# SIMPLICITY STUDY PARTICIPANT INFORMATION SHEET

***THIS IS FOR YOU TO KEEP.***

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| **Site:** | John Hunter |
| **Principal Researchers**:  Associate Investigator(s)  Location | *Dr Joshua Davis*  *Mel Young & Tracey Jones*  *John Hunter Hospital* |
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| **Full Project Title:** | **S**tandard versus m**I**ninal **M**onitoring : **P**ragmatic tria**L** **I**n hepatitis **C** **T**reatment - SIMPLICITY Trial |

We invite you to take part in this research project. If you decide to take part in this study we will give you a copy of this information sheet. Interpreters are available if you need them to help you make your decision. If you would like to use an interpreter who speaks your own language, please let a study team member know and we will be happy to arrange one for you.

### Purpose and background

In March 2016, several new, all oral treatments became available in Australia for chronic hepatitis C virus (HCV) infection, bringing the “interferon era” to a close. These new treatments are much easier to take and more effective than the previous standard treatment, which was based on an injected medicine called interferon.

Although we know these new treatments are very safe, with side effect rates in clinical trials similar to placebo (sugar pills), we don’t know exactly how much monitoring is needed during a course of treatment. A “standard” monitoring plan has recently been developed by Australian experts, but this is based on what we know of the new treatments, and it has never been directly compared with less intensive monitoring.

For the old interferon-based treatments, patients had some blood tests and a clinic appointment every 2 to 4 weeks for at least 24 weeks. For the new all-oral treatments, we know that much less intense monitoring is needed, but different monitoring strategies have not been tested in clinical trials.

The purpose of SIMPLICITY is to compare “standard monitoring” with “minimal monitoring”, to determine if minimal monitoring results in similar cure rates but with lower cost and better patient satisfaction. The SIMPLICITY trial is being co-ordinated by Associate Professor Joshua Davis, who is based at John Hunter Hospital in Newcastle, and at the Menzies School of Health Research in Darwin. It aims to enrol a total of 140 participants at three sites in Australia (Brisbane, Darwin and Newcastle).

“Minimal monitoring” does not mean missing out on medical care. It just means less frequent blood tests and clinic visits, as detailed under “procedures” below.

### Study medications

There are no medications being given specifically as part of this study. You will receive the same medications whether or not you choose to take part in this study. The only difference between the two study arms is the number of blood tests and clinic visits during your course of treatment. The new treatments that are relevant to this trial are a combination of two medicines: Sofosbuvir plus ledipasvir (also known as Harvoni, all in one pill), or Sofosbuvir plus Daclatasvir (2 pills). Which treatment you receive will be decided by your doctor, and is determined by which genotype of HCV you have.

### Procedures

After you have had a routine “pre-treatment assessment” by your treating team and you and your doctors/nurses are ready to start treatment, you may be invited to participate in this trial.

Taking part in the study involves:

* Being randomly allocated (like the flip of a coin) to either the “standard” or “minimal” monitoring arm – see the below table for details. In summary, the standard arm will have 4 clinic visits and 4 blood tests during and after the course of treatment, whereas the minimal arm will have 2 clinic visits, 2 phone calls to check on progress and 2 blood tests (one as part of pre-treatment assessment and one 12 weeks after the end of treatment).
* Having some information collected about your health and also your progress during and after your treatment
* You will receive the exact same treatment whether or not you choose to take part in the study. That treatment will be decided by your doctor, and will be either 8 or 12 weeks of Sofosbuvir-based treatment, 1-2 tablets per day.

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|  | **Standard Arm** | **Minimal Arm** |
| **Treatment day 0** | Clinic visit  Blood tests  Pick up medication from pharmacy | Clinic visit  Pick up medication from pharmacy |
| **Treatment week 4** | Clinic visit  Blood tests | Phone call |
| **End of treatment (week 8 OR 12)** | Clinic visit  Blood tests  Patient satisfaction survey | Phone call  Patient satisfaction survey |
| **12 weeks after the end of treatment (week +12)** | Clinic visit  Blood tests  Patient satisfaction survey | Clinic visit  Blood tests  Patient satisfaction survey |

* Whichever study arm you are in, you will be able to contact your treating team at any time if you have concerns about side effects or other aspects of your treatment
* If your treating team thinks it is needed, you may have extra clinic visits or blood tests during your treatment, regardless of study arm.
* The blood tests you have taken while on this trial are routine clinical tests. Your blood will not undergo any special testing that is not described in this patient information sheet, and your blood will not be retained for research purposes.
* The blood tests taken will include full blood count, electrolytes and kidney function, liver function tests, and hepatitis C viral load.

### Possible benefits

Due to the HCV treatment you will receive, there is an over 90% chance of being permanently cured. This is the case whether or not you take part in the study. If you are in the minimal monitoring arm, you will have less hospital visits and blood tests than the standard arm. For the study overall, there is no direct benefit to you, but there may be significant benefit to future patients and to the health care system.

You will not receive any payment for taking part in this study. The cost of your medicines and blood tests will be covered by the Federal and State governments (PBS and Medicare), whether or not you take part in the trial.

### Possible risks

If you are in the standard arm, there is no risk associated with being in the study over and above the risk of the treatment itself. If you are in the minimal monitoring arm, you will receive blood tests less often than in the standard arm, and it is thus possible we will miss a treatment-related side effect if you have no symptoms. As demonstrated below, this is very unlikely to pose an actual risk. In combined phase 3 clinical trials of sofosbuvir-based treatment, the only blood test abnormalities which occurred in >=1% of patients were:

* “Bilirubin” elevation to >1.5 times the upper limit of normal. This occurred in 1-3% of patients, caused no symptoms and completely resolved after the end of the treatment course.
* “Lipase” elevation to >3 times the upper limit of normal. This occurred in 1-3% of patients, caused no symptoms and completely resolved after the end of the treatment course.
* “Creatine Kinase” elevation to >10 times the upper limit of normal. This occurred in 0 to 1% of patients, caused no symptoms and completely resolved after the end of the treatment course.

### Privacy, Confidentiality and Disclosure of Information

Any information about you which we obtain for this research project will remain confidential and will only be used for the purpose of this research project. The study doctor and research team will use health data about you to conduct this study, as described in this document. This may include your name, address, phone number, medical history, date of birth, and information from your study visits.

### Participation is Voluntary

Participation in any research project is voluntary. If you do not wish to take part you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

Any decision you make will not affect your treatment or relationship with the [either the Immunology/Infectious Disease or Gastroenterology Department staff at the John Hunter Hospital].

### Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the Hunter New England Human Research Ethics Committee (application reference number 16/04/20/4.01)

This project will be carried out according to the National Statement on Ethical Conduct in Human Research (2007). This statement has been developed to protect the interests of people who agree to participate in human research studies.

### Further information and who to contact

If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project (for example, any side effects), you can contact the project manager, Mel Young on phone 49 21473 or email [Melissa.Young@hnehealth.nsw.gov.au](mailto:Melissa.Young@hnehealth.nsw.gov.au), or the principal study doctor, Dr Josh Davis on email Joshua.Davis@hnehealth.nsw.gov.au

If have any queries about the ethical approval of this project, or wish to make a complaint to an independent person, please contact the approving ethics and local research governance contact: Dr Nicole Gerrand, Manager, Research Ethics and Governance Unit, Hunter New England Human Research Ethics Committee, Hunter New England Local Health District, Locked Bag 1, New Lambton NSW 2305, telephone (02) 49214950, email [Hnehrec@hnehealth.nsw.gov.au](mailto:Hnehrec@hnehealth.nsw.gov.au), and quote reference number [insert SSA reference number]

**Thank you for taking the time to consider this study.**

**If you wish to take part in it, please sign the attached consent form.**

**Dr Joshua Davis,**

Senior Staff Specialist Infectious Diseases Physician, John Hunter Hospital

Principal Research Fellow, Menzies School of Health Research

Conjoint Professor, School of Medicine and Public Health, University of Newcastle

