Government of **Western Australia**
Department of **Health**

For Office Use Only	
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HREC#	
Version	V.1
Date	22 May 2017

APPLICATION FOR DATA

This form should be used for *all* requests for unit record data, linked data, and use – but not necessarily release – of Department of Health data collections, where Department of Health Human Research Ethics Committee (HREC) approval is required.

Double click appropriate box and select 'checked' option

REQUEST DETAILS

Data Linkage Branch services	**Other application for data**
☒ includes linked and geocoded data and sample selections (see Data Linkage WA)	☐ includes requests for unlinked data

SUBMISSION DETAILS

☐ **Draft application**

This step must be completed before applying to DoH HREC.

Email dataservices@health.wa.gov.au and attach Word versions of:

- the "Application for Data" form*
- data services forms (e.g. extraction, linkage, geocoding, family connections)
- variable lists for all datasets requested
- research protocol
- other supporting documentation

* no signatures or confidentiality agreements required for draft applications

☒ **Data application (final copy) for DoH HREC approval**

Application for Data form to accompany other HREC application forms. For submission instructions refer to the DoH HREC website.

☐ **Data application (final copy) *not* requiring DoH HREC approval**

Email dataservices@health.wa.gov.au and attach PDF versions of:

- signed Application for Data form
- data Services forms (e.g. cohort specifications, linkage, geocoding)
- variable lists for all datasets requested
- research protocol
- other supporting documentation.

☐ **Application for data amendment/update for an existing project**

Projects for which the most recent approval was granted more than a year ago, must complete this form in conjunction with the relevant amendment form.

1. Project title

Secondary falls prevention in older people presenting to the emergency department with a fall: A multi-centre randomised controlled trial of efficacy, cost-effectiveness and acceptability of the RESPOND program

2. Contact details

2.1 Principal Investigator

The principal investigator is the person with overall responsibility for management of the project; He/she must *not* be a student. The principal investigator must read and sign the legal declarations at the end of this form.

Title and name	Associate Professor Glenn Arendts			
Position	Associate Professor Medical Research			
Organisation	Centre for Medical Research, The University of Western Australia			
Address	35 Stirling Highway, Crawley WA 6009			
Phone	(w)	+61 8 9224 0363	(m)	
Email	glenn.arendts@uwa.edu.au			

2.2 Project Contact

The contact person for queries regarding the project ☒ As above

Title and name				
Organisation				
Address				
Phone	(w)		(m)	
Email				

2.3 Student Details ☐ Not applicable

Title and name	Rebecca Morris			
Organisation	Monash University			
Degree Course	PhD			
Supervisor	Associate Professor Anna Barker and Professor Keith Hill			
Phone	(w)	+61 3 9903 0620	(m):	+61 416 560 917
Email	rebecca.morris@monash.edu			

2.4 Student training and experience

Outline supervision to be provided, the proportion of work to be carried out by the student and the student's previous experience relevant to the proposed research and ethics application.

Ms Morris has a BSc (Hons) Physiotherapy, (First Class) and a Master of Health and Human Services Management. Ms Morris has extensive clinical experience as a physiotherapist working with elderly people in the context of falls prevention. She will be responsible for the program evaluation for RESPOND. Throughout her PhD candidature she has undertaken training in biostatistics, data management and research methods and ethics. She will be supervised by Associate Professor Anna Barker and Professor Keith Hill.

3. ORGANISATION RESPONSIBLE FOR APPLICATION

3.1 List all locations where the data will be analysed (specify departments at institutions).

Monash University – Department of Epidemiology and Preventive Medicine

3.2 Type of organisation

- ☐ WA Department of Health (DoH) /WA Health
- ☒ A State department or agency other than DoH (e.g. other state government department or public university
- ☐ A non-governmental organisation (e.g. private hospital, medical research institute, private university)
- ☐ Commonwealth department or agency
- ☐ Other, specify below

3.3 Does this project have any potential conflicts of interest?

☒ NO ☐ YES, please provide details below

- ☐ Commercially
- ☐ Financially
- ☐ Intellectually
- ☐ Other, specify below

3.4 Has this project received funding?

☐ NO ☒ YES, please provide details below

National Health and Medical Research Council Partnership Grant:

1. National Health and Medical Research Council (NHMRC) Partnership Grant $1,488,315
2. Health Networks Branch, Department of Health, WA ($60,000)
3. Royal Perth Hospital ($60,000)
4. The Alfred Hospital ($460,568)

5. Department of Health, WA ($200,000)
6. Curtin University ($5,000)
7. The Royal Perth Hospital Medical Research Foundation ($60,000)
8. Aged and Continuing Care Directorate, Department of Health, WA ($60,000)

In-kind support will be given from the following organisations:

1. Health Networks Branch, Department of Health, WA ($15,998)
2. The Royal Perth Hospital Medical Research Foundation ($60,000)
3. Curtin University ($53,329)
4. Sir Charles Gairdner Hospital (SCGH) Area Rehabilitation & Aged Care Falls Specialist Program ($6,003)
5. Injury Control Council of Western Australia (ICCWA) ($8,335)
6. The George Institute for Global Health ($14,000)
7. Monash University ($586,130)
8. Centre for Clinical Research in Emergency Medicine ($20,268).

4. PROJECT SUMMARY

4.1 Provide a lay summary (approximately 50–100 words) of your project.
Avoid highly technical terms, medical jargon and abbreviations.

Older people often present to the Emergency Department (ED) following a fall and frequently have a history of previous falls. RESPOND will test an intervention designed to reduce additional falls in older people presenting to the ED with a fall who are discharged home within 72 hours of presentation. This research will be conducted at Royal Perth Hospital and The Alfred Hospital in Melbourne. The practical yet rigorous design focuses on ensuring that research outcomes are feasible to achieve maximal impact. The project will evaluate the implementation, acceptability and feasibility to participants as well as cost-effectiveness compared to standard care.

4.2 Information about your project, including the lay summary above, may appear on the DoH HREC and/or Data Linkage WA website following approval to maintain public confidence in research. If you do not consent to this, please tick the box below and provide justification.

☐ **If you do *not* consent,** please provide justification below

5. PROJECT OUTLINE

5.1 Background

Provide an overview demonstrating the need for this study with appropriate references.

Falls in older people are a major concern in terms of frequency, disability, institutionalisation and mortality with an ever-growing socioeconomic burden[1]. Falls for older people presenting to the ED are not new events—Hill et al identified that >50% of older Victorians presenting to ED with a fall injury have fallen in the previous year [2]. In the six months following an index fall ED presentation, older patients frequently experience re-hospitalisation (49%) and functional decline [3]. This highlights a failure in secondary fall prevention in Australia. This outcome is disappointing considering the growth in evidence for effective prevention strategies and services such as falls clinics. We believe this represents an implementation failure due to a lack of patient engagement in selection of prevention strategies. Reviews by the investigator team support this hypothesis [2]. A review of 23 RCTs of home-based falls prevention exercise programs found that only 21% of program participants were adherent to the program during the period it was prescribed [4]. We have designed an innovative post-discharge program—RESPOND—that aims to address this important problem. RESPOND extends our previous falls prevention research and current practice models by incorporating patient focused education and behaviour change strategies that have proven effective in the secondary prevention of cardiovascular events [5].

Burden resulting from failure to prevent secondary falls

One in every ten days spent in hospital by older Australians is attributable to a fall injury [6]. Healthcare costs for the management of fall injuries in Australia are double the costs for motor vehicle accidents [7] and are expected to triple to $1,375 million per year in coming decades unless effective prevention and lower treatment costs occur [8]. The need for effective falls prevention is escalating with evidence of increasing fall-related health system burden [9-10]. The consequence of sub-optimal care for this group is increasing disability and morbidity; escalating demand for ED and health services that are already overwhelmed; and utilising considerable healthcare budget on management of a condition that is substantially avoidable if appropriate measures are implemented. The quality of care of older people presenting to the ED with a fall must improve.

Secondary falls prevention trials in the ED population

Eleven RCTs have studied the impact of secondary falls prevention programs in older people presenting to ED with a fall. The largest and most recent was completed by Hill et al. This RCT of 712 older people presenting to seven EDs found a multifactorial intervention based on existing community services had no effect on new falls, fall injuries or ED presentations in the year follow-up [2]. These findings are consistent with seven similar RCTs which also found no effect on falls or fall injuries with multifactorial interventions for older people presenting to an ED with a fall [11-17]. In contrast, there have been three trials that have found a positive impact on falls. The landmark ‘Prevention of Falls in the Elderly Trial (PROFET)’ RCT of 397 older people demonstrated an interdisciplinary program achieved a marked reduction in recurrent falls [18]. A second UK trial of 313 older people presenting to ED with recurrent falls found a multifactorial intervention reduced falls by 36% [2]. While these studies provide important insights, questions remain surrounding generalisability to the Australian setting and economic impact. Indeed when the successful PROFET intervention was tested in the Netherlands it was found to have no impact on falls [19]. The third successful trial tested vitamin D and calcium supplementation. This Australian RCT of 302 vitamin D deficient women who presented to an ED with a fall found a 19% reduction in falls risk with vitamin D and calcium supplementation[20]. Vitamin D supplementation is a key component of the RESPOND intervention. The characteristics that appear to differentiate the successful trials from others include timely delivery of the intervention following a fall and use of more

intensive interventions [21]. An Australian study of barriers to implementing falls prevention strategies recommends programs in this setting should focus on changing patients' attitudes towards the intervention [22].

Insights into the reasons for the failure in secondary fall prevention can be gained from prior studies undertaken by the CIs. Key factors inhibiting implementation and successful outcomes include: poor patient participation; delayed service delivery; and a limited focus on patient choice, engagement and empowerment. These factors underpin the design of the RESPOND program.

Poor patient participation

A recent survey (n=5,755) demonstrated that while older people may acknowledge concerns about falls risk, 63% have no interest in programs offered [11]. The RCT by CI Hill found few fallers attended services referred to by ED staff such as a falls clinic (<5%), physiotherapy (<30%) or occupational therapy (<17%) [2]. These findings of low patient participation in prevention activities after a fall-related ED presentation are consistent with several other studies. One Australian study reported that 72% of patients in this setting are reluctant to attend exercise classes, 59% are reluctant to cease psychotropic medications and 43% are reluctant to have a home safety assessment [22]. These results are consistent with overseas studies [2].

Inadequate functional health literacy (FHL)

FHL in older people may be an important factor in low participation in falls prevention activities. FHL is the degree to which individuals obtain, process, and understand basic health information. In Australia, 50% of people ≥65 years have inadequate FHL [23]. Older adults with lower FHL engage in less preventive behaviours than the general population [12]. The majority of older ED patients will not have adequate FHL skills to enable effective uptake of recommendations or referrals made in the ED setting. A recent US study reported 60% of older patients reported not understanding discharge information provided by ED staff [24]. The dynamic and unfamiliar environment of the ED may not be the optimal setting for providing post-discharge care instructions for older people.

Delayed service delivery

In the RCT by Hill et al, for those who did access falls services referred to by ED staff, the time lag between ED presentation and attending the service was too long—four months for falls clinics, two months for physiotherapy, and three months for occupational therapy [2]. Similar delays were reported in the Dutch trial of the PROFET intervention [18] and the Danish trial where the time lag was more than two months [11]. In contrast, the successful UK trial by Davison delivered services within one month of the patient being discharged from ED [19].

Lack of patient choice, engagement and empowerment

A systematic review of older people's perceptions of falls prevention strategies provides further insights. This review of 24 studies reported factors that facilitated participation in falls prevention activities were social support, low intensity exercise, greater education, involvement in decision-making, and a perception of the program as relevant and life-enhancing [25]. Barriers to participation included fatalism, denial and under-estimation of the risk of falling, poor self-efficacy and health and functional ability, and the stigma associated with programs for older people. These findings are consistent with the findings of studies by CI Hill, CI Haines & AI Hill that report patients recently discharged from hospital have low levels of falls prevention strategy knowledge and only 36% are engaging in a falls prevention exercise program 6 months after hospital discharge highlighting the need to provide education and support to enhance motivation and self-efficacy in this population [26, 27].

The RESPOND Program:

The RESPOND program is a patient-centred education and behaviour change falls prevention intervention. The program incorporates seven key components: (1) risk factor assessment and risk stratification; (2) education on key risk factors for falls and evidence based strategies to address: strength and balance, bone health, vision and sleep quality; (3) targeted risk factor management driven by patient choice, empowerment and goal-setting; (4) facilitation and/or co-ordination of health service access (5) a minimum of 2 telephone follow-up to support and review behaviour change and goals; and (6) information to the patient's general practitioner regarding the patients' involvement in the study and (7) re-assessment and feedback (as detailed in the RESPOND intervention program package). Please refer to Attachment 1, Appendices 5 and 6 for the RESPOND patient education modules and GP letters.

SUMMARY

There is growing evidence that only a minority of older people presenting to an ED following a fall follow recommendations provided by ED staff. It is also known that there are widespread deficits in the quality of care provided to older people presenting to the ED as a result of a fall. It is therefore not surprising that we have not been successful in achieving secondary fall prevention. RESPOND specifically targets the gaps outlined above by providing a patient-centred service that focuses on providing education and support to improve knowledge, self-efficacy and participation in falls prevention activities. The service will strengthen linkages between the ED and community care.

REFERENCES

[1] Sartini M, et al. The epidemiology of domestic injurious falls in a community dwelling elderly population: an outgrowing economic burden. *Eur J Public Health* 2010;20(5):604-6.

[2] Russell MA, et al. A randomized controlled trial of a multifactorial falls prevention intervention for older fallers presenting to emergency departments. *J Am Geriatr Soc* 2010;58(12):2265-74.

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[4] 22. Simek EM, et al. Adherence to and Efficacy of Home Exercise Programs to Prevent Falls: A Systematic Review and Meta-analysis of the Impact of Exercise Program Characteristics. *Prev Med* 2012.

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trial of a falls prevention service. *Aust Health Rev* 2003;26(3):88-97.

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5.2 Research Aim(s)

These should directly relate to the requested datasets, variables and timeframe.

The aim of the RESPOND project is to drive knowledge translation through implementation of an evidence-based patient centred falls prevention program for older people presenting to ED following a fall.

The research plan is a mixed methods evaluation and comprises a series of 3 interlinked evaluations that are underpinned by the following objectives:

1. To undertake a multi-centre RCT to investigate the impact of the RESPOND program on fall, fall injury and ED representation rates in older people presenting to the ED with a fall (Study 1);
2. To undertake a detailed program evaluation to assess participation, acceptability and feasibility of the RESPOND program, and to identify critical success factors and barriers to effectiveness and sustainability (Study 2); and
3. To undertake a multilevel economic evaluation to assess the cost-effectiveness of the RESPOND program compared to standard usual care, via an analysis of all ED presentations and hospitalisation admissions (Study 3).

It is hypothesised that falls, fall injuries and ED re-presentation rates will be reduced by at least 30% in the 12-months post-implementation of the RESPOND program for intervention participants compared with comparator group participants.

5.3 Design

e.g., retrospective cohort study, case-control study, single group pre/post

The methods for this RCT have been published. Please see attached manuscript. In brief, participants will be randomly allocated to the RESPOND intervention or standard care control group. RESPOND incorporates: (1) home-based risk factor assessment; (2) education, coaching, goal setting, and follow-up telephone support for management of one or more of four risk factors with evidence of effective intervention; and (3) healthcare provider communication and community connections delivered over six months. Primary outcomes are falls and fall injuries per-person-year. Secondary outcomes include hospital admissions and ED presentations. Secondary outcomes data will be triangulated with state-wide hospital admissions and ED presentation data (current data linkage request).

5.4 Methodology

Specify the data extraction process, proposed data analyses and how these will achieve your research aims

The methods for this RCT have been published *a priori* in a protocol paper. Please see attached manuscript. This application refers to the Western Australian half of the sample (n=252).

The primary outcomes are falls and fall injuries per person-year in the 12 months after recruitment. Recruitment occurred over a sixteen month period: 24 March 2014 – 31 July 2015. Secondary outcomes are ED re-presentations, hospitalisations, and fractures per-person year in the 12 months post randomisation. Change in falls risk status, falls self-efficacy and health-related quality of life in the 12 months post randomisation will also be evaluated. Participants in both groups of the trial completed monthly calendars over the 12-month follow-up documenting details of any falls, fall injuries, ED presentations and hospital admissions on a daily basis.

Calendar and telephone-verified data on falls, fall injuries, fractures, ED presentations and hospital admissions were triangulated with data recorded in hospital administrative datasets. Due to the high presentation rate of participants to hospitals other than their recruiting hospital, state-wide data are required for this triangulation.

Outcome analyses will be undertaken on an intention-to-treat basis by a statistician blinded to group allocation. Differences in falls, fall injuries, fractures, ED re-presentation rates and deaths will be compared between groups using negative binomial regression including a variable for adjustment by site. Secondary analysis that adjusts for age and cognitive ability (using FROP-Com cognitive status score obtained at baseline assessment) will be undertaken if significant imbalance in these factors is identified across groups. Differences in continuous outcomes including falls risk, quality of life and falls efficacy scores will be evaluated using General Linear Models (ANCOVA) or the non-parametric Mann–Whitney U statistic where data are not normally distributed. A significance level of $p<0.05$ will be used for all analyses. The multifactorial design (participants will choose different risk factors and strategies) means it is not possible to discern the effects of any single intervention on the primary outcomes.

For the purposes of acquiring linked data from the WA Data Linkage Branch (WADLB) the principle of separation will be observed. Dr Darshini Ayton will create two files based upon the RESPOND data:

1. A list of patients' identifiers including: Study ID, Full name, Date of Birth, Address, postcode, UMRN, Recruitment date, Participation end date – these data will be encrypted and supplied to WADLB via secure, online means (SUFEX).

2. All RESPOND data collected to date, inclusive of Study ID but excluding patient identifiers (ENR001–ENR006 and DEMO01–DEMO25), will be provided by Dr Ayton to the project data

analysts and she will take no part in the analysis of the linked data from WADLB.

WADLB will then supply the researchers with three files:

1. a map with two columns displaying Study ID in one and a corresponding encrypted linkage key for each patient in the other
2. ED service data linked to WADLB encrypted linkage keys; and
3. Hospital morbidity data linked to WADLB encrypted linkage keys.

6. PROJECT DURATION

6.1 Entire period spanning research design, approval, implementation, analysis to publication. Note that delivery of linked data can take several months depending on request complexity.

Expected start date	31/03/2014
Expected end date	01/11/2019

6.2 Do you have project deadlines to bring to our attention?

Every effort will be made to deliver your data within the requested timeframe, pending project complexity and existing workloads

☐ NO ☒ YES, please provide details, including specific dates, below

NHMRC funding for this project completes on the 31st of March 2017. Therefore we would like to receive this data as soon as possible to finalise the outcome paper for the trial. We understand that this is likely to be in the 3rd or 4th quarter of 2017.

7. PERSONNEL

List all personnel, describing qualifications, expertise, project role and institutional email.

Projects seeking linked data must have at least one team member based at a WA institution.

Non-WA Public Sector employees must sign a Declaration of Confidentiality.

Where multiple positions are held across organisations, list only the institution relevant to this application.

Title, full name, qualifications, employing institution and email *e.g. Prof Albert Smith, MBBS, The University of Western Australia, a.smith@uwa.edu.au*	Expertise and role in the project	Access to data required	Confidentiality Agreement submitted
Prof. Keith Hill PhD, Grad Dip Physio, BAppSc (Physio). Keith.Hill@curtin.edu.au	Principal investigator, Western Australia. Prof Hill will be responsible for overseeing all aspects of the project for the Western Australian arm of the project.	☐Yes ☒ No	☒Yes ☐ No
A/Prof. Glenn Arendts MBBS, MMed, FACEM glenn.arendts@uwa.edu.au	Principal investigator, Royal Perth Hospital. A/Prof Arendts will be responsible for overseeing all aspects of the project at Royal Perth Hospital.	☐Yes ☒ No	☐Yes ☒ No

Prof. Leon Flicker MBBS, Grad Dip Epid, PhD, FRACP leon.flicker@uwa.edu.au	Professor Flicker will be responsible for overseeing all aspects of the project at Royal Perth Hospital, together with A/Prof. Glenn Arendts.	☐Yes ☒ No	☒Yes ☐ No
Dr Nick Waldron MbChB, FRACP nicholas.waldron@health.wa.gov.au	Dr Waldron will assist A/Prof. Barker to develop the RESPOND education modules. He will also manage communications with the WA falls network and ensure that they have input into the design and refinement of the RESPOND service to optimize integration with existing WA falls prevention activities.	☐Yes ☒ No	☐Yes ☒ No
Prof. Christopher Etherton-Beer MBBS, PhD, FRACP christopher.etherton-beer@uwa.edu.au	Prof. Etherton-Beer will assist in conducting the study in WA, as well as assisting in dissemination and translation of practice of research findings.	☐Yes ☒ No	☐Yes ☒ No
A/Prof. Anne-Marie Hill PhD, BAppSc (Physio), MSc, Grad Cert Uni Teaching anne-marie.hill@curtin.edu.au	A/Prof. Hill will provide expert knowledge and support on the clinical working of the trial, problems of the post discharge period, falls prevention education for older persons.	☐Yes ☒ No	☒Yes ☐ No
A/Prof. Anna Barker B.Phty, M.Phty (Geriatrics), PhD Anna.Barker@monash.edu	Chief Investigator of RCT, Principal investigator Victoria. Will lead the data analysis. A/Prof. Barker is an experienced postdoctoral researcher in falls and healthy ageing. A/Prof. Barker will lead the project and supervise Victorian based staff. She will coordinate with Professor Keith Hill, who is nominated as the Western Australia lead investigator and the two site coordinators to oversee all aspects of the project.	☒Yes ☐ No	☒Yes ☐ No

Dr Darshini Ayton BBiomedSci(Hons), MPH, PhD Darshini.Ayton@monash.edu	Project manager. Dr Ayton will provide WADLB with patient identifiers but not take part in analysis of the linked data.	☐ Yes ☒ No	☒ Yes ☐ No
Dr Renata Morello B.Phty, MPH, PhD Renata.Morello@monash.edu	Research manager. Dr Morello will be involved in data management	☒ Yes ☐ No	☒ Yes ☐ No
Ms Laura Sellick BSc (Hons) Laura.Sellick@monash.edu	Research assistant. Ms Sellick will be involved in data management	☒ Yes ☐ No	☒ Yes ☐ No
Ms Rebecca Morris BSc(Physio), MHHSM Rebecca.Morris@monash.edu	Extensive clinical experience as physiotherapist working with elderly people in the context of falls prevention. Will be responsible for the program evaluation for RESPOND. Undertaken training in biostatistics, data management and research methods and ethics.	☒ Yes ☐ No	☒ Yes ☐ No

8. ETHICS REVIEW AND APPROVALS

8.1 Does your project require review by the DoH HREC? Refer to DoH HREC website

☐ NO ☒ YES

8.2 Does your project require approval by any other ethics committee?

This could include WA Health ethics committees and/or external ethics committees. Refer to DoH Research Development Unit information links:

- WA Health Research Governance Policy and Procedures 2012
- WA Health Research Ethics

☐ NO ☒ YES, please attach a copy of each ethics committee approval granted and provide details of the current status of all applications

Ethics approval for this project and was sought from The Alfred Hospital. See attached for copy of The Alfred Health HREC approval and approval of amendment for access to Victorian state wide data for ED presentations and hospital admissions. See attached for copy of the Eastern Metropolitan Health Service HREC approval and approval of amendment for access to WA state wide data for ED presentations and hospital admissions.

8.3 Does your project require other approvals?

☐ NO ☒ YES, please attach a copy of each approval granted and provide details of the current status of all applications

DLB requested that we inform Dr Aresh Anwar, the RPH Executive Director, of the possibility of re-identifying and comparing RPH data to other state hospitals' data. Attached is an email correspondence from Aresh Anwar giving his consent for access to the data after our assurances that the data will not be separately analysed from or compared with the state wide data and that it will only be analysed in composite to determine the effectiveness of the RESPOND program on hospital utilisation.

9. PROJECT DATA

Data Services

9.1 Specify each data service you seek.

Corresponding forms must be attached for each data service requested, available at the Data Linkage WA website.

DATA SERVICE		REQUEST
Extraction	Data extraction from one or more data collections	☒
Linkage	New data to be linked to one or more datasets	☒
Geocoding	New addresses requiring geocoding	☐
Sample Selection	Population sample to be selected from the WA Electoral Roll	☐
Genealogical Data	Family relationships or data for related individuals	☐
Study Recruitment	Use of DoH data to contact persons for research purposes	☐
Indigenous Status Flag	YES/NO flag that can be included in record-level data provided for data linkage projects. Created from a validated algorithm for each individual from one or multiple data records held in the WA Data Linkage System. All available linked records are used. Note, it may contradict specific records in any single data collection or other independently collected data.	☐

Data Collections				
9.2 Complete a separate form for each dataset requested, available at the DLB website. If a required variable list is unavailable, please contact dataservices@health.wa.gov.au. It is strongly recommended that requests are discussed with the corresponding data custodians prior to submission. For other datasets, attach a separate Word document with details including dataset name, data custodian with contact details, and data variables required.				
DATASET		**SELECT**	**FROM** *e.g. Jan 1984*	**TO** *e.g. latest available*
Birth Registrations	(since 1974)	☐		
Emergency Department Data Collection	(since 2002)	☒	24/03/2014	31/07/2016
Electoral Roll	(since 1988)	☐		
Hospital Morbidity Data System	(since 1970)	☒	24/03/2014	31/07/2016
Mental Health Information System	(since 1966)	☐		
Midwives Notification System	(since 1980)	☐		
Mortality Register	(since 1969)	☐		
WA Cancer Register	(since 1982)	☐		
WA Notifiable Infectious Diseases Data	(since 1988)	☐		
WA Register of Developmental Anomalies	(since 1980) Birth Defects Cerebral Palsy	 ☐ ☐		
Other datasets (please list below)		☐		

10. PRIVACY AND CONSENT

Personal Health Information

Personal health information is defined by the Practice Code for the Use of Personal Health Information from the Department of Health Data Collections (herein referred to the Practice Code) Section 3 as information about an individual or institution where the identity is apparent or can be reasonably ascertained from the information itself. If it is reasonably possible for a data recipient to identify individuals using other linked information they possess then this is also considered personal information.

Personal Information Variables

10.1 Specify if you require any of the following information in your data.

Note this does *not* apply to data used by DLB for linkage purposes or to contact people.

Participant names	☐ YES ☒ NO
Participant addresses	☐ YES ☒ NO
Participant *full* dates of birth (i.e., ddmmyyyy)	☐ YES ☒ NO
Patient identifiers (e.g., UMRN)	☐ YES ☒ NO
Clinician or health service provider identifications	☐ YES ☒ NO
Individual hospital or healthcare institution identifications	☐ YES ☒ NO
Geo-coded points (longitude and/or latitude)	☐ YES ☒ NO

10.2 Are you applying for the release of personal information?

If you ticked YES to any item in Question 10.1, you must answer YES to this question.

☐ NO ☒ YES, please explain why non-identifiable information cannot be used

The participants of this study have consented to the researchers obtaining emergency department presentations and hospital admission (representations) information from data collected by the RPH. The researchers have personal identifying information for all the participants including full name, date of birth, address and UMRN at recruitment for RPH. However, the principle of separation will be observed with Dr Ayton providing patient identifiers to DLB but not having access to the linkage keys or linked data subsequently provided by DLB. These will be received by Dr Morello who will have no access to the patient identifiers.

10.3 Describe all measures to protect privacy. Refer to the Practice Code (Section 3.1).

The information must only be used for the authorised purpose: The data received through this RCT and from DLB will only be used to address the aims and research questions of the RCT, program evaluation and economic evaluation.

The information must only be used by authorised person(s): Only researchers listed on the ethics applications will have access to the data.

The information must be protected by appropriate and approved security measures at all times: All physical copies of data are locked in filing cabinets in secure University offices. Only researchers authorised by ethics have access to these filing cabinets. Computers are password protected and access to electronic study files on the secure server must be granted by the project manager. Data on trial participants will be entered into the secure web-based database using this unique code. This will be password protected and will be housed on a

secure server. Data will also be encrypted using 128bit encryption. For security purposes the server will be enabled with a Secure Socket Layer protocol. Secure Sockets Layer (SSL) is an encryption technology that protects information while in transit via the Internet. It will help to prevent eavesdropping, tampering, or message forgery with HTTP transmissions based on server side public/private key pairs and provides support for client-side public/private key usage.

Only project investigators/researchers and people who are part of the project will have access to this database which is password protected. All computer devices used for this project are password protected and only approved staff listed on ethics have access to the secure server with the project files.

The information must not be further disclosed to any other institution, organisation or person without prior approval from the data custodians and DOH HREC: Only organisations listed on the ethics application will be able to receive this data. Researchers from Monash University will be responsible for performing the analysis.

The information must not be merged with any other information sets held by the user without prior approval from the Data custodians and DOH HREC: The information received from DLB will be merged with the participant data collected from participants during the trial. The data will not be merged with any other dataset.

The information must not be used to identify or contact any individual unless this is an approved purpose: The participants signed a consent form enabling the researchers to contact them for monthly follow up phone calls and three home visits (baseline, 6 month assessment and 12 month assessment). Participants are not contacted outside of these parameters.

The information must not be kept for longer than approved by the data custodians: Data will be stored in hard copy and electronically for the duration of 7 years as per Monash University policy. At the end of the approved retention period electronic data will be deleted and hard copy data will be disposed of confidentially.

Consent
10.4 Will consent be sought from participants for the use and disclosure of their information from the data collections?
☒ NO ⟶ go to 10.5 ☐ YES ⟶ describe below your consent procedure and attach contact letters, information sheets and consent forms.
10.5 If consent will not be sought, explain why it would be impracticable to obtain and provide details below.

☐ The size of the population involved in the research.

☐ The proportion of individuals likely to have moved or died since the health information was originally collected.

☐ The risk of introducing bias into the research.

☐ The risk of creating additional threats to privacy.

☐ The risk of inflicting psychological, social or other harm by contacting individuals.

☒ The difficulty of contacting individuals directly when there is no existing or continual relationship between the organisation and the individuals.

☐ The difficulty of contacting individuals indirectly through public means.

The researchers are no longer in contact with the participants as the 12 month follow period has been completed. At the time of recruitment, individual patients were invited to participate in the study and provided with verbal and written information that overtly explained the research project, how the research would be conducted and what their role was in the research and that their participation was voluntary. People indicating their willingness to participate in the evaluation were asked to sign a participant consent form which stated their participation in the study was voluntary (see attached). Participants were also asked to sign a Medicare consent form, in addition to the study consent form, to collect data on healthcare utilization costs.

However, the patient consent form did not mention possible access to linked data from WA hospitals, other than RPH. Further, the consent form explicitly stated "Researchers will not have access to your personal information such as your name, date of birth or contact details, so they will not be able to identify you." As such, we request that only de-identified data be supplied, linked by Study ID. We will observe the principle of separation to ensure that investigators with access to identifying patient information will not be involved in subsequent analysis of the raw, non-aggregated linked data.

11. OTHER SOURCES OF INFORMATION FOR THE PROJECT

11.1 Indicate other sources of information to be used in this project and provide details below.

☒ Information will be collected directly from participants

☐ Information will be collected about participants from another person (e.g. carers, doctors)

☒ Information will be used from existing records held by individuals or organisations other than the DoH

☐ Information previously collected by you or your organisation for other purposes

☐ Other DoH data collections

☐ Other

11.2 Describe below the source and nature of the information and specify whether your project involves the matching of records to these data.

Attach a separate Word document detailing each dataset name, the variables sought and the data custodian's name and contact details.

To avoid conflicts of interest, if the data custodian is one of the named investigators, then written approval is required from that person's manager for the release of the corresponding data. Provide details below.

(see attached Word document outlining all collected variables for the RESPOND project)

Data Custodians

Self-reported data collected from participants: Dr Renata Morello
Data collected from Royal Perth Hospital records: Eileen Boyle

12. SECURITY PLAN

12.1 Provide a detailed security plan for the information provided by DoH or collected as a result of DoH's actions. Your security plan will be assessed against the Practice Code.

Technological Security (Practice Code Section 4.3)

The data received from WADLB will be stored on the Monash University secure server. Only project investigators/researchers and people who are part of the project will have access to these folders. Staff need to be logged onto the Monash University system to be able to access the folder. All computer devices used for this project are password protected and only approved staff listed on ethics have access to the secure server with the project files.

Risk management is sponsored and managed by Monash's Risk and Compliance Unit. Monash's risk management methodology is based on the Risk management framework used by the university and the AN/NZS ISO 31000:2009. Monash University has established a security management framework that is aligned with best practices and industry standards such as ISO 27001:20103.

All computers are password protected for individual staff members with passwords changed every six months. Participant identifying information is never saved on computer hard drives and computer screens are locked and password protected when staff are away from the screen. Computer screens automatically lock after 10 minutes of inactivity. This is to prevent unauthorised staff from seeing participant information.

Monash University has implemented a security in depth strategy for its information and its information systems. The following controls are in place:

- Network segmentation.
- Network firewalls.
- Access controls.
- End point protection (Antiviruses for laptops, desktops).
- Web application firewalls.
- Data backups.
- Data encryption in transit and storage.
- Patch management.
- Vulnerability management.
- Security Operations Centre that monitors and responds to security incidents.
- Logging of system activities.

Physical Security (Practice Code Sections 4.2 and 4.6)

Data received from WADLB will not be in hardcopy. Monash University staff only have access to building areas, which they are assigned to. Access is controlled through swipe cards on a centralized system. Access to data centre and servers is restricted to authorised personnel. Monash University's infrastructure is hosted in third party data centres that have fire suppression systems; power outages controls; and designed in line with industry's best practice.

Transport (Practice Code Sections 4.4 and 4.7)

DoH prefers to send and receive data via secure online data transfer, such as MyFT or SUFEX.

Data will be transferred securely between the researchers and DLB via secure encryption. The Data Linkage Manager will email the researchers a request for personal identifiers via SUFEX. DLB will send linked the data to the researchers via MyFT. No further data transport will occur from the approved data location.

12.2 Nominated data recipient/s
Dr Renata Morello

13. RETENTION AND DISPOSAL PLAN

13.1 Provide a detailed retention and disposal plan for the information provided by DOH or collected as a result of DOH's actions. This must include the period of retention beyond the study and intended date of data destruction. Your plan will be assessed against the Practice Code (Section 5).

Data received from WADLB will be retained for 7 years after the completion of the project. Reasonable steps will be taken to permanently de-identify personal information once it is no longer needed – this may happen before the 7 year period. WADLB will be informed when data is de-identified and when it is destroyed. HREC approval from the different sites (Royal Perth Hospital, The Alfred Hospital) is until the 1/11/2019. Therefore data associated with this project will be destroyed on the 1/11/2026. All electronic folders with data will be deleted and devices used to access these folders will be sanitised. This will be done in line with National Statement for Ethical Research. Dr Ayton will be the custodian of the encryption key. If Dr Ayton leaves prior to the 1/11/2026 – Dr Renata Morello will be the nominated custodian.

Data destruction/ return date	1/11/2026

13.2 Does your security, retention and disposal plan comply with the Practice Code (Sections 4 and 5)?

☒ YES ☐ NO, please provide a justification below

14. DATA FORMAT

Optional (for our planning purposes only) Please describe the software packages and analytical tools you will use for this project, e.g. SPSS, SAS, Excel.

Excel, STATA

15. DISSEMINATION OF RESULTS

15.1 Explain how results will be disseminated, e.g. report, publication, conference, thesis.

Refer to the Practice Code (Section 8).

Note that final drafts of all reports, publications and presentations must be sent to the data custodians and/or Data Linkage Branch for comment at least two weeks prior to dissemination, as per Declarations in Section 17 below.

Publications

Conference presentations

PhD thesis

Knowledge translation seminars for clinicians, health services managers, researchers, public health practitioners.

Once the outcome paper has been published, media releases will be prepared to inform the general public of the study results.

Newsletters will be sent to RESPOND participants informing them of the study outcomes.

No individual or identifying information will be reported in any publication. All results will be reported in an aggregate fashion to protect the privacy of individuals on which the data pertains. For example, results will report mean age, % of males, rate of falls/fall injuries in intervention and comparator groups.

15.2 Describe how confidentiality of participants will be maintained in the dissemination of results.

The privacy of individuals is of paramount importance.

No individual or identifying information will be reported in any publication.

All results will be reported in an aggregate fashion to protect the privacy of individuals on which the data pertains and ensure that there is no distress, embarrassment or other harm caused when the data is reported.

No results will be reported for cell counts of <5.

16. GOVERNANCE

Head of Department / School / Research Organisation

Tick the boxes to indicate you have read and understood each clause.

I/ we certify that:

- ☐ I/we are familiar with this project and endorse its undertaking.
- ☐ The resources required to undertake this project are available.
- ☐ The researchers have the skill and expertise to undertake this project appropriately or will undergo appropriate training as specified in this application.
- ☐ I/we warrant that I/we are authorised to make this application and to bind the institution below in relation to the obligations arising out of the submission of this application.
- ☐ The conduct of the project has been approved by…

I/we certify that _____

(name of institution)

accepts the legal and ethical responsibility for the conduct of this project and have adequate indemnity insurance to cover the conduct of this project and indemnifies the Minister for Health, the State of Western Australia, the Department of Health and their officers, servants, agents and contractors for any loss or damage they suffer through any breach in the conduct of this project.

FULL NAME *(PRINTED)*:	
POSITION:	
ORGANISATION:	

SIGNATURE *	DATE

*** Note: if the Principal Investigator is the Head of Department / School / Research Organisation, then the next tier or authority above is required to sign the Indemnity Form. This section cannot be signed by a member of the Project Team.**

17. DECLARATIONS AND SIGNATURES

17.1 Applicant / Principal Investigator

Tick the boxes to indicate that you have read and understood each clause.

I certify that;

- ☐ All information in this application is truthful and as complete as possible.
- ☐ The project will be conducted in accordance with the ethical and research arrangements of the organisations involved.
- ☐ I am aware of and understand the relevant legislation and regulations, and the project will be conducted in accordance with these.
- ☐ I recognise that unit record data from DoH is confidential information and that I am responsible for ensuring that the information will be kept confidential.
- ☐ The information provided for this project by DoH will be used only for the project outlined in this application.
- ☐ The project will be conducted in accordance with the protocol and conditions approved for this project and in accordance with the provisions of the DoH *Practice Code for the Use of Personal Health Information from the Department of Health Data Collections.*
- ☐ I will make available all resulting draft manuscripts, reports or other presentations based on the analysis of linked data in this application to the relevant Data Custodians and will thereby allow DoH the opportunity to review and respond within 14 days (2 weeks).
- ☐ I will provide the Data Linkage Branch and/or Data Custodians with an electronic copy of all publications of results of analysis as they become publicly available.
- ☐ I will acknowledge the Data Linkage Branch and/or DoH in any publications, reports or presentations resulting from this application.

FULL NAME *(PRINTED)*:	Associate Professor Glenn Arendts
SIGNATURE	DATE

17.2 Supervisor/s of student/s

Tick the boxes to indicate that you have read and understood each clause.

I /we certify that:

- ☐ I/we will provide appropriate supervision to the student to ensure that the project is conducted in accordance with the undertakings above.
- ☐ I/we will ensure that any necessary training is provided to enable the project to be undertaken skilfully and ethically.

FULL NAME *(PRINTED)*:	Associate Professor Anna Barker
SIGNATURE	DATE

Government of **Western Australia**
Department of **Health**

For Office Use Only	
DL#	201702.01
HREC#	
Version	V.1
Date	22 May 2017

Linkage

Secondary falls prevention in older people presenting to the emergency department with a fall: A multi-centre randomised controlled trial of efficacy, cost-effectiveness and acceptability of the RESPOND program

Complete this module only if you are applying for a new dataset to be linked to one or more of the DOHWA core datasets.

DOHWA HREC approval is required for all new linkages. Please attach a separate word document of all variables that will be merged with DOHWA data.

Please note: Under no circumstances should data be emailed. Data for linkage must be transferred securely to a member of the Data Linkage Branch.

The Data Linkage Branch reserves the right to decline, suspend or charge extra for linkage work if dataset requirements are unmet.

Dataset Description

Please provide a basic description of the data you are providing for linkage purposes.

Demographic details self-reported by n=252 participants recruited into the study at RPH ED, plus UMRN sourced from RPH records.

Please provide the contact details of the Custodian of this dataset:

Name: Dr Darshini Ayton
Email: Darshini.Ayton@monash.edu
Phone Number: 0425 705 130

Dataset Requirements – Please read

1. These fields produce the highest quality linkage: given name, surname, date of birth and address.
2. Multi-field information should be broken down into separate components.

Ideal:

First name	Middle name	Surname	Address 1	Suburb	Postcode
John	Robert	Smith	189 Royal St	East Perth	6004

Undesirable:

Name	Address
John Robert Smith	189 Royal St East Perth 6004

3. Preferred formats: character-separated text (e.g. .csv, .tab), fixed-width text or Excel spreadsheet. If you are unable to provide your data in one of these formats, then contact the Manager, Data Linkage Systems, who may be able to assist with file conversion.
4. IDs that deterministically connect your data to another collection, such as Unique Medical Record Numbers or Elector Numbers, are very useful for linkage. Please note that the DLB cannot accept Medicare Numbers.
5. Please ensure your data is checked thoroughly for errors before sending. Common mistakes include duplicate or missing IDs, invalid characters and inconsistent formatting.

Dataset Specifications	
Total number of records and/or people in the dataset	252
Time period of data (when was the information collected?)	24/03/2014 – 31/07/2015
Data format (see Data Requirements)	See attached word document
Data fields supplied (see Data Requirements) **Every record must have a unique ID**	Study ID First name Last name Date of birth Residential Address Postcode UMRN Recruitment date Participation end date
Comments	

Government of **Western Australia**
Department of **Health**

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Extraction

Secondary falls prevention in older people presenting to the emergency department with a fall: A multi-centre randomised controlled trial of efficacy, cost-effectiveness and acceptability of the RESPOND program

Please specify the data to be extracted, listing all data sets and specific detail around selection of a cohort or cases and controls. Any date limits should also be given. If you require assistance with completing this form, please email DataServices@health.wa.gov.au.

Please note: DOHWA HREC approval is required for any personal health information*.

*Personal health information is information or opinions that relate to the health of a person where the identity of a person is apparent or can reasonably be ascertained from the information. For a more detailed explanation see the *Practice Code For the Use of Personal Health Information*. All project personnel who will have access to personal health information provided by the DOHWA must enter into a Confidentiality Agreement. Please contact the Manager or Project Manager of the Data Linkage Branch or the DOHWA HREC Executive Officer if you are unsure of the criteria for "personal health information".

1. COHORT/CASE GROUP

Cohort Description
Please provide a description of your cohort and how your study population is defined. E.g. all people living in Bunbury who were diagnosed with lung cancer between 1995 and 2005, defined through the WA Cancer Registry
Participants were individually recruited from the emergency department at Royal Perth Hospital from 24 March 2014 to 31 July 2015. Personal identifiers will be provided for linkage.
For quoting purposes please provide an estimate of how many people there will be in your cohort.
N=252
Disease and Procedure Codes
If your cohort is to be selected from specific disease or procedure groupings, please specify the version of ICD codes you require (i.e. ICD9, ICD10), and whether they should be applied only to the principal disease/procedure code or to any of the multiple codes within a record. For the time periods and versions of ICD codes used in WA please see http://www.datalinkage-wa.org.au/sites/default/files/HMDS_ICD_DRG.pdf **Please attach an Excel spreadsheet of all the specific ICD codes you require. Please note that the DLB cannot provide or check ICD codes.** E.g. ICD10, diagnosis codes for lung cancer. See attached spreadsheet.
N/A

Geographical areas
If your cohort is to be restricted to a specific residential or service area, please specify the relevant postcodes or CDs that define the area required. **Please attach an Excel spreadsheet of the postcodes or CDs you require.** *SEIFA and ARIA codes are available for Emergency, Death, Hospital and Midwives data. If you require SEIFA or ARIA codes, please select this in the variable lists for each dataset (Module 4).* E.g. People residing in Bunbury. See attached spreadsheet of postcode and collection districts.
n/a

Service data extraction
Please specify the datasets you require, the time period and any restrictions on which records you need. **WA Cancer Registry:** Please refer to the variable list for record scope. If you require specific exclusions please list them in the comments section of that form. **Midwives Notification System, Birth Registrations & WA Register of Developmental Anomalies:** Please specify below whether you need records for the birth of a person, records where they are the parent or both. ***Attach variable lists (Module 3)**

Dataset e.g. Hospital Morbidity	**Time period** e.g. Jan 1995 – most recent	**Restrictions** e.g. 'I wish to analyse comorbidities. Please extract all records for 5 years before and all after the index admission'
Hospital Morbidity	24/03/2014 – 31/07/2016	All admissions to hospital are required for all study participants from index date of study recruitment to 12 months afterwards.
Emergency Department Data Collection	24/03/2014 – 31/07/2016	All admissions to emergency departments are required for all study participants from index date of study recruitment to 12 months afterwards.

2. COMPARISON GROUP/CONTROLS

Control Group Description
Please provide a description of your controls. E.g. Random sample of people from the electoral roll, matched on year of birth and gender to the cohort 5:1.
N/A