Participant Information Sheet/Consent Form

Non-Interventional Study - *Adult providing own consent*

Fairfield Hospital

Title	*Screening Emergency Admissions at Risk of Chronic Hepatitis 3 – EXtension Pilot Program*
Short Title	*SEARCH 3X*
Protocol Number	*3.0*
Project Sponsor	*South Western Sydney Local Health District*
Coordinating Principal Investigator/ Principal Investigator	*Associate Professor Miriam Levy*
Site principal investigator and Location	*Dr Jeremy Lawrence* *Fairfield Hospital – Emergency Department* *Cnr Polding Street and Prairievale Rd* *PRAIRIEWOOD NSW 2176*

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in this research project, SEARCH 3X. This is because you have attended the emergency department and are having a blood test for your standard clinical care.

This project involves offering hepatitis B and C testing to all adult patients who present to the emergency department, who are having blood collected as part of their standard clinical care. No extra blood samples are required for this testing and participation will not impact your emergency department care in any way.

This project is being run in several emergency departments around New South Wales and has the support on the NSW Ministry of Health. This program is being run because many patients living with hepatitis infection are unaware. Untreated hepatitis places people at increased risk of many bad health outcomes including liver disease and liver cancer. Additionally, both hepatitis B and C now have readily available treatments and detection and treatment are critical to prevent complications.

Your emergency clinician will discuss the project will you and ask for your consent to perform a hepatitis B and C test. If you do not wish to be tested, simply inform them. Participation in this project is voluntary. If you don't wish to take part, you don't have to. You will receive the best possible care whether or not you take part.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and research involved. Knowing what is involved will help you decide if you want to take part in the research.

2 What is the purpose of this research?

The purpose of this project is to see if this method of hepatitis testing, which is - offering testing to all adult patients who are having blood collected within the emergency department, is effective. Effectiveness will be judged based on the rate of testing uptake, the number of tests performed and the results of the tests.

For patients found to have positive hepatitis tests the program will also evaluate if this program is an effective way to link these patients to clinical care and make sure they receive the best treatment based on their individual circumstances.

This research has been initiated by the study doctor, Associate Professor Miriam Levy. This research has been funded by The NSW Ministry of Health. This research is being conducted by South Western Sydney Local Health District and The Kirby Institute at the UNSW Sydney in Sydney Australia.

3 What does participation in this research involve?

If you choose to participate in this study, hepatitis B and C testing will be run along with your other standard tests within the emergency department. No additional blood samples will need to be collected for this.

4 What do I have to do?

If you wish to participate and be tested for hepatitis B and C, tell your emergency clinician when they ask you. If you test positive, a hospital nurse will contact you.

5 Other relevant information about the research project

This research project will run at several public hospital emergency departments across NSW, Australia. It is anticipated that over 20,000 patients will have testing performed throughout the life of the project. The project has the support of the NSW Ministry of Health.

6 Do I have to take part in this research project?

Participation is this program is voluntary. If you do not wish to take part, please inform your emergency clinician when they discuss this project with you. Your decision whether or not to take part will not affect your routine treatment or your relationship with those treating you in the emergency department.

7 What are the alternatives to participation?

Participation is this program is voluntary. If you chose to not participate you will receive standard care within the emergency department.

8 What are the possible benefits of taking part?

You may not receive any direct benefit from your participation. Your participation may help to improve hepatitis screening and elimination strategies used in the future.

If you test positive for hepatitis B or C, you will be contacted by a hospital nurse and you may benefit from being engaged with a Liver nurse and doctor to check your liver health and start treatment where required per standard clinical care.

9 What are the possible risks and disadvantages of taking part?

No risks or disadvantages in participating have been identified.

10 What will happen to my test samples?

Your test samples will be treated in the same way as all the other blood samples that are collected within the emergency department as part of your clinical care. These samples are stored for a set period of time and then disposed of as regulated by NSW Health Pathology laboratory standard operating procedures.

11 Could this research project be stopped unexpectedly?

This project could be stopped unexpectedly for a variety of reasons (although unlikely). This may include decisions from the sponsor or by local regulatory/health authorities.

12 What happens when the research project ends?

When the research is complete, results of the study will be disseminated by NSW Ministry of Health, published in peer reviewed journal articles and disseminated by community organisations representative of people living with Hepatitis B and C.

Part 2 How is the research project being conducted?

13 What will happen to information about me?

No identifying data will be collected about you. If you test negative for hepatitis you will not be contacted. If you test positive for hepatitis you will be contacted by a member of staff at the hospital to discuss the next steps for your clinical care.
Patients with positive hepatitis tests will also be contacted to see if they would be interested in participating in an observational study of patients detected through this program. This aspect of the project has a separate more detailed patient information sheet and consent process.

14 Compensation

You will not receive compensation for participating in this study.

15 Who is organising and funding the research?

The research project is being conducted by Associate Professor Miriam Levy and sponsored by South Western Sydney Local Health District. Funding has been provided by the NSW Ministry of Health. No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

16 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 HREC of South Western Sydney Local Health District 2022/ETH01158 and the Aboriginal Health & Medical Research Council of NSW 2037/22 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

17 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 principal study doctor on [phone number] or any of the following people:

Clinical contact person

Name	*Melissa Bagatella*
Position	*Liver Clinical Nurse Consultant*
Telephone	*02 8738 3571*
Email	*Melissa.fraser@health.nsw.gov.au*

18 Complaints contact person

This study has been approved by the South Western Sydney Local Health District Human Research Ethics Committee. Any person with concerns or complaints about the conduct of this study should contact the Research and Ethics Office, Locked Bag 7103, LIVERPOOL BC NSW 1871 on 02 8738 8304 / fax 02 8738 8310 / email SWSLHD-ethics@health.nsw.gov.au, website: http://www.swslhd.nsw.gov.au/ethics/default.html and quote [[2022/STE03847].

You may also contact:

Reviewing HREC name	Aboriginal Health & Medical Research Council Ethics Committee
HREC Executive Officer	Chairperson
Telephone	02 9212 4777
Email	ethics@ahmrc.org.au

Thank you for taking the time to consider this study.
If you wish to take part in it, please sign the attached consent form.
This information sheet is for you to keep.