COMBINED PROTOCOL & APPLICATION FOR DATA TEMPLATE
v.6 September 2019

This template has been designed for population health research utilising and/or linking routinely collected health data held by the NSW Ministry of Health or the Cancer Institute NSW. This template combines the research protocol template and data request form.

This research protocol template must be used in conjunction with, and complement, the HREA.

1. PROJECT DETAILS

TITLE: What is the impact of the National Bowel Cancer Screening Program on colorectal cancer outcomes for people over the age of 50 with severe mental illness?
REGIS Ref: 2020/PID00449
CHeRel Ref (if applicable): 2020.05
Other (eg Sax Institute or your ref)

2. SHORT TITLE (IF ANY)

COSMIC Study - Colorectal cancer Outcomes in people with Severe Mental Illness

3. VERSION CONTROL

Version	Date	Amendment (brief description)	Amendment date (as per amendment form)

4. INVESTIGATORS AND PARTICIPATING INSTITUTIONS

PRINCIPAL INVESTIGATOR 1	
Name & title	Professor Steve Kisely
Institution	The University of Queensland
Division	School of Medicine
Position	Professor of Psychiatry
Mailing address	Level 4, Building 1, Princess Alexandra Hospital, Ipswich Road, Woolloongabba, QLD 4102
Email address	s.kisely@uq.edu.au
Phone number	07 3176 5859
Access to unit record data (Y/N[1])	*Y Accessing the SURE from the University of Queensland*
Is this the contact person? Y / N	*N*
INVESTIGATOR / RESEARCHER	
Name & title	Associate Professor Susan Jordan
Institution	The University of Queensland
Division	Epidemiology & Biostatistics Division, School of Public Health
Position	Lead Investigator/Researcher
Email address	s.jordan@uq.edu.au
Phone number	07 3365 5473
Access to unit record data (Y/N[1])	*Y Accessing the SURE from the University of QLD*
Is this the contact person? Y / N	*Y*
INVESTIGATOR / RESEARCHER	
Name & title	Associate Professor David Lawrence
Institution	University of Western Australia
Division	Graduate School of Education
Position	Principal Research Fellow
Email address	david.lawrence@uwa.edu.au
Phone number	08 6488 3017
Access to unit record data (Y/N[1])	*Y Accessing the SURE from the University of WA*
Is this the contact person? Y / N	*N*

1. Access to tabulated results ONLY = N

INVESTIGATOR / RESEARCHER	
Name & title	Associate Professor Grant Sara
Institution	NSW Ministry of Health
Division	System Information & Analytics Branch
Position	Director, InforMH
Email address	Grant.Sara@health.nsw.gov.au
Phone number	02 8877 5120
Access to unit record data (Y/N[1])	*Y Accessing the SURE from NSW Ministry of Health*
INVESTIGATOR / RESEARCHER	
Name & title	Associate Professor Bradley Kendall
Institution	Princess Alexandra Hospital, Brisbane
Division	School of Medicine
Position	Clinical Academic Gastroenterologist and Cancer Epidemiologist.
Email address	bradley.kendall@uq.edu.au
Phone number	07 3176 2613
Access to unit record data (Y/N[1])	*N[1]*
INVESTIGATOR / RESEARCHER	
Name & title	Associate Professor Lisa Brophy
Institution	The University of Melbourne
Division	Centre for Mental Health, Melbourne School of Population
Position	Principal Research Fellow, Mind Australia
Email address	lbrophy@unimelb.edu.au
Phone number	03 94792387
Access to unit record data (Y/N[1])	*N[1]*
INVESTIGATOR / RESEARCHER	
Name & title	Associate Professor Dan Siskind
Institution	The University of Queensland
Division	School of Medicine
Position	Clinical Academic Psychiatrist
Email address	d.siskind@uq.edu.au
Phone number	07 3317 1040

Access to unit record data (Y/N[1])	*N[1]*

INVESTIGATOR / RESEARCHER	
Name & title	Doctor Melinda Protani
Institution	The University of Queensland
Division	School of Public Health
Position	Researcher and Lecturer in Epidemiology
Email address	m.protani@uq.edu.au
Phone number	0431 592 831
Access to unit record data (Y/N[1])	*Y Accessing the SURE from the University of QLD*
INVESTIGATOR / RESEARCHER	
Name & title	Andrea McMurtrie BN RN
Institution	The University of Queensland
Division	School of Public Health
Position	Research Assistant
Email address	a.mcmurtrie@uq.edu.au
Phone number	0407 148 776
Access to unit record data (Y/N[1])	*N[1]*

5. SUBMISSION CHECKLIST

REQUIRED DOCUMENTS	SUBMITTED
Cover letter - listing all submitted documents with date and version numbers - signed by the Principal Investigator 1	☒
Human Research Ethics Application (HREA) completed in REGIS. **OR** **Request for an Amendment to an Approved Research Project form**	☒
Research protocol OR Combined Protocol and CHeReL Application for Data* Amendment requests will not be accepted without tracked and clean versions of your Protocol or Combined Protocol and Application for Data.	☒
Data Linkage Flow Chart (if applicable) – required for all data linkage projects	☒
Data Variable list(s) for each data collection	☒
Data Custodian signoff for each data collection	☒
Centre for Health Record Linkage (CHeReL) Technical Feasibility Letter	☒
NSW Privacy Form	☒
Independent Peer Review Report	☒
CVs of all investigators	☒
All documentation relevant to the project, such as Participant Information and Consent form(s), survey tools, and questionnaires (*where applicable*)	☒
Correspondence with other HREC(s) in Australia (*where applicable*) *Please note: If your project is an extension or addendum to a project which already has approval from another HREC, ALL documentation reviewed by the original HREC must be provided (including HREC letter of approval).*	☒

All forms and further information is available on our website:
https://www.cancerinstitute.org.au/data-research/research-ethics/submissions

6. TABLE OF CONTENTS

1. PROJECT DETAILS 1
2. SHORT TITLE (IF ANY) 1
3. VERSION CONTROL 1
4. INVESTIGATORS AND PARTICIPATING INSTITUTIONS 2
5. SUBMISSION CHECKLIST 5
6. TABLE OF CONTENTS 6
7. BACKGROUND / RATIONALE 7
8. AIMS AND OBJECTIVES 9
9. METHODS 9
10. ANALYSIS PLAN 14
11. PROJECT FUNDING / SUPPORT 15
12. REFERENCES 16
13. DATA SOURCES 18
14. DATA LINKAGE 19
15. SECTION C - FAMILY LINKAGE 25

7. BACKGROUND / RATIONALE

Provide an introduction to the study including a brief literature review, outline of knowledge gaps, how the study will address these, and the intended contribution to the field (750 - 1000 words).

Mortality rates in psychiatric patients are much greater than in the general population.[1-17] Colorectal cancer (CRC), second only to lung cancer as a cause of cancer death in Australia, is a clear example of a cancer that has poorer outcomes in those with severe mental illness (SMI).[6-8] As with all cancer sites, people with mental illness have a greater risk of dying from CRC than those without mental illness although incidence rates are very similar to the general population. It is unlikely that this pattern is explained by lifestyle factors, such as diet or alcohol use, which have relatively little effect on CRC survival. It is likely therefore that factors associated with accessing optimal care, such as screening or specialised procedures, play a role and it is important that we determine the relative contributions of these. We will investigate the following possible explanations including: **1) low cancer screening** rates in those with mental illness;[4] **2) delays in presentation or diagnosis** leading to more advanced stage at diagnosis; and **3) poorer access to services** post-diagnosis.

Australia's National Bowel Cancer Screening Program (NBCSP) is a population-based program that screens for CRC in everyone aged 50-74 years using faecal occult blood testing (FOBT). The NBCSP, when linked with data from other national datasets, provides a unique opportunity to establish where the barriers to optimal care in CRC occur.[18] We propose a large-scale linkage of Commonwealth administrative data to investigate diagnostic pathways and patterns of care for CRC in people with SMI across Australia.

For NSW residents, these will be supplemented with information on CRC staging from the NSW cancer registry and treatment data from hospital records, as well as a qualitative consultation with consumers on barriers to screening and optimal care.

The National Bowel Cancer Screening Program (NBCSP): The NBCSP has implemented staged population-based CRC screening using FOBT for all Australians aged 50-74 years. The program started in 2006 and people were invited to participate at 5-yearly intervals from the age of 50 until 74 years by being sent a kit to collect stool specimens that were returned for FOBT testing. From 2015, there was a phased introduction of biennial screening. It is unknown whether the NBCSP has improved access to CRC screening for people with SMI or whether it has stayed the same or even worsened relative to the general population.

A 2011 study evaluated the effectiveness of the NBCSP in reducing morbidity and mortality in the general population, as well as the impact of earlier CRC diagnosis.[18] It compared differences in CRC outcomes between individuals who were invited into the NBCSP between 2006 and 2008, and those aged 50–69 who were diagnosed with CRC over the same time but were not invited into the NBCSP. It suggested that participation in the scheme was associated with reduced mortality from CRC. However there is evidence from Australia & overseas that people of lower socio-economic status or self-reported Indigenous status are less likely to participate in CRC screening programs.[19,20] Possible reasons include the need for enrolment in Medicare to receive the kit, the fact that it is posted, issues such as privacy, storage or test viability, education level, the nature of the screening procedure, and barriers to compliance with follow-up & treatment. There are no data on participation rates in people with SMI.

Diagnosis and access to care:

There is also evidence that having a mental illness affects the types of treatment people receive after a diagnosis with cancer. CIs Kisely and Lawrence showed that in Western Australia, people with any sort of mental illness were less likely to have a colorectal resection and also had less chemotherapy and less radiotherapy than people from the general population.[6] However, these results were limited by lack of information on cancer staging and the major impact that has on the types of treatment people with cancer receive. The results were also not specific to people with severe SMI. It is important that we understand where in the care pathway (screening, diagnosis or treatment) people with SMI are most disadvantaged so that appropriate interventions can be put in place to help remedy the situation.

Summary: People with SMI may be dying unnecessarily because of reduced access to medical or surgical interventions commonly received by the general community.[6] The effect of the NBCSP on people with SMI is unknown in terms of participation, uptake of colonoscopy, stage of disease at presentation, access to cancer care, and cancer-related mortality. Depending on the relative levels of participation in people with SMI and the general population, the existing disparities in outcomes could improve, remain the same or even worsen. Our study will investigate these factors to further understand the effect of the NBCSP in this very disadvantaged population. We will also investigate treatment pathways after diagnosis to determine whether variations in the treatment that SMI patients receive compared to those without SMI could explain some of the disparity in CRC outcomes in this group.

8. AIMS AND OBJECTIVES

Provide a statement of primary and secondary aims/objectives, key research questions, and/or a clearly defined hypothesis (where appropriate). The aims/objectives should reflect the datasets and variables requested. **Please do not list variables here – attach a separate data variable list with justifications for individual variables in the context of the statistical analysis plan.**

Among people eligible for the NBCSP (50-74 years) we aim to:

1. Compare NBCSP participation rates between those with and without SMI

2. Determine whether people with SMI with a positive NBCSP screen have diagnostic colonoscopy as often as those from the general population

3. Calculate and compare CRC mortality rates in those with and without SMI

    a. Overall; and

    b. According to participation in the NBCSP .

4. Amongst NSW residents diagnosed with CRC assess whether those with SMI

    a. Are diagnosed at a later cancer stage

    b. Receive surgery, or chemo- & radio-therapy, as often as those without SMI after adjusting for cancer stage at presentation.

    c. Experience any change in the above following the NBCSP

5. Investigate the experience of people with SMI and colorectal cancer from NSW (and their carers) in relation to the barriers and enablers to screening, diagnosis and optimal care.

We will test the following hypotheses:

1. With respect to the NBCSP, people with SMI
    a. Have lower participation rates in screening
    b. After a positive FOBT are less likely to receive a subsequent colonoscopy
2. With respect to CRC diagnosis, people with SMI
    a. Are more likely to present with more advanced cancer
    b. Are less likely to receive specialised interventions such as resection or chemotherapy.
3. Disparities in mortality will be less for people with SMI who participate in the NBCSP

9. METHODS

STUDY DESIGN

Describe the type of study (e.g. retrospective cohort study, case control study).

Data Linkage Study

COHORT/STUDY POPULATION

Please describe your cohort/study population, specifying any inclusion /exclusion criteria.

NSW cohort

All men and women aged 50-74 years, registered in the NSW Cancer Registry with a new diagnosis of cancer of the colon or rectum (ICD C18, 19, 20) diagnosed after 01/01/2006 to the latest available.

National cohort

People with SMI: We will define people as having SMI using PBS data. Those who have been dispensed at least two prescriptions for authority-only medications used specifically for SMI (ATC codes N05AH, N05AX, N05AE, N06AX) since 01/07/2002 (the commencement of the PBS dataset). We will include only people aged 50-74 years at 01/01/2006 or who turn 50 after this date or become Medicare eligible (and were 50-74 years) after this date.

Comparator group: The AIHW will randomly select a sample of people on the Medicare Enrolments File selecting 1 in 4 people from the entire population aged 50-74 years at 01/01/2006 or who turn 50 after this date or become Medicare eligible (and were ≥ 50 years) after this date. This group will consist of people who have not been dispensed a prescription for one of the specified PBS medicines (ATC codes N05AH, N05AX, N05AE, N06AX) between 1/7/2002 to latest available.

The Australian Institute of Health and Welfare (AIHW) will link data across the following data sets for detailed analyses of the screening, diagnostic & therapeutic pathways for those with CRC in Australia: Medicare Enrolment File, Pharmaceutical Benefits Schedule, Medicare Benefits Schedule, NBCSP, Australian Cancer Database & the National Death Index.

For NSW residents these data would be supplemented with information on cancer staging from the NSW Cancer Registry and hospital treatments from the NSW Admitted Patient Data Collection by linking the NSW cohort (described above) with the national cohort.

DATA COLLECTION

Please identify the nature of the data to be collected (multiple options may be selected).

☐ Primary data collection (e.g. original data from surveys, interviews, and/or focus groups etc.)

Please provide a description of primary data sources below.

Please specify the names of the sites for primary data collection.

☒ Secondary data collection (e.g. routinely collected data)

Please provide a description of the secondary data source(s) below.

Please specify the names of the sites or agencies for secondary data collection.

Please also complete Section 13 below.

i) NSW Cancer Central Registry 01/01/2006 – latest available (NSW Ministry of Health)

ii) NSW Admitted Patient Data Collection 01/01/2006 – latest available (NSW Ministry of Health)

iii) Medicare Enrolments File (MEF) 2006 - latest available (AIHW)

iv) Pharmaceutical Benefits Scheme (PBS) 01/07/2002 - latest available (AIHW)

v) National Death Index (NDI) 01/01/2006 - latest available (AIHW)

vi) Australian Cancer Database (ACD) Earliest - latest available year of diagnosis (AIHW)

vii) Medicare Benefits Scheme (MBS) 01/01/2004 - latest available (AIHW)

viii) National Bowel Cancer Screening Program (NBCSP) 01/08/2006 - latest available (AIHW)

Agency Type for secondary data (tick all that apply)	☒ State / Territory	☒ Commonwealth	☐ Private Sector

CONSENT

Briefly outline the consent process to be used in the study as indicated in the **HREA** and **NSW Privacy Form**. **Select one only:**

1. **Informed consent**
2. **Opt out consent**
3. **Request a waiver of consent – with strong justifications**

We request a waiver of consent for the following reasons:

We are requesting de-identified secondary (existing) data. There will be no contact with subjects and no new information will be collected. After approval from the relevant data custodians, the datasets will be released to AIHW for data linkage. Following linkage, identifying information will be stripped from the data and will then be sent to the Secure Unified Research Environment (SURE) at the Sax Institute (as required by Australian Institute of Health & Welfare). All analyses will be conducted in SURE. SURE is a secure, remote-access, high-powered computing environment. The data will not be physically given to the researchers.

It would be impossible to obtain informed consent from each potential subject in the administrative data sets given the 53,000 (NSW cohort) 124,974 (National cohort) and 1,630,000 (comparator group). In addition, trying to obtain informed consent would mean the re-identification of individuals in the currently de-identified databases. This would compromise the participants' anonymity. Obtaining consent from all the potential participants would be impractical for the following reasons:

1) The study aims to use large sets of administrative, routinely collected data for secondary purposes to answer our research questions. The large number of individuals is required to ensure that the study will have adequate power to answer the questions. Given the very large numbers of individuals involved, it would be impracticable to obtain individual consent from participants for use and disclosure of data for these purposes. The burden involved in contacting almost 2 million participants would make the study unfeasible.

2) We will not be able to contact participants directly to obtain consent as no identifying details will be passed on the research team.

3) There is no ongoing relationship between the data custodians and the participants to allow participants to be contacted directly by the data-holding organisations.

4) Contact details recorded in the PBS database are likely to be out of date or incorrect for many participants who have moved since their most recent script, particularly those whose last medication use (and accompanying details) was recorded a long time ago.

5) Many participants may have died, or become too ill to provide consent. This is of particular concern because participants who develop cancer (the outcome of interest) are more likely to have died (and therefore be unable to consent) than people who do not develop cancer, which would introduce considerable bias into the study.

6) A requirement to collect consent would prevent researchers from addressing the survival-related study aims (because consent cannot be obtained from participants who have experienced the event of interest, death). The use and disclosure of data will be conducted in accordance with guidelines approved under section 95A of the Privacy Act.

We believe that the public interest in the research outweighs, to a substantial degree the public interest in complying with the Australian Privacy Principles for the following reasons:
1) Cancer mortality rates are over 70% higher in people with severe mental illness (SMI) than in those from the general population. We need to understand why this gap exists so that we can design interventions to help improve survival.
2) The proposed research will highlight gaps in colorectal cancer care in people with SMI.
3) Other study designs could be used to attempt to answer these questions but would either be much more prone to bias (and thus potentially produce inaccurate results) or would be much less efficient and less cost-effective.
4) The risk to individual participants from having their data used in this study is negligible. Individuals will never be contacted and the information provided to researchers will not include names, dates of birth or addresses, and the other data items provided would not be sufficient to identify individuals. Analysed data will be presented at all times in aggregate (summary) form, with no results presented at the individual level.

DATA GOVERNANCE

Specify the data governance arrangements for the **entire data lifecycle** for the study. Where applicable, include information regarding:

1. Data collection: specify all site(s) where data will be collected.

CHeReL
NSW Cancer Central Registry
NSW Admitted Patient Data Collection

AIHW
Medicare Enrolment File (MEF)
Pharmaceutical Benefits Scheme (PBS)
National Death Index (NDI)
Australian Cancer Database (ACD)
Medicare Benefits Scheme (MBS)
National Bowel Cancer Screening Program (NBCSP)

2. Data transfer & security: specify the processes to be used between sites and methods of encryption.

CHeReL from NSW will link the NSW Cancer Registry data and the NSW Admitted Patient Data Collection and add project-specific person numbers (PPNs) to these data sets. They will then transfer these PPNs linked to identifiers to AIHW so that the NSW PPNs can be added to the Commonwealth data sets. The data sets with NSW-specific PPNs (stripped of identifiers) will be curated into SURE for access by the researchers.
AIHW will be responsible for the linkage of Commonwealth data sets.
PPNs will be added to each record in each of the Commonwealth data sets (Medicare Enrolments, PBS, MBS, NDI, ACD, NBCSP) by AIHW and personal identifiers (name, address) would be removed.
These data sets would then be curated into SURE where the investigators will access them and join the data sets for analysis based on the PPNs.

3. Data access, use and disclosure: specify the processes (including the use of a remote access facility).

The data will be securely stored at the Secure Unified Research Environment (SURE), a remote access computing environment at the Sax Institute in Sydney, for storage and management.

SURE protocols for managing personal data are clearly outlined on their public website. SURE has clear data security policies to protect data from misuse, interference, loss, and unauthorised access, modification or disclosure. This organization trains staff in data security and has strong physical and computer security mechanisms in place to ensure information is protected. Research staff who will be involved in this project have been trained in computer security and will be required to undertake SURE training on issues of privacy, information security and statistical disclosure and sign a terms and conditions deed prior to gaining access to SURE. All analyses of linked Commonwealth data will be undertaken via SURE. Data analysed within SURE are stored on dedicated servers, protected by multiple firewalls, hosted in a high security data centre with strict access controls and 24hour security surveillance. Accessing the SURE environment requires a password and a onetime access code from a physical authentication token. Study research staff will be accessing data at SURE via an encrypted connection, and will not be able to email, print, or copy the data.

4. Data storage: include all site(s) at which data will be stored.
Following linkage, identifying information will be stripped from the data before it is sent by the participating linkage units to the Secure Unified Research Environment (SURE) at the SAX Institute (as required by the Australian Institute of Health and Welfare).
Analysis will be conducted remotely through the SURE. The data will not be physically given to the researchers

5. Data retention: specify the period of retention of the data following completion of the project.
Anticipated completion date of the project work is: 31/12/2022
The retention period is typically seven years after completion of the project work: 31/12/2029

6. Data disposal: specify how the information will be destroyed and the methods to be used.
At the end of the data retention period data stored in SURE will be destroyed as per the SAX Institutes policies and procedures.
Core data tables within SURE will be disposed of by the system administrator. All working data files containing PPNs or potentially re-identifiable data will be securely deleted.

10. ANALYSIS PLAN

OUTCOMES/EXPOSURES AND COVARIATES

Describe the study outcome measures (primary and secondary) and include information on study exposure/s, covariates, and other factors and how these are defined based on the data. Please provide sufficient detail (200 word minimum).

Among people eligible for the NBCSP (50-74years) we aim to:

1. Compare NBCSP participation rates between those with and without SMI
2. Determine whether people with SMI with a positive NBCSP screen have diagnostic colonoscopy as often as those from the general population
3. Calculate and compare CRC mortality rates in those with and without SMI
    a. Overall; and
    b. According to participation in the NBCSP.
4. Amongst NSW residents diagnosed with CRC assess whether those with SMI
    a. Are diagnosed at a later cancer stage
    b. Receive surgery, or chemo- & radio-therapy, as often as those without SMI after adjusting for cancer stage at presentation.
    c. Experience any change in the above following the NBCSP

We will adjust for the following covariates: gender, age, marital status, education level, rurality, socio-economic status, country of birth, Indigenous status and comorbidity. Rurality & socio-economic status determined by the place of usual residence using the 'Socioeconomic Indices For Areas' (SEIFA) and 'Accessibility/ Remoteness Index of Australia' (ARIA) respectively. We will adjust for comorbidities by constructing a Charlson comorbidity score using principal and additional diagnosis codes.

STATISTICAL ANALYSIS

Provide a statistical analysis plan outlining how the aims/objectives will be met, the statistical methods to be used, and who will be carrying out the analysis. Please provide sufficient detail (200 word minimum).

Analyses will be conducted within the Secure Unified Research Environment (SURE) at the Sax Institute, which has the capacity for analyses of large datasets. We will investigate differences in screening rates in those with and without SMI, as well as cancer stage at diagnosis.

Incidence analyses:
We will use Poisson regression to calculate incidence rates and rate ratios (IRRs) for each outcome (FOBT, colonoscopy, cancer diagnosis, surgery, chemo/radiotherapy and mortality), comparing those with and without SMI and the effects of the NBCSP on these outcomes. Person-years will be calculated from 2006 (the year of commencement of the NBCSP), or from the year that people become eligible for screening (i.e. age 50), whichever occurs later. If an individual becomes eligible for screening before they are dispensed a medicine for an SMI then the years prior to the first prescription will be considered 'unexposed'. For NSW residents we will also assess for cancer stage at diagnosis.

We will undertake sensitivity analyses of whether NBCSP participation by people with SMI reduces any disparity in mortality or cancer care outcomes (e.g. colonoscopy Australia-wide following a +ve FOBT a in the NBCSP and surgery in NSW) compared to those 50-74 years who participated in the program (Australia-wide), or everyone who was 50-74 years old (NSW).

Adjusting for confounders: The models using only the national data will be adjusted for age, area-level Socio-economic status and state. We will also explore the possibility of adjusting for concessional status (holding a health care card or similar to receive further subsidisation on costs of medicines or health services) as a further marker of socio-economic status. Data on the number and type of medical consultations for each person during the study period, (from Medicare) will be considered as mediators in the model. For analyses using NSW data we will also adjust for comorbidities by constructing a Charlson comorbidity score using principal and additional diagnosis codes from hospital morbidity data.

The analyses will be conducted by a post-doctoral research fellow who will be recruited in the next six months. S/he will work under the guidance of the CI team. Drs Kisely, Jordan, Lawrence and Protani may also contribute to analyses.

11. PROJECT FUNDING / SUPPORT

INDICATE HOW THE PROJECT WILL BE FUNDED?

[Please note that all fields in any selected funding detail column will need to be completed.]

Funding	**Confirmed or Sought?**			**Amount of funding $**
External Competitive Grant	Confirmed ☒	Sought ☐	Not Sought ☐	$591,841.60
Internal competitive grant	Confirmed ☐	Sought ☐	Not Sought ☐	
Sponsor	Confirmed ☐	Sought ☐	Not Sought ☐	
By Researchers' department or organisation	Confirmed ☐	Sought ☐	Not Sought ☐	

External Competitive	
Name of Grant/Sponsor	Cancer Australia
Internal Competitive	
Name of Grant/Sponsor	
Sponsor	
Name of Grant/Sponsor	
By Researchers Department or Organisation	
Name of Grant/Sponsor	

12. REFERENCES

1. **Lawrence D**, Hancock KJ, **Kisely S**. The gap in life expectancy from preventable physical illness in psychiatric patients in Western Australia: retrospective analysis of population based registers. BMJ. 2013 May 21;346:f2539. doi: 10.1136/bmj.f2539.

2. **Kisely S,** Smith M, **Lawrence D**, Maaten S. Mortality in individuals who have had psychiatric treatment: population-based study in Nova Scotia. *Br J Psychiatry* 2005; **187**: 552-8.

3. Saha S, Chant D, McGrath J. A systematic review of mortality in schizophrenia: is the differential mortality gap worsening over time? *Arch Gen Psychiatry* 2007; **64**: 1123-31.

4. Weinstein LC, Stefancic A, Cunningham AT, Hurley KE, Cabassa LJ, Wender RC. Cancer screening, prevention and treatment in people with mental illness. CA Cancer J Clin 2016;66:133-151.

5. Brown S, Inskip H, Barraclough B. Causes of the excess mortality of schizophrenia. *Br J Psychiatry* 2000; **177**: 212-7.

6. **Kisely S**, Crowe E, **Lawrence D**. Cancer-related mortality in people with mental illness. JAMA Psychiatry. 2013 Feb;70(2):209-17. doi: 10.1001/jamapsychiatry.2013.278.

7. **Kisely S**, Forsyth S, **Lawrence D**. Why do psychiatric patients have higher cancer mortality rates when cancer incidence is the same or lower? Aust N Z J Psychiatry. 2016 Mar;50(3):254- 63. doi: 10.1177/0004867415577979. Epub 2015 Mar 31.

8. **Lawrence D**, Holman CD, Jablensky AV, Threlfall TJ, Fuller SA. Excess cancer mortality in Western Australian psychiatric patients due to higher case fatality rates. *Acta Psychiatr Scand* 2000; **101**: 382-8.

9. **Kisely S,** Sadek J, MacKenzie A, **Lawrence D**, Campbell LA. Excess cancer mortality in psychiatric patients. *Can J Psychiatry* 2008; **53**: 753-61.

10. **Lawrence D**, Holman CD, Jablensky AV, Hobbs MS. Death rate from ischaemic heart disease in Western Australian psychiatric patients 1980-1998. *Br J Psychiatry* 2003; **182**: 31-6.

11. **Kisely S**, Campbell LA, Cox M. The effect of study design on the reporting of mortality due to colorectal cancer in adults with mental illness in Nova Scotia. Can J Psychiatry. 2012 Jun;57(6):389-94

12. Goldman LS. Medical illness in patients with schizophrenia. *J Clin Psychiatry* 1999; **60** Suppl 21: 10-5.

13. Oud MJ, Schuling J, Slooff CJ, Meyboom-de Jong B. How do General Practitioners experience providing care for their psychotic patients? *BMC Fam Pract* 2007; **8**: 37.

14. Roberts L, Roalfe A, Wilson S, Lester H. Physical health care of patients with schizophrenia in primary care: a comparative study. *Fam Pract* 2007; **24**: 34-40.

15. Burns T, Cohen A. Item-of-service payments for general practitioner care of severely mentally ill persons: does the money matter? *Br J Gen Pract* 1998; **48**: 1415-6.

16. Jablensky A, McGrath J, Herrman H, Castle D, Gureje O, Evans M, et al. Psychotic disorders in urban areas: an overview of the Study on Low Prevalence Disorders. *Aust N Z J Psychiatry* 2000; **34**: 221-36.

17. Australian Institute of Health and Welfare 2016. Australian Cancer Incidence and Mortality (ACIM) books.

18. Australian Institute of Health and Welfare 2014. Analysis of bowel cancer outcomes for the National Bowel Cancer Screening Program. Cat. no. CAN 87. Canberra: AIHW.

19. Christou A, Katzenellenbogen JM, Thompson SC. Australia's national bowel cancer screening program: does it work for indigenous Australians? BMC public health. 2010 Jun 25;10(1):373.

20. Von Wagner C, Baio G, Raine R, Snowball J, Morris S, Atkin W, Obichere A, Handley G, Logan RF, Rainbow S, Smith S. Inequalities in participation in an organized national colorectal cancer screening programme: results from the first 2.6 million invitations in England. International journal of epidemiology. 2011 Feb 17;40(3):712-8.

DATA REQUEST SECTION

13. DATA SOURCES

Is this a data linkage application?			
☐ No **Please provide a description of your data sets below, and provide data variable lists for each dataset.** ☒ Yes **Please skip to Section 14.**			
DATASET 1			
Name and/or brief description of dataset			
Number of records		Year span of dataset	
Custodian name		Email/Phone no.	
Agency Type (tick one only)	☐ State / Territory	☐ Commonwealth	☐ Private Sector
DATASET 2			
Name and/or brief description of dataset			
Number of records		Year span of dataset	
Custodian name		Email/Phone no.	
Agency Type (tick one only)	☐ State / Territory	☐ Commonwealth	☐ Private Sector
DATASET 3			
Name and/or brief description of dataset			
Number of records		Year span of dataset	
Custodian name		Email/Phone no.	
Agency Type (tick one only)	☐ State / Territory	☐ Commonwealth	☐ Private Sector

14. DATA LINKAGE

Who is undertaking the data linkage?

☒ Centre for Health Record Linkage (CHeReL)

☒ Other linkage provider - Australian Institute for Health & Welfare (AIHW)

Describe the data linkage process.

☒ Extract from data collection held in the CHeReL MLK

☒ Other collections to be linked by the CHeReL or other linkage provider - AIHW

The NSW linkage team CHeReL will:

- Select the 'NSW cohort' from NSW Cancer Registry data
- Assign a CHeReL_PPN to the members of the NSW cohort
- Link the NSW cohort to NSW Admitted Patient Data Collection
- Transfer a file with CHeReL_PPN and personal identifiers for the NSW cohort to AIHW
- Extract content data for the NSW cohort from the NSW Cancer Registry and NSW Admitted Patient Data Collection
- Use a map file provided by AIHW to attach the AIHW_PPN to the content data from the NSW Cancer Registry and NSW Admitted Patient Data Collection, and load this content data to SURE.

AIHW will:

- Extract the 'National cohort' from the PBS.
- Select the 'National control group' from the Medicare Enrolment File.
- Link the NSW cohort, the National cohort and the control group to the PBS, MBS, MEF, ACD, NDI and NBSCP.
- Create an AIHW_PPN for all individuals in the NSW cohort, the national cohort and the control group.
- Send a PPN Map file to CHeReL with the CHeReL_PPN and AIHW_PPN.
- Extract content data from the MEF, PBS, MBS, ACD, NDI and NBSCP for the three study populations. AIHW will attach the AIHW_PPN and load these content datasets to SURE.

All data transfers will be via secure messenger service, with encrypted and password protected files.

Are updates required?

☒ No

☐ Yes (please specify) *(e.g. "annually until 2015", "one further extract in 2012")*

Does the project involve family linkage?
(e.g. mother-baby, mother-other parent-baby, mother-baby-sibling links)

☒ No - **Please complete Section B only**

☐ Yes - **Please complete Section C only**

Provide a concise and simple description of the project (max 400 words)

Cancer is one of the major causes of death among people with a psychiatric illness. Our previous research has shown that cancer incidence rates in people with severe mental illness (SMI) - i.e. those with schizophrenia or bipolar affective disorder, are similar to those in the general population, but that cancer mortality is higher in those with SMI than those in the general population. Lifestyle factors, such as diet or alcohol use, are unlikely to be the explanation. Other reasons could include: 1) Poor cancer screening participation rates in those with mental illness; 2) delays in diagnosis leading to more advanced disease at diagnosis; and 3) sub-optimal post-diagnosis management.

Australia's National Bowel Cancer Screening Program (NBCSP) provides a unique opportunity to determine where the major barriers to optimal cancer care for those with SMI occur. We propose a data linkage study using Commonwealth data (NBCSP, Medicare Enrolment File, Medicare Benefits Schedule, Pharmaceutical Benefits Scheme, Australian Cancer Database and the National Death Index) to compare bowel cancer screening participation in people with SMI to those from the general population.

We will additionally link these to the NSW cancer registry and hospital data to examine care pathways from diagnosis through treatment and end-of-life care. We have decided to focus on NSW for this part of the study as it is the only large jurisdiction that holds data on estimated cancer stage at diagnosis.

People with SMI will be defined using the Pharmaceutical Benefits Scheme (PBS) streamlined authority system. Second generation antipsychotics, the mainstays of treatment for SMI, require an indication-specific authority code for subsidy through the PBS. These are used almost solely for treatment of either schizophrenia or bipolar affective disorder. We will also include lithium prescriptions, for which the specific indication is bipolar affective disorder.

We hypothesise that people with SMI will have lower screening rates and be more likely to present with more advanced cancer. They will also be less likely to receive the appropriate specialist surgical procedures, chemotherapy or radiotherapy.

(SECTION B) EXTRACT FROM CHEREL MLK COLLECTIONS

What collections are being used?		*Years*	
		From *(e.g. Jul 2001)*	*To* *(e.g. Dec 2006)*
NSW Admitted Patient Data Collection (from Jul 2001) [2] Based on: ☐Admission date **OR** ☐Separation date	☒	01/01/2006	Latest available
NSW Perinatal Data Collection (from 1994)[3]	☐		
NSW Central Cancer Registry (from 1972) [3]	☒	01/01/2006	Latest available
NSW RBDM Birth Registrations (from 1994)	☐		
NSW Perinatal Death Review Database (from 2000)	☐		
NSW Mental Health Ambulatory Data Collection (from 2001)	☐		
NSW Pap Test Register (from Jul 1996)	☐		
NSW Ambulance (from 2009)	☐		
NSW Emergency Department Data Collection (from 2005)	☐		
The 45 and Up Study	☐		
NSW RBDM Death Registrations (from 1985) [3]	☐		
NSW Notifiable Conditions Information Management System (from 1993)	☐		
Cause of Death Unit Record File (from 1985) [3]	☐		
NSW ANZDATA (From 1963)	☐		
NSW Australian Early Development Census (from 2009)	☐		
BreastScreen NSW (from Jan 1988)	☐		
ACT Admitted Patient Collection [2] (from Jul 2004) Based on: ☐ Admission date **OR** ☐ Separation date	☐		
ACT Cancer Registry (from 1994) [3]	☐		
ACT Emergency Department Data Collection (from Jul 2004)	☐		
ACT Perinatal Data Collection (from 1997) [3]	☐		
ACT Notifiable Diseases Register (from 2000)	☐		
ACT BDM Death Registrations (from 1997)	☐		

[2] Records in the NSW APDC and ACT APC are based on separations and do not include data for patients who have been admitted but not discharged from hospital.

[3] For National datasets (e.g. NDI; ACD) please refer to OTHER COLLECTIONS on the following page.

ACT BDM Birth Registrations (from 1997)	☐		
ACT Australian Early Development Census (from 2009)	☐		
ACT Cervical Screening Registry (from 1994)	☐		
ACT Kindergarten Health Check (from 2014)	☐		
ACT ANZDATA (from 1963)	☐		
Comments:			

COHORT AND RESTRICTIONS

Approximately how many records/individuals are in the cohort?
53,000
How is your cohort to be defined? *Please include datasets from which your cohort will be drawn and any inclusion and exclusion criteria*
The NSW cohort will be derived from the NSW Cancer Registry. It is defined as all men and women aged 50-74 years, registered on the NSW Cancer Registry with a new diagnosis of cancer of the colon or rectum with the ICD codes C18, C19, C20 after 01/01/2006.
If your cohort is defined by ICD codes please select:
☐ Principal diagnosis/procedure codes only OR ☐ Any of the multiple diagnosis/procedure codes within a record
Please describe the ICD codes required (e.g. from the APDC - all separations during 2002 with the following ICD diagnoses) and attach an excel spread sheet (filename – abbreviation_cohort code list_date.xlsx)
ICD codes C18, C19, C20
Do you require:
☒ All linked records required for these individuals ☐ Only records relating to the specified condition
Do you require any restrictions/subsets for data collections not in your cohort? (e.g. Hepatitis A records from the NSW Notifiable Conditions Information Management System)

OTHER COLLECTIONS (NOT HELD IN CHEREL MLK) [1]

[1] Please include any external datasets and national datasets (e.g. PBS, MBS, NDI or ACD).

DATASET 1			
Name and/or brief description of dataset	Medicare Enrolment File (MEF)		
Number of records	1,630,000	Year span of dataset	2006 – Latest available
Custodian name	AIHW	Email/Phone no.	alice.crisp@aihw.gov.au
Agency Type (tick one only)	☐ State / Territory	☒ Commonwealth	☐ Private Sector
Personal identifiers available for linkage*			
DATASET 2			
Name and/or brief description of dataset	Pharmaceutical Benefits Scheme (PBS)		
Number of records	124,974	Year span of dataset	2002 – latest available
Custodian name	AIHW	Email/Phone no.	eve.kelly@aihw.gov.au
Agency Type (tick one only)	☐ State / Territory	☒ Commonwealth	☐ Private Sector
Personal identifiers available for linkage*			
DATASET 3			
Name and/or brief description of dataset	Medicare Benefits Schedule (MBS)		
Number of records		Year span of dataset	2004 to latest available
Custodian name	AIHW	Email/Phone no.	eve.kelly@aihw.gov.au
Agency Type (tick one only)	☐ State / Territory	☒ Commonwealth	☐ Private Sector
Personal identifiers available for linkage*			
DATASET 4			
Name and/or brief description of dataset	National Death Index (NDI)		
Number of records		Year span of dataset	2006-latest available
Custodian name	AIHW	Email/Phone no.	alice.crisp@aihw.gov.au
Agency Type (tick one only)	☐ State / Territory	☒ Commonwealth	☐ Private Sector

Personal identifiers available for linkage*			
DATASET 5			
Name and/or brief description of dataset	Australian Cancer Database (ACD)		
Number of records		Year span of dataset	Earliest available year of diagnosis **to** latest available year of diagnosis
Custodian name	AIHW	Email/Phone no.	alice.crisp@aihw.gov.au
Agency Type (tick one only)	☐ State / Territory	☒ Commonwealth	☐ Private Sector
Personal identifiers available for linkage*			
DATASET 6			
Name and/or brief description of dataset	National Bowel Cancer Screening program (NBCSP)		
Number of records		Year span of dataset	2006 – Latest available
Custodian name	Commonwealth Department of Health	Email/Phone no.	david.meere@aihw.gov.au
Agency Type (tick one only)	☐ State / Territory	☒ Commonwealth	☐ Private Sector
Personal identifiers available for linkage*			

**Contact the CHeReL* for advice on personal identifiers*

Please note: variable list(s) and Data Custodian sign off MUST be obtained for each data collection.

- *Variables lists are available here.*
- *CHeReL will facilitate data custodian sign off for Ministry of Health datasets.*

15. SECTION C - FAMILY LINKAGE

Please provide a description of family relationships required (e.g. mother-baby, mother-other parent-baby, mother-baby-sibling links)
Is sibling status required?
Are restrictions on family relationships required? (e.g. only full and not half siblings required)

EXTRACT FROM DATA COLLECTION HELD IN THE CHEREL MLK

Dataset *CHeReL MLK datasets listed below.* *Please add or remove datasets as required*	*Years*		*Relationship*[4]			
	From (e.g. Jul 2001)	*To (e.g. Dec 2006)*	*M*	*B*	*S*	*O*
NSW Admitted Patient Data Collection (from Jul 2001) [5] Based on: ☐Admission date **OR** ☐ Separation date						
NSW Perinatal Data Collection (from 1994)[3]						
NSW Central Cancer Registry (from 1972) [3]						
NSW RBDM Birth Registrations (from 1994)						
NSW Perinatal Death Review Database (from 2000)						
NSW Mental Health Ambulatory Data Collection (from 2001)						
NSW Pap Test Register (from Jul 1996)						
NSW Ambulance (from 2009)						
NSW Emergency Department Data Collection (from 2005)						
The 45 and Up Study						

[4] M - Mother records; B - Baby records; S - Sibling records; O - Other parent records

[5] Records in the NSW APDC and ACT APC are based on separations and do not include data for patients who have been admitted but not discharged from hospital.

NSW RBDM Death Registrations (from 1985) [6]						
NSW Notifiable Conditions Information Management System (from 1993)						
Cause of Death Unit Record File (from 1985) [3]						
NSW ANZDATA (From 1963)						
NSW Australian Early Development Census (from 2009)						
BreastScreen NSW (from Jan 1988)						
ACT Admitted Patient Collection [2] (from Jul 2004) Based on: ☐ Admission date **OR** ☐ Separation date						
ACT Cancer Registry (from 1994) [3]						
ACT Emergency Department Data Collection (from Jul 2004)						
ACT Perinatal Data Collection (from 1997) [3]						
ACT Notifiable Diseases Register (from 2000)						
ACT BDM Death Registrations (from 1997)						
ACT BDM Birth Registrations (from 1997)						
ACT Australian Early Development Census (from 2009)						
ACT Cervical Screening Registry (from 1994)						
ACT Kindergarten Health Check (from 2014)						
ACT ANZDATA (from 1963)						