

Participant Information Statement



THE UNIVERSITY OF
SYDNEY

Research Study: OCEAN Nurse Practitioner (NP) Pilot Study



UNIVERSITY
OF WOLLONGONG
AUSTRALIA

Dr Christopher Harrison & Dr Julie Gordon
Chief Investigators of the OCEAN Study
Sydney School of Public Health
Faculty of Medicine
Phone: 1800 262 326 (free call)
Email: ocean.study@sydney.edu.au

You are invited to pilot test a new data collection method for use by nurse practitioners (NPs). The method involves entering data about patient encounters into an internet-based electronic interface called OCEAN (Occasions of Care Explained and Analysed).

What is the study about? While nurses have been working in general practice for many years, the lack of large-scale research of their practice activity means there is no reliable information about the problems that present to, or are managed by, general practice nurses (GPNs) and nurse practitioners in a primary care/community health setting. They see a broad range of the population daily, including those who have difficulty accessing health care services due to differences in culture/language; sexual orientation/practices; gender diversity; substance use/abuse; and mental health problems. To devise the most appropriate policies for care delivery by NPs, base-line evidence is needed. OCEAN provides a method through which we can measure the care provided and inform the policies directing it.

The OCEAN tool has been created for use in several planned projects about NP activity. The OCEAN tool has undergone technical testing, and we are ready to pilot test the data collection process to assess how well the tool works in planning a larger study. We are seeking up to 10 NPs to participate in the pilot study. **Please read this sheet carefully and ask questions about anything that you don't understand or want to know more about.**

Who is running the study? The study is being carried out by the following researchers:
At the University of Sydney -

- Dr Christopher Harrison, Senior Lecturer, Sydney School of Public Health
- Dr Julie Gordon, Senior Research Fellow, Sydney School of Public Health, Senior Lecturer, Sydney Medical School
- Prof Susan Randall, Professor of Nursing (Rural and Remote/Primary Health Care), University Department of Rural Health
- A/Prof Joan Henderson, Associate Professor, Sydney School of Public Health
- Prof Sarah Dennis, Professor of Allied Health, Sydney School of Health Sciences
- Ms Imelda Noti, Classifications Business Co-ordinator, WHO-CC for Strengthening Rehabilitation Capacity in Health Systems, Classifications and Terminologies
- Dr Yang Lu, Research Fellow, Sydney School of Public Health
- Dr Kate Milledge, Project Manager, Sydney School of Public Health

At the University of Wollongong -

- Prof Elizabeth Halcomb, Professor of Primary Health Care Nursing
- Dr Jason Zhang, Software Engineer
- Dr Ruth Mursa, Research Fellow, Registered Nurse

Who is funding the study? The study is being funded by the Australian Government Department of Health and Aged Care (DoHAC) to provide information about the clinical and non- clinical activity of nurse practitioners working in Australian general practices. There are no potential or actual conflicts of interest for the researchers, sponsors or institutions involved in the project. There are no financial benefits to the researchers or the University that might arise from this research.

Who can take part in the study? Endorsed NPs currently working in a general practice setting.

What will the study involve for you? There are two parts to the study:

1. Completing a Professional Profile form
2. Completing 100 clinical encounter forms.

In Part 1, you will be asked to complete the Professional Profile form, which involves entering information about your education, skills and experience to gather information about the NP workforce, for future planning. We expect that the form will take 20-30 minutes to complete. You do not need to complete the form immediately. You can log into the OCEAN platform to complete it at a later time. The survey works best if you enter the data on a computer or laptop, but you can also complete the survey on a tablet/iPad or mobile phone.

In Part 2, you will be asked to enter information about 100 consecutive encounters with consenting patients into an electronic 'form'. The form works best if completed on a computer (not a tablet/iPad or mobile phone). The information will be about that day's visit only and will include: patient's age and sex/gender; reasons for their encounter (i.e., the reason/s they are seeing you); the problems/conditions you are managing/treating for them at the encounter; and any medications and other treatments you provide for those problems/conditions (not a complete medical history). We ask that you collect this information for 100 encounters from patients you see at your workplace, who consent to having their information collected. Because general practice software products differ, this information cannot be extracted from the practice's GP software record. A separate electronic form will be used for each patient. It will take a few minutes to enter each patient's information, however initial entries may take a little longer. Clear instructions for completing each 'form' will be included in the electronic template. No patient names, addresses or other identifying information will be collected, and we will provide a Patient Information Sheet for patients to read in the waiting room before they see you. At the beginning of the encounter please ask if they consent for their information to be collected, and record 'OCEAN Y' (for yes) in the notes section of their medical record. If the patient is not able to give consent because of cognitive impairment, and the person legally able to consent on their behalf is not present, please **do not** include that patient in the study.

Once you have completed your 100 clinical encounter forms, you will be asked to complete a short feedback survey about your experience.

We aim to describe the breadth of work carried out by NPs to demonstrate the importance of NPs within general practice teams. Information about the project will also be provided for you to share with your practice team so they understand why you are participating in the project.

Can I withdraw once I've started? Participating is optional so you do not have to take part. Your decision will have no impact on your current or future relationship with the researchers or anyone else at the University of Sydney or the University of Wollongong. If you decide to take part and then change your mind, you can withdraw by contacting our Project Manager (contact details below).

Are there any risks or costs? Aside from your time (which we estimate to be 5 – 7 hours in total), we do not foresee any risks or costs associated with taking part in this study.

Are there any benefits? Your response will be invaluable in helping us gather insights for the NP profession. We greatly appreciate your time and contribution, which will help us advance our knowledge and understanding of nurse practitioner's scope of practice in primary healthcare settings.

What will happen to information that is collected? OCEAN is an internet-based data collection tool. Some personal information (such as your name, phone number, and email address) will be collected when you first log in. This information will only be used for corresponding with you about the study. This information will be kept confidential, and only told to others with your permission, except as required by law. It will be stored separately from the information you record about the practice you work in, and the information about encounters with your patients. You can access your personal information by logging into the website with your password and going to the 'My account' section. The OCEAN website is maintained by the research team's senior software engineer and supported by the Information and Communication Technology (ICT) department of the University of Sydney. The database is secured behind the University's firewall, and any user connection is safeguarded by HyperText Transfer Protocol Secure (HTTPS) to ensure user data is transmitted securely to the server. Only members of the research team will have access to the information collected. Any publication of results will be in aggregated format only. No individual NP or patient will be identifiable. The information will be destroyed after the approved retention period (5 years) as prescribed by the State Records Authority of NSW.

Will I be told the results of the study? You have a right to receive feedback about the overall results of this study. Feedback will be provided in the form of an easy-to-read summary.

What if I would like further information? When you have read this information, please do not hesitate to contact us to answer any questions you may have.

What if I have any complaints or concerns? The study has been approved by the Human Research Ethics Committee (HREC) of The University of Sydney [2024/HE000108] according to the *National Statement on Ethical Conduct in Human Research (2007)*. If you are concerned about the way this study is being conducted or wish to make a complaint to someone independent from the study, please contact the University:

Human Ethics Manager
human.ethics@sydney.edu.au
+61 2 8627 8176

If you would like to participate, please click on [this link](#).

If you have any questions, contact our [Project Manager, Kate Milledge](#), at ocean.study@sydney.edu.au. Thank you for taking the time to read this letter. We would greatly appreciate your involvement.

Yours sincerely,

Dr Christopher Harrison & Dr Julie Gordon
Chief Investigators of the OCEAN Study
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(On behalf of the project Co-Investigators).

This information sheet is for you to keep