ePROMs-MEL

Pilot study to embed **e**lectronic **P**atient **R**eported **O**utcome **M**easure**s** into routine care for patients with Stage III **MEL**anoma (ePROMs-MEL)

Protocol Version 3, 11 March 2022

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SECTION 1. ADMINISTRATIVE INFORMATION

1. Title

Pilot study to embed **e**lectronic **P**atient **R**eported **O**utcome **M**easure**s** into routine care for patients with Stage III **MEL**anoma (ePROMs-MEL)

2. Study registration

2.1 Registration information

This study is registered through the Australian New Zealand Clinical Trials Registry. (ACTRN12620001149954) 15/01/2021.

2.2 World Health Organization Trial Registration Data Set

All items from the World Health Organization Trial Registration Data Set are available in Appendix 1.

3. Protocol version

Version 4, 23/02/2022

4. Funding sources

KD's salary is supported through the Australian National Health and Medical Research Council (NHMRC) Centre for Research Excellence in Melanoma grant (Grant No.1135285). SH's salary is supported by a grant from The University of Sydney's DVCR Support Fund for COVID-19 impacted research. Support is also provided by Melanoma Institute Australia for IT programming and educational design, as well as access to the Melanoma Research Database to aid in the selection of eligible patients.

5. Roles and responsibilities

5.1 Role of protocol contributors

The ePROMs-MEL Steering Committee (Rachael Morton (RLM), Robyn Saw (RPMS), Iris Bartula (IB), Serigne Lo (SL), Craig Lawn (CL) and Kathy Dempsey (KD)) has been responsible for the development of this protocol. A full list of Investigators, including Steering Committee members, is available in Appendix 2. RLM is a Chief Investigator on the Melanoma CRE and conceived of the study. RLM worked with RPMS and IB on the study design. SL is the project biostatistician and consumer representative Mr Craig Lawn was substantially involved in the development of this protocol. KD was responsible for protocol revisions.

5.2 Name and contact information for the trial sponsor

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5.3 Role of study sponsor and funders

This study is funded by the Australian National Health and Medical Research Council (NHMRC) Centre for Research Excellence in Melanoma grant (Grant No.1135285). The study funder has no role in, or influence on, the study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication.

The study sponsor is the University of Sydney. It is represented by the chief investigator (RLM) and project Manager (KD) listed in section 5.2. The full team of investigators will play a significant role in all aspects of the study including: study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication.

5.4 Study oversight

The ePROMs-MEL Steering Committee is responsible for all aspects of study oversight, including

agreement of final protocol, patient recruitment, reviewing study progress and updating of protocol if required. Members of the Steering Committee are: Professor Rachael Morton, Associate Professors Robyn Saw and Serigne Lo, Drs Iris Bartula and Kathy Dempsey and Mr Craig Lawn.

SECTION 2. INTRODUCTION

6.1 Lay description

This project will use iPads to present short surveys called patient reported outcome measures (PROMs) to collect information directly from people with Stage III melanoma (i.e. with lymph node involvement and/or in transit disease) about their emotional and physical well-being. The information that patients provide will be reported to their treating doctors prior to regularly scheduled appointments. This information will improve melanoma treatment by highlighting patient-important outcomes following surgery, including symptoms, and quality of life issues that are central to assessing the value of melanoma care from a patient's perspective. This project will produce a feedback framework that could be used by other medical or cancer specialties to assess the quality of life and/or clinical care that patients are receiving.

6.2 Consumer engagement

To determine the specific and most appropriate PROMs to be included in this study, a stakeholder reference panel was formed. Members of this panel included experts in the field of melanoma (various clinical and non-clinical specialties), experts in patient reported measures research, and a small group of representatives/advocates for patients with current and previously treated melanoma. The nominated consumer representative for this project is Mr Craig Lawn. Other consumers who provided input into the prioritization of patient-centred research and subsequently development of ePROMs-MEL included Ms Sue Suchy, and more recently, Ms Linda Seaman and Ms Tamara Dawson. Consumer involvement was considered vital to ensure that the needs and preferences of patients are incorporated alongside the knowledge and background of treating clinicians and researchers.

6.3 Background and rationale

PROMs are questionnaires that allow patients to report how they feel and function without any interpretation from healthcare professionals.[1] Previous research has shown that the use of PROMs can improve clinician-patient communication. One study of women with gynaecological cancers found a PROMs questionnaire helped with discussion of symptoms not typically addressed for nearly all participants (95%, n = 40) and improved patient care for 97% (n = 41) of participants.[2] Other studies have found PROMs can facilitate clinician awareness and improve patient management,[3,4] contribute to prognostic information,[3] potentially prolong survival outcomes in patients with advanced cancer,[5] as well as allow patients to play a greater role in the clinical decision-making process.[1] Currently, PROMs are not routinely collected as part of melanoma treatment in Australia.

People diagnosed with Stage III melanoma (i.e. melanoma involving lymph nodes with or without in transit melanoma) are prone to high levels of psychosocial distress and poor quality of life (QoL).[6,7] A high proportion of patients treated at Melanoma Institute Australia (MIA) are Stage 3 and there has been no formal assessment of their levels of psychosocial distress to date. When patients with Stage III melanoma attend follow up appointments with their treating physician, the focus is primarily on detection and treatment of recurrence of disease. There is minimal focus on assessing the patients'

QoL or psychological health status, despite recommendations from The Cancer Institute NSW[8] and the Australian Commission on Safety and Quality in Health Care.[9] An audit of Australian cancer services reported that 'evidence from clinical settings suggests timely identification of distress is only effective in improving medical management and patient wellbeing when paired with structures supportive care referrals'.[10] While there has been extensive research on estimating the extent of psychosocial distress in a vast range of clinical settings 'subsequent translation of that knowledge into programs and services currently lags behind gains in the medical treatment of advanced melanoma, a troubling circumstance that requires immediate and focused attention'.[11] The ePROMs-MEL project will address this urgent need.

By including PROMs data (entered via iPads) into the routine care for patients with melanoma, the treating clinician will be able to identify patients who are experiencing deterioration in QoL or psychological distress. Previous research has demonstrated that fear of cancer recurrence, depression, anxiety, and low levels of QoL are commonly reported among patients with melanoma.[12] If identified, these patients can then be referred to the appropriate allied health professionals for suitable intervention (e.g. psychologist, nurse, physiotherapist, occupational therapist, social worker).

This research aims to assess the feasibility and acceptability of embedding electronic versions of PROMs into the routine care of patients with melanoma, from the perspective of patients and their treating clinical team including surgeons, dermatologists, medical oncologists, psychologists and nurses.

6.4 Explanation for choice of comparators

This pilot study is based on a single cohort of patients over a 12-18 month period. Although there is no control group, the design incorporates Baseline data allowing for comparisons of psychosocial health and QoL in individuals with Stage III melanoma before and after the introduction of electronic PROMs (ePROMs).

7. Objectives and hypothesis

7.1 Primary objective

The primary objective is to evaluate the feasibility and acceptability of embedding electronic PROMs into routine care from the perspective of Stage III melanoma patients and their treating clinical team (i.e. surgeons, dermatologists, medical oncologists, psychologists and nurses).

7.2 Secondary objectives

1. To evaluate whether embedding ePROMs leads to improved patient outcomes through the identification and prompt treatment of unmet psychosocial or health-related quality of life needs.
2. To produce a data systems framework to enable efficient electronic data capture and feedback to clinicians, useful in many other applications and clinical specialties.

7.3 Hypothesis

The hypothesis is embedding ePROMs into the clinical care of patients with melanoma is feasible and acceptable for both clinicians and patients and provides benefits to patients.

8. Study design

Prospective, longitudinal cohort intervention study incorporating mixed methods (quantitative surveys and qualitative interviews).

SECTION 3. Methods: Participants, interventions and outcomes

9. Study setting

Private surgical and medical oncology melanoma clinics at Melanoma Institute Australia (MIA) and Royal Prince Alfred Hospital (RPAH), Sydney, NSW, Australia.

10. Eligibility criteria

10.1 Patient selection criteria

Patients (adults aged 18 years or over) who:

- Have had a diagnosis of Stage III melanoma 3 months earlier, or are attending their second or subsequent consultation with an oncologist following initial treatment.
- Attend for regular follow-up appointments at least twice per year.
- Are under the care of melanoma clinicians at Melanoma Institute Australia (MIA) or Royal Prince Alfred Hospital (RPAH)
- Have sufficient English and cognitive ability to comprehend study materials, provide informed consent and participate in the study.

Minimum sample size of 120 patients.

Patients who progress from Stage III to Stage IV during the trial (i.e. after recruitment) may remain in the study.

10.2 Clinician selection criteria

- Clinicians currently treating and managing patients with stage III melanoma at MIA or RPAH.

11. Interventions

11.1 Description of interventions

Figure 1 provides a study Flow Chart from the patient's perspective and Figure 2 provides the study overview from the clinician's perspective.

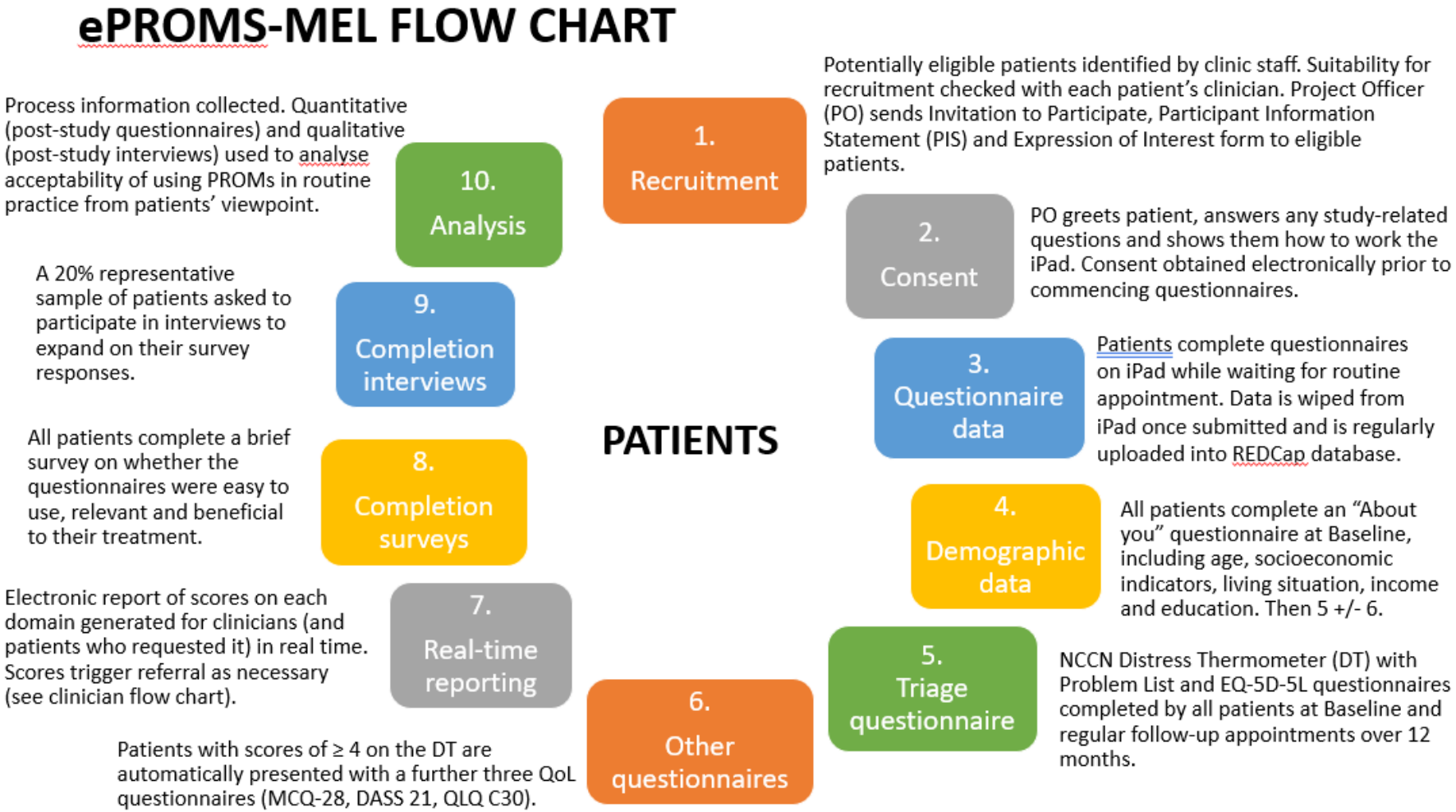

Fig 1: Patient's Perspective

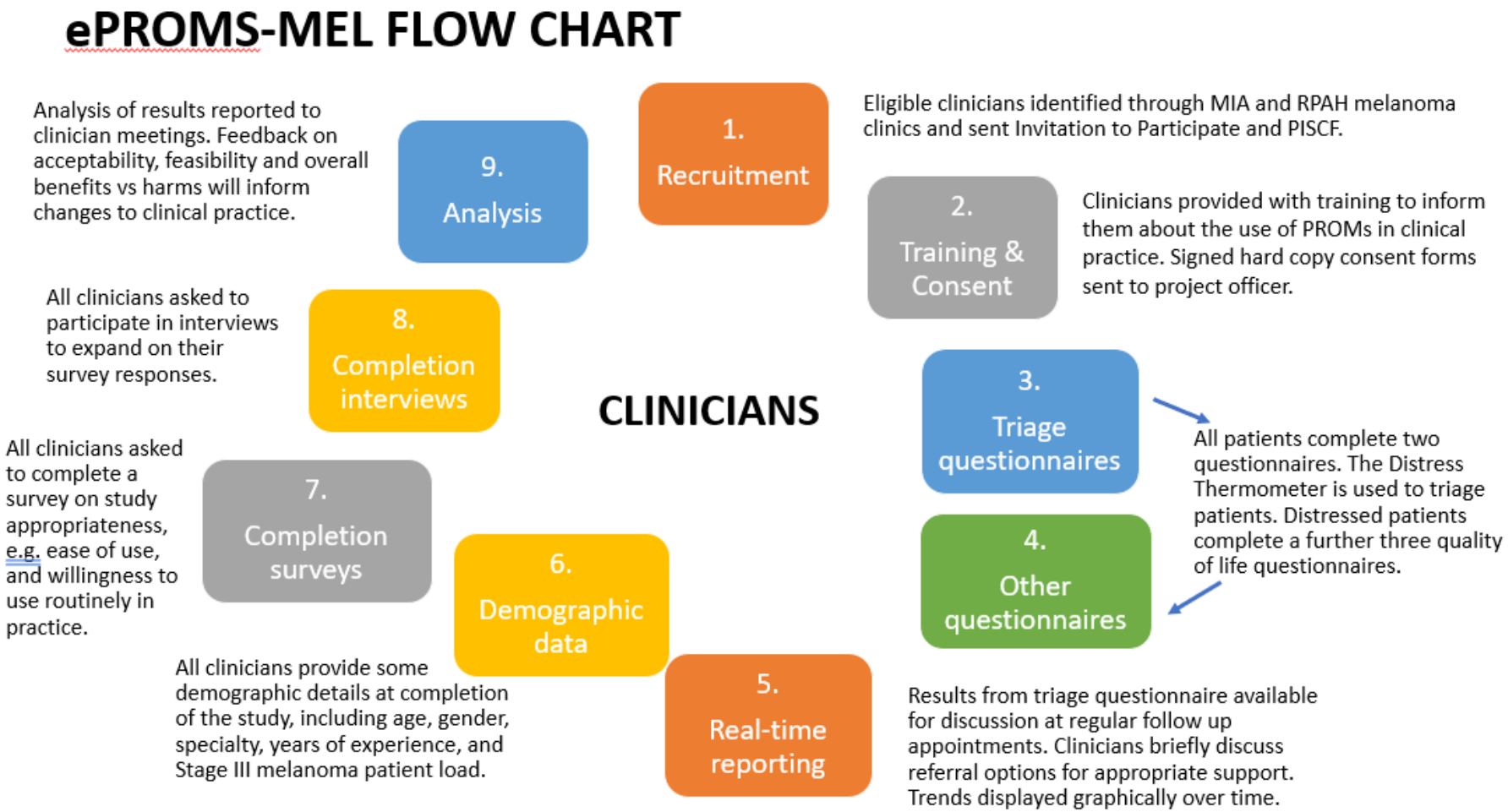

Fig 2: Clinician's Perspective

Patients who were recruited as Stage III patients but progress to Stage IV during the study can choose whether to continue in the study or not. Any continuing Stage IV patients will be asked to complete an interview at the end of the study to provide an assessment of how helpful they found this project to be considering their changing treatment and needs.

At each visit, all patients will be required to complete two short questionnaires that are used to assess their psychosocial distress and quality of life: 1. the National Comprehensive Cancer Network (NCCN)'s Distress Thermometer (DT) and Problem List for Patients[13] (Appendix 3); and 2. EuroQoL's EQ-5D-5L and visual analogue scale.[14] (Appendix 4). Patients who score 4 or above on the DT (the accepted clinical cut off score indicating the need for clinical intervention)), will automatically be triaged to complete an additional three questionnaires: the Melanoma Concerns Questionnaire (MCQ-28)[15] (Appendix 5), the Depression, Anxiety and Stress Scale (DASS-21)[16] (Appendix 6) and the European Organisation for Research and Treatment of Cancer (EORTC)'s QLQ-C30)[17] (Appendix 7). These additional questionnaires will provide more detailed information about potential areas of support needs.

The study questionnaires will be repeated at subsequent regularly scheduled follow-up appointments with their clinicians, approximately every 3 months alongside standard clinical follow-up visits over the course of 12 months, i.e. baseline, 3, 6, 9, 12 months (depending upon appointment schedules; maximum number of questionnaire sets is five). iPads were chosen because they are portable, have a user-friendly interface, are capable of hosting software that can automatically generate reports and associated documents and are a secure format for data management as they are encrypted by default.

The results from the completed questionnaires will be automatically generated by the program and sent to the treating clinician in real time, so they can be discussed during their consultation, along with medical concerns. Patients who request a copy of their results (by selecting the appropriate box in the 'About You' survey) will receive a summary of their scores by email, prior to their imminent appointment.

Participants who score 3 or above on any of the five domains covered in the EQ-5D-5L questionnaire (mobility, self-care, usual activities, pain/discomfort and anxiety/depression) may require clinical intervention (3= moderate, 4= severe, 5 = extreme limitations). There are no melanoma-specific cut-off scores, for the QoL questionnaires MCQ-28[15] and EORTC QLQ-C30.[17] For the initial appointment, these scores will be recorded as baseline measures. At subsequent visits, changes in the scores for all questionnaires will be graphically represented by domain and included in the results for clinicians to examine trends. A deterioration in EORTC QLQ-C30 scores that is 10 points or greater between visits is commonly regarded as clinically significant[18] and will represent a further trigger for discussion and possible referral to an appropriate service/support. Recommendations and referrals for additional support/services will be based on the questionnaire scores and clinical experience of the clinicians, and in collaboration with the patient.

After all rounds of patient questionnaires have been completed, all patients, clinicians and clinic staff will be asked to complete a survey providing quantitative and open-ended assessments of their experiences of using the PROMs questionnaires on iPads [Appendices 8-10].

In addition, approximately 24 patients, all study clinicians and some clinic staff will be asked whether they would be willing to be contacted by the research team to participate in a short (10-minute) confidential interview to expand on their survey responses [Appendices 11-13]. An additional Participant Information Sheet and Consent Form (PISCF) will be distributed to interested patients [Appendix 14], clinicians [Appendix 15] and clinic staff [Appendix 16] and signed consent forms will be returned to the project officer prior to interviews being conducted. Patients will be purposively sampled to maximise response variation and those who complete an interview will be offered a $30 Coles/Myer gift card to thank them for their time. Clinicians and clinic staff who participate in an interview will not be reimbursed for their time. Finally, patients will also be given the option of receiving feedback on the overall study results by selecting the appropriate box on the 'About You' survey (Appendix 17). This feedback will be in the form of a one-page lay summary, which participants will receive after the study has finished. Participating clinicians will receive feedback on study outcomes via seminars and MDT presentations.

All clinicians are experienced in treating Stage III melanoma patients and will undergo an ePROMs-MEL training session to familiarise themselves with the study prior to consenting and participating in the project. Additional video training resources are also available for clinicians and clinic staff.

11.2 Criteria for discontinuing or modifying interventions

Any participant is free to withdraw from the study at any time by contacting the project officer. As this is a pilot study, the intervention will be administered as described, and data will inform a subsequent expansion of the study if study processes are found to be feasible and acceptable to both patients and clinicians, and if outcomes are found to be beneficial. Modification of the intervention may be introduced at that time.

11.3 Strategies to monitor and improve adherence to the intervention protocol

Adherence to the intervention protocol will be closely monitored by the Steering Committee. The project officer will collate all quantitative data and inform the Steering Committee of questionnaire completion rates at 3 monthly intervals. Data will also be collected on referrals of patients who have questionnaire scores indicative of distress/poor quality of life to other members of the treatment team and/or to external support services. The uptake of these services will be included in the collated data. Qualitative interviews with patient and clinician participants at the end of the study will highlight the perceived ease of use, usefulness, relevance and importance of ePROMs to each group.

As this is a pilot study, we have deliberately chosen to not use any strategies to improve adherence to the protocol. If patients and clinicians do not want to enrol in, or continue with, this study, then that is an important indicator of the lack of feasibility and acceptability of this trial and is a crucial finding.

11.4 Relevant concomitant care and interventions that are permitted or prohibited during the study

Not relevant for this study.

12. Outcomes

12.1 Primary outcomes

The primary intended outcome of this study is to determine whether completion of PROMs electronically are considered by both patients and clinicians as feasible and acceptable when incorporated into routine clinical care. Important secondary outcomes include an assessment of whether these measures can help identify people who need and would benefit from further support/referral; and the production of a framework for the data systems required to enable electronic data capture and feedback to clinicians, useful in many other applications and clinical specialties.

Specifically, this project will:

1. Evaluate the collection of ePROMs in clinic-based settings;
2. Build the necessary framework to implement the efficient electronic capture of PROMs on tablet-based devices;
3. Identify the specific PROMs that are most useful and important from the perspectives of clinicians and patients;
4. Conduct brief quantitative surveys and qualitative interviews with patients who completed the PROMs in a clinic-based setting; and
5. Conduct quantitative surveys and qualitative interviews with the clinical teams that are treating/managing these patients.

The primary outcome of patient and clinician perceptions of the feasibility and acceptability of the intervention has two components.

12.1.1 Patient perceptions

Patient ratings of feasibility and acceptability will be assessed in several ways. The first is by the proportion of eligible patients approached who completed baseline and at least one set of follow-up PROMs data. If 60% of patients meet this requirement, the study will be deemed feasible and acceptable overall.

Data on individual patient measures of feasibility and acceptability will also be collected. In the first set of two questionnaires, all questions are mandatory, but with the second set of three questionnaires, patients are not required to answer all questions. Metadata from the patients who are triaged to complete the second group of questionnaires will be collected to provide an estimate of the mean time taken to complete the PROMs questionnaires and the amount of missing data (providing a second measure of patient acceptability for those who completed all five questionnaires). If patients take more than 30 minutes to complete the five questionnaires, they will be considered as not having met this acceptability criteria. Additional measures will include changes in baseline and follow-up scores and the proportion of patients who: 'agree or strongly agree' that the PROMs were easy to complete and that the questions they completed measured things they considered important to their QoL. Post-completion surveys of all patients [Appendix 8] and semi-structured interviews [Appendix 11] will be conducted with a subset of patients to assess feasibility and acceptability through the following main question themes: enjoyment of completing the

PROMs; changes in patient-clinician communication; changes in their management; and improvements or challenges they found in the processes.

12.1.2 Clinician perceptions

It is also important to assess the feasibility and acceptability of this project from the clinicians' perspective. These include whether they found the PROMs data provided to them to be useful, timely, easy to understand and appropriate for their patient population. Clinicians will be approached to expand on their survey responses [Appendix 9] in a semi-structured interview [Appendix 12]. The key themes these interviews will aim to address are related specifically to the PROMs instruments and the data that they received; changes in patient management; improvements in patient-clinician communication; and any key challenges or improvements that they can identify regarding the processes.

12.1.3 Clinic staff perceptions

The impact of introducing changes to clinic practice and routines on clinic staff is another key outcome. This will be measured through surveys [Appendix 10] and semi-structured interviews [Appendix 13] with these important health care team members at the end of the study.

12.2 Secondary outcomes

Research and clinical psychologists at MIA will use identified unmet needs from this study to inform future research into the development of support programs at MIA. The extent to which the routine use of PROMs in clinical practice can improve patients' emotional and physical problems will be assessed through changes in referral rates, referral uptake rates and patients' QoL scores over time. Patient and clinician interviews will allow for more extensive evaluation of this aspect of the study. The utility of this framework for the data systems required to enable electronic data capture and feedback to clinicians will be assessed in patient and clinician surveys and interviews as well as by the views of the project team. As adjuvant drug treatment of stage III melanoma has only just begun to be routinely implemented (based on trials run at MIA), the findings from this study will also be able to be readily translated to other melanoma units where these patients will receive care.

12.3 Framework for assessment of outcomes

The overall success of the project will be assessed using the Proctor et al. framework for implementation research[19] which considers not only the intervention outcomes (service and client) but also the implementation outcomes, as outlined in Fig. 3.

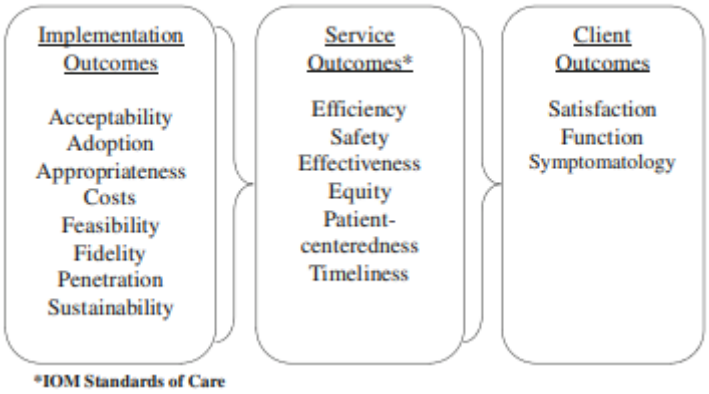

Fig. 3 Types of outcomes in Implementation Research[19]

13. Participant timeline

Table 1. Participant timeline

	STUDY PERIOD					
	Baseline	3 months	6 months	9 months	12 months	End of study
TIME POINTS[1]	T0	T1	T2	T3	T4	T5
ENROLMENT						
Eligibility screen	X					
Informed consent	X					
Recruitment	X					
INTERVENTIONS						
Baseline patient questionnaires	X					
Baseline patient demographic info	X					
Follow-up patient questionnaires		X	X	X	X	
Clinician completion surveys						X
Patient completion surveys						X
Clinician completion interviews						X
Patient completion interviews						X
Clinician referral data						X
Patient referral uptake data						X
Patient change over time (T0-T5)						X
ASSESSMENTS						
Clinician acceptance						X
Patient acceptance						X
Referral rate						X
Referral uptake rate						X

Table 1 adapted from the template designed by the SPIRIT Group ©2013[20]

1. For each time point, a window of +/- 2 months is acceptable due to variation in routine clinical appointments.

14. Sample size

The sample size for this pilot feasibility study is 120 patients and approximately 10 clinicians. It is estimated that only 5% of all Stage III melanoma patients currently receive referrals for psychological care (Melanoma Institute Australia, data unpublished). Assuming 30% of Stage III melanoma patients have levels of distress that indicate the need for clinical intervention,[21] we would expect to identify approximately 36 patients within our sample who will be triaged for discussion of referrals to support services.

15. Recruitment

15.1 Patient recruitment

Patients will be recruited through surgical and medical melanoma clinics at MIA and RPAH. Approval from the treating clinical team, e.g. oncologist or clinical nurse consultant, will be requested before contacting patients for the ePROMs-MEL study. This process will be organised by the project officer to ensure minimal disruption for clinic staff.

Eligible and appropriate patients will be initially contacted by the project officer who will send them three documents along with a covering letter (either by email or post; posted documents will contain a stamped self-addressed envelope). The email/letter will briefly introduce the study and ask patients to read the Invitation to Participate (Appendix 18) and the Participant Information Sheet (PIS Appendix 19), and to complete and return an Expression of Interest form (EoI – Appendix 20). The EoI form provides patients with three options to select from. The first option denotes their willingness to participate in the study; the second denotes their potential willingness to participate in the study; and the third option states that they are not interested in participating. If patients do not respond to the request to return the EoI, the project officer will telephone them once to check whether they have received it. A draft telephone script is provided in Appendix 21.

The project officer will follow up with the patients who have indicated their willingness or potential willingness to participate, answer any questions and concerns they may have about the study and ask them to arrive 15-30 minutes earlier for their scheduled appointment to allow time to complete the questionnaires. The PIS contains contact numbers of the academic (RM) and clinical leads (RS) for this project so patients may contact them prior to making their decision to participate. When patients arrive at the clinic for a regular appointment, they will again be given the opportunity to discuss any questions they may have regarding their participation with the project officer who will greet them, obtain their electronic consent on the iPad and explain to them how to complete the questionnaires on the iPad.

Patient recruitment is expected to be around two to ten per week over a 6-month period. If recruitment takes longer, the ePROMs-MEL Steering Committee will consider possible changes to the protocol to increase the recruitment rate (e.g. recruitment of additional clinicians).

15.2 Clinician recruitment

Clinical staff will be informed about the project through education sessions at clinical and multi-disciplinary team (MDT) meetings and be given a written Invitation to Participate [Appendix 22]. Interested clinicians will be provided with an electronic Participant Information Sheet and Consent Form (PISCF) to read [Appendix 23]. Either hard copies of signed consent or scanned electronic versions will be acceptable and collated by the project officer prior to the clinician seeing study patients.

SECTION 4. Methods: Assignment of interventions (for controlled trials)

16. Allocation

This study is not a randomised controlled trial so these items are not applicable.

17. Blinding

This study is not a randomised controlled trial so these items are not applicable.

SECTION 5. Methods: Data collection, management and analysis

18. Data collection

18.1 Plans for assessment and collection of outcome, baseline and other trial data.

All project data will be managed according to the standards of the University of Sydney Research Data Management Policy.[22] Electronic questionnaire data will be collected via a purpose-built electronic data capture management system developed by MIA. iPads have been purposely chosen as the data collection device as they are encrypted by default. The study instruments have been described in Section 11. All five PROMs questionnaires (Appendices 3-7) have been validated and all except the recently-released MCQ-28 have been extensively used in oncology trials. All other data collection forms to be used in this study are available as Appendices 8-24.

18.3 Plans to promote participant retention and complete follow-up.

This project aims to establish the acceptability and feasibility of the routine use of PROMs in clinical practice. As a result, the project will not include specific strategies to promote participant retention and complete follow-up. However, the study design does include assessments at regularly scheduled clinician appointments which the patients are likely to attend. The study has been designed to minimise patient burden by triaging the questionnaires, so that only patients who have self-reported responses indicative of psychosocial distress/poor QoL go on to complete a further three questionnaires. It is expected the majority of patients (approximately 70%)[21] will only need to complete two very short measures of distress/QoL at each visit (Appendices 3 and 4).

Participants who do not wish to continue with the study may leave at any time by contacting a member of the research team and completing a Withdrawal of Consent form (Appendix 24). Participants may also stop completing questionnaires if they are finding them distressing by handing the iPad back to the clinic reception. These participants will still be considered as enrolled in the study, and their incomplete data will be included in the analysis, unless they complete the Withdrawal of Consent form. Patients who have withdrawn from the study will also be given the opportunity to participate in a post-study interview if they wish to discuss why they chose to withdraw, but they will not be coerced to do so. The project officer will keep a record of any patients who have withdrawn or failed to complete the study tasks and the date of these events.

19. Data management

All participants in this study will be sequentially allocated a unique study ID at recruitment (e.g. P01 for the first patient and C01 for the first clinician). A REDcap project database has been established on a secure MIA server. Hard copy data will be scanned or entered into this project database, and any hard copy forms will be stored separately and securely in a locked cupboard belonging to a Steering Committee member within MIA. Processes to ensure confidentiality of data are covered is section 27.

20. Data analysis / Statistical methods

20.1 Quantitative analysis

Participant demographics and characteristics will be summarised for all participants using means and standard deviations. In addition, the consent, participation, and completion rates will be analysed. Consent will be defined as agreeing to participate in the study and returning a signed consent form; participation, as completing some of the components of the study; and completion, as completing all components of the study. Specifically, the proportion of eligible participants who completed the project tasks will be assessed to determine whether the inclusion of ePROMs are acceptable for patients undergoing follow-up treatment for stage III melanoma. Descriptive statistics will be reported for QoL and other questionnaire domain scores at baseline and follow-up time points. Referral and referral uptake rates will also be calculated. The small sample size of 120 for this pilot study precludes any sub-group analysis. As noted previously, the proportion of missing data is a project outcome that will not require adjustment.

20.2 Qualitative analysis

Results from semi-structured patient interviews conducted at the conclusion of the project will be reported to assess patient views on the usability, benefits and limitations of the study questionnaires they completed, whether questionnaire results were discussed within the subsequent clinical consultation, and if so whether this led to any change in management. Similarly, results from end of study clinician interviews will report their views on the feasibility, acceptability, benefits, limitations and usefulness of including ePROMs into the routine care for patients within their practice. Electronic qualitative analysis software (such as NVivo) will be used to assist in the

development of a framework of key themes identified from the interview data that will then form the basis of a thematic analysis.[23]

SECTION 6. Methods: Monitoring

21. Data monitoring

As this is a pilot study of 120 participants, the Project Steering Committee will provide independent oversight for monitoring. The project officer will produce monthly reports on participation, withdrawals and protocol deviations to this Steering Committee. Despite this being a low-risk study (see Harms section), any adverse events will be reported to the Steering Committee immediately for prompt action.

22. Harms

There are no foreseeable harms, risks or costs associated with taking part in this study. It is possible some patients may experience short-term distress while answering the questionnaires. If a patient does not wish to answer a question, they may skip it and go to the next question, or immediately stop completing the questionnaires. A melanoma clinical nurse consultant and/or treating clinician will be available to talk with a distressed patient if their distress continues once they have stopped completing the questionnaire. Patients are free to withdraw from the study at any time. Clinicians may experience frustration with having to review patient summary scores from the questionnaires if they are particularly busy.

23. Auditing

External auditing of this Pilot study is not expected. Study conduct and progress will be reported in the minutes of the ePROMs-MEL Steering Committee meetings.

SECTION 7. Ethics and dissemination

24. Research ethics approval

Ethics approval was obtained from St Vincent's Hospital Human Research Ethics Committee on 19/09/2019 (2019/ETH10558).

Site authorisation was obtained for the following two project sites on 19/09/2019:

- Sydney Melanoma & Surgical Oncology, MIA, Poche Centre
- Sydney Melanoma & Surgical Oncology, Royal Prince Alfred Hospital (RPAH) Camperdown

25. Protocol amendments

This protocol has undergone significant revision since the first version was drafted in April 2019. Further major revisions are unlikely. However, should any important protocol modifications be required, the Steering Committee will approve them and changes will be made to the relevant participant documents. Revisions of these documents will be tracked and submitted to the approving Human Research Ethics Committee for their approval or noting.

26. Consent or assent

Patient and clinician consent will be obtained by the project officer. All patients will have already seen the Participant Information Sheet and will have chosen one of three options from an Expression of Interest form (see Section 15 and Appendix 18). Additional Participant Information Sheet and Consent Forms will be sent to participants who indicate their willingness to participate in these interviews (Appendices 13 and 14).

27. Confidentiality

All patient and clinician data will be de-identified. Only the project officer will know the participant identification numbers.

Summary questionnaire scores will be incorporated into the patient's medical record at MIA and RPAH, either electronically or as a hard copy, and be stored under the usual patient record security systems. Electronic PROMs data, collected via iPads, will be exported to the secure REDCap database on the MIA server along with patient demographic and completion survey data (from patients and clinicians).

Audio files of interviews will be deidentified (by use of the participant study ID number only) and sent to a professional transcription service which has signed a confidentiality agreement. Electronic interview transcripts will be stored on the MIA project server. Any identifying information will be stored separately from the transcripts at all times. The participants' identity will not be revealed in any publication or presentation. We will endeavor to preserve participant anonymity by ensuring quotes used in publications or presentations do not include any identifying information such as position, place of work, geographical location (e.g. state). Instead, generic terms such as 'surgeon', 'medical oncologist' or 'patient' will be used.

Project materials will ultimately be disposed of via secure document destruction services and using best-practice disposal mechanisms, as specified in the current University of Sydney research policies.[22]

28. Declaration of interests

RPMS has received honoraria for advisory board participation from Merck Sharp Dohme, Novartis and Qbiotics and speaking honoraria from Bristol Myers Squibb. This study does not involve any project-specific financial, commercial or other competing interests for the principal investigators.

29. Access to data

Only the named investigators will have access to the full final trial dataset. There are no contractual agreements that limit access for investigators. De-identified individual results from the newly-developed Melanoma Concerns Questionnaire (MCQ-28) will be provided to the questionnaire developers to help them further assess the reliability of it in different populations and settings.

30. Ancillary and post-trial care

There are no provisions for ancillary and post-trial care. Clinicians will discuss with their patients the options for being referred to other health professionals to support them with their self-reported problems. Study investigators are not responsible for ensuring that referral is taken up by the patient, although we will be reporting on the rate of referral uptake. We do not anticipate any harm to the patients from trial participation and have not made any provisions for compensation.

31. Dissemination policy

31.1 Communication of trial results

Study results will be communicated to participants via a short, lay summary of overall study findings at the end of the study. Patients can also opt in to receive their personal questionnaire results at each scheduled visit over the study time period. Overall study results will be communicated to healthcare professionals and other relevant groups through publication in peer-reviewed journals, seminar/webinar presentations and presentations at scientific conferences.

31.2 Public access to data

De-identified data only will be made available through a nominated data repository on request. Public access to participant-level data will not be available due to patient privacy concerns.

31.3 Authorship guidelines

Authorship eligibility guidelines will be published according to journal requirements. Professional writers will not be used to report on this study. The full protocol will be published in an open access peer-reviewed journal. There are no specific publication restrictions.

31.4 Publications policy

A Publications policy has been created for this study. It outlines processes for authorship and will guide the appropriate recognition of all contributors to the intellectual property developed within the study. It applies to all publications that present research arising from and/or receiving funding from the pilot study and main study.

SECTION 8. Appendices

There are 24 Appendices to this study protocol (see Appendix 2 for full list).

32.1 Informed consent materials

14. PISCF – for end of study interviews – Patients
15. PISCF – for end of study interviews – Clinicians
16. PISCF – for end of study interviews – Clinic staff
17. 'About you' patient survey
18. Invitation to participate – Patients
19. Participant Information Sheet – Patients
20. Expression of Interest form - Patients
21. Telephone script for follow-up of non-responders – Patients
22. Invitation to participate – Clinicians
23. Participant Information Sheet and Consent Form – Clinicians
24. Withdrawal of Consent form

32.2 Biological specimens

Not applicable

SECTION 9. References

1. Bantug ET, Coles T, Smith KC, Snyder CF, Rouette J, Brundage MD. Graphical displays of patient-reported outcomes (PRO) for use in clinical practice: What makes a pro picture worth a thousand words? Patient Educ Couns. 2016;99: 483-490.

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We thank Sam Robinson for his work on developing an earlier version of this protocol, Gayan Jayaweera for his development work on the computer programming components of this study, and Linda Seaman and Craig Lawn for providing consumer-focused feedback.

SECTION 10. List of Appendices

1. World Health Organization Trial Registration Data Set
2. ePROMs-MEL Investigators (and Steering Committee members)
3. National Comprehensive Cancer Centre (NCCN)'s Distress Thermometer (DT) and Problem List for Patients PROMS questionnaire*
4. EuroQoL's EQ-5D-5L and visual analogue scale PROMS questionnaire*
5. Melanoma Concerns Questionnaire (MCQ-28)*
6. Depression, Anxiety and Stress Scale (DASS-21)*
7. European Organisation for Research and Treatment of Cancer (EORTC)'s QLQ-C30*
8. Completion patient survey
9. Completion clinician survey
10. Completion clinic staff survey
11. Patient interview schedule
12. Clinician interview schedule
13. Clinic staff interview schedule
14. PISCF – for end of study patient interviews
15. PISCF – for end of study clinician interviews
16. PISCF – for end of study clinic staff interviews
17. 'About you' patient survey
18. Invitation to Participate – Patients
19. Participant Information Sheet – Patients
20. Expression of Interest form - Patients
21. Telephone script for follow-up of non-responders – Patients
22. Invitation to participate – Clinicians
23. Participant Information Sheet and Consent Form – Clinicians
24. Withdrawal of Consent form.

* To preserve formatting of these five PROMs, they are saved in one separate PDF file named **All instruments comb-1-05-NOV-2020**
There have been no subsequent changes to this file since it was approved on 27 Nov 2020 (2019/ETH10558: General Amendment (42927) - Approved)

Appendix 1. All items from the World Health Organization Trial Registration Data Set[17]

Data category	**Information**
Primary registry & trial identifying number	Australia New Zealand Clinical Trials Registry (ANZCTR). ID number: ACTRN12620001149954
Date of registration in primary registry	15/01/2021.
Secondary identifying numbers	U1111-1257-2777
Source(s) of monetary or material support	Australian National Health and Medical Research Council (NHMRC) Centre for Research Excellence in Melanoma grant (Grant No.1135285). Melanoma Institute Australia (material support).
Primary sponsor	The University of Sydney
Secondary sponsor(s)	Not applicable
Contact for public queries	Dr Kathy Dempsey kathy.dempsey@sydney.edu.au
Contact for scientific queries	Dr Kathy Dempsey kathy.dempsey@sydney.edu.au
Public title	Pilot study to embed **e**lectronic **P**atient **R**eported **O**utcome **M**easure**s** and into routine care for patients with Stage III **MEL**anoma (ePROMs-MEL)
Scientific title	Pilot study to embed **e**lectronic **P**atient **R**eported **O**utcome **M**easure**s** into routine care for patients with Stage III **MEL**anoma (ePROMs-MEL)
Countries of recruitment	Australia
Health condition(s) or problem(s) studied	Stage III Melanoma
Interventions	Administration of Patient-Reported Outcome Measures (PROMs) Administration of surveys and interviews regarding patient, clinic staff and clinician views on the acceptability and feasibility of using these PROMs

Key inclusion and exclusion criteria	Inclusion criteria: **Adult patients (over 18) who:** - Have had a diagnosis of Stage III melanoma 3 months earlier or are attending their second or subsequent consultation with an oncologist following initial treatment. - Attend for regular follow-up appointments at least twice per year. - Are under the care of melanoma clinicians at Melanoma Institute Australia (MIA) or Royal Prince Alfred Hospital (RPAH) - Have sufficient English and cognitive ability to comprehend study materials, provide informed consent and participate in the study. **Clinicians who:** - Are currently treating and managing patients with stage III melanoma at MIA or RPAH. Exclusion criteria: None.
Study type	Prospective, longitudinal cohort intervention study incorporating mixed methods (quantitative surveys and qualitative interviews).
Date of first enrolment	28 May 2021
Target sample size	120 (Pilot study)
Recruitment status	Commenced; delays due to COVID-19
Primary outcomes	To determine whether completion of PROMs electronically are feasible and acceptable to both patients and clinicians when incorporated into routine clinical care
Key secondary outcomes	1. An assessment of whether these measures can help identify people who need further support/referral; 2. The production of a framework for the data systems required to enable electronic data capture and feedback to clinicians.

Appendix 2. ePROMs-MEL Investigators

Professor Rachael Morton* (Chief Investigator) Rachael.Morton@ctc.usyd.edu.au	Director of Health Economics, NHMRC Clinical Trials Centre, The University of Sydney NSW Australia & Melanoma Institute Australia (MIA) Faculty
Associate Professor Robyn Saw* Robyn.Saw@melanoma.org.au	Melanoma Surgeon, MIA Faculty, Royal Prince Alfred Hospital (RPAH), and Mater Hospitals & University of Sydney
Associate Professor Sergine Lo* Serigne.Lo@melanoma.org.au	Senior Statistician, MIA Faculty and Senior Research Fellow in Biostatistics, The University of Sydney.
Dr Iris Bartula* Iris.Bartula@melanoma.org.au	Research and Clinical Psychologist, MIA
Dr Kathy Dempsey* Kathy.Dempsey@sydney.edu.au	Senior Research Fellow, Cancer Health Policy. NHMRC Clinical Trials Centre, University of Sydney.
Mr Craig Lawn*	Consumer Representative
Dr Thomas Pennington Thomas.Pennington@melanoma.org.au	Melanoma Surgeon, MIA
Professor Andrew Spillane Andrew.Spillane@sydney.edu.au	Melanoma and Breast Cancer Surgeon, MIA; Professor of Surgical Oncology, Royal North Shore Hospital & University of Sydney.
Professor Georgina Long Georgina.Long@melanoma.org.au	Medical Oncologist, MIA; Co-Director, MIA.
Assoc Professor Alex Menzies Alex.Menzies@melanoma.org.au	Medical Oncologist, MIA
Professor Frances Boyle Frances.Boyle@sydney.edu.au	Medical Oncologist, MIA; Director, Patricia Ritchie Centre for Cancer Care and Research, Mater Hospital, North Sydney; Professor of Medical Oncology, University of Sydney.
Dr Mbathio Dieng Mbathio.Dieng@sydney.edu.au	Postdoctoral Fellow, NHMRC Clinical Trials Centre, University of Sydney.
Dr Skye Dong Skye.Dong@melanoma.org.au	Clinical Psychologist, MIA
Mr Samuel Herzog Samuel.Herzog@melanoma.org.au	Project Officer, ePROMs-MEL, MIA
Ms Shahn Coburn Shahn.Coburn@melanoma.org.au	Clinical Nurse Consultant, MIA
Ms Kate Willis Kate.Willis@melanoma.org.au	Clinical Nurse Consultant, MIA
Ms Rebecca Biviano Rebecca.Biviano@melanoma.org.au	Clinical Nurse Consultant, MIA
Ms Natalie Osborne Natalie.Osborne@melanoma.org.au	Clinical Nurse Consultant, RPAH
Ms Emel Fikri Emel.Fikri@health.nsw.gov.au	Melanoma Nurse, RPAH
Dr Donna Milne Donna.Milne@petermac.org	Melanoma Nurse, Peter MacCallum Cancer Centre
Mr Jake Thompson Jake.Thompson@melanoma.org.au	Research Officer ePROMs-MEL, MIA

* Member of ePROMs-MEL Steering Committee

Appendix 8. **Completion survey - patient**

Professor Rachael Morton
Director, Health Economics & Health Technology Assessment
Deputy Director, NHMRC Clinical Trials Centre

Camperdown, NSW 2050, Australia
Tel: 61-2-9562-5000
Fax: 61-2-9565-1863
Email: Rachael.morton@sydney.edu.au

Study ID number. _____

Please circle/select the appropriate response.

1. Do you agree the questionnaires were easy to complete?

0	1	2	3	4
Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree

Please provide reasons for your choice

_____
_____
_____
_____

2. Do you agree the questionnaires you completed measured the things that you consider important to your quality of life?

0	1	2	3	4
Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree

Are there other questions you would have preferred to be asked in relation to your quality of life?

_____
_____
_____
_____

3. Do you agree your "whole of person" health and welfare has been improved because of the collection and consideration of the data on a real time basis with your clinician?

0	1	2	3	4
Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree

Please provide reasons for your choice

_____
_____
_____
_____

4. Do you think your "whole of person" health and welfare has been improved because of the availability of support resources and groups? (0 = completely agree; 4 = completely disagree)

_____

0	1	2	3	4
Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree

Please provide reasons for your choice

_____
_____
_____
_____

5. Would you be willing to be contacted by the research team for a 10-20 minute confidential face to face or telephone interview to discuss your thoughts about the questions that you completed?

Yes No

If yes: Please provide your contact details below and a member of the research team will be in touch with you soon to discuss this further, and to provide you with a Participant Information Sheet and Consent Form for the interview.

Phone number: _____

Email address: _____

THANK YOU FOR COMPLETING THIS SURVEY.

Your time and cooperation is highly valued. We will keep you updated about the results.

The ePROMs-MEL team

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Appendix 9. Completion survey - clinician

Professor Rachael Morton
Director, Health Economics & Health Technology Assessment
Deputy Director, NHMRC Clinical Trials Centre

Camperdown, NSW 2050, Australia
Tel: 61-2-9562-5000
Fax: 61-2-9565-1863
Email: Rachael.morton@sydney.edu.au

Name: _____

Please circle/select the appropriate response

1. Age group: <30 31-40 41-50 51-60 >60

2. Gender: Male Female Other

3. How many years' experience do you have managing patients with stage III melanoma?

   < 1 year 1-5 years 6-10 years 11-15 years 16-20 years >20 years

4. What is your medical specialty?
   Surgeon
   Oncologist
   Nurse
   Specialist GP
   Allied Health (please specify) _____
   Other (please specify) _____

5. Currently, how many patients with stage III melanoma do you manage per year?

   <20 21-50 51-100 >100

6. Do you agree the results of the PROMs were useful?

0	1	2	3	4
Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree

Please provide reasons for your choice

_____
_____
_____
_____

7. Do you agree the format of information provided to you was easy to read and understand?

0	1	2	3	4
Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree

If not – how could this be improved?

_____
_____
_____

8. Do you agree that the questionnaires were appropriate for your patients' Stage of disease?

0	1	2	3	4
Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree

If not appropriate – why not?

_____
_____
_____

9. Do you agree the questionnaires were adequately detailed to capture your patients' concerns related to quality of life or current health status?

0	1	2	3	4
Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree

If not – what additional questions or topics would you like to be included in future sets of ePROMs / ePREMs?

_____
_____
_____
_____

10. Would you consider implementing ePROMs / ePREMs for other patients that you manage?

Yes No

If yes – for what other patient populations would you consider implementing ePROMs/ ePREMs? *For example, stage II, stage IV etc.*

_____
_____
_____

If no – why would you not implement ePROMs/ ePREMs?

_____
_____
_____

11. Overall, do you agree that incorporating ePROMs / ePREMs in routine care for patients with stage III melanoma is feasible?

_____

0	1	2	3	4
Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree

If agree or strongly agree: What factors make incorporating ePROMs / ePREMs in routine care for patients with stage III melanoma feasible?

_____
_____
_____

If disagree or strongly disagree: Why do you believe that incorporating ePROMs / ePREMs in routine care for patients with stage III melanoma is not feasible?

_____
_____
_____

12. Would you be willing to be contacted by the research team for a 10-20 minute confidential interview to discuss the feasibility and practicality of incorporating ePROMs/ ePREMs into routine care for patients with stage III melanoma?

Yes No

If yes: Please provide your contact details below and a member of the research team will be in touch with you soon to discuss this further, and to provide you with a Participant Information Sheet and Consent Form for the interview.

Phone number:_____

Email address:_____

THANK YOU FOR PARTICIPATING IN THIS STUDY – we know how busy you are!

Your time and cooperation is highly valued. We will keep you updated about the results.

The ePROMs-MEL team.

Appendix 10. Completion survey - clinic staff

Professor Rachael Morton
Director, Health Economics & Health Technology Assessment
Deputy Director, NHMRC Clinical Trials Centre

Camperdown, NSW 2050, Australia
Tel: 61-2-9562-5000
Fax: 61-2-9565-1863
Email: Rachael.morton@sydney.edu.au

Please circle/select the appropriate response

1. Which clinic do you work in? (you may select more than one)

   SMSO Poche

   SMSO RPAH

   Long/Menzies

2. Did you find the ePROMs project disruptive to clinic processes?

0	1	2	3	4
Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree

   If yes, in what ways?

   _____
   _____
   _____
   _____

3. Do you think the patients benefited from the project?

0	1	2	3	4
Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree

   If yes, in what ways?

   _____
   _____
   _____

4. Would you be pleased if ePROMs became part of routine care in your clinic?

0	1	2	3	4
Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree

If no, why not?

_____
_____
_____

5. Can you suggest changes that could be made to the project that would minimise clinic disruption?

Yes No

If yes, please share your suggestions below.

_____
_____
_____
_____

6. Would you consider implementing ePROMs for all patients in your clinic if additional resources were available?

Yes No

If yes, what additional resources would you want?

_____
_____
_____

7. Would you be willing to be contacted by the research team for a 10-20 minute confidential interview to discuss the feasibility and practicality of incorporating ePROMs/ ePREMs into routine care for patients with stage III melanoma?

Yes No

If yes: Please provide your contact details below and a member of the research team will be in touch with you soon to discuss this further, and to provide you with a Participant Information Sheet and Consent Form for the interview.

Phone number:_____

Email address:_____

THANK YOU FOR PARTICIPATING IN THIS STUDY – we know how busy you are!
Your time and cooperation is highly valued. We will keep you updated about the results.
The ePROMs-MEL team.

Appendix 11. Interview Schedule - Patient

Professor Rachael Morton
Director, Health Economics & Health Technology Assessment
Deputy Director, NHMRC Clinical Trials Centre

Camperdown, NSW 2050, Australia
Tel: 61-2-9562-5000
Fax: 61-2-9565-1863
Email: Rachael.morton@sydney.edu.au

Major themes	Prompts
1. Completing the questionnaires	Did you enjoy filling in the PROMs in the waiting room? What did you enjoy most? What did you enjoy least?
	Did you find them easy to complete or did you have some problems completing them? - If so, what kind of problems did you find? (e.g. using the iPad, understanding the questions, not finding appropriate answers among the options, or too nervous about your appointment with the doctor to focus on the questions?
	How did you find using the iPad? Do you use an iPad or similar tablet frequently? Would you have preferred a pen and paper version of the questions over the iPad?
	How long did they typically take you to fill in? Did you get quicker over time?
2. Patient-clinician communication	When you went into your appointment with your doctor, who typically initiated the conversation related to the questions that you filled out?
	Who raised the questions about your questionnaire results? If the doctor initiated the conversation: when did they usually bring up the questions with you? Before or after your normal consultation? Did this always happen or did it vary a bit?
	If patient initiated: how did you feel about bringing up the discussion? Was it always left up to you or did it vary a bit? Would you have preferred your doctor to start the conversation?
	Did you talk about other problems that have been worrying you with your doctor? Did they seem interested?
	If yes: do you think you would have brought up these issues if you hadn't completed the questionnaires? Do you think doing the questionnaires has increased your confidence to talk about problems or not?
	If no: have you previously had questions that you would like to ask your doctor in appointments? What do you think stopped you from asking them?
3. Changes in management	Do you think completing the questionnaires has changed how you are managed by your doctor? In what ways? Is it generally better now, worse or the same?
	Were you referred to any allied health professionals after discussing anything raised in these questionnaires with your doctor? If yes, do you think that you would have been referred without this discussion with your doctor? If no, do you feel like you would benefit from a referral to an allied health professional? E.g. a physiotherapist for your physical functioning, an occupational therapist for your home environment, or a psychologist for your mental health and well-being?
	Do you think doing these questionnaires has changed your relationship with your doctor? If yes, in what ways?

4. Changes in all aspects of health?	Do you feel like they helped you to reflect on yourself, your health and your current care?
	Do you fell your “whole of person” health and welfare has improved because of the collection and consideration of the data on a real time basis with your clinician?
	Do you fell your “whole of person” health and welfare has improved because of the availability of support resources and groups?
5. Improvements on PROMs/PREMs processes	Do you see any room for improvement for: The way you reported these questions? I.e. the iPad in the waiting room? The way the clinician reported the results to you? Do you think doing these questionnaires has been helpful for you or not? Can you give any examples of how they have affected your consultations and life outside the clinic? Did you feel like the topics raised in the questionnaires were important to you or not? Overall, how worthwhile was the recording or reporting of these questions to you?

Appendix 12. Interview Schedule - Clinician

Professor Rachael Morton
Director, Health Economics & Health Technology Assessment
Deputy Director, NHMRC Clinical Trials Centre

Camperdown, NSW 2050, Australia
Tel: 61-2-9562-5000
Fax: 61-2-9565-1863
Email: Rachael.morton@sydney.edu.au

Major themes	Prompts
1. PROM/PREM questionnaires	How timely was the information you received from the PROMs for the clinical consultation? Did it vary depending on individual patient characteristics such as current health state, age, comorbidities? Do you think patient anxiety prior to the appointment skewed the results?
	Was the data presented to you in a useful or meaningful way? • If yes, what did you like about it? • If no, where or what could be improved?
	Have there been any issues related to the data capture process for patients? Any questions or concerns that they have reported to you or your staff directly about the project? Using the iPads? The questions they complete?
	Have you noticed the length of your consultations have changed since this trial implementation of PROMs? • If longer, is there anything that you think could streamline processes? • Do you think the longer appointments have been beneficial to discuss additional concerns or questions with your patients or not?
2. Patient-clinician communication	Did you or your patient bring up any questions or concerns related to issues raised in the PROMs?
	Did the patient bring up any other concerns that had not been discussed previously?
	When and how did you bring up the information in the PROM with your patient? Before or after the general consultation began?
	Did discussing the PROMs lead to a change in general patient management? Did the discussion identify any new problems or underlying issues with your patient that were not apparent otherwise? Did it lead to referrals to allied health?
	Any issues with discussing this information/feedback with your patients? If yes: Is there anything else that you think would help this discussion?
3. Benefits of PROMs/PREMs	Overall, have the implementation of PROMs into routine care been useful in your practice? Can you give any examples? [Identifying underlying quality of life issues from patients? Referral pathways for patients reporting low levels of quality of life or other issues? Noticed any changes in patient's confidence/ability to communicate with you? i.e. do you feel like this has improved clinician patient communication and relationship? Have you seen improved patient outcomes? Do you feel more satisfied because you have been able to pay better attention to whole of person issues?]
4. Improvements or comments on PROMs/PREMs processes	Any room for improvement that you have identified related to: The data collection process for patients? The way you are presented with your data report of the PROMs? Any other questions, or concerns related to the implementation of PROMs into the routine care for your patients?

Appendix 13. Interview Schedule - Clinic Staff

Professor Rachael Morton
Director, Health Economics & Health Technology Assessment
Deputy Director, NHMRC Clinical Trials Centre

Camperdown, NSW 2050, Australia
Tel: 61-2-9562-5000
Fax: 61-2-9565-1863
Email: Rachael.morton@sydney.edu.au

Major themes	Prompts
1. Interaction with project staff	How satisfied were you with the information/training you received for this Pilot study?
	How would you rate overall communication with project staff out of 10?
	Were the project staff on time, polite and friendly? Did they ask you to do anything you did not want/expect to have to do?
	Did you find project staff were physically in the way during clinics? If so, how big a problem was this for you?
	Did project staff interfere with the smooth running of the clinic? If yes, in what ways?
	Did questionnaire administration by project staff delay consultation commencements? If yes, by how much?
	Do you have any other comments on interaction with project staff?
2. Patient-clinician communication	Do you have any views on whether or not patient-clinician communication was improved during the project? Did patients seem to value being asked questions about their physical and emotional health? Did any patients seem to be annoyed or inconvenienced by being asked to complete questionnaires?
3. Advantages of project participation	Overall, has the pilot implementation of PROMs into routine care been useful in your clinic? Did you hear any positive feedback from patients? What about negative feedback? Have you noticed any changes in patient's confidence/ability to communicate with you? Have you seen improved patient outcomes? Do you feel more satisfied because you have been able to facilitate better attention to issues of concern for patients?
4. Disadvantages of project participation	Overall, what did not work for you/your clinic in terms of implementing this Pilot? Do you think the benefits are worth the trouble?
5. Improvements or comments	Have you identified any room for improvement related to the administration of ePROMs by research staff in your clinic? Any other questions, or concerns related to the implementation of PROMs into the routine care for your patients?

Appendix 14: PISCF – for end of study interviews - Patients

Professor Rachael Morton
Director, Health Economics & Health Technology Assessment
Deputy Director, NHMRC Clinical Trials Centre

Camperdown, NSW 2050, Australia
Tel: 61-2-9562-5000
Fax: 61-2-9565-1863
Email: Rachael.morton@sydney.edu.au

PARTICIPANT INFORMATION SHEET & CONSENT FORM
PATIENT INTERVIEW

Study title: Pilot study to embed **e**lectronic **P**atient **R**eported **O**utcome **M**easure**s** into routine care for patients with Stage III **MEL**anoma (ePROMS-MEL)

Thank you for participating in this project over the last year. We are now asking if you will be willing to undergo a short additional interview about the project to provide us with more detailed information about what worked and what didn't work from your perspective as a melanoma patient.

What does my participation involve?
Please read this information carefully. Ask questions about anything that you don't understand or want to know more about.

Participation in this research is voluntary. If you don't wish to take part, you don't have to.

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 be involved in the research described
- ✓ Consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information Sheet to keep.

What is the purpose of this research?
You are already familiar with the project that aims to test the acceptability of using electronic patient reported outcome and experience measures in the routine care of patients with melanoma.

What does participation in this research involve?
Further participation in this study involves a short interview on your thoughts and experiences about completing these questionnaires.

If you decide to take part in the research project, and return the signed consent form, you will be contacted by a member of the research team to organise a time to complete the interview. Completing the interview will take approximately 10-20 minutes, and you can choose whether to complete the interview in person or over the telephone. To enable us to collect the most accurate data that we can, we will record the interview. If you do not

wish for the interview to be recorded, you can indicate this on the consent form. Any identifying information that you provide will be de-identified to protect your privacy.

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 care, your relationship with professional staff or your relationship with the University of Sydney, Melanoma Institute Australia or Royal Prince Alfred Hospital.

What are the possible benefits of taking part?
We hope that the results from this study will help us to improve the care of patients with melanoma in the future. Patients who complete an interview will be offered a $30 Coles-Myer gift card to thank them for their time.

What are the possible risks and disadvantages of taking part?
Aside from giving up your time, we do not expect that there will be any risks or costs associated with taking part in this study. If you do not wish to answer a question, you may skip it and go to the next question, or you may stop the interview at any time.

What happens when the research project ends?
By providing your consent, you are agreeing to us collecting personal information about you for the purposes of this research study. Your information will only be used for the purposes outlined in this Participant Information Sheet, unless you consent otherwise. Your information will be stored securely and your identity/information will be kept strictly confidential, except as required by law. Study findings may be published, but you will not be individually identifiable in these publications.

You have a right to receive feedback about the overall results of this study. You can tell us that you wish to receive feedback by ticking the relevant box on the consent form. This feedback will be in the form of a one page lay summary. You will receive this feedback after the study is finished.

What will happen to information about me?
Any information obtained in connection with this research project that can identify you will remain confidential. Confidentially will be maintained by reporting average results and no individual level results, and your identity/information will be kept strictly confidential and not reported.

Electronic information collected from the study will be kept on the secure, password protected servers at the University of Sydney. Non-electronic information collected from the study will be kept in a locked filing cabinet in a secure office with pass card access in the Melanoma Institute Australia building. Only approved researchers named on this project will have access to any of this information.

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, except with your express permission. Confidentially will be maintained by reporting the average results with no individual level results, furthermore, no identifiable information will be reported. 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.

Who is organising and funding the research?
This research project is being organised by: Professor Rachael Morton, Associate Professor Robyn Saw, Dr Iris Bartula and Dr Kathy Flitcroft. These researchers are members of the Melanoma Institute Australia or National

Health and Medical Research Council (NHMRC) Centre of Research Excellence in Melanoma: Person, tumour and system-focused knowledge to drive better outcomes in melanoma.

This research has been funded by an NHMRC Centre of Research Excellence (ID: 1135285). No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages). No members of the research team declare any conflicts of interest.

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 St Vincent's Hospital Sydney (Approval number: 2019/ETH10558). 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.

Further information and who to contact:

When you have read this information, the people listed below are available to discuss it with you further and answer any questions you may have. If you would like to know more at any stage, please feel free to contact: Associate Professor Rachael Morton, Director of Health Economics, The University of Sydney, Tel: (02) 9562 5013; Associate Professor Robyn Saw, Melanoma Surgeon, Melanoma Institute Australia and Royal Prince Alfred Hospital, Tel: (02) 9911 7200.

This information sheet is for you to keep.

Any person with concerns or complaints about the conduct of this research study can contact the St. Vincent's Hospital Sydney Human Research Ethics Committee's Executive Officer on +612 8382 4960, or SVHS.Research@SVHA.org.au and quote ethics approval number: 2019/ETH10558.

PARTICIPANT CONSENT FORM
PATIENT INTERVIEW

Study title: Pilot study to embed **e**lectronic **P**atient **R**eported **O**utcome **M**easure**s** into routine care for patients with Stage III **MEL**anoma (ePROMS-MEL)

I, _____[PRINT NAME], agree to take part in an end of study interview about this research project.

In giving my consent I state that:

- ✓ 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 care.
- ✓ I understand that I will be given a signed copy of this document to keep.
- ✓ I understand that I can withdraw from the study at any time
- ✓ I understand that I may stop the interview at any time if I do not wish to continue, and that unless I indicate otherwise any recordings will then be erased and the information provided will not be included in the study. I also understand that I may refuse to answer any questions I don't wish to answer
- ✓ I understand that personal information about me that is collected over the course of this project will be stored securely and will only be used for the purposes that I have agreed to. I understand that information about me will only be told to others with my permission, except as required by law.
- ✓ I understand that the results of this study may be published, and that publications will not contain my name or any identifiable information about me

I consent to:

Audio recording	Yes		No	

I would like to receive feedback about the overall results of this study	Yes		No	

If you answered YES to receive feedback, please indicate your preferred form of feedback by providing the details below:

Postal:
Email:

Signature:

Appendix 15: PISCF for end of study interviews - Clinicians

Professor Rachael Morton *Director, Health Economics & Health Technology Assessment*
Deputy Director, NHMRC Clinical Trials Centre

Camperdown, NSW 2050, Australia
Tel: 61-2-9562-5000
Fax: 61-2-9565-1863
Email: Rachael.morton@sydney.edu.au

Print name:_____

Date:_____

PARTICIPANT INFORMATION SHEET & CONSENT FORM
CLINICIAN INTERVIEW

Study title: Pilot study to embed **e**lectronic **P**atient **R**eported **O**utcome **M**easure**s** into routine care for patients with Stage III **MEL**anoma (ePROMS-MEL)

Thank you for having participated in this project over the last year. We are now asking if you will be willing to undergo a short additional interview about the project to provide us with more detailed information about what worked and what didn't work from your perspective as a melanoma clinician.

What does my participation involve?
Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Participation in this research is voluntary. If you don't wish to take part, you don't have to.

If you decide you want to take part in the post-study interview, 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 be involved in the research described
- ✓ Consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information Sheet to keep.

What is the purpose of this research?
You are already familiar with this project that aims to test the acceptability of using electronic patient reported outcome and experience measures in the routine care of patients with melanoma.

What does participation in this research involve?
Further participation in this study involves a brief interview on your thoughts and experiences about incorporating these questionnaires into routine clinical care.

If you decide to take part in the post-study interview, and return the signed consent form, you will be contacted by a member of the research team to organise a time to complete the interview. Completing the interview will take approximately 10-20 minutes, and you can choose whether to complete the interview in person or over the telephone. To enable us to collect the most accurate data that we can, we will record the interview. If you do not

wish for the interview to be recorded, you can indicate this on the consent form. Any identifying information that you provide will de-identified to protect your privacy.

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.

What are the possible benefits of taking part?
We hope that the results from this study will help us to improve the care of patients with melanoma in the future.

What are the possible risks and disadvantages of taking part?
Aside from giving up your time, we do not expect that there will be any risks or costs associated with taking part in this study. If you do not wish to answer a question, you may skip it and go to the next question, or you may stop the interview at any time.

What happens when the research project ends?
The results will be collated and analysed. Participating clinicians will be invited to a post-study information session to discuss the results and ask and questions.

What will happen to information about me?
Any information obtained in connection with this research project that can identify you will remain confidential. Electronic information collected from the study will be kept on the secure, password protected servers at MIA. Non-electronic information collected from the study will be kept in a locked filing cabinet in a secure office requiring pass card access in the Melanoma Institute Australia building. Only approved researchers named on this project will have access to any of this information.

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, except with your express permission. Confidentially will be maintained by reporting the average results with no individual level results, furthermore, no identifiable information will be reported. 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.

Who is organising and funding the research?
This research project is being organised by: Professor Rachael Morton, Associate Professor Robyn Saw, Dr Iris Bartula and Dr Kathy Flitcroft. These researchers are members of the Melanoma Institute Australia or National Health and Medical Research Council (NHMRC) Centre of Research Excellence in Melanoma: Person, tumour and system-focussed knowledge to drive better outcomes in melanoma.

This research has been funded by an NHMRC Centre of Research Excellence (ID: 1135285). No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages). No members of the research team declare any conflicts of interest.

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 St Vincent's Hospital Sydney (Approval number: 2019/ETH10558). 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.

Further information and who to contact:

When you have read this information, the people listed below are available to discuss it with you further and answer any questions you may have. If you would like to know more at any stage, please feel free to contact: Professor Rachael Morton, Director of Health Economics, The University of Sydney, Tel: (02) 9562 5013; Associate Professor Robyn Saw, Melanoma Surgeon, Melanoma Institute Australia and Royal Prince Alfred Hospital, Tel: (02) 9911 7200.

This information sheet is for you to keep.

Any person with concerns or complaints about the conduct of this research study can contact the St. Vincent's Hospital Sydney Human Research Ethics Committee's Executive Officer on +612 8382 4960, or SVHS.Research@SVHA.org.au and quote ethics approval number: 2019/ETH10558.

PARTICIPANT CONSENT FORM
CLINICIAN INTERVIEW

Study title: Pilot study to embed **e**lectronic **P**atient **R**eported **O**utcome **M**easure**s** into routine care for patients with Stage III **MEL**anoma (ePROMS-MEL)

I, _____[PRINT NAME], agree to take part in an end of study interview about this research project.

In giving my consent I state that:

- ✓ 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 care.
- ✓ I understand that I will be given a signed copy of this document to keep.
- ✓ I understand that I can withdraw from the study at any time
- ✓ I understand that I may stop the interview at any time if I do not wish to continue, and that unless I indicate otherwise any recordings will then be erased and the information provided will not be included in the study. I also understand that I may refuse to answer any questions I don't wish to answer
- ✓ I understand that personal information about me that is collected over the course of this project will be stored securely and will only be used for the purposes that I have agreed to. I understand that information about me will only be told to others with my permission, except as required by law.
- ✓ I understand that the results of this study may be published, and that publications will not contain my name or any identifiable information about me

I consent to:

Audio recording	Yes		No	

I would like to receive feedback about the overall results of this study	Yes		No	

If you answered YES to receive feedback, please indicate your preferred form of feedback by providing the details below:

Postal:
Email:

Signature:
Print name:
Date:

Professor Rachael Morton
Director, Health Economics & Health Technology Assessment
Deputy Director, NHMRC Clinical Trials Centre

Camperdown, NSW 2050, Australia
Tel: 61-2-9562-5000
Fax: 61-2-9565-1863
Email: Rachael.morton@sydney.edu.au

Print name:_____

Date:_____

PARTICIPANT INFORMATION SHEET & CONSENT FORM
CLINIC STAFF INTERVIEW

Study title: Pilot study to embed **e**lectronic **P**atient **R**eported **O**utcome **M**easure**s** into routine care for patients with Stage III **MEL**anoma (ePROMS-MEL)

Thank you for having participated in this project over the last year. We are now asking if you will be willing to undergo a short interview about the project to provide us with more detailed information about what worked and what didn't work from your perspective as a clinic staff member.

What does my participation involve?
Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Participation in this research is voluntary. If you don't wish to take part, you don't have to.

If you decide you want to take part in the post-study interview, 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 be involved in the research described
- ✓ Consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information Sheet to keep.

What is the purpose of this research?
You are already familiar with this project that aims to test the acceptability of using electronic patient reported outcome and experience measures in the routine care of patients with melanoma.

What does participation in this research involve?
Further participation in this study involves a brief interview on your thoughts and experiences about incorporating these questionnaires into routine clinical care.

If you decide to take part in the post-study interview, and return the signed consent form, you will be contacted by a member of the research team to organise a time to complete the interview. Completing the interview will

take approximately 10-20 minutes, and you can choose whether to complete the interview in person or over the telephone. To enable us to collect the most accurate data that we can, we will record the interview. If you do not wish for the interview to be recorded, you can indicate this on the consent form. Any identifying information that you provide will de-identified to protect your privacy.

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.

What are the possible benefits of taking part?
We hope that the results from this study will help us to improve the care of patients with melanoma in the future.

What are the possible risks and disadvantages of taking part?
Aside from giving up your time, we do not expect that there will be any risks or costs associated with taking part in this study. If you do not wish to answer a question, you may skip it and go to the next question, or you may stop the interview at any time.

What happens when the research project ends?
The results will be collated and analysed. Participating clinic staff members will be invited to a post-study information session to discuss the results and ask and questions.

What will happen to information about me?
Any information obtained in connection with this research project that can identify you will remain confidential. Electronic information collected from the study will be kept on the secure, password protected servers at MIA. Non-electronic information collected from the study will be kept in a locked filing cabinet in a secure office requiring pass card access in the Melanoma Institute Australia building. Only approved researchers named on this project will have access to any of this information.

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, except with your express permission. Confidentially will be maintained by reporting the average results with no individual level results, furthermore, no identifiable information will be reported. 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.

Who is organising and funding the research?
This research project is being organised by: Professor Rachael Morton, Associate Professor Robyn Saw, Dr Iris Bartula and Dr Kathy Flitcroft. These researchers are members of the Melanoma Institute Australia or National Health and Medical Research Council (NHMRC) Centre of Research Excellence in Melanoma: Person, tumour and system-focussed knowledge to drive better outcomes in melanoma.

This research has been funded by an NHMRC Centre of Research Excellence (ID: 1135285). No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages). No members of the research team declare any conflicts of interest.

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 St Vincent's Hospital Sydney (Approval number: 2019/ETH10558). 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.

Further information and who to contact:

When you have read this information, the people listed below are available to discuss it with you further and answer any questions you may have. If you would like to know more at any stage, please feel free to contact: Professor Rachael Morton, Director of Health Economics, The University of Sydney, Tel: (02) 9562 5013; Associate Professor Robyn Saw, Melanoma Surgeon, Melanoma Institute Australia and Royal Prince Alfred Hospital, Tel: (02) 9911 7200.

This information sheet is for you to keep.

Any person with concerns or complaints about the conduct of this research study can contact the St. Vincent's Hospital Sydney Human Research Ethics Committee's Executive Officer on +612 8382 4960, or SVHS.Research@SVHA.org.au and quote ethics approval number: 2019/ETH10558.

PARTICIPANT CONSENT FORM
CLINIC STAFF INTERVIEW

Study title: Pilot study to embed **e**lectronic **P**atient **R**eported **O**utcome **M**easure**s** into routine care for patients with Stage III **MEL**anoma (ePROMS-MEL)

I, _____[PRINT NAME], agree to take part in an end of study interview about this research project.

In giving my consent I state that:

- ✓ 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 care.
- ✓ I understand that I will be given a signed copy of this document to keep.
- ✓ I understand that I can withdraw from the study at any time
- ✓ I understand that I may stop the interview at any time if I do not wish to continue, and that unless I indicate otherwise any recordings will then be erased and the information provided will not be included in the study. I also understand that I may refuse to answer any questions I don't wish to answer
- ✓ I understand that personal information about me that is collected over the course of this project will be stored securely and will only be used for the purposes that I have agreed to. I understand that information about me will only be told to others with my permission, except as required by law.
- ✓ I understand that the results of this study may be published, and that publications will not contain my name or any identifiable information about me

I consent to:

Audio recording	Yes		No	

I would like to receive feedback about the overall results of this study	Yes		No	

If you answered YES to receive feedback, please indicate your preferred form of feedback by providing the details below:

Postal:
Email:

Signature:
Print name:
Date:

Appendix 17: 'About you' patient survey (included in baseline electronic survey)

About you

Please select from the following options:

☐ Yes ☐ No I would like to be emailed a summary of my questionnaire scores at each visit.

☐ Yes ☐ No I would like to be emailed a summary of the project summary and findings at the completion of the study.

EMPLOYMENT STATUS

Which of the following best describes your employment status?

Please select ONE OPTION from the drop down menu

- Employed full-time ☐
- Employed part-time ☐
- Employed casual ☐
- Student ☐
- Retired ☐
- Not currently working but looking for work ☐
- Not looking for work ☐
- Other ☐

LANGUAGE SPOKEN AT HOME

Please type your answer in the box below.

☐

HEALTH INSURANCE STATUS

Please select ONE OPTION from the drop down menu

Public (Medicare only) ☐

Private ☐

Department of Veterans' Affairs ☐

Other ☐

WHO LIVES WITH YOU AT HOME?

Please select ALL OPTIONS THAT APPLY from the drop down menu

Live alone ☐

Live with partner/spouse ☐

Live with children ☐

Live with parents ☐

Live with extended family ☐

Live with friends/other ☐

ARE ANY OF THESE PEOPLE FINANCIALLY DEPENDENT ON YOU?

Yes ☐

No ☐

If yes, what is your relationship with them (e.g. your parent, partner)

WHAT IS YOUR HIGHEST EDUCATIONAL LEVEL?

Please select ONE OPTION from the drop down menu

Did not complete high school ☐

Completed high school ☐

Vocational training (e.g. TAFE apprenticeship) ☐

University qualification ☐

WHAT IS YOUR INDIVIDUAL ANNUAL INCOME RANGE?

(earnings from employment or Government benefits only, before tax).

Click here to find out why we are asking you for this information*

Please select ONE OPTION from the drop down menu

< $31,999 per year	☐
$32,000 - $61,999 per year	☐
$62,000 – $91,999 per year	☐
$92,000 - $121,999 per year	☐
$122,000 - $151,999 per year	☐
> $152,000 per year	☐
Prefer not to say	☐

[Text explaining why we are asking about patient income].

* We realise that some people are uncomfortable about answering questions on their income. There are two reasons why this information is important for the study:

1. It will provide anonymous information about the cohort of patients who are participating in this Pilot study (only the project officer will see this information). This information allows us to assess the proportion of participants within each income bracket, so we can state X% were from Y bracket, X% from Z bracket etc. (the same as we do for age brackets).
2. More importantly, it allows us to anonymously link participant's income with their emotional and physical well-being (PROMs outcomes) and with their access to services (change in referral patterns and attendance at these appointments). There is good evidence that people on lower incomes have higher levels of unmet health needs and do not have the same access opportunities to services as those on higher incomes. This is very useful information as it helps us to make a case for better targeting of services to meet different people's needs.

Appendix 18: Invitation to participate — Patients

Professor Rachael Morton
Director, Health Economics & Health Technology Assessment
Deputy Director, NHMRC Clinical Trials Centre

Camperdown, NSW 2050, Australia
Tel: 61-2-9562-5000
Fax: 61-2-9565-1863
Email: Rachael.morton@sydney.edu.au

INVITATION TO PARTICIPATE

*Pilot study to embed **e**lectronic **P**atient **R**eported **O**utcome **M**easure**s** and patient reported experience measures into routine care for patients with Stage III **MEL**anoma (ePROMS-MEL)*

Dear _____,

We would like to invite you to participate in a new study being run by The University of Sydney at Melanoma Institute Australia (MIA) and Royal Prince Alfred Hospital (RPAH). Your treating doctor, xxxxxx is taking part in this study and s/he has suggested you as a possible participant.

Many people with Stage III melanoma experience psychosocial distress and/or reduced quality of life. Yet follow-up after lymph node surgery tends to focus on a person's physical recovery. There is limited time within standard 15-minute appointments to discuss psychological or emotional issues and patients are often reluctant to bother busy doctors with their problems. Unreported and undiagnosed psychosocial distress and/or poor quality of life may make living with melanoma harder than it needs to be.

The study is investigating if giving patients the opportunity to complete Patient Reported Outcome Measures (PROMs) and Patient Reported Experience Measures (PREMs) before they see their treating doctor, will help to improve communication about problems that the patient is experiencing, but that would not normally be discussed in a follow-up consultation. PROMs are questionnaires that ask you about how you are feeling and how you are coping with melanoma treatment and the impact it can have on your lives.

The purpose of this email is to identify people who may be interested in helping us with this research. We have enclosed/attached a Participant Information Sheet (PIS) and an Expression of Interest (EoI) form for you to read. The PIS tells you all about the study and what you can expect if you agree to participate. The EoI asks you to respond to this invitation in one of three ways:

- You *are* interested in participating in the study and are happy to be contacted by the project officer.
- You *may* be interested in participating in the study and are happy to be contacted by the project officer to discuss the project to find out more.
- You are *not* interested in participating in the study and do not wish to be contacted by the project officer.

Participation is entirely voluntary and if you do not wish to participate it will not affect your relationship with your surgeon, other clinicians or members of the research team in any way.

With best wishes,
Professor Rachael Morton, on behalf of your treating team:

Assoc Prof Robyn Saw
Professor Georgina Long
Dr Tom Pennington
Assoc Prof Alex Menzies
Assoc Prof Omgo Nieweg

Appendix 19: Participant Information Sheet – Patients

Professor Rachael Morton
Director, Health Economics & Health Technology Assessment
Deputy Director, NHMRC Clinical Trials Centre

Camperdown, NSW 2050, Australia
Tel: 61-2-9562-5000
Fax: 61-2-9565-1863
Email: Rachael.morton@sydney.edu.au

PARTICIPANT INFORMATION SHEET

*Pilot study to embed **e**lectronic **P**atient **R**eported **O**utcome **M**easure**s** into routine care for patients with Stage III **MEL**anoma (ePROMS-MEL)*

What does my participation involve?

You are invited to take part in this research project, which is called ePROMs-MEL. You have been invited because you are a patient with a diagnosis of stage III melanoma who is being treated at Melanoma Institute Australia (MIA).

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

Please read this information carefully. You will have the opportunity to ask questions about anything that you don't understand or want to know more about.

Participation in this research is voluntary. If you don't wish to take part, you don't have to.

If you decide you want to take part in this research project, you will be asked to give your consent beforehand. By doing this, you are telling us that you:

- ✓ Understand what you have read
- ✓ Consent to take part in the research project
- ✓ Consent to be involved in the research described
- ✓ Consent to the use of your personal and health information as described.

This Participant Information Sheet is for you to keep.

What is the purpose of this research?

You are invited to take part in a research study that aims to introduce electronic patient reported outcome measures into the routine care for patients with melanoma. Patient reported outcome measures (PROMs) are information that is collected directly from patients regarding their physical and emotional well-being. Previous research has shown that the use of PROMs can improve clinician-patient communication. Currently, PROMs are not routinely collected as part of melanoma treatment in Australia.

We are inviting English-speaking people with a current Stage III melanoma diagnosis to participate in this study. The researchers have focused this study on people with Stage III melanoma because they have frequent follow-up. Additionally, as patients will be providing informed consent, and responding to survey questions, an understanding of the English language is required. Study participants must also be under the care of a melanoma doctor at MIA.

What does participation in this research involve?

You will also be asked to complete and return the Expression of Interest form that accompanies this Participant Information Sheet to indicate your interest in participating. If you return this form to the project officer indicating that you are not interested in participating, you will not be contacted again about the study. If you are interested, or are potentially interested, in participating in the study, you will be contacted by the project officer who will address any questions and concerns you may have. If you do agree to participate, you will be asked to arrive at MIA 30 minutes earlier for your next scheduled appointment to allow time to complete the questionnaires. When you arrive at the clinic you will again be given the opportunity to discuss any questions with the project officer who will show you how to use the iPad.

If you agree to participate, you will be asked to provide your consent electronically prior to commencing a series of short questionnaires related to your emotional and physical well-being. This information will be collected using an iPad, while in the waiting room prior to your regularly scheduled follow-up appointments with your treating doctor. The questionnaires will take no more than 30 minutes to complete, depending on how many questionnaires you are asked to complete. You may choose to stop completing the questionnaires at any time by returning the iPad to the clinic. If completed, your treating doctor will be able to read your responses and discuss any areas of concern with you in your appointment. You can also receive a copy of your questionnaire report prior to your consultation, by selecting a box on the last page of the questionnaires.

At the initial consultation, you will also be asked to complete a brief one-off survey “About you” which contains general non-medical questions such as who lives with you, language spoken at home, education level, employment and income. This information will be used to provide an overview of patients taking part in the study – no individual information will be made available, so your privacy is protected.

The study will run until the end of 2022, and you will be asked to complete the same series of questionnaires at each of your follow-up visits over this time period. You will also be asked to complete a short evaluation survey at the end of the study to provide your views on what completing the study questionnaires was like.

We are also interested in interviewing a subset of participants at the end of the study to further explore their thoughts and experiences of completing these electronic patient reported outcome measures. You will be contacted towards the end of the study to see if you are interested. If you are, an additional Participant Information Sheet with more details will be provided at that time, and separate consent will be obtained for this part of the study.

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. Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine

care, your relationship with professional staff or your relationship with the University of Sydney, Melanoma Institute Australia or Royal Prince Alfred hospital.

What are the possible benefits of taking part?

We cannot guarantee or promise that you will receive any benefits from this research. It is possible you may benefit from improved communication with your doctor about issues that are important to you, and that this may lead to an improved sense of "whole of person" health and welfare. We hope that the results from this study will help us to improve the care of patients with melanoma in the future.

What are the possible risks and disadvantages of taking part?

It is possible you may experience mild distress from reflecting on problems you are facing and how they could be managed. There is also the inconvenience of giving up some time to complete the questionnaires. We do not anticipate any other risk or costs associated with taking part in this study. If you do not wish to answer a question, you may skip it and go to the next question, or you may stop immediately and return the iPad to the clinic.

What if I withdraw from this research project?

If you do consent to participate, you may withdraw at any time. If you decide to withdraw from the project, please notify a member of the research team before you withdraw and you will be asked to complete and sign a 'Withdrawal of Consent' form. You can withdraw your responses if you change your mind about having them included in the study, up to the point when we have analysed and published the results. If you decide to withdraw from the study, we will not collect any more information from you.

What if my treating clinician withdraws from this research project?

You have been invited to participate in this research project because your treating clinician has agreed to participate in trialing the use of ePROMs to identify psychosocial distress and/or poor quality of life in his/her patients. Your clinician is also free to withdraw from the study at any time. In the unlikely event that this happens, s/he will discuss with you the options of you continuing in the study if you wish to, with either the study psychologist or your clinical nurse consultant receiving your questionnaire data on their behalf.

What happens when the research project ends?

In addition to receiving your own questionnaire report at each visit, you also have the right to receive feedback about the overall results of this study. This feedback will be in the form of a one-page lay summary. You will receive this feedback after the study is finished if you select this option on the last page of the iPad questionnaires.

What will happen to information about me?

By signing the electronic consent form you give permission to the research team to collect and use personal information about you, only for the purposes of this research project. Any information obtained in connection with this research project that can identify you will remain confidential. Confidentially will be maintained by the use of a Study ID number, rather than your name, on study documents. Study reporting will only refer to average results,not individual level results, and your identity/information will remain anonymous.

Electronic information collected from the study will be kept on the secure, password protected servers at the Melanoma Institute of Australia. Non-electronic information collected from the study will be kept with the project officer in a locked filing cabinet in a secure office within MIA. Only approved researchers named on this project will have access to any of this information.

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. The personal information that the research team will collect and use includes information from the study questionnaires, including the 'About You' questionnaire, clinical information used to determine your eligibility for the study and information provided on your consent form. Information

about you may be obtained from your health records held at this and other health organisations for the purpose of this research (for example, information about whether you saw other health professionals recommended by your treating clinician). By signing the consent form you agree to the research team accessing health records if they are relevant to your participation in this research project.

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, except with your explicit permission. Confidentially will be maintained by reporting the average results with no individual level results; furthermore, no identifiable information will be reported. Any information obtained for the purpose of this research project that can identify you will be treated as confidential and securely stored. De-identified individual results from the newly-developed Melanoma Concerns Questionnaire (MCQ-28) will be provided to the questionnaire developers to help them further assess the reliability of it in different populations and settings. Otherwise, information will be disclosed only with your permission, or as required by law.

Who is organising and funding the research?

This research project is being organised by: Professor Rachael Morton, Associate Professor Robyn Saw, Dr Iris Bartula and Dr Kathy Flitcroft. These researchers are members of the Melanoma Institute Australia or National Health and Medical Research Council (NHMRC) Centre of Research Excellence in Melanoma: Person, tumour and system-focussed knowledge to drive better outcomes in melanoma.

This research has been funded by an NHMRC Centre of Research Excellence (ID: 1135285). No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary salary). No members of the research team declare any conflicts of interest.

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 St Vincent's Hospital Sydney (Approval number 2019/ETH10558). 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.

Further information and who to contact:

When you have read this information, the people listed below are available to discuss it with you further and answer any questions you may have. If you would like to know more at any stage, please feel free to contact: Professor Rachael Morton, Director of Health Economics, The University of Sydney, Tel: (02) 9562 5013; Associate Professor Robyn Saw, Melanoma Surgeon, Melanoma Institute Australia and Royal Prince Alfred Hospital, Tel: (02) 9911 7200.

This information sheet is for you to keep.

Any person with concerns or complaints about the conduct of this research study can contact the St. Vincent's Hospital Sydney Human Research Ethics Committee's Executive Officer on +612 8382 4960, or SVHS.Research@SVHA.org.au and quote ethics approval number 2019/ETH10558

Appendix 20. Expression of Interest form – Patients

Professor Rachael Morton
Director, Health Economics & Health Technology Assessment
Deputy Director, NHMRC Clinical Trials Centre

Camperdown, NSW 2050, Australia
Tel: 61-2-9562-5000
Fax: 61-2-9565-1863
Email: Rachael.morton@sydneyedu.au

EXPRESSION OF INTEREST FORM

*Pilot study to embed **e**lectronic **P**atient **R**eported **O**utcome **M**easure**s** into routine care for patients with Stage III **MEL**anoma (ePROMS-MEL).*

This is to certify that I, _____, [first and last name]
have read the ePROMs-MEL Participant Information Sheet and … [please tick **ONE** of the following options]

☐ I **AM** interested in participating in the study and am happy to be contacted by the project officer.
Best phone number to contact you:_____

☐ I **MAY BE** interested in participating in the study and am happy to be contacted by the project officer to discuss the project to find out more.
Best phone number to contact you:_____

☐ I **AM NOT** interested in participating in the study and do not wish to be contacted by the project officer.

Thank you for letting us know your preference. Please email this completed form or post it (in the stamped, self-addressed envelope provided) back to:

Mr Samuel Herzog
Project Officer
e-PROMs-MEL Study
Melanoma Institute Australia
40 Rocklands Rd Wollstonecraft NSW 2065.
Email: samuel.herzog@melanoma.org.au

Appendix 21. Telephone script for follow-up of non-responders – Patients

Hello _____

My name is XXXX and I am contacting you about some information I emailed/mailed to you about a new trial we are running at Melanoma Institute Australia (MIA) and Royal Prince Alfred Hospital (RPAH) on XXXXXX [date]. The project is called:

*Pilot study to embed **e**lectronic **P**atient **R**eported **O**utcome **M**easure**s** into routine care for patients with Stage III **MEL**anoma (ePROMS-MEL).*

I'm just ringing to see if you received the information? It included a Participant Information Sheet and an Expression of Interest form. You may remember the study involved you completing some questionnaires on how you are feeling and coping with your melanoma treatment? It also asked you to return the Expression of Interest form so I know whether you are interested in participating in the trial.

a). If you haven't received it, would you mind me checking the email/postal address we have for you so I can resend it to you?

[Great – I'll send it to you again]

OR

b). If you have read it and are not interested in participating, I will just mark that on our project records.

[Thank you for considering the request - I'll not bother you again].

Thanks very much for your time.

XXXXXePROMs-MEL Project Officer

Appendix 22. Invitation to participate – Clinicians

Professor Rachael Morton
Director, Health Economics & Health Technology Assessment
Deputy Director, NHMRC Clinical Trials Centre

Camperdown, NSW 2050, Australia
Tel: 61-2-9562-5000
Fax: 61-2-9565-1863
Email: Rachael.morton@sydney.edu.au

INVITATION TO PARTICIPATE

*Pilot study to embed **e**lectronic **P**atient **R**eported **O**utcome **M**easure**s** into routine care for patients with Stage III **MEL**anoma (ePROMS-MEL)*

Dear _____,

We would like to invite you to participate in a new study being run by The University of Sydney at Melanoma Institute Australia (MIA) and Royal Prince Alfred Hospital (RPAH). You are invited to participate in this study because you are a melanoma clinician treating people with Stage III melanoma at MIA and/or RPAH and are associated with clinics run by Assoc Prof Robyn Saw, Professor Georgina Long and Associate Professor Alex Menzies.

Previous research has shown that the use of Patient Reported Outcome Measures (PROMs) can improve clinician-patient communication. Currently, PROMs are not routinely collected as part of melanoma treatment in Australia. The study is investigating if giving patients the opportunity to complete PROMs before they see their treating doctor will help to improve communication about problems that the patient is experiencing, but that would not normally be discussed in a follow-up consultation.

Many people with Stage III melanoma experience psychosocial distress and/or reduced quality of life. Yet follow-up after lymph node surgery tends to focus on a person's physical recovery. There is limited time within standard 15-minute appointments to discuss psychological or emotional issues and patients are often reluctant to bother busy doctors with their problems. Unreported and undiagnosed psychosocial distress may make living with melanoma harder than it needs to be.

The purpose of this email is to identify melanoma clinicians who may be interested in helping us with this research. We have enclosed/attached a Participant Information Sheet and Consent Form (PISCF) for you to read. The PIS tells you all about the study and what you can expect if you agree to participate.

With best wishes,

Professor Rachael Morton, on behalf of the ePROMs-MEL research team.

Appendix 23: Participant Information Sheet and Consent Form – Clinicians

Associate Professor Rachael Morton
Director, Health Economics & Health Technology Assessment
Deputy Director, NHMRC Clinical Trials Centre

Camperdown, NSW 2050, Australia
Tel: 61-2-9562-5000
Fax: 61-2-9565-1863
Email: Rachael.morton@sydney.edu.au

PARTICIPANT INFORMATION SHEET AND CONSENT FORM
CLINICIAN

Study title: Pilot study to embed **e**lectronic **P**atient **R**eported **O**utcome **M**easure**s** into routine care for patients with Stage III **MEL**anoma (ePROMS-MEL)

What is the purpose of this research?
You are invited to take part in a research study that aims to introduce electronic patient reported outcome and experience measures into the routine care for patients with melanoma. Patient reported outcome measures (PROMs) are information that is collected directly from patients regarding their care, treatment and outcomes. These measurements will be collected from your Stage III patients on an iPad, while in the waiting room prior to their regularly scheduled follow-up appointments with you.

Previous research has shown that the use of Patient Reported Outcome Measures (PROMs) can improve clinician-patient communication. Currently, PROMs are not routinely collected as part of melanoma treatment in Australia. The study is investigating if giving patients the opportunity to complete PROMs before they see their treating doctor will help to improve communication about problems that the patient is experiencing, but that would not normally be discussed in a follow-up consultation.

This Information Sheet tells you about the research study. Participation in this research study is voluntary.

What does participation in this research involve?
If you decide to take part in the research project, and return the signed consent form to the project officer (Sam Herzog: Samuel.herzog@melanoma.org.au), your eligible patients will be sent an Invitation to Participate, a Participant Information Sheet and an Expression of Interest Form. Patients will be recruited through surgical melanoma clinics at MIA and RPAH. Clinic staff will determine which patients meet the eligibility criteria of the study. Approval from the treating clinician will be requested before contacting patients for the ePROMs-MEL study.

Those patients whom you have deemed as eligible and who express interest in participating, will be approached by the study project officer (Sam Herzog) who will answer any questions they may have about the study, consent the patients and briefly guide them through the PROMs questionnaires on the iPad. General demographic information will also be collected on each patient to allow an overview of participants to be created.

Consenting patients will initially complete either two or five PROMs questionnaires. The study questionnaires will be repeated at subsequent regularly scheduled follow-up appointments with their clinicians, approximately 2-3 months apart until the end of November 2022. iPads were chosen because they are portable, have a user-friendly interface, are capable of hosting software that can automatically generate reports and associated documents and are a secure format for data management as they are encrypted by default.

At each visit, all patients will be required to complete two short questionnaires that are used to assess their psychosocial distress / QoL: 1. the National Comprehensive Cancer Centre (NCCN)'s Distress Thermometer (DT) and Problem List for Patients; and 2. EuroQoL's EQ-5D-5L and visual analogue scale. Patients who score above the clinical cut off score on these measures, indicating a moderate or higher level of psychosocial distress / poor QoL, will then be required to complete an additional three questionnaires: the Melanoma Concerns Questionnaire (MCQ-28), the Depression, Anxiety and Stress Scale (DASS-21) and the European Organisation for Research and Treatment of Cancer (EORTC)'s QLQ-C30). These additional questionnaires will provide more detailed information about potential areas of support needs.

The results from the completed questionnaires will be automatically generated by the MIA server and sent to the treating clinician in real time, so they can be discussed during their consultation, along with medical concerns. Patients may also receive an email copy of their results if they wish.

There are no melanoma-specific cut-off scores for the QoL questionnaires (MCQ-28 and EORTC QLQ-C30). For the initial appointment, these scores will be recorded as baseline measures. At subsequent visits, changes in the scores for all questionnaires will be graphically represented by domain and included in the results for clinicians to examine trends. A deterioration in EORTC QLQ C-30 scores that is 10 points or greater between visits is commonly regarded as clinically significant and will represent a further trigger for discussion and possible referral to an appropriate service/support. Recommendations and referrals for additional support / services will be based on the questionnaire scores and clinical experience of the clinicians, and in collaboration with the patient.

Clinicians will be able to track their patients' progress over the study period. Data will also be collected on the number of referrals for additional supportive care and on patient uptake of these referrals. An electronic or hard copy of the patient summary scores will be added to the patient file, depending on clinic preferences.

After all rounds of patient questionnaires have been completed, all patients and clinicians will be asked to complete a survey providing quantitative and open-ended assessments of their experiences of using the PROMs questionnaires. Finally, all clinicians and approximately 20% of patients will be invited to participate in short interviews to tease out their views on this pilot study further.

All participating clinicians will have access to training sessions and supplementary information is available on the education portal of the MIA website.

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.

What are the possible benefits of taking part?
We cannot guarantee or promise that you will receive any benefits from this research. It is possible you will find the implementation of PROMs into your practice useful and beneficial to both yourself and your patients. We hope that the results from this study will help us to improve the care of patients with melanoma in the future.

What are the possible risks and disadvantages of taking part?
A common perceived problem by clinicians is that using PROMs in their routine practice will increase their workload and the appointment times. Evidence from previous PROMs studies have shown that while the content of the consultation changes, the length of the consultation does not. The main additional work for clinicians that we foresee is additional referrals to support services. This will be facilitated by a list of relevant support services in NSW that will be hosted on the MIA website, making this process as time-efficient as possible.

What if I withdraw from this research project?
If you do consent to participate, you may withdraw at any time. If you decide to withdraw from the project, please notify a member of the research team before you withdraw and you will be asked to complete and sign a 'Withdrawal of Consent' form. If you wish to withdraw and have patients who are already enrolled in the study, you may nominate a psychologist or clinical nurse consultant to receive that patient's data on your behalf.

What happens when the research project ends?
The results will be collated and analysed. Participating clinicians will be invited to a post-study information session to discuss the results and ask and questions.

What will happen to information about me?
Any information obtained in connection with this research project that can identify you will remain confidential. Electronic information collected from the study will be kept on the secure, password protected servers at MIA. Non-electronic information collected from the study will be kept in a locked filing cabinet in a secure office requiring pass card access in the Melanoma Institute Australia building. Only approved researchers named on this project will have access to any of this information.

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, except with your express permission. Confidentially will be maintained by reporting the average results with no individual level results, furthermore, no identifiable information will be reported. 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.

Who is organising and funding the research?
This research project is being organised by: Professor Rachael Morton, Associate Professor Robyn Saw, Dr Iris Bartula and Dr Kathy Flitcroft. These researchers are members of the Melanoma Institute Australia or National Health and Medical Research Council (NHMRC) Centre of Research Excellence in Melanoma: Person, tumour and system-focussed knowledge to drive better outcomes in melanoma.

This research has been funded by an NHMRC Centre of Research Excellence (ID: 1135285). No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages). No members of the research team declare any conflicts of interest.

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 St Vincent's Hospital Sydney (Approval number 2019/ETH10558). 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.

Further information and who to contact:

When you have read this information, the people listed below are available to discuss it with you further and answer any questions you may have. If you would like to know more at any stage, please feel free to contact: Professor Rachael Morton, Director of Health Economics, The University of Sydney, Tel: (02) 9562 5013; Associate Professor Robyn Saw, Melanoma Surgeon, Melanoma Institute Australia and Royal Prince Alfred Hospital, Tel: (02) 9911 7200.

Any person with concerns or complaints about the conduct of this research study can contact the St. Vincent's Hospital Sydney Human Research Ethics Committee's Executive Officer on +612 8382 4960, or SVHS.Research@SVHA.org.au and quote ethics approval number 2019/ETH10558.

This information sheet is for you to keep.

CLINICIAN CONSENT FORM

Study title: Pilot study to embed **e**lectronic **P**atient **R**eported **O**utcome **M**easure**s** into routine care for patients with Stage III **MEL**anoma (ePROMS-MEL)

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

Name of Participant: (please print)	
Signature:	Date:
Email address:	

I would like to receive feedback about the overall results of this study: YES NO

If you answered YES to receive feedback, please indicate your preferred form of feedback by providing the details below:

POSTAL ADDRESS:

EMAIL ADDRESS:

Appendix 24. Withdrawal of Consent form

Professor Rachael Morton
Director, Health Economics & Health Technology Assessment
Deputy Director, NHMRC Clinical Trials Centre

Camperdown, NSW 2050, Australia
Tel: 61-2-9562-5000
Fax: 61-2-9565-1863
Email: Rachael.morton@sydney.edu.au

PARTICIPANT WITHDRAWAL OF CONSENT

Study title: Pilot study to embed **e**lectronic **P**atient **R**eported **O**utcome **M**easure**s** into routine care for patients with Stage III **MEL**anoma (ePROMs-MEL)

Declaration by Participant

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine care, or my relationships with the researchers, University of Sydney, Melanoma Institute Australia or Royal Prince Alfred Hospital.

Name of Participant (please print) _____

Signature _____ Date _____

In the event that the participant's decision to withdraw is communicated verbally, the Senior Researcher must provide a description of the circumstances below.

Declaration by 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.

Name of Researcher (please print) _____

Signature _____ Date _____

[†] An appropriately qualified member of the research team must provide information concerning withdrawal from the research project.
Note: All parties signing the consent section must date their own signature.