**Participant Information Sheet/Consent Form**

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**Interventional Study** -*Adult providing own consent*

*Flinders Centre for innovation in cancer (FCIC), Flinders Private Hospital (FPH) and Southern Oncology SA (SOSA)*

|  |  |
| --- | --- |
| **Title** | Effect of anti-inflammatory dietary intervention on dietary inflammatory load in oncology patients undergoing immunotherapy with check point inhibitors, with or without chemotherapy : A single arm feasibility study |
| **Short Title** | Effect of an anti-inflammatory diet on dietary inflammation load in immunotherapy patients |
| **Protocol Number** |  |
| **Coordinating Principal Investigator/ Principal Investigator** | Dr Shawgi Sukumaran |
| **Associate Investigator(s)**  *(if required by institution)* | Professor Michelle Miller (Principal supervisor), Ms Mitali Mukherjee |
| **Location** *(where CPI/PI will recruit)* | Flinders Centre for innovation in Cancer (FCIC) , Flinders Private Hospital (FPH) and Southern Oncology SA (SOSA) |

**1 Introduction**

You are invited to take part in this research project titled, ‘Effect of anti-inflammatory diet on dietary inflammation load in oncology patients undergoing immunotherapy with check point inhibitors , with or without chemotherapy : A feasibility study*.’* This is because you have been diagnosed with cancer and about to commence immunotherapy (with or without chemotherapy).

This project is being conducted by researchers from Flinders Medical Centre (FMC) Flinders Centre for Innovation in cancer (FCIC), Cancer wellness centre, Flinders Private Hospital (FPH) and Southern Oncology South Australia (SOSA). The researchers are trying to determine whether an anti-inflammatory diet can help in reducing inflammation related side effects experienced due to immunotherapy treatment. However, this is a feasibility study aiming to determine whether anti-inflammatory dietary intervention is feasible in the immunotherapy population by determining adherence to the intervention.

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.

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 local 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.

Page 1 of 7

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

• Understand what you have read

• Consent to take part in the research project

• Consent to the tests and research that are described

• Consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep. Your GP will be notified about your participation in the study.

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

The purpose of the study is to determine if an anti-inflammatory diet (Mediterranean diet) is well accepted and feasible in patients receiving immunotherapy. We are also trying to measure how changes in the inflammatory load of your diet affects inflammation in your body and tolerance to immunotherapy. We are also interested in determining if the dietary intervention can reduce immunotherapy related side effects of your treatment These results will be compared with historical controls consisting of cancer patients that received immunotherapy with no dietary modifications.

To our knowledge, there has been no research previously conducted to determine whether dietary modifications reduce irAEs in immunotherapy patients. If the results of this study are favourable, the Mediterranean diet could become a safe and feasible method to reduce side effects in patients receiving immunotherapy.

This project will be completed by an Accredited Practicing Dietitian (APD) , Ms Mitali Mukherjee, as part of her Doctor of Philosophy candidature at Flinders University. She will be supervised by experienced researchers, Professor Michelle Miller and Dr Shawgi Sukumaran, who have initiated the project due to needs identified through their previous research and provision of care at Flinders Centre for Innovation in Cancer.

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

Should you decide to participate in the research project, you will need to indicate your willingness to enter the study by informing your doctor, nurse, dietitian, pharmacist or any other member of your treating team as soon as you have been prescribed immunotherapy. You will be provided a copy of this information sheet at that stage. After receiving this document, you can provide verbal consent to be contacted by the researcher of this study, Mitali Mukherjee, to any staff member. Ms Mukherjee will contact you to assess your interest and explain the project further and receive your verbal consent to participate in the study in the first instance. Alternatively, you could contact Ms Mukherjee on +61 420 264 042 to indicate your willingness to participate or not. You can provide verbal consent on phone or video call so dietary data collection can commence before your next visit to the clinic. This will involve a 1-2 hour interview with Ms Mukherjee on phone, video call or in person according to your convenience. This will allow Ms Mukherjee to plan an individualised intervention for you before your next visit to the clinic. During your next visit to the clinic (prior to commencement of immunotherapy), the signed copy of the consent form will be collected from you. In addition, you will be provided with an individualised dietary prescription and food starter pack (including samples of mixed nuts and extra virgin olive oil).

Participation in their research will involve the collection of your information such as age, gender, level of education, employment, profession, marital status, living status; medical information such as identifier, BMI, cancer type and stage, regime, medical history and conditions; side effects experienced, any complementary medications; and blood test results. Your medical records will be accessed by the researchers of this study to collect this data. Your treating clinician may also add additional blood tests to measure inflammatory markers in your body. As far as possible, this will be added to your routine blood tests and will not require you to make any additional visits to the pathology clinics. However, it will require additional amount of blood (10-15 ml, 1tablespoon approximately) and will occur up to a maximum of 2 times over a 12 week period. This is being done to determine if the inflammation levels in your body have any relationship to your dietary intake. Please let our team know if you do not wish to provide additional blood samples for these tests.

Page 2 of 7

In addition, dietary data in the form of a diet history and food frequency questionnaire will be collected from you at before commencement of treatment (during phone/video/in-person contact) and at 12 weeks. Based on your diet, modifications (acceptable to you) that will increase the anti-inflammatory foods in your diet will be advised by Ms Mitali Mukherjee which you will be asked to follow for 12 weeks from the start of your immunotherapy. Ms Mukherjee will provide a dietary prescription, extra virgin olive oil and nuts to you in person. You will be encouraged to ask any questions during this time. You will receive a call weekly to determine your progress with the diet plan. Approximate duration for the call will be 10-20 minutes depending on your situation. You will also be asked to complete a diet checklist every day which will take 5 minutes per day so that the researchers can determine how well you are adhering to the suggested diet plan. If you face any difficulty in completing the checklist or wish to gain further clarification, please call Ms Mukherjee on +61 420264042. Finally, you will also be asked to complete a survey to determine your satisfaction with the diet in terms of taste, cost, duration and any barriers experienced.

Diet plans will be individualised to suit you. Examples of potential suggested dietary changes are provided below. Participants could be asked to:

* Consume 4 or more tbsp. of EVOO every day (50g)
* Consume 3 or more serves of nuts per day (30 g composed of 15 g of walnuts, 7.5 g of almonds and 7.5 g of hazelnuts)
* Include 3 or more portions of fresh fruits per day (>300g per day)
* Include 5 or more portions of vegetables/legumes per day (>250g per day)
* Include 3 or more portions of fatty fish or seafood per week (>250 g per day)
* Replace red meat with white meat (meat <80 g per day)
* Drink wine with meals (habitual drinkers)
* Limit soda drink to 1 or less portion per day
* Limit bakery goods, sweets, and pastries to 3 or less portions per week
* Limit fat spreads drink to 1 or less portion per day
* Limit red processed meats to 1 or less portion per day
* Limit dairy to 2 or less portions (<270 g per day)

You will receive a complimentary starter pack with nuts (250 g) and extra virgin olive oil (500 ml) to provide samples and get you started with the diet plan. For the rest of study period, you would have to purchase products relevant to your diet plan from any store or brand of your choice which may alter, and possibly increase your food related expenditure. You will be reimbursed for any reasonable parking costs incurred associated with the research project.

**4 What do I have to do?**

You will be asked to attend an interview for approximately 1-2 hours via phone, video call or in-person with Ms Mukherjee before start of treatment and around 12 weeks’ time point at your convenience. You will be asked to follow an individualised diet plan (decided keeping your preferences in mind) for 12 weeks after the start of your treatment. This will be provided to you in print or via email. You will receive a starter food pack with nuts and extra virgin olive oil to get you started. You will also be asked to complete a dietary checklist which will take 5 minutes every day to complete and attend a phone call with Ms Mukherjee weekly at your convenience. Around 12 weeks, you would be asked to complete a short survey to determine your experience with taste, cost, duration and any barriers experienced due to the diet which will take 5 minutes to complete.

Page 3 of 7

After receiving the study information sheet and consent form, should you have any further questions or wish to speak to a study researcher, please feel to call Mitali Mukherjee on **+61 420 264 042**. Alternatively, if you indicate interest verbally to your doctor, dietitian, nurse or pharmacist or any treating member of your team about your interest in participating in the study, Mitali Mukherjee will call you to provide further details about the project.

Once you decide to enter the study, please provide verbal consent over phone/video call/in person to indicate your willingness to participate. Once the researcher receives your verbal consent, she will arrange a suitable time either in person, via phone or video call to complete the next steps. This will involve collection of dietary data. On the next visit to the clinic, consent forms will be collected and an individualised dietary prescription will be provided to you to follow for the next 12 weeks.

**5 Other relevant information about the research project**

The researchers aim to recruit up to 12 participants to participate in this research project, all of which will be patients from the Department of Medical Oncology at Flinders Medical Centre (FMC), Flinders Centre of Innovation in Cancer (FCIC), Cancer wellness centre, Flinders Private Hospital (FPH) and Southern Oncology SA (SOSA). All the researchers involved are employed or studying at Flinders University, with Dr Shawgi Sukumaran also working as a Consultant in the Department of Medical Oncology for the Southern Adelaide Local Health Network and SOSA and Mitali Mukherjee working as a Dietitian at SOSA.

**6 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, will not affect your routine treatment, your relationship with those treating you or your relationship with Flinders Centre for Innovation in Cancer, Flinders Private Hospital or Flinders University.

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

You do not have to take part in this research project to receive treatment at this hospital.

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

We cannot guarantee or promise that you will receive any benefits from this research. However, you will receive dietary advise to increase the anti-inflammatory food content in your diet. The research may help us determine whether such modifications are feasible to make in patients receiving immunotherapy and whether an anti-inflammatory diet can aid in reducing irAEs and inflammation. This will also provide us data for future studies.

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

Page 4 of 7

While this research does not involve any provision of supplements or drugs, you will be asked to follow an anti-inflammatory diet plan. You may also experience discomfort due to the change in taste or cost of the diet. In addition, you may experience some burden involved in attending interviews, completing weekly checklists and a survey as part of this project.

If you become upset or distressed because of your participation in the research, the study doctor will be able to arrange for counselling or other appropriate support. Any counselling or support will be provided by qualified staff from Flinders Medical Centre, who are not part of the research team. This counselling will be provided free of charge.

**10 What will happen to my test samples?**

You will be asked to provide additional consent for the collection of your blood samples during the research project. Blood test samples will be collected as part of your routine care to help determine whether the anti-inflammatory diet can reduce inflammation. You will not be required to make any additional visits to the pathology clinics as far as possible. This information will be kept confidential and only be used for the purpose of this research.

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

Whilst you are participating in this research project, you will be able to continue taking all of the medications as per usual.

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

If you decide to withdraw from this research project at any stage, please notify a member of the research team and they will discuss this with you. If you do withdraw your consent during the research project, the data collected up to that point will be used for analysis.

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

There will be no active follow-up required from your side in this research project after all data collection is completed around 12 weeks. However, this data, which will be deidentified will be presented in conferences and journals. The results of the study will be communicated to you in a language that you’d understand. A hard copy of the dietary inflammatory index score can be provided to you at your request. Your data may also be used when designing studies in future.

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

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

Any information obtained in connection with this research project that can identify you will remain confidential. The consent form will be stored in a locked cabinet at Flinders University and will only be able to be accessed by researchers involved in this project. A participant ID number will be assigned to each participant and recorded on the consent form. A participant ID allocated to you, will allow researchers to re-identify you if required. All the data collected will be stored in a password-protected folder on the Flinders University computer drive and will only be accessible to the researchers involved in this project. Your information accessed from this research and medical records will only be used for the purpose of this research project and related research studies and Human Research Ethics Committee (HREC) approval will be sought for these projects. You information will only be disclosed with your permission, except as required by law. The consent forms and data will be stored for five years before being destroyed.

Demographic data, dietary data, medical history and blood test results to explore trends in side effects and inflammation will be gathered in this study.

Page 5 of 7

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified. No findings from individual’s data will be published. Only the findings of the comparison of data will be published and there will be no way that participants will be identifiable through the interpretation of this information.

In accordance with relevant Australian and/or South Australian privacy and other relevant laws, you have the right to request access to the information collected and stored by the research team about you. . Please contact the research 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.

**17 Complaints and compensation**

In the unlikely event that you suffer any injuries or complications because of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical 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.

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

The majority of this research project is being conducted by Ms Mitali Mukherjee as part of the requirements of her Doctor of Philosophy candidature and therefore, funds available are organised through the Flinders university and her supervisors. Currently $6000 as part of Flinders University Research Maintenance Funds are available for use for this study.

If knowledge acquired through this research leads to discoveries that are of commercial value to Flinders University/Flinders Centre for Innovation in Cancer, the researchers or their institutions, there will be no financial benefit to you or your family from these discoveries.

No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

**19 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 Southern Adelaide Health (Flinders Centre for Innovation in Cancer and Flinders University). 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.

**20 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, you can contact Dr Shawgi Sukumaran at the Department of Medical Oncology at Flinders Centre for Innovation in Cancer and Flinders Private Health on 8204 8997, or any of the following people:

Page 6 of 7

**Clinical contact person**

|  |  |
| --- | --- |
| Name | Dr Shawgi Sukumaran |
| Position | Consultant, Department of Medical Oncology, Flinders Centre for Innovation in Cancer |
| Telephone | 8204 8997 |
| Email | Shawgi.Sukumaran@sa.gov.au |

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

**Complaints contact person**

|  |  |  |
| --- | --- | --- |
| Position | |  | | --- | | Director, Office for Research | |
| Telephone | 8204 6453 |
| Email | SALHNofficeforresearch@sa.gov.au |

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:

|  |  |
| --- | --- |
| Reviewing HREC name | Southern Adelaide Clinical |
| Telephone | 82046453 |
| Email | SALHNofficeforresearch@sa.gov.au |

**Reviewing HREC approving this research** **and HREC Executive Officer details**

**Local HREC Office contact (Single Site -Research Governance Officer)**

|  |  |
| --- | --- |
| Position | Research Governance Officer |
| Telephone | 82046453 |
| Email | [SALHNofficeforresearch@sa.gov.au](mailto:SALHNofficeforresearch@sa.gov.au) |

Page 7 of 7

**Consent Form -** *Adult providing own consent*

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| --- | --- |
| **Title** | Effect of anti-inflammatory dietary intervention on side effects experienced, EDII and inflammation in oncology patients undergoing immunotherapy: A single arm Pilot study. |
| **Short Title** | Effect of an anti-inflammatory diet on immunotherapy side effects |
| **Protocol Number** |  |
| **Coordinating Principal Investigator/ Principal Investigator** | Dr Shawgi Sukumaran |
| **Associate Investigator(s)**  *(if required by institution)* | Professor Michelle Miller (Principal supervisor), Ms Mitali Mukherjee |
| **Location** *(where CPI/PI will recruit)* | Flinders Centre for innovation in Cancer (FCIC), Flinders Private Hospital (FPH) and Southern Oncology SA (SOSA) |

**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 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 project without affecting my future health care.

I understand that my GP will be notified about my participation in this study.

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

I understand that I have been given the option to opt out of providing additional blood samples as part of this study.

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

**Form for Withdrawal of Participation -** *Adult providing own consent*

|  |  |
| --- | --- |
| **Title** | Effect of anti-inflammatory dietary intervention on side effects experienced, EDII and inflammation in oncology patients undergoing immunotherapy: A single arm Pilot study. |
| **Short Title** | Effect of an anti-inflammatory diet on immunotherapy side effects |
| **Protocol Number** |  |
| **Coordinating Principal Investigator/ Principal Investigator** | Dr Shawgi Sukumaran |
| **Associate Investigator(s)**  *(if required by institution)* | Professor Michelle Miller (Principal supervisor), Ms Mitali Mukherjee |
| **Location** *(where CPI/PI will recruit)* | Flinders Centre for innovation in Cancer (FCIC), Flinders Private Hospital (FPH) and Southern Oncology SA (SOSA) |

**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 Flinders Centre for Innovation in Cancer.

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|  | | | | | | |
|  | Name of Participant (please print) | |  |  |  |  |
|  | | | | | | |
|  | Signature |  | | Date |  |  |
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**Declaration by Study Doctor/Senior Researcher†**

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

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|  | Name of Study Doctor/  Senior Researcher† (please print) | |  | | |  |
|  | | | | | |  |
|  | Signature |  | | Date |  |  |
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† A senior member of the research team must provide the explanation of and information concerning withdrawal from the research project.

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