Clinical Trial Protocol

Physiological, Psychological, Psychiatric, Surgical or Health Interventions

Development and pilot of a rapid-response, virtual, falls risk assessment and management service for community-dwelling aged care clients.

Version 1, 29/04/2024

Dr Lindsey Brett

Contents

1. General Information

Protocol Title				
Protocol identifying number	U1111-1306-1500			
Version Number	1	**Version date**	27/03/2024	
Amendment History				
Version Number		**Version date**		
Clinical Trial Sponsor				
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Type of Appointment with UNSW	☐ UNSW Employee ☒ UNSW Conjoint ☐ Other (Please describe)			
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Human Research Ethics Committee	
Name	UNSW Human Research Ethics Committee
Status of ethical review	☐**Approved** ☒ **In progress** ☐ **To be submitted**
Trial Sites	HammondCare at Home (NSW, ACT, Vic.)
Funding for the Clinical Trial	
Funding Body 1 Name	Ageing Futures Institute, UNSW
Amount of Funding	$50,000
Interests that the funding body has in the clinical trial	Involvement in innovative research that may lead to more extensive studies and funding.
Funding Body 2 Name	HammondCare
Amount of Funding	$50,000
Interests that the funding body has in the clinical trial	Develop a model of care for a virtually delivered allied health rapid falls assessment service that can be used with community aged care clients.
Insurance for Clinical Trial	
Insurer	HammondCare
Type of Insurance	Medical malpractice and general liability insurances.
Confirmation of Insurance	☒**Attached** ☐ **In progress** ☐ **To be submitted**

2. Safety and Monitoring Contacts

Independent Safety Monitoring Board Members

• HammondCare Research Governance Committee
  • Chair: Associate Professor Colm Cunningham
  • Secretary: Dr Najwa Reynolds
  (full list of committee members is confidential, but would be provided if needed, e.g. if research study was audited)

Trial Management Group

• HammondCare Research Governance Committee
  • Chair: Associate Professor Colm Cunningham
  • Secretary: Dr Najwa Reynolds
  (full list of committee members is confidential, but would be provided if needed, e.g. if research study was audited)

Sponsors Independent Physician/Medical Expert

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3. Delegation of Clinical Trial Duties

Responsibilities for the conduct and oversight for the trial are delegated to you as the Coordinating Principal Investigator. You may delegate trial related responsibilities to the listed Principal Investigator(s) and any trial-related personnel. All trial-related duties delegated by the Coordinating Principal Investigator or Principal Investigator(s) and trial-related personnel must only be delegated to those that are qualified by experience and training. The HammondCare Sponsor's Delegate and the HammondCare Research Governance Committee are to be notified of the following:

- Protocol deviation reports outlined in the HammondCare Research Complaints policy.
- Any serious breach of Good Clinical Practice, the clinical trial protocol, the clinical trial standard operating procedures, or the human ethics approval that is likely to affect to a significant degree the safety or rights of participants or the reliability and robustness of the data generated in the clinical trial.
- Significant safety issues that are likely to (or have the potential to) affect to a significant degree the safety or rights of participants or the reliability and robustness of the data generated in the clinical trial.
- Urgent safety measures implemented to remove or prevent a significant safety issue.
- Safety reports relating to the continuation, suspension, or discontinuation of the clinical trial for safety reasons.
- Non-compliance with the protocol, SOPs, GCP, and applicable regulatory requirement(s) significantly affects or can potentially affect human subject protection or reliability of trial results significantly.
- Participant complaints or concerns received concerning the conduct of the research.
- Significant modifications to the clinical trial are likely to affect a significant degree the safety or rights of participants or the reliability and robustness of the data generated in the clinical trial.
- Addition of participating trial sites, contractual arrangements at participating sites or modifications to legal agreements.
- The intention to conduct the trial in other countries.

4. Trial Objectives and Purpose

This research in context:

To place this clinical trial in context: HammondCare is a not-for-profit aged care provider. The Centre for Positive Ageing (a unit within the HammondCare Health and Palliative Care Business Unit) provides a large, allied health team that undertakes a range of community-based assessments and programs for older clients at risk of falling. The allied health team already provides some virtually delivered services to regional and rural NSW.

This research is to work alongside the Centre for Positive Ageing's allied health team to determine the ideal clinical model for a rapidly available, virtually delivered, allied health assessment service, able to reach a broader range of older people at risk of falls in a timely manner.

Aims:

The overarching aim of this study is to develop an evidence-based falls risk stratification algorithm and virtual model of service delivery for an Allied Health Professional (AHP) falls service. In summary, this research involves four phases; the first three of which are to develop the algorithm and virtual service delivery model, with the fourth and final phase being a small pilot study using the algorithm and model with consenting clients identified at risk of falls (based on the falls risk stratification algorithm), in which participants will be offered a virtually delivered AHP falls risk assessment. Community-dwelling aged care clients of HammondCare's community team (HammondCare At Home) will be those from whom the study population will be derived for the pilot phase.

The specific study aims are:

(i) Conduct a scoping literature review on falls assessment protocols and algorithms, interventions, and risk minimisation evidence relevant to community-dwelling older adults.
(ii) Develop an evidence-based falls risk stratification algorithm for use by community aged care staff, understanding the scope of practice of aged care workers.
(iii) Collate and select a set of evidence-based falls risk assessments and interventions that could be delivered virtually by AHPs (referred to as the virtual AHP falls risk assessment throughout this protocol).
(iv) Pilot the implementation of both the falls risk stratification algorithm and virtual AHP falls risk assessment to determine feasibility, suitability, and usability in the community aged care sector.

Research questions:

Will an evidence-based falls risk stratification algorithm and a structured, virtual AHP falls risk assessment, using evidence-based tools, (i) be perceived as suitable by community aged care staff and AHPs, (ii) be able to be practically deployed within a community aged care service, and (iii) be perceived to be acceptable to community aged care clients?

The primary endpoint to be measured during this study will be immediately post the three-month pilot of both the falls risk stratification algorithm and virtual AHP falls risk assessment (anticipated to be December 2024), but with some flexibility to extend the study dependent on the recruitment rate.

5. Background Information

In Australia, a significant majority (94%) of older adults reside in their own homes, with 23% receiving support through government-subsidised community aged care programs.[1] This figure is expected to grow as the Australian Government increases funding for these services.[2] Despite this, only a small fraction (2%) of these clients use AHP services like physiotherapy or occupational therapy.[3] This is concerning, as these individuals are often at a heightened risk of falls due to factors such as limited mobility, reduced strength, and chronic pain.[4] The lack of regular AHP input could contribute to the delayed identification of those community aged care clients at risk of falls, and thus missed opportunities for implementation of preventative strategies.

Falls are a leading cause of injury, accounting for 77% of hospitalisations and 71% of injury-related deaths among older Australians,[5] with a cost of over AU$2.3 billion to the healthcare system during the 2018-19 financial year.[5] Timely access to AHPs could mitigate this, but current systems face challenges, especially workforce shortages and the logistical difficulties of providing in-home services, particularly in rural and remote areas. Growth in the number of direct care workers in aged care (nurses, AHPs and care assistants) is predicted to not keep pace with population ageing. If this occurs, there will be a shortfall of more than 110,000 direct care workers in the next decade, and 400,000 by 2050,[6] further impacting timely access to AHPs. Additionally, community aged care workers, despite their regular and close contact with older clients, are not equipped with the training to conduct clinically-oriented falls risk assessments. This lack of specialised input can lead to delayed identification of clients at risk of falls, missing critical opportunities for early intervention.

Virtual care delivery has emerged as a promising solution, which have been well-received in several studies.[7-9] However, critical gaps remain in effectively identifying those at the highest risk of falls, and in developing and evaluating virtual care delivery models to understand how best to deliver AHP assessments remotely. Best-practice guidelines recommend the use of falls risk stratification questionnaires/algorithms for this purpose.[10, 11] The challenge lies in leveraging the vast existing network of community care workers who regularly interact with vulnerable older people, to screen and identify those at risk. Once identified, these at-risk people could then receive timely and skilled AHP assessment and management through a virtual, cost-effective manner.

References:

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6. Statement of Compliance

The clinical trial will be conducted in compliance with the following guidelines and documentation:

- ICH Guidelines for Good Clinical Practice (GCP)
- National Statement on Ethical Conduct in Human Research (National Statement)
- As approved by the Human Research Ethics Committee (HREC), the clinical trial protocol is responsible for monitoring the trial's conduct.
- The responsibilities set out by the HammondCare Sponsor's Delegate.
- The onsite or remote monitoring standard operating procedures as put in place by the clinical trial sponsor.

7. Trial Design

A mixed-methods four-phase study, with each phase informing subsequent phases has been selected to address the study aims (see Figure 1. Flow of trial stages):

Stage 1: Scoping literature review

The scoping literature review will consider current evidence on falls assessment protocols and algorithms, interventions, and risk minimisation relevant to community-dwelling older adults. It will directly inform the development of the rapid-response falls risk assessment and management service tool (falls risk stratification algorithm and virtual AHP falls risk assessment) and virtual model of delivery.

Stage 2: Community aged care staff and AHPs focus groups

Focus groups will be conducted with HammondCare at Home (HC@H) clinical and client care managers, and HammondCare Restorative Care Team AHPs. The focus groups will ensure that the rapid-response falls risk assessment and management service tool is not only theoretically sound but also practically applicable and able to be effectively delivered in the community aged care context, including within the scope of practice of community aged care staff (care worker, clinical manager, client care managers) and AHPs.

Stage 3: Rapid-response falls risk assessment and management service tool development

This stage focuses on development of the two components of the tool, building on insights from Stage 1 and 2:

(i) A falls risk stratification algorithm that can be used by community aged care staff to identify deteriorating clients at an increased risk of falls. This could be either a paper-based or a dynamic questionnaire built into HC@H's client management software.

(ii) Collation of a focussed set of evidence-based falls risk assessments and interventions that can be incorporated into an AHP assessment and able to be conducted virtually with the client (with the support of a HC@H staff member present in the home if needed).

Once the tool has been developed, participants (i.e. HC@H clinical and client care managers, and HammondCare Restorative Care Team AHPs) will be asked to work through real-world case scenarios using either the falls risk stratification algorithm (HC@H care workers and clinical and client care managers) or the virtual AHP falls risk assessment (HammondCare Restorative Care Team AHPs) then participate in an interview with a member of the research team to discuss the component of the tool they reviewed.

Stage 4: Pilot of the rapid-response falls risk assessment and management service tool

This stage will assess the practicality and effectiveness of the developed tool in a community aged care service, incorporated into routine practice (when indicated). The falls risk stratification algorithm will be pilot tested by HC@H staff and clients; the virtual AHP falls risk assessment to be pilot tested by HammondCare Restorative Care Team AHPs and clients, with the support of a HC@H care worker or manager being present in the home.

The piloting of both the falls risk stratification algorithm and virtual AHP falls risk assessment will include a focus on the clinical utility, user acceptance, and ability for the rapid-response falls risk assessment and management service tool to be incorporated into routine practice. Pilot data will be collected from clinical records, an anonymous online survey completed by HC@H staff and HammondCare Restorative Care Team AHPs at the end of Stage 4, and an online Patient-Reported Experience Measure (PREM) survey (a paper-based alternative will be provided if needed/request) completed by HC@H clients after completion of their participation in Stage 4. The PREM survey will not be anonymous to allow for linkage with client demographic and clinical outcome data during the analysis stage.

Once the virtual AHP falls risk assessment has been completed, the AHP's recommendations will be reported back to the client's HC@H clinical or client care (as appropriate) manager. Potential options may include a virtually delivered falls prevention program, a face-to-face AHP visit, liaison with GP or other usual care, which are all currently available services from HammondCare and are not the subject of this research (which is focussed on the development and pilot of the falls risk stratification algorithm and the virtual AHP falls risk assessment).

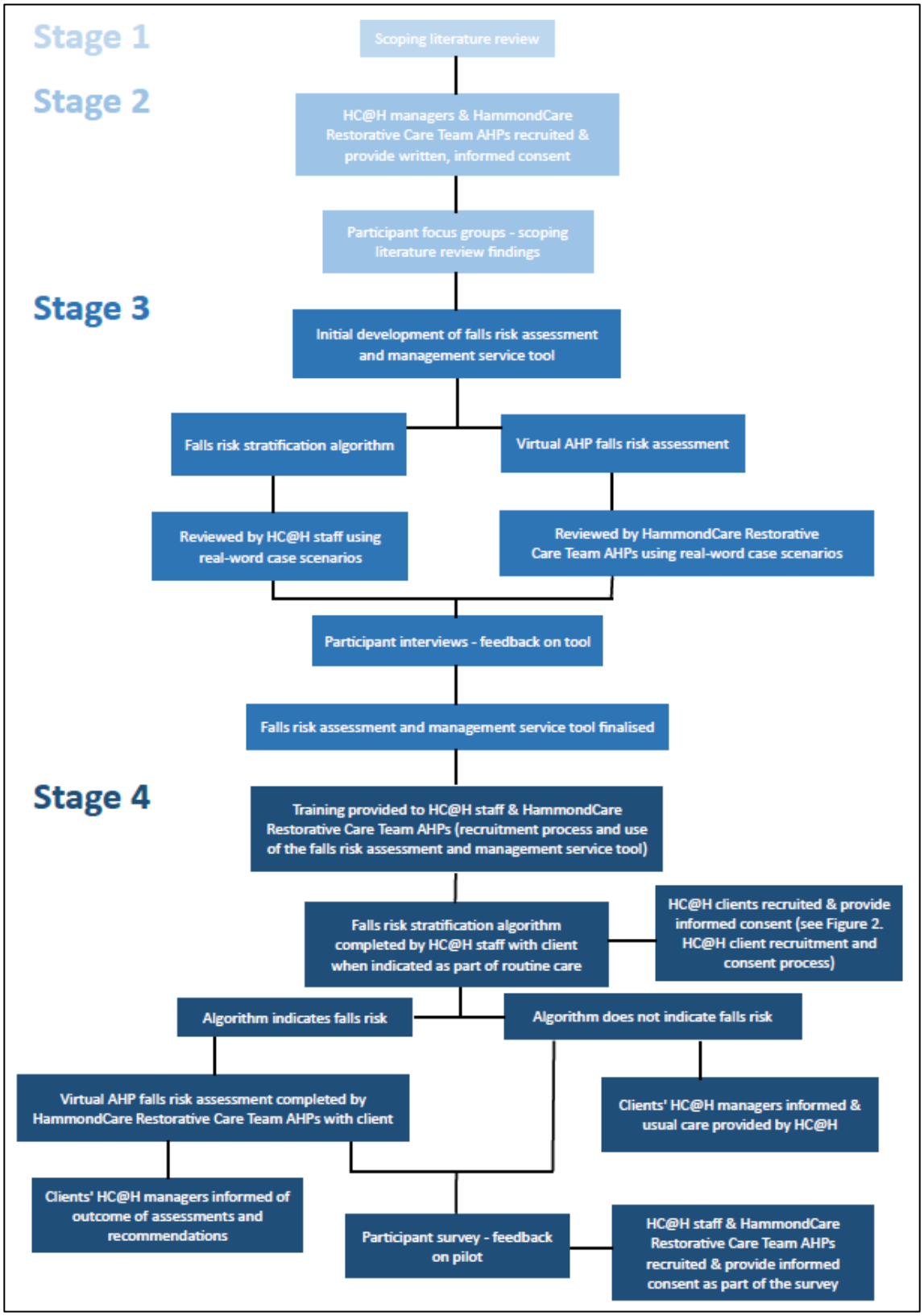

Figure 1. Flow of trial stages

8. Sample Size

Across Stages 2-4 HammondCare staff and clients will be enrolled in this study. HammondCare staff can consent to be involved in multiple stages. The target sample sizes for each stage are:

Stage 2:

Based on current literature, the target sample size is 18 (two to three focus groups of six to eight participants per group).[12] Ideally the sample size will be evenly distributed across the two participant groups: nine HC@H managers (a mix of clinical and client care managers), and nine HammondCare Restorative Care Team AHPs (a mix of physiotherapists, occupational therapists, and exercise physiologists).

Stage 3:

Based on other interview and survey studies, the target sample size is 22.[12] To ensure both components of the rapid-response falls risk assessment and management service tool are equally reviewed the sample size will be evenly split to include 11 HC@H staff (a mix of care workers, and clinical and client care managers) and 11 HammondCare Restorative Care Team AHPs (a mix of physiotherapists, occupational therapists, and exercise physiologists).

Stage 4:

The client target sample size is 13 HC@H community aged care clients, based on an anticipated referral rate of one per week (determined by staff feedback) over a three-month period. Potentially not all participants will require a virtual AHP falls risk assessment (dependent on the outcome of the falls risk stratification algorithm). To ensure sufficient data is collected for both components of the rapid-response falls risk assessment and management service tool a minimum of 50% of participants will need to have completed both the falls risk stratification algorithm and virtual AHP falls risk assessment. Therefore, recruitment will continue beyond the target sample size of 13 until the 50% minimum for completion of both components of the rapid-response falls risk assessment and management service tool is reached.

The staff target sample size is 13, based on recruitment of at least one member of staff per client participant (i.e. based on the falls risk stratification algorithm outcome for each client participant, a virtual AHP falls risk assessment may/ may not be indicated).

9. Selection and Withdrawal of Subjects

9.1 Inclusion Criteria

Stage 2:

Study group	Inclusion criteria
HC@H managers	• Clinical or client care manager for HC@H at the time of the study. • 18 years or older. • Provide written, informed consent.
HammondCare Restorative Care Team AHPs	• Physiotherapist, Occupational Therapist (OT), or Exercise Physiologist (EP) that are part of HammondCare's Restorative Care Team at the time of the study. • 18 years or older. • Provide written, informed consent.

Stage 3:

HC@H staff	• Care worker, clinical manager, or client care managers for HC@H at the time of the study. • 18 years or older. • Provide written, informed consent.
HammondCare Restorative Care Team AHPs	• Physiotherapist, OT, or EP that are part of HammondCare's Restorative Care Team at the time of the study. • 18 years or older. • Provide written, informed consent.

Stage 4:

HC@H clients	• Receiving community aged care services from HC@H at the time of the study. • 65 years or older. • Provide written, informed consent.
HC@H staff	• Care worker, clinical manager, or client care managers for HC@H at the time of the study. • 18 years or older. • Provide written, informed consent.
HammondCare Restorative Care Team AHPs	• Physiotherapist, OT, or EP that are part of HammondCare's Restorative Care Team at the time of the study. • 18 years or older. • Provide written, informed consent.

9.2 Exclusion Criteria

Stage 2:

Study group	**Exclusion criteria**
HC@H managers	• Participants that do not meet the inclusion criteria above. • Work outside of New South Wales (NSW), Australian Capital Territory (ACT), and Victoria.
HammondCare Restorative Care Team AHPs	• Participants that do not meet the inclusion criteria above. • AHPs other than those specified in the inclusion criteria. • Work outside of New South Wales (NSW), Australian Capital Territory (ACT), and Victoria.

Stage 3:

HC@H staff	• Participants that do not meet the inclusion criteria above. • Work outside of New South Wales (NSW), Australian Capital Territory (ACT), and Victoria.
HammondCare Restorative Care Team AHPs	• Participants that do not meet the inclusion criteria above. • AHPs other than those specified in the inclusion criteria. • Work outside of New South Wales (NSW), Australian Capital Territory (ACT), and Victoria.

Stage 4:

HC@H clients	• Participants that do not meet the inclusion criteria above. • Reside outside of New South Wales (NSW), Australian Capital Territory (ACT), and Victoria. • Insufficient English proficiency that prevents involvement in the virtual AHP falls risk assessment or survey. • Cognitive impairment that prevents their ability to provide informed consent. • Identified as at risk of falls and requires same day/urgent attention/referral as part of their usual care (e.g. urgent GP review due to a syncopal episode, same day review in the Emergency Department due to suspected head injury or fracture).
HC@H staff	• Participants that do not meet the inclusion criteria above. • Work outside of New South Wales (NSW), Australian Capital Territory (ACT), and Victoria.
HammondCare Restorative Care Team AHPs	• Participants that do not meet the inclusion criteria above. • AHPs other than those specified in the inclusion criteria. • Work outside of New South Wales (NSW), Australian Capital Territory (ACT), and Victoria.

9.3 Recruitment Strategy

Stages 2 and 3:

Stage 2 and 3 participants will be invited to be involved in this study through recruitment emails sent to HC@H staff and HammondCare Restorative Care Team AHPs via HC@H and HammondCare Restorative Care Team senior managers respectively, independent of the research team. Information on this study will also be provided to senior managers from within both the HC@H team and the HammondCare Restorative Care Team so it can be shared via internal team communications (e.g. staff/team meetings). Study information will include contact details of the research team to allow potential participants to ask further questions.

In addition for Stage 3, at the end of the Stage 2 focus groups participants will be provided with information on Stage 3 and invited to participate in the subsequent stage (review of the rapid-response falls risk assessment and management service tool and interview).

Stage 4:

HC@H staff (care workers, and clinical and client care managers) involved in Stages 2 and 3 of this study will be engaged to assist with recruitment of HC@H clients for Stage 4. They will receive training on the use of the falls risk stratification algorithm prior to recruitment. For instance, when the HC@H staff member observes a deterioration in the client's mobility or function during routine care, or is concerned that the client may be at an increased risk of falls (e.g. sustained a recent fall or near miss) they will deploy the falls risk stratification algorithm developed in this study. They will also ask the client if a HC@H clinical or client care manager who is not involved in their direct care can phone them to discuss participating in this study (Figure 2. HC@H client recruitment and consent process).

If the client provides verbal consent to be contact at the time the falls risk stratification algorithm is deployed, arrangements will be made for a HC@H clinical or client care (as appropriate) manager who is not involved in the direct care of the client to contact them via phone within 48 hours. Prior to the phone call, a Participant Information Sheet (PIS) will be provided to the client by HC@H staff so they can refer to it during the phone call. The HC@H clinical or client care manager will use the information available within the client's clinical notes and their own clinical judgement to initially screen the client (similar to how they would determine suitability of services in clinical practice). They will then complete the recruitment telephone call which would include discussion about this study, the client's potential participation in the study and what it would involve, completion/confirmation of screening questions, and gaining verbal, informed consent (provision of verbal consent will be audio recorded).

Where indicated (i.e. falls risk stratification algorithm identifies the client is at risk of falls), virtual delivery is possible (i.e. suitable virtual delivery device and connectivity available), and the client consents to participate in the study, clients will be offered participation in a virtually delivered AHP falls risk assessment (at no cost to the client). The virtual AHP falls risk assessment will be conducted by a HammondCare Restorative Care Team AHP, who will receive training on the use of the virtual AHP falls risk assessment prior to recruitment.

NOTE: For clients who are **not identified as being at risk of falls**, or who may have been identified as being at risk of falls but who **do not have the required connectivity** for a virtual assessment or **who chose not to participate** in the study, these clients **will receive usual care** by HC@H (which may variously include standard referral to allied health, liaison with the client's GP, liaison with family members, review by a HC@H clinical care manager).

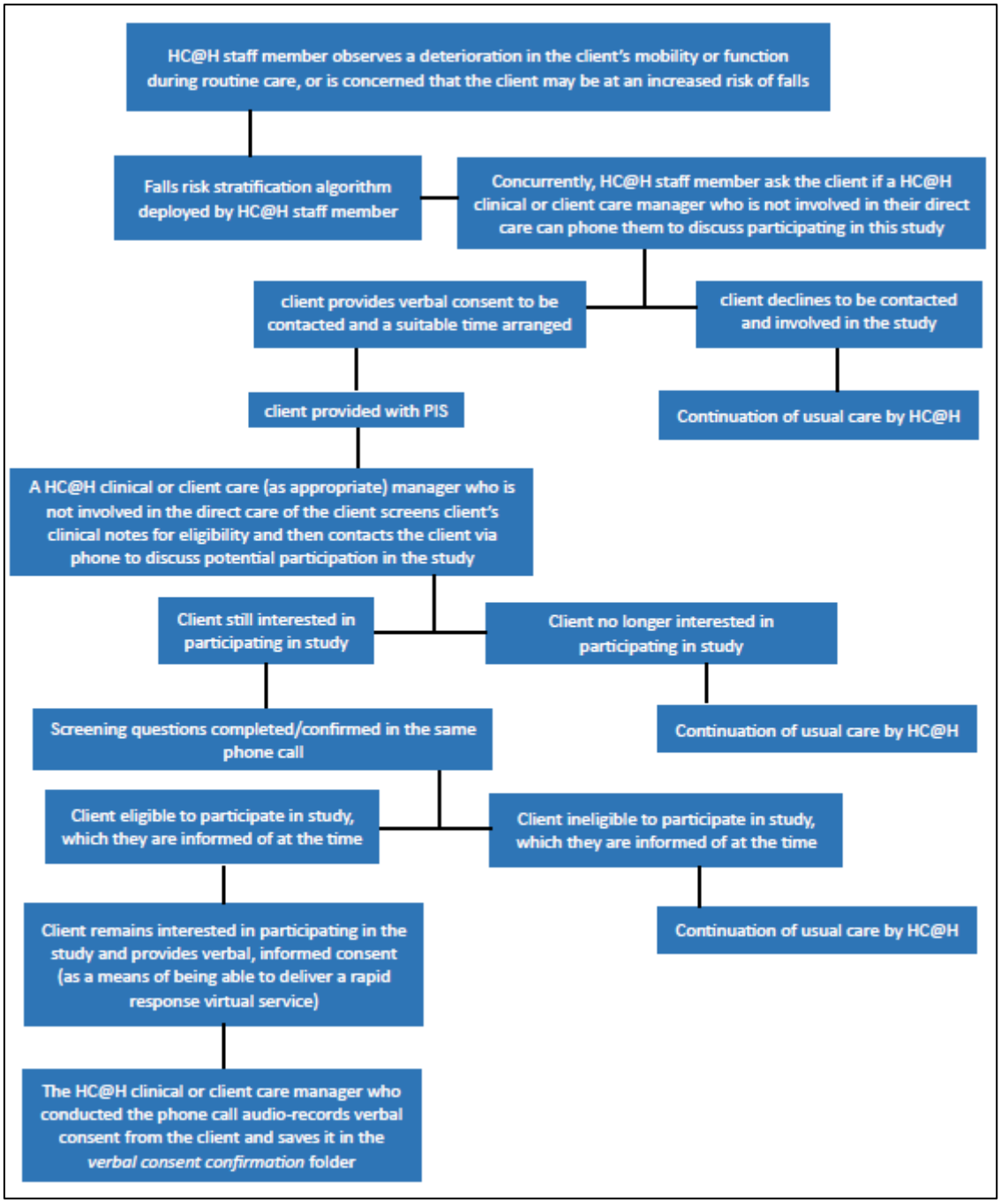

Figure 2. HC@H client recruitment and consent process

HC@H staff and HammondCare Restorative Care Team AHPs that assist in the provision of the falls risk stratification algorithm or virtual AHP falls risk assessment (respectively) will be identified through review of the associated documentation within the clinical notes of Stage 4 client participants by a member of the research team. They will then be invited to participate in Stage 4 via a staff recruitment email sent via HC@H/HammondCare Restorative Care Team senior managers, independent of the research team. This email will include information about this stage of the study, the PIS, a link to the anonymous online survey, and the contact details of the research team to allow potential participants to ask further questions. The email will detail the steps the potential participant needs to follow if they would like to consent to participate in

this stage of the study (click on survey link, read the consent declaration [first page on weblink before starting survey], click the 'I agree, start survey' button at the bottom of the PIS page).

9.4 Screening

Stages 2 and 3:

When potential participants contact a member of the research team to discuss their possible involvement in the study, the research team member will provide a PISCF and ask screening questions based on the inclusion and exclusion criteria. They will inform them of their eligibility or ineligibility to participate in the study at this time.

Stage 4:

HC@H clinical and client care managers will assist with screening of potential client participants in Stage 4. They will receive training on the screening process (including the inclusion and exclusion criteria) prior to the recruitment stage. When a client is identified as at risk of falls and could benefit from the falls risk stratification algorithm, they will also have the opportunity to be involved in this study (Figure 2. HC@H client recruitment and consent process). Recruitment will be completed by a HC@H clinical or client care manager who is not involved in the direct care of the client (as detailed in the *recruitment* section above). It is at this stage the HC@H clinical or client care manager will also screen clients if they are interested in participating in this study. They will first use the information available within the client's clinical notes and their own clinical judgement to determine if the client meets the study requirements (similar to how they would determine suitability of services in clinical practice), and then (re)confirm via the recruitment telephone call. They will inform the client of their eligibility or ineligibility to participate in the study at the time of the telephone call.

When potential HC@H staff and HammondCare Restorative Care Team AHP participants click the 'I agree, start survey' button at the bottom of the consent declaration (the first page of the survey) they will be taken to the screening questions (based on the inclusion and exclusion criteria). On completion of these questions they will be informed of their eligibility or ineligibility to participate in the study at this time. If they are eligible they will progress to the first survey question. If they are ineligible they will progress to the end page of the survey.

9.5 Consent

Stages 2 and 3:

Stage 2 and 3 participants will be able to contact the research team to answer any questions they have before providing consent to participate in this study (using contact details provided in the recruitment email and information shared in staff/team meetings). At this time they will also be provided with a PISCF, and complete the screening questions (as outlined above in the *screening* section). They will have a one-week period to consider their participation and provide consent. This timeframe was considered sufficient whilst preventing delays in the completion of the study as both Stages 2 and 3 are required to inform subsequent stages and thus the development of the rapid-response falls risk assessment and management service tool. If they then decide to participate, they will be asked to sign and complete the consent portion of the PISCF (paper-based or electronic) and return it to the research team prior to data collection either by emailing it to the researchers or returning it to the researchers' office based at HammondCare (in person or the internal mail system).

Stage 4:

Consent from client participants will be obtain verbally by a HC@H clinical or client care manager who is not involved in the direct care of the client (Figure 2. HC@H client recruitment

and consent process). Verbal, informed consent will be obtained during a phone call to discuss the study and screen the client's eligibility, as a means of being able to deliver a rapid response virtual service (within 48 hours of client being identified as a potential participant for this study). Prior to this phone call, the PIS will be provided to the client by HC@H staff so the client has this to refer to during the phone call. This process will occur after the falls risk stratification algorithm developed in this study has been deployed by HC@H staff during routine care (as detailed above in the *recruitment* and *screening* sections). The confirmation of verbal consent by the client will be audio recorded, and then securely stored in the *verbal consent confirmation* folder. Consent will be reconfirmed by the client when they complete the online (or paper-based equivalent) survey by clicking the 'I agree, start survey' button at the bottom of the consent declaration page (first page) of the survey (this must be selected in order to start the survey).

HC@H staff and HammondCare Restorative Care Team AHPs that are potential participants in Stage 4 (as detailed above in the *recruitment* and *screening* sections) will be provided with a copy of the PIS and link to the survey in the invitation email they are sent. If they would like, they can speak to the research team and ask any questions before providing consent. If participants consent to be involved in this stage of the study they will click on the survey link in the invitation email and then be asked to click the 'I agree, start survey' button at the bottom of the consent declaration page of the survey (this must be selected in order to start the survey). The survey will remain open for two weeks after the last invitation email is sent. The research team felt this was ample time for all potential participants to consider their involvement in the study and complete the survey. Reminder emails will not be sent as the survey is anonymous so it would not be possible to check which potential participants required a reminder email.

9.6 Withdrawal of Consent or Participant

All participants in Stages 2 and 3, and HC@H client participants in Stage 4 will have the opportunity to withdraw their consent and data during this study up until the completion of data analysis. Once data has been collated in the analysis stage and group findings produced, the research team will no longer be able withdraw a participant's individual data.

HC@H staff and HammondCare Restorative Care Team AHP participants in Stage 4 can withdraw their consent at any time during completion of the online survey by closing the survey before submitting. However, once it has been submitted they will not be able to withdraw their responses as the survey is anonymous.

It is not anticipated that involvement in this study will cause psychological distress. However, if a participant is observed to be distressed by their involvement in this study, the research activity will be ceased, and they will be given the opportunity to withdraw from this study. If HC@H staff and HammondCare Restorative Care Team AHP participants withdraw from this study they will be encouraged to contact their direct manager (e.g. regional lead or service manager) to arrange suitable physical or psychological support as needed (as per routine guidelines already in place to support HammondCare staff). If a HC@H client participant withdraws from this study they will be referred back to their HC@H clinical manager to then pursue the usual care pathway and any additional support required.

10. Treatment of Subjects

<u>Stage 2:</u>

Two to three focus groups will be conducted at Stage 2 (dependent on recruitment rates). Each participant will only have to attend one focus group. The focus groups are expected to run up to one hour (dependent on depth of discussion generated at the time). They will be conducted

online via Microsoft Teams during regular work hours (which the relevant HammondCare team will be reimbursed for) and audio recorded to support data transcription.

Stage 3:
Participants will be asked to work through real-word case scenarios using either the falls risk stratification algorithm (HC@H staff) or the comprehensive set of evidence-based falls risk assessments and interventions (HammondCare Restorative Care Team AHPs) on their own during regular work hours (which the relevant HammondCare team will be reimbursed for). They will then participate in an interview with a member of the research team to discuss this process and the component of the rapid-response falls risk assessment and management service tool they reviewed. The interview will be conducted online via Microsoft Teams during regular work hours (which the relevant HammondCare team will be reimbursed for) and audio recorded to support data transcription. Both activities during this stage (real-world case scenarios and interview) are expected to take approximately 30 minutes each, and only have to be completed once by each participant.

Stage 4:
HC@H staff will use the falls risk stratification algorithm to identify clients at increased falls risk during routine visits to clients as part of their HC@H service, taking up to 15 minutes. When clients consent to participate in a virtual AHP falls risk assessment, it will be conducted by HammondCare Restorative Care Team AHPs during regular work hours using a suitable device. The assessment is expected to take approximately 60 minutes. Time taken by staff to complete each components of the rapid-response falls risk assessment and management service tool will be reimbursed to the relevant HammondCare team. **The virtual service will be at no cost to the client**.

Once the virtual AHP falls risk assessment has been completed the AHP will liaise with the client's HC@H clinical or client care (as appropriate) manager about the recommended next steps. Potential options may include a virtually delivered falls program, a face-to-face AHP visit, liaison with GP or other usual care, which are all currently available services from HammondCare and are not the subject of this research (which is focussed on the development and pilot of the falls risk stratification algorithm and the virtual AHP falls risk assessment).

HC@H staff and HammondCare Restorative Care Team AHP participants will complete one anonymous survey using the online platform Qualtrics at the end of the pilot stage. HC@H client participants will complete one online PREM survey (via the Qualtrics platform) after their participation in Stage 4 (i.e. after completing either the falls risk stratification algorithm or the virtual AHP falls risk assessment). All surveys will take up to 15 minutes to complete. HC@H clients will be supported by HC@H staff as required to access and complete the online PREM survey (if needed/preferred an alternative paper version will be provided).

10.1 Trial Intervention

The trial intervention that will be piloted during Stage 4 will be developed in earlier stages (Stages 1-3) of the study, therefore it is not possible to detail specific components of the assessment intervention. However, both components of the rapid-response falls risk assessment and management service tool will be evidence-based on existing falls-related tools and best practice guidelines (i.e. neither component of the tool will be a new stand-alone development rather take a ‘best of breed’ approach). They will be developed based on existing

evidence of safety and efficacy, including consideration of tools most suitable for virtual assessments. The rapid-response falls risk assessment and management service tool will be administered by HC@H staff (falls risk stratification algorithm component) and HammondCare Restorative Care Team AHPs (virtual AHP falls risk assessment component), all of whom will receive training on the relevant component of the tool prior to Stage 4.

Following the virtual AHP falls risk assessment, the AHP will liaise with the client's HC@H clinical or client care (as appropriate) manager about their recommendations, which may include a virtually delivered falls program, a face-to-face AHP visit, liaison with GP or other usual care (all of which are currently available services from HammondCare and are not the subject of this research).

NOTE: For clients who are **not identified as being at risk of falls**, or who may have been identified as being at risk of falls but who **do not have the required connectivity** for a virtual assessment, or **who chose not to participate** in the study, these clients **will receive usual care** by HC@H (which may variously include standard referral to allied health, liaison with the client's GP, liaison with family members, review by a HC@H clinical care manager).

11. Safety and Monitoring

11.1 Assessment of Safety Event Report Forms

Safety reporting and monitoring will be in accordance with the HammondCare Institutional Research Governance Framework in accordance with the National Health and Medical Research Council's Management of Data and Information in Research: A guide supporting the Australian Code for the Responsible Conduct of Research (2019). Safety reports will be assessed on the seriousness, causality, and expectedness of the event to the trial treatment(s), intervention(s), investigational medical product(s), investigational medical device(s). The following are known and expected adverse effects, harms, risks or discomforts associated with trial procedures, treatments or interventions.

a) Known Adverse Effects

Nil

b) Known Harms, Risks or Discomforts

A fall

Physical exertion or discomfort

NOTE: The falls risk stratification algorithm and virtual AHP falls risk assessment will be conducted with the client's HC@H manager or care worker present, they will be closely monitored for any distress, inability to fully participate, or potential safety risk (e.g. a fall). They pose no greater risk than an AHP falls risk assessment conducted face-to-face.

11.2 Adverse Events or Adverse Reactions

Adverse events (AE) are considered any untoward medical occurrence in a patient or clinical trial participant administered the intervention, which does not necessarily have a causal relationship with this treatment.

Adverse Reactions (AR) are considered untoward and unintended responses to the trial intervention related to any intervention procedures.

AEs and ARs are assessed using the safety monitoring flow chart. Those classified as "not serious" are assessed by the qualified physician/medical expert specified in section 2 of the protocol. The Qualified Physician cannot delegate this responsibility to other research personnel.

Adverse event reports must be reported to the Coordinating Principal Investigator and the HammondCare Research Governance Committee within 48 hours. All adverse event reports must be recorded in HammondCare's Riskman database (an incident, hazard, near Miss, and feedback reporting database).

11.3 Serious Adverse Events

Serious Adverse Events(SAEs) that result in or lead to one or more of the following and the event is **not related** to the trial intervention:

- The death of a trial participant.
- A life-threatening illness or injury involving a trial participant.
- A participant's permanent impairment of body structure or body function.
- In-patient or prolonged hospitalisation (not for a pre-existing condition or an elective surgery) of a trial participant.
- Medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or function of a trial participant.
- Fetal distress, fetal death or congenital abnormality or birth defect.

SAE reports are classified following the safety assessment flowchart and are assessed by Sponsors Independent Medical specified in section 2 of the protocol. The Sponsors Independent Medical cannot delegate this responsibility to other research personnel. SAE reports are reported to the Coordinating Principal Investigator and the HammondCare Research Governance Committee within 48 hours of the event occurring for multicentre clinical trials. SAR reports must be recorded in HammondCare's Riskman database (an incident, hazard, near Miss, and feedback reporting database).

11.4 Serious Adverse Reactions

A Serious Adverse Reactions (SAR) is an SAE that is **related** to the trial intervention. SAR reports are classified following the safety assessment flowchart and are assessed by Sponsors Independent Medical specified in section 2 of the protocol. The sponsors independent medical expert must determine whether the SAR was expected or unexpected. The Sponsors Independent Medical cannot delegate this responsibility to other research personnel.

a) Expected Serious Adverse Reaction

A serious adverse reaction by its nature, incidence, severity, or outcome is anticipated and identified in the current version of the intervention safety information are classified as a SAR report. SAR reports are reported to the Coordinating Principal Investigator within 48 hours for multicentre clinical trials. Serious Adverse Reaction reports must be recorded in HammondCare's Riskman database (an incident, hazard, near Miss, and feedback reporting database).

b) Suspected Unexpected Serious Adverse Reaction (SUSAR)

A serious adverse reaction by its nature, incidence, severity, or outcome is unanticipated and not identified in the interventions instructions for use or safety information are classified as a SUSAR.

Fatal or life-threatening Australian SUSAR reports are reported to the Coordinating Principal Investigator, the sponsor's delegate, the HammondCare Research Governance Committee, and the approving HREC within 7 calendar days after being made aware of the case follow up information reported within a further 8 calendar days.

All other Australian SUSAR reports are to be reported to the Coordinating Principal Investigator, the sponsor's delegate, the HammondCare Research Governance Committee, and the approving HREC within 15 calendar days after being made aware of the case follow up information reported within a further 8 calendar days. SUSAR reports must be recorded in HammondCare's Riskman database (an incident, hazard, near Miss, and feedback reporting database).

11.5 Significant Safety Issue (SSI)

A safety issue that could adversely affect participants' safety or materially impact the trial's continued ethical acceptability or conduct. The Human Research Ethics Committee, the HammondCare Research Governance Committee, and Sponsor's Delegate must be notified of all significant safety issues within 15 calendar days of the sponsor instigating or being made aware of the issue**.** SSI reports must be recorded in HammondCare's Riskman database (an incident, hazard, near Miss, and feedback reporting database).

11.6 Urgent Safety Measure (USM)

A measure that is taken to eliminate an immediate hazard to a participant's health or safety. Significant safety issues where an urgent safety measure is required to be taken to eliminate an immediate hazard must be classified as a significant safety issue requiring an urgent safety measure. The Human Research Ethics Committee, the HammondCare Research Governance Committee, and the Sponsor's Delegate must be notified of any significant safety issues that meet the definition of an urgent safety measure should be notified within 72 hours. Examples include:

- a serious adverse event that could be associated with the trial procedures and that requires modification of the conduct of the trial
- a patient population hazard, such as lack of efficacy of an intervention used for the treatment of a life-threatening disease.

USM reports must be recorded in HammondCare's Riskman database (an incident, hazard, near Miss, and feedback reporting database).

11.7 Register of Clinical Trial Safety Monitoring Reports

A register of all event reports assessed and classified is to be retained by the Coordinating Principal Investigator and reported to the trial sponsor and HammondCare Research Governance Committee annually, and the HREC if required.

11.8 Reporting of Clinical Trial Safety Monitoring Reports

Single case reports of Adverse Events Adverse Reactions, Serious Adverse Events (SAEs), Serious Adverse Reactions (SARs), reports do not need to be reported to the HammondCare Sponsor's Delegate or the HREC. All single case reports must be recorded in a safety monitoring register and are reported to the HammondCare Sponsor's Delegate and HammondCare Research Governance Committee annually.

a) Emerging Safety Issues

The Trial Safety Committee is responsible for reviewing the safety information to identify any serious emerging safety concerns. If safety concerns are identified, this body will establish a plan to minimise the time participants may be placed at excess risk of harm. Before implementing the plan, the Trial Safety Committee must seek the advice of the human research ethics committee and sponsor's delegate.

b) Annual assessment of safety

The following information must be provided in a report to the sponsors delegate annually:

- Documented evidence that the Trial Safety Committee (e.g. meeting minutes, annual study reports) confirmed that regular safety reviews occurred.
- Analysis of the trial intervention(s) and its implications for participants considering all available safety data and relevant clinical or non-clinical studies results.
- Any reports of emerging safety issues and a description of any measures taken or proposed to minimise risks.
- A copy of the safety monitoring register.

12. Non-compliance, Protocol Deviation and Serious Breaches of Good Clinical Practice

12.1 Protocol Deviation

A protocol deviation is defined as any breach, divergence or departure from the requirements of Good Clinical Practice, the clinical trial protocol, the clinical trial standard operating procedures, or the human ethics approval that does not have a significant impact on the continued safety or rights of participants or the reliability and robustness of the data generated in the research or clinical trial. Protocol deviations are events that do not occur persistently or systematically and do not potentially result in participant harms. Examples of protocol deviations include but are not limited to:

- Deviations because of participant adherence to the protocol, including rescheduled study visits, participants refusal to complete scheduled research activities or failure to complete self-report questionnaires required by the study protocol.
- Blood samples obtained or clinical trial testing occurring at times close to, but not precisely at the time points specified in the protocol.
- The completion of consent forms, safety monitoring report, case report forms or data collection tools in a manner that is not consistent with the protocol instructions or failure to make reports within the required reporting timeframes.
- Administration of the clinical trial investigational medical product or device in a manner that is not consistent with the manufacturer's instructions for use.
- Use of an unapproved version of the participant information statement or recruitment of participants using unapproved recruitment procedures.
- Inclusion of a participant that does not meet the inclusion criteria.
- An urgent safety measure must be taken to eliminate an immediate hazard to a participant's health or safety.

12.2 Serious Breach of Good Clinical Practice

A serious breach is defined as a breach of Good Clinical Practice, the clinical trial protocol, the clinical trial standard operating procedures, or the human ethics approval that is likely to affect to a significant degree the safety or rights of participants or the reliability and robustness of the data generated in the clinical trial. Examples of serious breaches include but are not limited to:

- Persistent or systematic non-compliance with the instructions for completing consent forms, safety monitoring forms, case report forms or data collection tools that result in continued missed or incomplete data collection.
- Failure to record or report adverse events, serious adverse events, suspected unexpected serious adverse reactions, significant safety issues where urgent safety measures were implemented.
- Failure to conduct clinical trial procedures following the clinical trial delegation log.
- Widespread and uncontrolled use of protocol waivers affecting eligibility criteria, which leads to harm to trial subjects.
- Failure to report investigational medical product or device defects to the clinical trial sponsor or any relevant regulatory body.
- Failure to conduct research following the issued approvals, permits or licences by required laws, regulations, disciplinary standards, and HammondCare policies relating to the responsible or safe conduct of research.
- Concealing or facilitating breaches (or potential breaches) of the Research Code by others.
- Researching without the requisite approvals, permits or licences required by laws, regulations, disciplinary standards, and HammondCare policies related to the responsible or safe conduct of research.
- Failure to conduct research as approved by an ethics review body where that conduct leads to (or has the potential to) results in participant harms.
- Researching without ethics approval as required by the National Statement on Ethical Conduct in Human Research where that conduct leads to (or has the potential to) result in participant harms.
- Any breaches as outlined in the HammondCare Research Complaints Policy or the Australian Code for responsible conduct of research that leads to (or can potentially) result in participant harms.

12.3 Reporting Protocol Deviations

- Protocol deviations occurring at a site must be documented in site files and reported by the principal site investigator to the Coordinating Principal Investigator.
- The Coordinating Principal Investigator must review the protocol deviation and the clinical trial protocol to establish the corrective actions and preventative steps to prevent the deviation from reoccurring.
- The protocol deviation and corrective action plan must be reported to the HammondCare Sponsor's Delegate and HammondCare Research Governance Committee by the Coordinating Principal Investigator or Coordinating Research Team.

12.4 Reporting of a Serious Breach

- The Principal Investigator must report a serious breach occurring at a participating site to the Coordinating Principal Investigator within a specified timeframe.
- The Coordinating Principal Investigator must review the serious breach, along with the clinical trial protocol, to develop a Corrective and Preventive Action (CAPA) that defines the steps to prevent the serious breach from reoccurring.
- The serious breach report and the CAPA must be provided to the approving HREC, the HammondCare sponsor's delegate, and the HammondCare Research Governance Committee for review and approval.

12.5 Reporting of Serious Breaches by Third Parties

- A Suspected Breach is a report judged by the reporter as a possible serious breach but has yet to be formally confirmed as a serious breach by the sponsor.

- A Suspected Breach form must be completed when a third party (e.g., individual/institution) wishes to report a suspected breach of Good Clinical Practice or the protocol and should be reported directly to the reviewing HREC without reporting through the sponsor.
- Recording of Protocol Deviation and Serious Breach Reports
- A register of protocol deviation and serious breach reports must be recorded. Written records and copies of documentation sent to the sponsor must be retained in the Investigator Site File.
- Copies of protocol deviation and serious breach reports must be recorded, written records and copies of documentation sent to the sponsor, referrals made to the HREC or establishing whether a breach of the Australian Code for Responsible conduct of research must be retained in the Master Site File.

13. Review of a Protocol Deviation and a Serious Breach

- The HammondCare Sponsor's Delegate and/or HammondCare Research Governance Committee will review reports to establish whether the event meets the definition of a protocol deviation or serious breach, establish whether the proposed CAPA is appropriate and establish whether there is or will be ongoing impact reliability and robustness of the data generated.
- The HammondCare Sponsor's Delegate will seek advice from the approving HREC on the corrective and preventive actions.
- Protocol deviation or serious breach reports where a UNSW researcher, staff or student is responsible for the protocol deviation or the serious breach will be reviewed as per the UNSW Research Misconduct Procedure to establish a breach of the UNSW Research Code of Conduct has occurred.
- Protocol deviation or serious breach reports where the HammondCare Sponsor's Delegate and/or HammondCare Research Governance Committee determines that HammondCare personnel are responsible for a protocol deviation or the serious breach will be referred onto their responsible institution for review under their Research Misconduct procedures to establish whether a breach of the Australian Research Code for the Responsible Conduct of Research has occurred.

14. Statistics

Qualitative analysis:

A phenomenology methodology will be adopted for the analysis of qualitative data from all stages (transcripts from focus groups, interviews, and open-ended survey responses). This approach is designed to capture the lived experiences and perceptions of participants, focusing on their subjective experiences and interpretations. Thematic analysis using an inductive framework will be conducted to identify, analyse, and report themes within the data in NVivo. Two investigators will independently code the data, grouping similar content into themes that emerge directly from the data. A third investigator will review discrepancies to ensure consensus is reached.

Quantitative analysis:

Descriptive methods in SPSS will be used to summarise the client demographics and PREM survey results to get an overview of participant characteristics, participant experiences, and user acceptance. Clinical utility and operational feasibility will be considered through analyse of frequency of falls risk stratification algorithm use, time taken to complete assessments, recruitment rates, assessment outcomes and recommendations (relevant to the pilot stage), and falls incidence.

15. Data Ownership

All research data collected during this trial is governed and handled following the Research Communications and Reporting Protocol and the SharePoint Document Management policy. HammondCare, rather than any individual or Organisational Unit, is the Custodian of data and materials and any information derived from the data. Original research data and primary materials generated in the research conducted within HammondCare services will be owned and retained by HammondCare subject to any contractual, statutory, ethical, or funding body requirements.

16. Handling and Reporting Data

Principal Investigators are responsible for maintaining adequate and accurate source documents and trial records that include all pertinent observations on each site's trial subjects. Source data must be attributable, legible, contemporaneous, original, accurate, and complete.

Trial subjects will be assigned a participant ID, and re-identifiable data will be reported using the *study data evaluation* spreadsheet. The electronic list linking a participant's identity to their record (code key) will be stored separately and only accessible by the research team. Data reported on the *study data evaluation* spreadsheet derived from source documents, should be consistent with the source documents, or the discrepancies must be explained. Any change or correction to the study data evaluation spreadsheet should be dated, initialled, and explained (if necessary) and should not obscure the original entry (i.e., an audit trail should be maintained); this applies to both written and electronic changes or corrections.

All paper-based study documents (signed consent forms and PREM surveys) will be stored in a locked filing cabinet at the Centre for Positive Ageing, HammondCare (where some of the research team are located). All electronic data and audio recordings will be stored securely within a HammondCare SharePoint folder and a UNSW OneDrive folder that will be on password-protected and only accessible to members of the research team listed on the ethics application. In addition audio recordings will be stored on HammondCare's Microsoft Teams; the platform used to create the recordings.

During the recruitment and consent periods of Stage 4, the *verbal consent confirmation* folder will be securely stored on HammondCare's Microsoft Teams accessible by both the research team and the HC@H managers that assist with collecting verbal consent. Once these periods are completed, the *verbal consent confirmation* folder will be moved to the same location as all other electronic study data, which can then only be accessed by the research team.

All data will be retained for five years after publication of study data.

14.1 Direct Access to Source Data and Documents

Site principal investigator(s) and institution(s) will permit trial-related monitoring, audits, IRB/IEC review, and regulatory inspection(s), providing direct access to source data/documents.

17. Monitoring Quality Control and Quality Assurance

The Coordinating Principal Investigator and Principal Investigator(s) 'responsibility are to monitor the clinical trial. The Coordinating Principal Investigator and Principal Investigator(s) are responsible for undertaking or participating in site initiation or protocol-specific training before recruitment and data collection commences. A monitoring report demonstrating regular compliance monitoring with the clinical trial protocol, procedures, and HREC approval is provided to the HammondCare Sponsor's Delegate and HammondCare Research Governance Committee annually.

Root, cause, analysis reports are to be completed by the Coordinating Principal Investigator for reports of non-compliance and serious breaches. A corrective and preventative action plan must be developed and actioned for any reports of non-compliance and serious breaches.

18. Clinical Trial Research Agreement

The Coordinating Principal investigators must ensure that agreements are executed at each of the following sites before site initiation, recruitment, and data collection commences:

- HammondCare at Home – NSW, ACT, Victoria regions.

19. Research Governance Site Authorisation

Site authorisation is to be obtained, or if a research site is added, a site authorisation letter from the Research Governance Committee of an institution responsible for any participating site is obtained. It is to be stored as a GCP essential document before participants are recruited at a participating site.

20. Good Clinical Practice Requirements

It is recommended that the Coordinating and Principal Investigators' ensure that all investigators and trial-related staff have current Good Clinical Practice Training. Once completed, the evidence of training confirmation is to be stored as a GCP essential document.

It is the responsibility of the Coordinating and Principal Investigators to familiarise themselves with the requirements of the Guideline for Good Clinical Practice (E6, R2)

21. Essential Documents for the Conduct of a Clinical Trial

All essential documents referred to in section 8.2 of the Guideline for Good Clinical Practice (E6, R2) are to be retained by all trial investigators.