

**Participant Information Sheet/Consent Form**

**Non-Interventional Study**

**Screening Study**

**Royal North Shore Hospital**

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| **Title** | A Quality Improvement Study on Psychosocial Screening and Outcome Tracking Following Burn Injury  screening and |
| **Short Title** | Burns Screening |
| **Coordinating Principal Investigator/ Principal Investigator** | A/Prof Loyola Mclean, Dr Rachel Kornhaber & Dr Vlasios Brakoulias |
| **Associate Investigator(s)** | Julia Kwiet, Anne Darton, Diane Elfleet,  Dr Jeffrey Streimer & Dr John Vandervord |
| **Location** | Royal North Shore Hospital |

**Part 1 Introduction**

You are invited to take part in a research project titled; *A quality improvement study on psychosocial screening and outcome tracking following burn injury.* This is because you have recently experienced a burn injury. The research project is aiming to screen all burn patients for depression, anxiety, Post-Traumatic Stress Disorder (PTSD) and coping, as well as track mental health outcomes following injury.

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

Please read this information carefully. Ask questions about anything that you don’t understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or treating doctor.

Participation in this research 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.

**1 What is the purpose of this research?**

The purpose of this study is to learn more about burn survivors’ social and emotional health and improve services to aid better recovery. Burn injuries can result in conditions such as depression, anxiety and Post-Traumatic Stress Disorder (PTSD) which negatively affects burn survivors’ recovery and quality of life. The primary aim of this project is to identify early those patients most at risk of developing these problems. For this we need to collect information from as many burn injury patients as possible. This information will be studied in ways that may help to improve health care options.

The results of this research will be used by the associate researcher Julia Kwiet to obtain a Masters of Philosophy degree. This research has been initiated by the study doctor, A/Professor Loyola McLean and has been funded by The NSW Institute of Psychiatry.

**2 What does participation in this research involve?**

If you decide to participate in this study you will be asked to complete a set of questionnaires relating to how you normally cope with stress, your social supports, drug and alcohol use and how you are responding to what has happened to you since your burn injury. This usually takes about one hour to complete and will take place during and after your stay in hospital. No aspect of your care will be affected by your participation.

You will be asked to complete a set of questionnaires (see table 1) within 2 weeks of admission (or within 2 weeks of leaving Intensive Care Unit). This is called screening. You will be asked to complete the same questionnaires again, at 3-monthly time intervals in the first year after your injury and then at yearly intervals for 5 years. The follow-up appointments after your discharge from hospital will be arranged at the same time as your outpatient burns clinic appointments. This means you will have 9 visits with members of the research team over the next 5 years.

At each visit, we will ask you to complete the following questionnaires and we will ask you some questions about your current pain levels and drug and alcohol use

1) The Impact of Event Scale-Revised (IES-R), which detects post-traumatic stress symptoms.

2) A questionnaire on your coping strategies called the COPE.

3) A questionnaire called the DS-16 that looks at how you generally feel and whether you use social relationships to help manage difficult feelings.

4) A questionnaire called the Relationships Questionnaire (RQ) which describes how you feel in close relationships.

5) A questionnaire called the ABCD-SRR (ABCD-Self Report, revised) which describes how you feel at times of stress.

6) The Depression Anxiety and Stress Scale (DASS) which measures levels of depression, anxiety and perceived stress.

7) Measure of Alcohol use.

**Table 1: Schedule of questionnaires and study visits**

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| --- | --- | --- | --- | --- | --- | --- |
| Procedures | Visit 1:  2-4 weeks | Visit 2:  3 months | Visit 3:  6months | Visit 4:  9 months | Visit 5:  12-18 months | Visit 6-9:  Yearly follow-up for 5 years |
| Consent |  |  |  |  |  |  |
| Questionnaires:  1.Impact of Event Scale-Revised (IES-R) |  |  |  |  |  |  |
| 2. COPE |  |  |  |  |  |  |
| 3. DS-16 |  |  |  |  |  |  |
| 4. Relationship Questionnaire (RQ) |  |  |  |  |  |  |
| 5. ABCD-Self Report, revised  (ABSD-SRR) |  |  |  |  |  |  |
| 6. The Depression Anxiety and Stress Schedule (DASS) |  |  |  |  |  |  |
| 7. Measure of Alcohol use |  |  |  |  |  |  |
| Burns Specific Health Scale( BSHS-B) |  |  |  |  |  |  |
| Estimated time for each visit: | 30 – 60  minutes | 30 – 60  minutes | 30 – 60  minutes | 30-60  minutes | 40-70  minutes | 30-60  minutes |

At 12 – 18 months after your injury you will also be asked to complete the Burn Specific Health Scale – Brief (BSH-B) which measures quality of life following burns injury.

Your responses to the questionnaires will determine whether you are eligible to participate in a related study, aimed at treating burn patients at risk of PTSD. This other study will be explained in a separate Participant Information Sheet.

If you have a local doctor, we strongly recommend that you inform them of your participation in this research project. If your results show that you are at risk of developing coping problems we would communicate this to your local doctor as this is considered best practice and it is important that you receive appropriate intervention.

**3 Do I have to take part in this research project?**

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.

If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep. Your decision whether to take part or not to take part, or to take part and then withdraw from this study, will not affect your routine treatment, your relationship with those treating you or your relationship with staff from Royal North Shore Hospital.

**4 What are the alternatives to participation?**

You do not have to take part in this research project to receive counselling and/or other supportive interventions for depression, anxiety, PTSD or other distress related symptoms at this hospital. Other options are available; these include speaking with the burns social worker and routine psychiatric assessment.

**5 What are the possible benefits of taking part?**

We cannot guarantee or promise that you will receive any benefits from this research; however possible personal benefits may include early identification of coping problems. We may also learn more about how a severe burn injury affects people and this may improve care for future patients.

**6 What are the possible risks and disadvantages of taking part?**

This research does not involve any medical treatment or use of medications. It is unlikely that participation in this study will cause any risk or discomfort. If this research does raise any personal or upsetting issues, the Burns Team will organise counselling or refer you to the Consultation-Liaison Psychiatry at this hospital for assessment and follow up. Any counselling or support will be provided by qualified staff who are not members of the research team. This counselling will be provided free of charge.

**7 Can I have other treatments during this research project?**

Whilst you are participating in this research project, you are able to take all of the medications or treatments you have been taking for your condition or for other reasons. It is important to tell the study staff about any treatments or medications you may be taking, including over-the-counter medications, vitamins or herbal remedies, acupuncture or other alternative treatments. You should also tell your study doctor about any changes to these during your participation in the research project.

**8 What if I withdraw from this research project?**

If you decide to withdraw from this research project, please notify a member of the research team before you withdraw. If you do withdraw your consent during the research project, the relevant study staff will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected up to the time you withdraw will form part of the research project results. If you do not want them to do this, you must tell them before you join the research project.

**9 Could this research project be stopped unexpectedly?**

This research project may be stopped unexpectedly for a variety of reasons. While this is highly unlikely, possible reasons could be withdrawal of funding or staff shortages.

**10 What happens when the research project ends?**

Upon completion of this project, and throughout the course of this project, your questionnaire responses

will be monitored and if your questionnaires suggest that you may be unwell or distressed, then you will be referred to the Consultation-Liaison Psychiatry team or Social Work Department at Royal North Shore Hospital. This might include high levels of distress, depression, anxiety or PTSD. Project results will be communicated to interested participants directly by members of the research team upon completion of the project.

**11 Could I be approached to participate in further research?**

You may also be asked to participate in a treatment study, if your post-traumatic stress scores are high. You would be asked about this within one week of participating in this study. If you agree to participate in the second phase of this study you will be assessed further, to make sure it is safe for you to have the intervention tested. This assessment would take place within one week of being asked to participate in the second part of the study and the intervention would follow within 1 to 7 days.

**Part 2 How is the research project being conducted?**

**12 What will happen to information about me?**

By signing the consent form you consent to the members of the research team collecting and using personal information about you for this research project. Any information obtained in connection with this

research that can identify you will remain confidential. Any identifiable information will be kept in a secure and locked area to which only members of the research team have access and your confidentiality will be assured. Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law. All data will be stored in accordance with NSW Health Records regulations and stored accordingly.

Information about you may be obtained from your health records held at this or other health services for the purpose of this research.

It is anticipated that the results of this research project will be published and/or presented in a variety of ways. In any publication and/or presentation, information will be provided in such a way that you cannot be identified. Any identifiable information will be removed and only non- identifiable data will be published and presented. Information about your participation in this research project may be recorded in your health records. In accordance with relevant Australian and NSW Health privacy and other relevant laws, you have the right to request access to your information collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please contact the study team member named at the end of this document if you would like to access your information.

Any information obtained for the purpose of this research project that can identify you will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law.

**13 Complaints and compensation**

If you suffer any injuries or complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical or psychological treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

**14 Who is organising and funding the research?**

This research project is being funded by the NSW Institute of Psychiatry via the provision of a yearly research fellowship to Ms Julia Kwiet. Otherwise the research is funded by the research team from the Burns Unit.

**15 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 Northern Sydney Local Health District (NSLHD). It has also been reviewed by an expert panel of members of the NSW Institute of Psychiatry.

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.

**16 Further information and who to contact**

The person you may need to contact will depend on the nature of your query. 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, A/Prof Loyola McLean on 02 96657314 or speak with Julia Kwiet on 02 9462 9477.

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact the Northern Sydney Local

Health District Human Research Ethics Committee (HREC) quoting HREC reference number HREC/14/HAWKE/79.

**Reviewing & local HREC approving this research**

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| Reviewing HREC name | *Northern Sydney Local Health District (NSLHD)* |
| HREC Executive Officer | *Ethics Manager* |
| Telephone | *02 9926 4590* |
| Email | [*nslhd-research@health.nsw.gov.au*](mailto:nslhd-research@health.nsw.gov.au) |

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**Consent Form**

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| --- | --- |
| Title | A Quality Improvement Study on Psychosocial Screening and Outcome Tracking Following Burn Injury |
| **Short Title** | Burn Screening |
| **Coordinating-Principal Investigator/**  **Principal Investigator** | A/Prof Loyola McLean, Dr Vlasios Brakoulias & Dr Rachel Kornhaber |
| **Associate Investigator(s)** | Julia Kwiet, Anne Darton, Diane Elfleet,  Dr Jeffrey Streimer & Dr John Vandervord |
| **Location** | Royal North Shore Hospital |

**Declaration by Participant**

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to Royal North Shore Hospital concerning my symptoms and treatment for the purposes of this project. I understand that such information will remain confidential.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the study without affecting my future health care.

I understand that I will be given a signed copy of this document to keep.

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|  | | | | | | |
|  | Name of Participant (please print) | |  |  |  |  |
|  | | | | | | |
|  | Signature |  | | Date |  |  |
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|  | Name of Witness\* to Participant’s Signature (please print) | |  | | |  |
|  | | | | | | |
|  | Signature |  | | Date |  |  |
|  | | | | | | |

\* Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older.

**Declaration by Study Doctor/Senior Researcher†**

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

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|  | Name of Study Doctor/  Senior Researcher† (please print) | |  | | |  |
|  | | | | | |  |
|  | Signature |  | | Date |  |  |
|  | | | | | | |

† A senior member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.

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**Form for Withdrawal of Participation**

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| **Short Title** | Burns Screening |
| **Coordinating Principal Investigator/**  **Principal Investigator** | A/Prof Loyola McLean, Dr Vlasios Brakoulias & Dr Rachel Kornhaber |
| **Associate Investigator(s)** | Julia Kwiet, Anne Darton, Diane Elfleet,  Dr Jeffrey Streimer & Dr John Vandervord |
| **Location** | Royal North Shore Hospital |

**Declaration by Participant**

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with *Royal North Shore Hospital.*

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|  | | | | | | |
|  | Name of Participant (please print) | |  |  |  |  |
|  | | | | | | |
|  | Signature |  | | Date |  |  |
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