐ Not applicable	Specimen for HCV RNA collected: ☐ Yes ☐ No Date of collection (dd-mmm-yyyy), if different from visit date: _____ HCV RNA quantitation result: ☐ *Non-quantifiable and undetected* ☐ *No quantifiable and detected* ☐ *Quantifiable Result:* _____IU/mL ☐ Not applicable
FU5 (week 84) Visit date: ☐ Not attended Why?_____ _____	☐ Follow up behavioural and health outcomes (EQ-5D-5L) survey	Sample collected: ☐ Yes ☐ No If yes, result: If no, why?_____ ☐ Not detected ☐ Detected *Viral Load ___IU/mL* ☐ Invalid ☐ Error *Error Code:_____* ***NOTE*** *if the HCV RNA POC is* ***positive (detected)*** *or displays and* ***error*** *OR* ***invalid*** *result a research sample and local lab sample will need to be collected.*	Date of collection (dd-mmm-yyyy), if different from visit date: _____ Research samples collected: EDTA plasma (10mL): Yes ☐ **PLUS** No ☐ *Make sure to complete the research specimen log* ☐ Not applicable	Specimen for HCV RNA collected: ☐ Yes ☐ No Date of collection (dd-mmm-yyyy), if different from visit date: _____ HCV RNA quantitation result: ☐ *Non-quantifiable and undetected* ☐ *No quantifiable and detected* ☐ *Quantifiable Result:* _____IU/mL ☐ Not applicable

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1605-□□□□□-□□	□□□□
	E.g. <u>Smith</u> John SMJO

SHARP-C

Visit	Study questionnaires	Hepatitis C testing *HCV RNA – Finger-stick point of care testing*	Research specimen collection *If the HCV RNA point of care test is **positive** or returns and **error OR invalid** result.*	HCV RNA testing (Local Laboratory)
FU6 (week 96) Visit date: ☐ Not attended Why?_____ _____	☐ Follow up behavioural and health outcomes (EQ-5D-5L) survey	Sample collected: ☐ Yes ☐ No If yes, result: If no, why?_____ ☐ Not detected ☐ Detected *Viral Load ___IU/mL* ☐ Invalid ☐ Error *Error Code:_____* **NOTE** *if the HCV RNA POC is **positive (detected)** or displays and **error** OR **invalid** result a research sample and local lab sample will need to be collected.*	Date of collection (dd-mmm-yyyy), if different from visit date: _____ Research samples collected: EDTA plasma (10mL): Yes ☐ **PLUS** No ☐ *Make sure to complete the research specimen log* ☐ Not applicable	Specimen for HCV RNA collected: ☐ Yes ☐ No Date of collection (dd-mmm-yyyy), if different from visit date: _____ HCV RNA quantitation result: ☐ *Non-quantifiable and undetected* ☐ *No quantifiable and detected* ☐ *Quantifiable Result:* _____IU/mL ☐ Not applicable
FU7 (week 108) Visit date: ☐ Not attended Why?_____ _____	☐ Follow up behavioural and health outcomes (EQ-5D-5L) survey	Sample collected: ☐ Yes ☐ No If yes, result: If no, why?_____ ☐ Not detected ☐ Detected *Viral Load ___IU/mL* ☐ Invalid ☐ Error *Error Code:_____* **NOTE** *if the HCV RNA POC is **positive (detected)** or displays and **error** OR **invalid** result a research sample and local lab sample will need to be collected.*	Date of collection (dd-mmm-yyyy), if different from visit date: _____ Research samples collected: EDTA plasma (10mL): Yes ☐ **PLUS** No ☐ *Make sure to complete the research specimen log* ☐ Not applicable	Specimen for HCV RNA collected: ☐ Yes ☐ No Date of collection (dd-mmm-yyyy), if different from visit date: _____ HCV RNA quantitation result: ☐ *Non-quantifiable and undetected* ☐ *No quantifiable and detected* ☐ *Quantifiable Result:* _____IU/mL ☐ Not applicable

Visit	Study questionnaires	Hepatitis C testing *HCV RNA – Finger-stick point of care testing*	Research specimen collection *If the HCV RNA point of care test is* **positive** *or returns and* **error OR invalid** *result.*	HCV RNA testing (Local Laboratory)
FU8 (week 120) Visit date: ☐ Not attended Why?_____ _____	☐ Follow up behavioural and health outcomes (EQ-5D-5L) survey	Sample collected: ☐ Yes ☐ No If yes, result: If no, why?_____ ☐ Not detected ☐ Detected *Viral Load ___IU/mL* ☐ Invalid ☐ Error *Error Code:_____* **NOTE** *if the HCV RNA POC is* **positive (detected)** *or displays and* **error** OR **invalid** *result a research sample and local lab sample will need to be collected.*	Date of collection (dd-mmm-yyyy), if different from visit date: _____ Research samples collected: EDTA plasma (10mL): Yes ☐ **PLUS** No ☐ *Make sure to complete the research specimen log* ☐ Not applicable	Specimen for HCV RNA collected: ☐ Yes ☐ No Date of collection (dd-mmm-yyyy), if different from visit date: _____ HCV RNA quantitation result: ☐ *Non-quantifiable and undetected* ☐ *No quantifiable and detected* ☐ *Quantifiable Result:* _____IU/mL ☐ Not applicable
FU9 (week 132) Visit date: ☐ Not attended Why?_____ _____	☐ Follow up behavioural and health outcomes (EQ-5D-5L) survey	Sample collected: ☐ Yes ☐ No If yes, result: If no, why?_____ ☐ Not detected ☐ Detected *Viral Load ___IU/mL* ☐ Invalid ☐ Error *Error Code:_____* **NOTE** *if the HCV RNA POC is* **positive (detected)** *or displays and* **error** OR **invalid** *result a research sample and local lab sample will need to be collected.*	Date of collection (dd-mmm-yyyy), if different from visit date: _____ Research samples collected: EDTA plasma (10mL): Yes ☐ **PLUS** No ☐ *Make sure to complete the research specimen log* ☐ Not applicable	Specimen for HCV RNA collected: ☐ Yes ☐ No Date of collection (dd-mmm-yyyy), if different from visit date: _____ HCV RNA quantitation result: ☐ *Non-quantifiable and undetected* ☐ *No quantifiable and detected* ☐ *Quantifiable Result:* _____IU/mL ☐ Not applicable

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1605-☐☐☐☐☐-☐☐	☐☐☐☐ E.g. Smith John SMJO	SHARP-C

Visit	Study questionnaires	**Hepatitis C testing** *HCV RNA – Finger-stick point of care testing*	**Research specimen collection** *If the HCV RNA point of care test is **positive** or returns and **error OR invalid** result.*	**HCV RNA testing (Local Laboratory)**
FU10 (week 144) Visit date: ☐ Not attended Why?_____ _____	☐ Follow up behavioural and health outcomes (EQ-5D-5L) survey	Sample collected: ☐ Yes ☐ No If yes, result: If no, why?_____ ☐ Detected *Viral Load* ___ *IU/mL* ☐ Not detected ☐ Invalid ☐ Error *Error Code:_____* **NOTE** *if the HCV RNA POC is **positive (detected)** or displays and **error** OR **invalid** result a research sample and local lab sample will need to be collected.*	Date of collection (dd-mmm-yyyy), if different from visit date: _____ Research samples collected: EDTA plasma (10mL): Yes ☐ **PLUS** No ☐ *Make sure to complete the research specimen log* ☐ Not applicable	Specimen for HCV RNA collected: ☐ Yes ☐ No Date of collection (dd-mmm-yyyy), if different from visit date: _____ HCV RNA quantitation result: ☐ *Non-quantifiable and undetected* ☐ *No quantifiable and detected* ☐ *Quantifiable Result:* _____*IU/mL* ☐ Not applicable

Study number 1605-□□□□□-□□	Patient initials □□□□ E.g. <u>Smith</u> John SMJO	SHARP-C

STUDY TERMINATION

Study termination date: □□-□□□□-□□□□ (DD – MMM – YYYY)

STUDY TERMINATION DATA

Include reason for non-completion of study (if applicable) and last date of patient contact.
For patient death include date and cause of death.

Reason for non-completion: _____

_____

_____

_____

Date of last contact (dd-mmm-yyyy): _____

In the event of death, please complete SHARP-C SAE form.