**Master Participant Information Sheet/Consent Form**

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

|  |  |  |
| --- | --- | --- |
| **Title** | Safety and adherence to medications and self-care advice in oncology. A randomised controlled feasibility and acceptability trial of a pharmacist and nurse-supported m-health platform | |
| **Short Title** | SAMSON: A PHARMACIST, NURSE AND MOBILE PHONE APP SUPPORTED MEDICATION SAFETY AND ADHERENCE TRIAL | |
| **Protocol Number** | *[Protocol Number]* | |
| **Project Sponsor** | Swinburne University of Technology | |
| **Project Funder** | Victorian Cancer Agency | |
| **Coordinating Principal Investigator/ Principal Investigator** | Dr Lisa Grech | |
| **Associate Investigator(s)** | Prof Penelope Schofield  Prof John Seymour  A/Prof Constantine Tam  Mr Senthil Lingaratnam  Mr Abdul Forkan  Ms Amanda Pereira-Salgado  Dr Stephen Quinn | Prof Sanchia Aranda  Dr Eliza Hawkes  A/Prof Billingsley Kaambwa  Dr Kate Burbury  Mr Andrew Dunlevie  Mr Jim Coomes |
| **Location** | [site name] | |

**Part 1: What does my participation involve?**

1. Introduction

|  |
| --- |
| You are invited to take part in the research project “SAMSON” because you have recently been prescribed ibrutinib (brand name: Imbruvica) for chronic lymphocytic leukaemia (CLL), small lymphocytic lymphoma (SLL), mantle cell lymphoma (MCL) or Waldenström’s macroglobulinaemia (WM).  The SAMSON research project aims to develop and test a new way of providing information and support for people when taking oral medication as recommended by their doctor (this is called ‘medication adherence’), and improve safety to reduce problems that may occur when taking medication (this is called ‘medication errors’).  This Participant Information and Consent Form informs you about the SAMSON research project. It explains the procedures involved. Knowing what is involved will help you to decide if you want to take part in this 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 healthcare worker.  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 you take part or not.  If you decide you want to take part in the SAMSON 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 SAMSON project; * Consent to participate in the research processes 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. |

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

|  |
| --- |
| The SAMSON intervention is aimed at supporting patients who are receiving ibrutinib by improving patient’s adherence (taking medication as required) to ibrutinib, and reducing problems that may occur when taking medications. This SAMSON research project will assess whether the SAMSON intervention is acceptable to patients taking ibrutinib, the healthcare professionals whom are providing the support via SAMSON, as well as whether this new program can be delivered through the current hospital system.  We understand that people with CLL, SLL, MCL or WM are often required to take oral medication for an indefinite period, often life-long. We know that ibrutinib is excellent at keeping CLL, SLL, MCL and WM from progressing when taken daily as prescribed. However, we also understand that as many as 50% of people find it difficult to take medication continually as prescribed. This can occur for many reasons, such as forgetting or because of unpleasant side-effects. The SAMSON intervention has been developed to provide information and support to help you to identify self-care strategies to self-manage difficulties with taking medication continually as prescribed, and to reduce your chance of problems occurring due to medications. In this way, the SAMSON intervention hopes to support peoples’ use of medication for optimal treatment outcomes.  This research project has been initiated by Dr Lisa Grech and it has been supported by research funding from the Victorian Cancer Agency (VCA). Dr Grech will work closely with researchers, including Professor Penelope Schofield, Professor John Seymour and Professor Sanchia Aranda. This research team previously trialled a similar intervention at Peter MacCallum Cancer Centre (PMCC) with 10 people diagnosed with chronic myeloid leukaemia (CML) who were receiving an oral medication, Imatinib. Patients and healthcare personnel found the intervention to be useful, and feedback from this initial trial has enabled improvements to the intervention. The SAMSON research project will now assess these improvements at PMCC and at several other hospitals across Victoria, including St Vincent’s Hospital, the Austin Hospital, Box Hill Hospital and Cabrini Hospital.  We will be inviting up to 60 people to take part in the SAMSON research project. Participation in this research project will be for 6 months. We will assess participants given the SAMSON intervention with participants receiving ‘usual care’, that is, the standard support that is currently provided when a person is prescribed ibrutinib. This means that half of the participants will receive the SAMSON intervention and half will not. Once the project finishes, we will assess participants in in both of these groups and gather feedback on the SAMSON intervention, to understand whether this intervention helped patients to take their medication as prescribed, as well as helped them to self-manage any side-effects that they may have experienced throughout their involvement with the study. |

1. **What does participation in this research involve?**

|  |
| --- |
| To be able to participate in this research project, you require a diagnosis of CLL, SLL, MCL or WM, be prescribed ibrutinib (for less than 2 months at initial study enrolment), be at least 18 years of age, and have access to the internet and use a smartphone.  If you decide to participate, the research coordinator will inform your treating haematologist/oncologist.  **Group allocation**  You will be participating in a randomised controlled trial. This means we will compare a group of people given the SAMSON intervention with a group of people provided with usual care. To try to make sure the groups are the same, each participant is put into a group by chance (at random) to either the intervention or non-intervention group. You will have an equal chance of being randomised to either group. If you are randomised to the intervention group you will receive the SAMSON intervention. If you are randomised to the usual care group you will receive standard usual care from your medical team. This is the level of care that is provided to all patients currently prescribed ibrutinib at the hospital where you receive your medical management for CLL/SLL/MCL/WM.  **Intervention and non-intervention group**  People in both the intervention and non-intervention groups will receive their ibrutinib medication in a bottle with a medication adherence measurement device, which will measure how regularly you open the bottle to take your ibrutinib. The pharmacist will dispense your medication in this special bottle, which means that for the duration of the research project (six months) you will be required to collect your medication from the hospital pharmacy, rather than a community pharmacy. The first time your medication is dispensed the research assistant will meet with you to show you how the bottle measures when you take your medication. At this time, the research assistant will also ask you to complete a 90 second task that is used to assess your thinking speed in comparison with the average thinking speed of other people of your age.  People in both groups will also be asked to complete some online questionnaires at the start, middle, and at the end of the 6-month study period. These questionnaires will assess how often you take your medication, any symptoms you experience, your mood and quality of life. Basic demographic and clinical questions will be asked (e.g. sex, age, occupation, time since diagnosis, etc.).  As part of the SAMSON research project, information about your haemoglobin and platelet counts will be collected from your routine blood tests at the beginning, three-month time-point and six-month time-point (end) of the study. All of the information we collect about you will be de-identified once collected. We will store this information using a unique participant code (paper based, recorded, and online) and will be stored in a secure location to maintain your confidentiality. Identifying information, such as your name and contact details will be stored in a separate password protected file and only accessed by the principal investigator or research coordinator.  At the end of the research project we will compare people in the intervention and non-intervention groups to see whether the SAMSON intervention is acceptable to patients and healthcare personnel, and can be feasibly delivered within the current healthcare system. This is an important stage of the research project, and is required before we can assess whether the SAMSON intervention makes a difference in terms of improving medication adherence. This final step will ensure that the findings from this research project are interpreted and recorded accurately and appropriately.  There are no additional costs associated with participating in this research project, nor will you be paid. You will continue to pay the patient contribution costs for ibrutinib. That is, the cost set by government for pharmaceutical benefits scheme listed medications (PBS; $39.50 for general patients; $6.40 for concession patients).  **Intervention Group**  If you are randomised to the group that receives the intervention you will receive an initial face-to-face consultation from a pharmacist to talk about your medication (in week 1), five telephone consultations with an intervention nurse to support you taking your medication (in weeks 2, 3, 6, 10 and 12). Each of these appointments will take between 30-60 minutes and will be arranged at a time that suits you. A written summary of each telephone consultation with the nurse will be sent to your email address. You will also receive a smartphone application (app) that will: 1) send you an initial survey about information you may like to know about CLL/SLL/MCL/WM, to complete prior to your first nurse teleconsultation, 2) send you daily medication reminders, and 3) send you a weekly survey to monitor your medication side-effects. Your treatment team may receive correspondence informing them of your progress while you are in the study, especially if you report any serious side-effects.  When you start on the SAMSON research project, you will be provided assistance by a member of our research team to install the SAMSON app onto your smartphone and provide you with the required app access (login) details. You will have your medication reminders programed in the app for a time that suits you. These times can be changed at a later date if required. You will also be shown how to access information about your medication taking and reported side-effects on the SAMSON website. This training and information discussion will take place at your next clinic visit or at your pharmacist consultation, and will usually take around 20-30 minutes.  At the end of the study (6 months after your initial consultation), in addition to the online surveys that people in both research groups will complete, a member of the research team from PMCC will telephone you to conduct an interview to ask you what you think about the intervention program. During this interview, you will be asked for your feedback on how useful and appropriate the SAMSON smartphone app was, as well as the regular nurse teleconsultations and the pharmacy consult in helping you to take your medication as advised, and in helping you to self-manage any side-effects that you may have experienced. You will also be asked if you may have any suggestions about ways to improve the intervention package (that is, the smartphone app, the nurse and pharmacy consultations). This interview should take about 30 minutes to complete.  All nurse and research assistant consultations will be voice recorded for data collection and quality assurance purposes. |

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

|  |
| --- |
| Participation in any research project is voluntary. If you decide to take part and later change your mind, you are free to withdraw from the research project at any time.  Your decision about whether or not to take part, or to take part and then withdraw from this research project, will not affect your medical care at this hospital. Nor will it negatively affect your relationship with your treating team or any hospital services you receive now or in the future. |

1. **What are the alternatives to participation?**

|  |
| --- |
| You do not have to take part in this research project to receive treatment at this hospital. The option of usual care through your treating team remains available to you.  A person from the research team will explain the option of usual care to you before you decide whether or not to take part in this research project. You may also like to discuss it with a member of your treating team. |

1. **What are the possible benefits?**

|  |
| --- |
| We cannot guarantee or promise that you will receive any benefits from this research. However, you may find the information and support provided to be useful. The findings of this research project will be used to improve the care of patients with CLL, SLL, MCL and WM, or another medical condition that requires long-term medication administration in the future. |

1. **What are the possible risks?**

|  |
| --- |
| There are no known risks to you from being involved in this research project. However, given the personal nature of the information being collected there is a small risk of psychological discomfort.  A structured internet questionnaire will be undertaken to obtain information about whether you are experiencing depressive symptoms. If you demonstrate clinically relevant depressive symptoms we will notify your treating team of the results, so that they can discuss this with you and provide treatment options, if required. Your level of depressive symptoms will not impact your ability to participate in this research project.  If you become upset or distressed as a result of participating in this research project, we are able to arrange counselling or other appropriate support for you. 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. Some relevant support services are listed below:  **Cancer Council Australia** **Life line:** **PMCC Psychology Service:**  13 11 20 13 11 14 (03) 8559 5220 |

1. **What if new information arises during the project?**

|  |
| --- |
| During the research project, new information about the risks and benefits of the project or intervention may become known to the researchers. If this occurs, you will be informed about this new information and we will discuss whether this new information affects you. |

1. **What if I withdraw from this research project?**

|  |
| --- |
| If you decide to withdraw, please notify a member of the research team. The research coordinator can be contacted on (03) 8559 8611 (9am-5pm, Monday to Friday).  If you decide to withdraw from the project, the researchers and relevant study staff will not collect any more personal information from you, although we would like to keep the information about you that has already been collected. This is to make sure that the results of the research project can be measured properly. If you do not want them to keep any of your information or data, please tell someone on the research team before you join the research project. |

1. **Could this research project be stopped unexpectedly?**

|  |
| --- |
| This research project could be stopped unexpectedly due to unforeseen circumstances pertaining to efficacy and/or the continuing feasibility of the study. While these circumstances are unlikely to occur, all participants will be informed immediately by a member of the research team if any such circumstances do arise during the course of the trial.  As a participant, your involvement in the research project could be stopped unexpectedly if:   * You cease treatment with ibrutinib, or * Your treatment team decides it is no longer in your best interest to continue in the research project. |

1. **What happens when this research project ends?**

|  |
| --- |
| When the project ends the SAMSON intervention will be evaluated for further research and will cease to be available for patient use more broadly. You will continue to receive treatment and care from your medical team as previously.  If you wish to obtain a final copy of the research report describing the results of this study, please tell a member of the research team and s/he will arrange for one to be sent to you. |

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

1. **What will happen to information about me?**

|  |
| --- |
| By signing the consent form you are consenting to the research team and other relevant research staff collecting and using personal information about you for purposes of this research project and for a future project of a similar type following ethics approval, such as the next stage of this research, which will assess the SAMSON intervention to see if it is more helpful than current standard care for patients. Any information obtained in connection with the SAMSON research project that can identify you will remain confidential and will only be used for the purposes of this research project. If you are randomised to the intervention group, your study data will be identifiable to the intervention nurses at your hospital. This is so that they can conduct the teleconsultations with you, throughout the study. Aside from this, your study data will only be disclosed with your permission, except as required by law.  Information about you (such as your pathology results for platelet and haemoglobin levels) may be obtained from your health records held at your recruiting hospital for the purposes of this research project.  All of the information that you have provided will be coded so that you cannot be identified by name, and only the research team will have access to the list that can link your name to your individual data. All information will be stored in a locked filing cabinet in the office of the research staff, and will be disposed of as confidential waste after 15 years.  In any publication, information will be provided in such a way that you cannot be identified. You will not, for example, be mentioned by name in any future publication of the results.  In accordance with relevant Australian and/or Victorian privacy and other relevant laws, you have the right to access your information that has been collected and stored by the researchers about you. You also have the right to request that any information, with which you disagree, be corrected. Please contact one of the researchers listed in the last section below if you would like to access your information. |

1. **Complaints and injuries**

If you incur any injuries or complications as a result of participating in this research project, you should contact a member of the research 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.

1. **Who is organising and funding the research?**

The SAMSON research project is being led by Dr Lisa Grech, and is a collaboration between Swinburne University of Technology, Peter MacCallum Cancer Centre, St. Vincent’s Hospital, Austin Hospital, Box Hill Hospital, and Cabrini Health. The research project is being funding by the Victorian Cancer Agency.

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

1. **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 through the multi-site ethics review process by the HREC of Peter MacCallum Cancer Centre, an accredited multi-site reviewer.  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. |

1. **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 research coordinator on (03) 8559 8611 or the Principal Investigator, Dr Lisa Grech on 0410 946 444, or any of the following people: |

**Research team contact**

|  |  |
| --- | --- |
| **Name** | Dr Sharnel Perera |
| **Position** | Research Project Coordinator |
| **Telephone** | 03 8559 8611 |
| **Email** | sperera@swin.edu.au |

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

**Recruiting hospital complaints contact**

|  |  |
| --- | --- |
| **Name** |  |
| **Position** |  |
| **Telephone** |  |
| **Email** |  |

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 Peter MacCallum Cancer Centre complaints:

**Peter MacCallum Cancer Centre complaints contact**

|  |  |
| --- | --- |
| **Position** | Consumer Liaison |
| **Telephone** | (03) 8559 7517 |
| **Email** | consumerliaison@petermac.org |

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

|  |  |
| --- | --- |
| **Reviewing HREC name** | Peter MacCallum Cancer Centre |
| **HREC Executive Officer** | Ethics Committee Secretariat |
| **Telephone** | (03) 8559 7540 |
| **Email** | ethics@petermac.org |

**Consent Form**

|  |  |  |
| --- | --- | --- |
| **Title** | Safety and adherence to medications and self-care advice in oncology. A randomised controlled trial of a pharmacist and nurse-supported m-health platform | |
| **Short Title** | SAMSON: TRIAL OF A NURSE AND PHARMACIST-LED MOBILE PHONE MANAGEMENT SYSTEM | |
| **Project Number** | [project number] | |
| **Project Sponsor** | Swinburne University of Technology | |
| **Project Funder** | Victorian Cancer Agency | |
| **Principal Investigator** | Dr Lisa Grech | |
| **Associate Investigators** | Prof Penelope Schofield  Prof John Seymour  A/Prof Constantine Tam  Mr Senthil Lingaratnam  Mr Abdul Forkan  Ms Amanda Pereira-Salgado  Dr Stephen Quinn | Prof Sanchia Aranda  Dr Eliza Hawkes  A/Prof Billingsley Kaambwa  Dr Kate Burbury  Mr Andrew Dunlevie  Mr Jim Coomes |
| **Location** | [site name] | |

**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 SAMSON project.

I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to Peter MacCallum Cancer Centre concerning my disease and treatment for the purposes of this project. I understand that such information will remain confidential.

I understand that information may be provided to my treating medical team if the research team deems it necessary for my health and safety (such as my reporting of moderate-to-severe depressive symptoms or a temperature of 38 degrees or more).

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.

***Please tick either ‘Yes’ or ‘No’ to the following question:***

|  |  |  |
| --- | --- | --- |
| I consent to my study data being viewed by my doctor from my primary treating team at my hospital.  Would you like a copy of the overall study results to be emailed to you once the study is completed? Please note that these results are for the complete study, they are not your individual results. | 🞎 Yes 🞎 No  🞎 Yes 🞎 No | Initials: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Initials: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Email address:  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

**Name of Participant (printed):**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Signature:**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Date:** \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_