# Innovation Project Application Form

## Salford Innovation and Improvement Fund Locality Call 2022/2023

Each question in this application form is very specific about the information required. **Please ensure that you read the separate 'Application Guidance' document carefully, complete all sections of this form and provide all the information requested**. Please ensure that any abbreviations/acronyms are explained at the start of the application; they may then be abbreviated throughout the remainder of the application.

## SUBMISSION DETAILS

| | |
|---|---|
| **SUBMITTED BY** *(name, role, org.)* | Dr Emma Stanmore, Reader & Healthy Ageing Research Group Lead, University of Manchester & Prof Emma Vardy, Consultant Geriatrician, Salford, Northern Care Alliance NHS Foundation Trust |
| **CONTACT NUMBER** | 07917 870055 |
| **EMAIL ADDRESS** | Emma.stanmore@manchester.ac.uk |
| **SUBMITTING ORGANISATION** | University of Manchester |
| **PARTNER ORGANISATION(S)** *(if a joint bid)* | Northern Care Alliance NHS Foundation Trust |
| **DATE SUBMITTED** | 31/8/22 |

| | |
|---|---|
| *Details of how to complete each section of this form correctly are found in the Application Guidance document. Please confirm that you have followed this guidance* | ☑ I have read and followed the Innovation Fund Application Guidance document |

## SECTION ONE: PROPOSAL OUTLINE

### 1) NAME OF YOUR PROPOSED PROJECT

Promoting function & preventing falls in Salford Care Homes using the NHS approved, KOKU digital falls prevention & healthy ageing program.

### 2) SUMMARY OF PROPOSAL

**What is the Problem?**
Falls are a common, distressing and costly concern for older residents and their carers and families in Salford Care Homes especially with the **disproportionate number of older adults affected and needing support to recover from Covid-19 or from functional decline/deconditioning.**

In a non-pandemic period, fall-related injuries are already the largest cause of accidental death in older people across the UK; **30% of people aged 65+ and 50% of people aged 80+ fall at least once per year.** Falls are more common in residents in care homes than those living independently due to factors such as multimorbidity, physical inactivity, cognitive impairment, multiple medications and the unfamiliarity of the environment. Research has shown that a tailored intervention programme is needed to reduce risk and maintain (or even improve) physical function. In addition, there is **strong evidence from systematic reviews that concludes strength and balance based exercises reduce falls by up to 42%**; yet levels of tailored exercise in over 65s in care homes are generally low without therapist input.

Salford has previously reported one of the highest rates of injurious-falls requiring hospital admission amongst older adults in Greater Manchester at 11,667 falls per year. At a minimum of £564 per person (which can spiral to £13k + for a hip fracture) this costs £6.58m per year. A targeted, evidence-based and scalable digital programme that enables an improvement of 42% would prevent 4,900 falls and save £2.76m.

**What is the proposed innovation?**

The applicants have developed 'Keep On Keep Up' (KOKU); a digital falls prevention and healthy ageing program, to promote access and engagement to **personalised strength and balance exercise for older adults based on clinically proven routines.** KOKU draws on **health behaviour change theory to increase adherence through digital nudges, feedback and rewards.** It also incorporates health literacy games (based on best evidence) to improve awareness of activities to promote bone health, nutrition, hydration and home safety. See https://kokuhealth.com/

KOKU does not require clinicians to assess, oversee or monitor use due to its self-assessment descriptors and user-centred design. **KOKU has been tested in clinical trials with pre-frail to moderately frail older adults with multimorbidity (some with dementia supported by carers or family). The OTAGO/FaME based exercises have been demonstrated to reduce falls by up to 42%. User's report improved function, confidence with activities of daily living as well as improved balance and strength.** Reducing functional decline and falls will keep older people out of hospital and more independent, saving costs for healthcare providers and saving pain and poor quality of life for older people.

**NHS Digital (NHSX) have approved KOKU as a low risk device**, compliant with regulatory clinical safety and GDPR standards (DCB 0129/0160 compliant). KOKU has also been awarded the ORCHA (the world's leading health app evaluator organisation) quality badge of approval and has therefore KOKU has been recommended for NHS use.

**What are you proposing to do and why?**
This Salford Innovation Fund would enable a **real world evaluation of KOKU in Salford Care Homes in a collaboration supported by Jeff Niels (Salford Care Homes Quality assurance Manager) and approved by Natalie Garratt (Head of Innovation) at the Norther care Alliance NHS Foundation Trust.** This will inform future implementation of KOKU across Salford and GM as well as have wider application for the implementation of digital technology in Care Homes. Dr Stanmore has recently presented to 3 Care home managers and engaged with a further 3 managers who have expressed interest in trialing KOKU with older residents. A substantial proportion of care homes residents who have low to moderate mobility would be eligible to use KOKU, supported by carers or activity co-ordinators (eligibility criteria to ensure safety and consent will be applied)**.** We will aim to support 40 older users during a 12 week study.

Digital transformation requires not just high quality, user centred technology but also an understanding about best practices for uptake and implementation to ascertain whether wider adoption should be considered. The intent is to understand what, why, and how the digital intervention works in a "real world" care home setting for particular groups of users and the approaches that may be required to improve this.

**Research design/methods:** A mixed methods design will be used to understand multiple perspectives and outcomes to inform the implementation research questions (ethics approval will be gained from The University of Manchester).

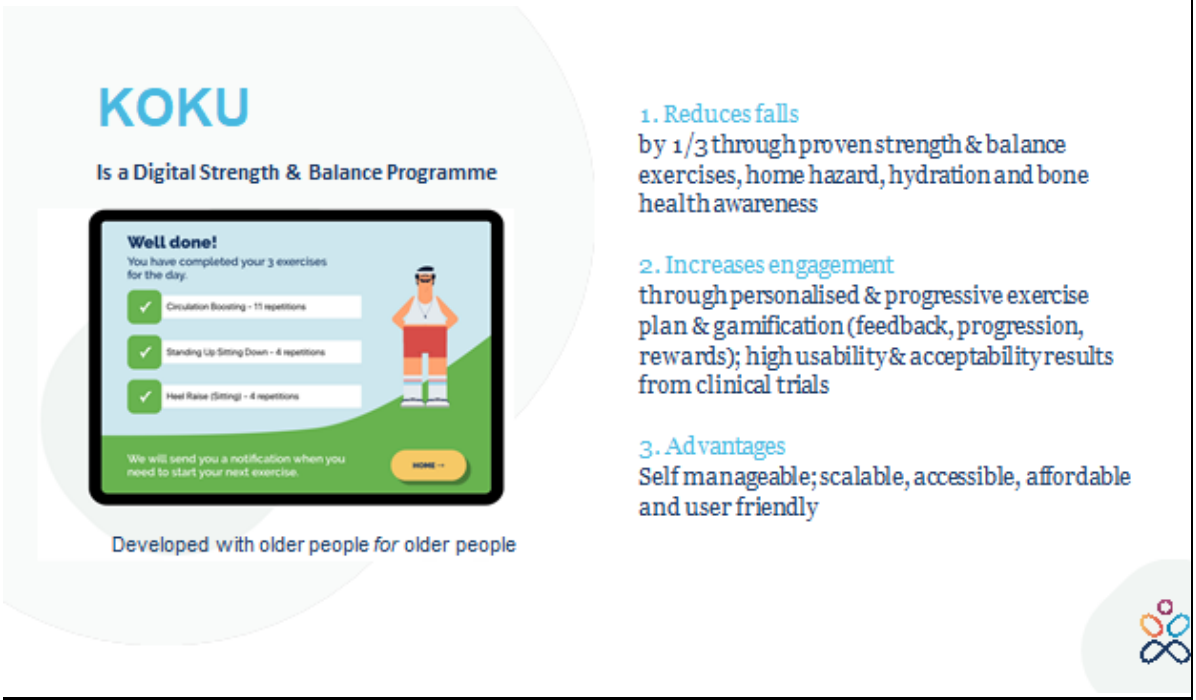
**Study setting, participants, training and intervention:** Four Care Homes in Salford will be invited to take part. Training will be given to nurses/carers on how to use screen potential users and how to safely use KOKU. Older residents will be identified and screened for eligibility by the Care Home managers with support from the research team. Residents will be asked to use KOKU for 30 minutes, 3 times per week, for 12 weeks. During the 12 week intervention, support will be given to residents and carers as required by the research associate and team.

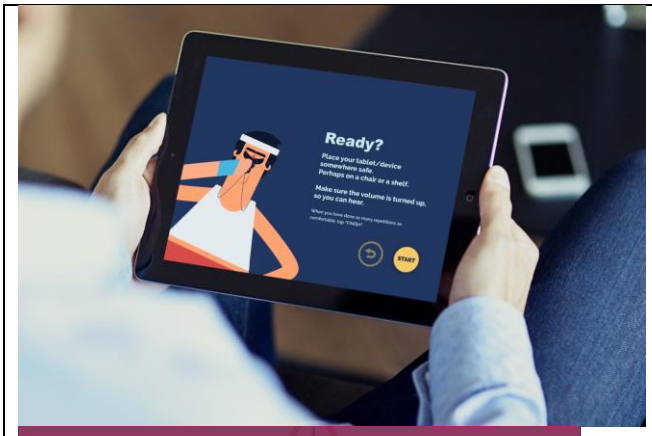
**Data collection**: Demographic data and short standardised questionnaires (medical history, fall history, medication, co-morbidities, and self-reported level of vision; level of frailty; risk of falling; fear of falling; digital health literacy; quality of life; level of physical activity) will be completed by the RA at baseline and 12 weeks. Questionnaires about usability and motivation to use KOKU will be completed at 8 weeks.

After the intervention, a purposive sample of 10 older participants and 10 Care Home staff (managers/nurses/carers) will approached to take part in a short semi structured interview to explore their perspectives regarding usability and acceptability of KOKU and implementation processes **(covering training, resources, usability, acceptability, barriers, facilitators) to inform future scale up of the technology with other potential stakeholders.** To guide this process, the nonadoption, abandonment, scale-up, spread, and sustainability (NASSS) framework will be used (Greenhalgh et al., 2017). This framework enables evaluative knowledge and understanding to be gained regarding technology implementation that also considers factors that could be used to improve the technology as well as considerations related to the context that may inform wider scale up and adoption.

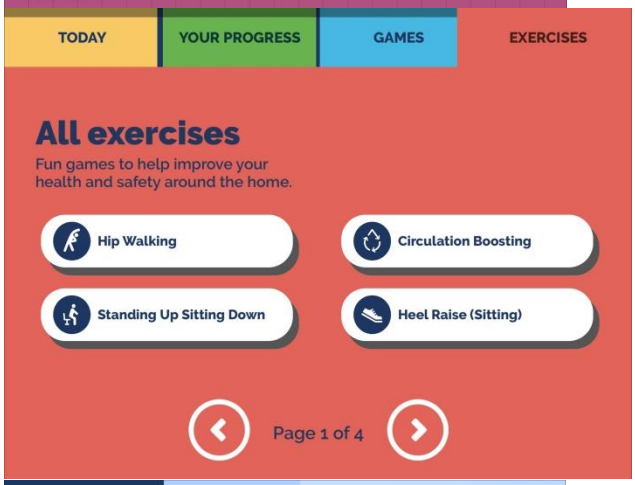
The research team will refine the research plan with the involvement of the care home managers and jeff Niels to ensure minimal disruption to usual care home routines and staff workload. The longer term aims of this innovation project are to improve accessibility to personalised strength and balance exercises that will be delivered using the care home based digital KOKU program. Engagement with KOKU will benefit and positively impact the older users by improving their physical function, confidence and self-efficacy and subsequently improve their quality of life. Carers may also find the program useful for prompting evidence-based practice in falls prevention, safety, hydration, nutrition, and bone health.

To summarise, improving the lives and health of older people living in care homes is a major priority for Salford Integrated Care Partnership. This application directly fits the Salford Innovation Fund call for initiatives focused on quality and safety across the care sector, in particular through addressing challenges such as: falls and quality of life, nutrition & hydration, the challenges and outcomes of frailty, and supporting ageing well in Salford.




Ready?
START


4 Choices Remaining
BONE DENSITY
CHOOSE AN ITEM
← GO BACK


TODAY
YOUR PROGRESS
GAMES
EXERCISES
All exercises
Fun games to help improve your health and safety around the home.
Hip Walking
Circulation Boosting
Standing Up Sitting Down
Heel Raise (Sitting)
Page 1 of 4

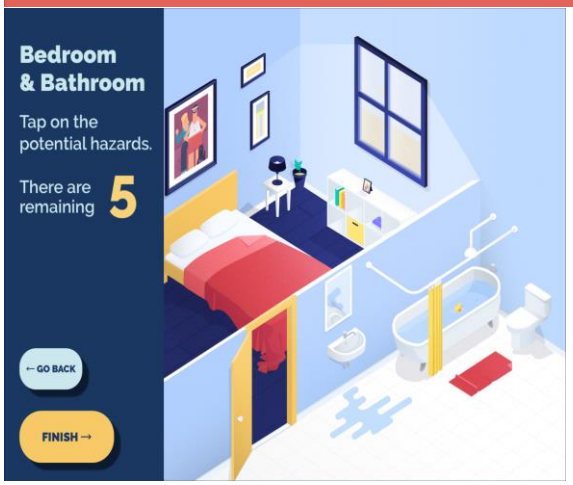

Bedroom & Bathroom
Tap on the potential hazards.
There are remaining 5
← GO BACK
FINISH →

Figure 1. Images of KOKU (exercise coach, health literacy games for hazard information and bone health awareness raising)

*NB KOKU can be used individually or as a group by linking to a TV or interactive table in the care home environment.*

## 3) KEY OBJECTIVES: WHAT ARE YOU TRYING TO ACHIEVE?

*(Key things that need to happen for the project to be considered successful)*

These objectives need to be **SMART (Specific, Measurable, Achievable, Realistic and Timed).** Project objectives and associated payments need to be completed within the 12 month period after the agreed project start date.

If the project has more than five objectives, please list additional objectives in the comments section.

| | |
|---|---|
| **Objective 1:** | - By end of month 1 (Dec 2022) engagement of 4 Care Homes in Salford (Managers, Nurses, Carers) through presentation and KOKU training. |
| **Objective 2:** | University of Manchester Ethics submission and approval by end of month 3 (Feb 2023). |
| **Objective 3:** | - By Aug 2023, completed analysis and evidence of adherence (over 12 weeks), acceptability and impact of the KOKU digital health intervention. |
| **Objective 4:** | - By moth 12 (Nov 2023) evidence on the training and resources needed for implementation of KOKU in Salford Care Homes with older residents. |
| **Objective 5:** | - By month 12 (Nov 2023) An understanding of the barriers and facilitators for optimal upscaling of the technology across the wider care home infrastructure in Salford, written up as a final report. |

***Comments: Engagement with the care homes has commenced.***

## 4) WHICH CITIZENS / PATIENTS / COMMUNITIES / VULNERABLE GROUPS WITHIN SALFORD WILL SEE A BENEFIT AS A RESULT OF THIS PROPOSAL?

| Group/s | What benefit/s will be realised for this particular group? |
|---|---|
| **Care Homes Managers** | The project will directly **support the 4 participating Salford Care homes to meet CQC and Health & Social Care Act regulations for preventing avoidable harm or risk of harm through slips, trips and falls.**<br><br>It may also **reduce time/costs due to fewer ambulance call outs, requirements for GP or hospital appointments and the accident reporting and relative complaints that can be associated with falls.**<br><br>Staff may find it enjoyable and engaging to work with the Healthy Ageing Research Group at the University of |

| | |
|---|---|
| | Manchester (and vice versa) and the use of the KOKU program will also **promote evidence-base practice**, particularly useful for newer care home staff.<br><br>As the current landscape for digital health interventions is complex and confusing, it is not easy to know what technologies have been NHS approved and rigorously tested, therefore this project also enable **increased convenience, access and adherence to an evidence-based intervention.**<br><br>The learnings from this project will also more widely benefit the Care Home providers, residents and staff in the Salford and GM localities. |
| **Salford Integrated Care Partnership** | **Cost and efficiency savings** as the KOKU exercise program (based on OTAGO/FaME strength and balance exrcises) are shown to reduce falls by up to 42%4 (reduced ambulance call outs, fractures, hospital admissions, care home placements etc). |
| **Care Home Residents (40 initially), their Carers and Families in the 4 participating Care Homes.** | KOKU leads to improved quality of life and independence for older people. Strength and balance exercise reduces falls, and increased exercise reduces risk of hip fracture by 68%, diabetes by 40%, dementia by 30%, and depression by 30%; and improves function and mental health in older people<br>Users of KOKU have reported<br>'Peace of mind'; 'maintains independence' which is highly valued by older adults even when requiring some care support; 'user-friendly', KOKU was been developed with older people, many with sensory/dexterity impairments. |

## 5) HAVE YOU PREVIOUSLY SUBMITTED ANY APPLICATIONS FOR FUNDING TO DELIVER THIS PARTICULAR INNOVATION WITHIN SALFORD?

*Please tick the relevant box, and provide details where necessary*

| | | Details |
|---|---|---|
| ☒ | **No** | I have supported another applicant with a different project in the past but have not applied with this project before. |
| ☐ | **Yes** – and it was **not funded** | |
| ☐ | **Yes** – and it **was funded** | |

## 6) HAS YOUR PROPOSED IDEA BEEN IMPLEMENTED OUTSIDE OF SALFORD PRIOR TO THIS APPLICATION?

*(If yes, please state where, when and provide details of the impact of this in the comments section below)*

☐ Yes
☒ No

***Comments:***
Co-development, usability and acceptability testing has been undertaken with older adults in assisted living facilities and in those living at home in receipt of home care in GM.

## 7) PLEASE EXPLAIN HOW THIS PROPOSAL IS "INNOVATIVE"

KOKU is innovative in a number of ways:

1. There are scarce co-designed digital programs specifically for older people that have scored high for usability, acceptability
2. Trustworthy – NHS Digital have assessed and certified KOKU as compliant with DCB0160 and DCB 0129 safety and regulatory approvals as a low-risk digital program as well as Orcha approved.
3. KOKU is based on best evidence strength and balance exercises that have been tested with older adults in their 90s; as well as incorporating health literacy games that raise awareness of health promoting activities needed for healthy longevity.
4. KOKU provides visual (animation), audio and written instructions to enable those with sensory deficits or diverse accessibility needs to use independently. All functionality and design elements of KOKU have been carefully developed to enable users with multimorbidity to access thereby reducing digital exclusion.
5. KOKU is available in a growing number of languages (Urdu, Spanish, Danish, Norwegian with Chinese and German in development) again to reduce digital exclusion. The Urdu version is also culturally sensitive with the animated characters for the strength and balance exercises and the health literacy characters dress, skin tone and nutritional content reflecting the diverse South Asian communities (the second largest ethnic group after white Caucasians in Salford).
6. Embedded health behaviour change techniques (nudges, feedback, progress charts) to encourage engagement and adherence.
7. Additional health literacy games to promote positive behaviour and inform about evidence based wellbeing practices to improve bone density, home safety, hydration and nutrition specific to the needs of an older generation.
8. Data metrics on adherence, progression, quality of life, falls, injuries and confidence in activities of daily living – that give insights for local health needs.
9. Other digital inclusion considerations – KOKU can be used online or offline with android and iOS tablet devices.
10. Self-manageable – no need for clinicians, for those unfamiliar with using tablet/iPads we have produced a step-by-step instruction video.

**Form Continues on Next Page**

## SECTION TWO: ALIGNMENT WITH SALFORD LOCALITY PRIORITIES

### 8) WHICH OF THE 2022-23 INNOVATION PRIORITIES DOES YOUR PROPOSAL ADDRESS?

*(This year's Innovation Priorities are summarised below. Please tick the **ONE** most relevant box for the priority area your proposal aligns with.)*

| | 2022-23 Innovation and Improvement Themes |
|---|---|
| ☐ | Neighbourhood based care |
| ☒ | Safer Salford Care Homes and Domiciliary Care |
| ☐ | Workforce Transformation |
| ☐ | Sexual Health |
| ☐ | Frailty and ageing |
| ☐ | Screening |
| ☐ | Tackling vaccine / immunisation hesitancy |

***A full breakdown of these themes is available in the separate Application Guidance document.***

| | | |
|---|---|---|
| **NONE / OTHER** | ☐ | *Please select this option if your proposal does not clearly align to any of the above priority topics, but you believe it addresses a current un-met need* |

### 9) WHICH OF OUR CORE INNOVATION PRINCIPLE/s DOES YOUR PROPOSAL EVIDENCE?

*(Please tick all that apply)*

| | |
|---|---|
| ☒ | *Exploiting the use of **Technology and Digital** Innovation* |
| ☒ | ***Partnership Working** - Developing links between Health & Social Care and external organisations that are looking to test and evaluate innovative solutions in this field* |
| ☐ | ***Neighbourhood Working** - Developing, delivering and structuring Health & Social Care within the 5 Salford Neighbourhoods / GP Networks* |
| ☒ | *Addressing **Health Inequalities and Wider Determinants of Health*** |
| ☒ | *Improving the **Environmental Sustainability** of care* |

**Form Continues on Next Page**

## SECTION THREE: PROJECT DELIVERY

### 10) KEY PROJECT TIMESCALES

*(What is expected to happen, when?)*

| | |
|---|---|
| **Month 1** | Presentations at Salford Care Homes and engagement with 4 care homes, University of Manchester ethics application submitted, training commences with care home staff, iPads/Tablets set up. |
| **3 months:** | Ethics approval gained, 12 weeks KOKU testing, baseline measurements |
| **6 months:** | Completion of KOKU testing, follow up measurements, interviews and focus groups. |
| **9 months:** | Analysis of quantitative and qualitative data |
| **12 months:** | Complete analysis and writing up, present to Salford Innovation funders and Care Homes |

### 11) HOW IS THE PROJECT GOING TO BE MANAGED?

The project will be overall managed by Drs Emma Stanmore and Vardy, both of whom are experienced researchers in managing complex projects across health and social care including digital health development and implementation. Weekly meetings will be scheduled with the Research Associate (who will project manage the day to day running of the project using Microsoft office project management tools and gantt charts to keep track of progress) to keep to time and schedule and regular reports will be submitted to the funder at agreed intervals throughout the project, including an interim and final report.

This project will benefit from the wider infrastructure and support available with the Healthy Ageing Research Group, Biostatisticians, Digital Health Groups and the Applied Research Collaboration Healthy Ageing Theme.

We plan to collaborate with key Stakeholders to both enable the success of the project and further promote research in healthy ageing in the Salford community to link in current priorities in ageing well strategies.

### 12) HOW WILL YOU MEASURE AND EVALUATE YOUR PROJECT?

**A) Does your proposal involve an external / independent evaluation?**

☒ Yes
☐ No

**B) Who will be carrying out the evaluation of this project?**

The evaluation will be led by the applicants (Drs Stanmore and Vardy) and a dedicated research associate (Danielle Harris).

**C) Please outline your plan for measurement and evaluation of the project**

For a short summary please see project methods and delivery plan in section 2 .

**Study aim and objectives**

**Primary aim:**
The primary aim of this study is to conduct an implementation evaluation of a digital falls prevention program known as, 'Keep-on-Keep Up (KOKU) for care home residents in Salford.

**Secondary objectives:**
To determine the challenges, facilitators, value, contextual features, resource needs and costs of delivering the KOKU Digital Falls Prevention intervention relative to usual care.

The specific objectives are to:

a. develop a thorough understanding of the implementation context (e.g. what features of KOKU affect uptake (functionality, dependability, acceptability and usability), what usual routines need consideration; how to check if user is using correctly and progressing sufficiently; what training and support needs for both care home staff and users are necessary for sustainable use; how to monitor the frequency, duration and time of use of the KOKU intervention).

b. understand barriers, facilitators and impact of implementing the KOKU digital health intervention for users and care home staff (Observations/questionnaires/semi-structured interviews).

c. use this understanding to select theoretically informed and evidence based implementation strategies and develop them into an implementable plan

d. consider the extent to which the implementation team have considered elements of digital inclusion (provision of digital devices; support and skills required; non-digital alternatives)

e. consider the value of KOKU (for users, care home providers and staff) and estimate the cost of adoption and sustainability of KOKU as a care home-based intervention for older adults with mild-moderate frailty.

f. execute, evaluate and make adaptations to the implementation plan.

**Research design/methods**
A mixed methods design will be adopted to provide a practical way to understand multiple perspectives, and multiple types of outcomes to inform the implementation research questions. The findings will inform both future implementation of KOKU in Salford Care Homes and may also have wider implications for the implementation of digital interventions. The quantitative components of the study will fulfil objectives a, b and c whilst the qualitative components will address a, b, c, d and e. We will integrate the data at the sampling stage and during interpretation where possible. The sample for the intervention phase will be used to identify a sub-set of participants for interview, whilst in-depth data obtained via qualitative methods will inform interpretation of questionnaires focusing on app usability and motivation to use the KOKU program as well as implementation processes (readiness to deliver, capability for digital provision, infrastructure and ongoing implementation plans) .

**Study setting**

Care Home Managers in Salford (x 6) have been approached and invited to take part in this study. Participants will be identified and screened for eligibility by the research team with support from the Care Home managers. Approvals from the University of Manchester will be obtained before commencing participant recruitment.

**Study participants**

Older residents (aged 60y+) in receipt of care by above care home providers will be eligible to take part in the study if they are: willing and able to give informed consent (assessed by the trained researchers who will ask the participant to explain their understanding of the study); speak English; are able to see the tablet-based app and read instructions with or without glasses and can use tablet technology safely, as assessed by the trained research staff (with consultation with the care home staff).

Exclusion criteria are: (1) acute or uncontrolled medical condition (e.g. severe congestive cardiac failure, uncontrolled hypertension, acute systemic illness, neurological problems, poorly controlled diabetes); (2) recent fracture or surgery; (3) orthopaedic surgery in the past six months or on a waiting list to have orthopaedic surgery; (4) myocardial infarction or stroke in the past six months ; (5) severe cognitive impairment; (6) conditions requiring a specialist exercise programme (e.g. uncontrolled epilepsy, severe neurological disease, wheelchair user); (6) severe auditory or visual impairment; (7) peripheral neuropathy; (8) any other medical condition likely to compromise the ability to use app technology. Local Care Home Managers and Carer/Nursing staff will also be recruited to either give their insights and feedback on the usability of KOKU, the implementation processes and/or help supervise participants.

**Sample size**

A purposive sample of 40 older residents (10 in each care provider) will be recruited to obtain a broad range of views from a diverse, heterogenous sample about the implementation processes, usability and acceptability of KOKU. As the proposed intervention is an implementation study, it will not be powered to detect a difference.

Purposive sampling will also be used to select 10 older adults from the original sample to participate in the qualitative phase of the study. Individuals will be selected to ensure that high, medium and low adherence users, males and females and a range of ages and ethnic backgrounds are represented.

A purposive sampling strategy will also be adopted to recruit 10 professionals to take part in the study, including Care Staff and Care Managers.

**Technology usability, acceptability and adoption measures**

Self-reported questionnaires will be completed at 8 weeks to measure usability, acceptance and motivation to use the KOKU software, these include the Technology Assessment Model (TAM; Brooke et al., 1996) and the System Usability Scale (SUS; Chutter et al., 2009).

**Outcome measures**

Previously validated and short questionnaires will also be used to assess other outcomes including:

Level of frailty (7-point Clinical Frailty Scale (Rockwood et al., 2005));
Risk of falling (adapted Fall Risk Assessment Tool (FRAT)) (adapted from Nandy et al 2005);
Confidence carrying out activities of daily living (The 7-item Short Falls Efficacy Scale (Short FES-I)) (Kempen et al 2008);

Digital Health literacy (e-Health Literacy Questionnaire (HLQ)) (Osbourne et al., 2018); Quality of life (European Quality of Life 5 Dimensions (EQ5D-5L)) (Herdman et al. 2011); Level of physical activity (Physical Activity Scale for the Elderly (PASE)) (Washburn et al 1993).

Falls and associated injuries and use of health or social care services will be monitored weekly.

**Analysis**

**Quantitative:**
Analysis will be mainly descriptive. Baseline characteristics and outcome data will be summarised, as appropriate, using means (with standard deviations) or median (inter-quartile range). For dichotomous or categorical data, frequency will be reported by number or percentage of responses within each category. Calculations will be conducted using SPSS.

**Qualitative:**
Data gathered from interviews will be transcribed verbatim and managed using NVivo 12 software for qualitative data analysis. Data generation and analysis will continue in parallel. Framework Analysis (Ritchie et al 2003) will be used to analyse both interview and focus group data. This approach delineates five stages to aid data reduction and analysis: i) data familiarisation ii) development of a conceptual index iii) labelling and linking data to the index iv) developing thematic charts and v) using the charts to inform descriptive/explanatory accounts. An iterative approach to analysis will be adopted, moving backwards and forwards through the stages to help develop and refine themes. To reduce bias, a reflexive approach will be adopted to critically evaluate the researcher's influence on knowledge generated.

Two researchers will conduct the qualitative analysis, and any discrepancies will be discussed and resolved. If a resolution is not achieved, a third party will be approached to help reach a consensus.

## 13) WILL THE PROJECT REQUIRE A CHANGE TO AN ESTABLISHED CARE PATHWAY?

*If you are currently unable to assess if the activity will require a change to an established pathway, please indicate so using the Don't Know option. Applications selected to progress will be able to work with their sponsor to establish this.*

- ☐ Yes
- ☐ No
- ☒ Don't Know

*If Yes, please provide details of the existing care pathway and explain how your project will require a change to this.*

## 14) IS THIS A DIGITAL HEALTH TECHNOLOGY (DHT)?

☒ Yes
☐ No

***IF YES**, please answer the below questions:*

## A) How would you categorize the function of this Digital Health Technology (DHT)?

*(tick **ONE** option only)*

| | Functional Classification | Description | Examples May Include |
|---|---|---|---|
| ☐ | **System service** | Improves **system efficiency**. Unlikely to have direct and measurable individual patient outcomes. | Back office systems, Electronic prescribing, health record platforms, Ward management systems. |
| ☒ | **Inform** | Provides **information and resources** to patients or the public. Can include information on specific conditions or about healthy living. | DHTs describing a condition and its treatment. Apps providing advice for healthy lifestyles (such as recipes). Apps that signpost to other services. |
| ☐ | **Health Diaries** | Allows users to record health parameters to create health diaries. This information is **not shared** with or sent to others. | Health tracking information such as from fitness wearables. Symptom or mood diaries. No data transmitted. |
| ☐ | **Communicate** | Allows **2-way communication** between users and professionals, carers, third party organisations or peers. Clinical advice is provided by a professional using the DHT, not by the DHT itself. | Instant messaging apps for health and social care. Video conference-style consultation software. Platforms for communication with carers or professionals. |
| ☒ | **Preventative behaviour change** | Designed to improve **health behaviours** to prevent ill health consequences associated with smoking, eating, alcohol use, sexual health, sleeping and exercise. Based on accepted behaviour change theories | Smoking cessation DHTs and those used as part of weight loss programmes. DHTs marketed as aids to good sleep habits. |
| ☐ | **Self-manage** | Aims to help people with a diagnosed condition to **manage their health**. May include symptom tracking function that connects with a healthcare professional | DHTs that allow users to record, and optionally to send, data to a healthcare professional to improve management of their condition. |
| ☐ | **Treat** | **Provides treatment** for a diagnosed condition (such as CBT for anxiety), or **guides treatment** decisions. | DHTs for treating mental health or other conditions. Clinician-facing apps that advise on treatments in certain situations. Electronic prescribing systems that provide patient-level advice on prescribing. |
| ☐ | **Active Monitoring** | Automatically records information and **transmits the data** to a professional, carer or third-party organisation, without any input from the user, to inform clinical management decisions. | DHTs linked to devices such as implants, sensors worn on the body or in the ward/home/care setting. Data automatically transmitted through for remote monitoring. |
| ☐ | **Calculate** | Tools that perform **clinical calculations** that are likely to affect clinical care decisions. | DHTs for use by clinicians, professionals or users to calculate parameters pertaining to care, such as early warning system software. |
| ☐ | **Diagnose** | **Uses data to diagnose** a condition in a patient, or to **guide a diagnostic decision** made by a healthcare professional. | DHTs that diagnose specified clinical conditions using clinical data. AI systems making diagnostic or triage decisions. |

***Functional Classifications from NICE Evidence Standards Framework for Digital Health Technologies (April 2021)***

## B) Does the Digital Health Technology have a CE mark?

☐ Yes
☒ No

## C) Is the Digital Health Technology classed as a medical device?

☐ Yes
☒ No

## If yes, please state classification and whether currently approved by MHRA

## 15) WILL YOUR PROPOSED PROJECT ACTIVITY REQUIRE ACCESS TO, CHANGES TO, OR INTEGRATION WITH, EXISTING IT SYSTEMS TO ENABLE DELIVERY?

☐ Yes
☒ No
☐ Don't Know

*Please only select the 'Don't Know' option if you are currently unable to assess whether the activity will require access or changes to IT systems or infrastructure. If selected for progression, you will need to engage the relevant IT departments of pilot sites to complete this assessment and establish any requirements prior to achieving final sign-off for funding.*

*If Yes, please answer the below questions:*

**A) Which system/s or infrastructure will you require access to, changes to, or integration with?**

**B) What changes / integrations are required, and the timescales needed for this?**

**C) Who owns or manages this system / infrastructure?**

**D) How have you engaged with the relevant system owners / managers / IT departments so far to determine the feasibility of making these necessary changes?**

## 16) WHAT RISKS HAVE YOU IDENTIFIED FOR THIS PROJECT, AND HOW WILL YOU MITIGATE THEM?

**Technology not fit for purpose; low usability and acceptability**
KOKU has been developed **with** older adults, iteratively tested with high usability and acceptability scores from validated questionnaires. User feedback is continually collected to inform improvements.
**Residents/Care Homes won't own technology**
Care homes and older adults are **increasingly** using tablets/smartphones. Our early engagement with Care Homes in Salford has revealed that all have been allocated iPads that will be able to be used in this project and they also discussed adding KOKU to their interactive tables or linking up to a TV. Over a quarter of \>75 year olds use tablet-technology and internet use over 65s has increased to 78% (ONS, 2017). KOKU can be used on iOS and android tablets of which the care homes and study team will be able to lend to residents for the study. More widely, ICSs/CCGs are using increasing tablets to upscale digital health adoption.
**Regulatory/security breach**
We are working with NHS Digital (**KOKU assessed as wellbeing NOT medical device**) and following the University's governance, ethics and integrity guidelines. GDPR then compliance is gained.
**Digital system not effective**

KOKU is based on evidence from clinical trials; personalisation enables built-in progression; expanding exercise programme and health behaviour change theory motivates users to continue to progress.

**System unsafe**

The strength and balance exercises are effective in preventing falls in older adults. We have had no adverse events to date. We will continue our clinical testing and work with NHS Digital on clinical safety of the system.

**Delay in project deliverables.**

Ensure adequate monitoring. Act on early warning signs (e.g. low responses). Maintain stakeholder communication lines to inform and agree solution.

**Form Continues on Next Page**

## SECTION FOUR: BUDGET & FINANCE

### 17) WHAT IS THE TOTAL AMOUNT OF FUNDING YOU ARE REQUESTING?

*This must be a set figure – requests for variable amounts will not be accepted. Please ensure the amount stated is fully inclusive of all VAT*

**£100,931**

| *Payment schedules for successfully funded projects will be finalised prior to sign-off. The typical arrangement is to pay 50% of awarded funds up front, with the remaining 50% released upon receipt of a successful 6-month project update report. If you would require any different payment schedule or arrangement, please give details below* |
|---|
| |

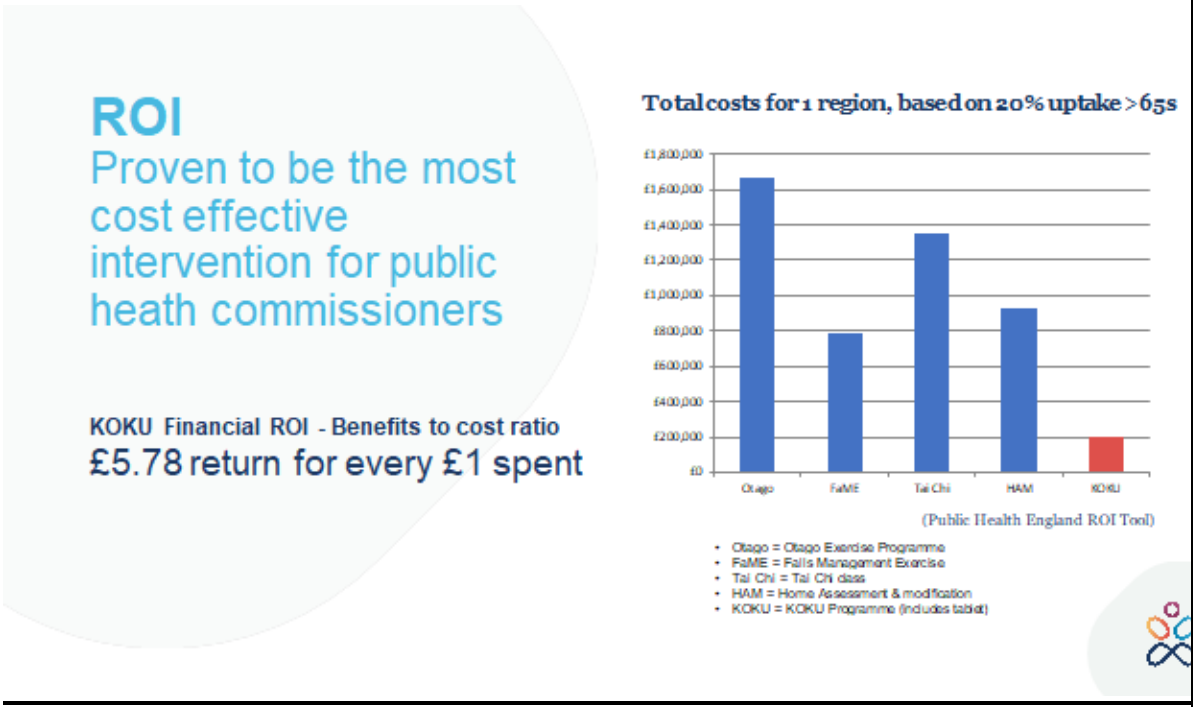
## 18) PLEASE PROVIDE A FULL BREAKDOWN OF HOW THE REQUESTED FUNDS WILL BE UTILISED

*Please include a comprehensive budget, ensuring you include VAT where applicable.*

| | | | |
|---|---|---|---|
| | PI: | PI Emma Stanmore & Emma Vardy | |
| | Funder: | Salford Innovation Fund | |
| | | 04-Dec-22 | 03-Dec-23 |
| | Costing reference: University of Manchester (RSM Wendy Lee) | 13726 | |
| | | | |
| | Description | University fEC | Application fEC |
| | Staff academic | 29,683 | 29,683 |
| | Fees | 5,600 | 5,600 |
| | General travel | 540 | 540 |
| | Equipment | - | - |
| | Consumables | 1,200 | 1,200 |
| | Miscellaneous | 4,200 | 4,200 |
| | DA Estates | 8,766 | 8,766 |
| | DA PI | 4,228 | 4,228 |
| | DA CoI | 4,004 | 4,004 |
| | DA indirect costs | 42,711 | 42,711 |
| | Total DA costs | 59,708 | 59,708 |
| | Total | 100,931 | 100,931 |

## 19) HOW WILL THE PROJECT ACHIEVE A RETURN ON INVESTMENT / COST BENEFIT?

An independent Health Economist evaluation of KOKU using the Public Health England Return on Investment Tool has demonstrated a financial ROI benefits to costs ration of £5.78 return for every £1 spent (a conservative estimate that includes licence, hardware and training). This is a much greater ROI than current strength and balance programmes. Savings are made through reduced ambulance call outs, health and social care service use, and hospital admissions. KOKU has also demonstrated a high societal benefit of over £12 for every £1 spent through improved quality of life for users and reduced burden on carers and families.




## 20) WHAT COMES NEXT AFTER THIS FUNDING? HOW WILL YOU ENSURE THAT ACTIVITIES, OR RESULTS, ARE SUSTAINABLE AFTER THE 12 MONTH FUNDED PERIOD HAS ENDED?

We plan to work closely with key stakeholders who are also focused on the quality of care for older adults at Salford who are also named in this application and have been a support with engaging with interested care home managers. The learnings and outputs from the project will inform future tenders to Salford Integrated Care Partnership. We are working with the Innovation Factory at the University of Manchester and Social Enterprise experts and analysts regarding the longer term sustainable vision, mission and business plan for KOKU. As a University of Manchester spin out, a collaboration with Salford Integrated Care Partnership through this innovation fund is a step closer to the ambition that KOKU will be implemented across GM with resulting case studies helping with further implementation across the health and social care sectors. We are also working with Health Innovation Manchester on our licencing model for health and social care procurement and tenders.

We also plan to disseminate our findings through local, regional and national presentations and publications that will also aim to showcase excellence in research in Salford.

Form Continues on Next Page

## SECTION FIVE: DATA PRIVACY IMPACT ASSESSMENT

**21) WILL THE PROJECT COLLECT / USE / PROCESS PERSONAL CONFIDENTIAL DATA?**

☒ Yes
☐ No

*If 'yes', please tick below which of the personal and sensitive data items the asset / system /project will process.*

Personal Data Items

☒ Forename(s)
☒ Surname
☒ Address
☒ Postcode
☒ Date of Birth
☐ Home Telephone Number
☐ Mobile Telephone Number
☐ Other Contact Number
☐ GP Name and Address
☐ Legal Representative Name (Next of Kin)
☐ NHS Number
☐ National Insurance Number
☐ Photographs / Pictures of persons
☐ Other – please state below:

We follow rigorous data management approaches through our research governance processes so all data is anonymised at the earliest opportunity and stored as per data governance and management policies.

Sensitive Data Items

☒ Gender
☐ Religion
☒ Ethnic Origin
☒ Medical Information
☐ Occupation / Employment
☐ Other – please state below:

*A Data Privacy Impact Assessment (DPIA) form will need to be completed if your proposal is shortlisted to Interview.*

- *If Yes is selected, a full DPIA will need to be completed*
- *If No is selected, the DPIA only needs to be completed up to Screen 5*

**Form Continues on Next Page**

## SECTION SIX: SOCIAL VALUE, EQUALITY AND INCLUSION

### 22) EQUALITY & DIVERSITY POLICY AND COMPLIANCE

| A) Do you have an up-to-date Equal Opportunities (or equivalent) Policy in place? |
|---|
| ☒ Yes |
| ☐ No |

| B) Have you been involved in any Equality Act 2010 litigation breaches in the last 3 years? | |
|---|---|
| ☐ Yes | *If Yes, please give details here* |
| ☒ No | |

### 23) PLEASE DESCRIBE HOW THIS PROJECT WILL ENSURE THE RIGHTS OF PROTECTED CHARACTERISTICS IN PARTICIPANTS, AND CONTRIBUTE TOWARDS TACKLING HEALTH INEQUALITIES IN SALFORD?

**Digital inclusion**

We have worked with older adults from deprived, socially isolated communities who are digitally marginalised in Greater Manchester. Users have included participants with visual or hearing impairments as well as a range of co-morbidities and KOKU has both written and audio instructions built into the system plus simple instruction manuals and videos to aid access and uptake. iPads/tablets are loaned IPads/Tablets to older adults and digital literacy is taught to users and specifically how to use the KOKU App. We have completed separate development for both iOS and Android devices to widen access to those with different operating systems/tablet devices and will include aspects of digital inclusion in the interview schedule in this project (provision of devices, access support) and socio-demographics of users.

**General Ethical and Regulatory Compliance and Data Management for Salford participants.**

Data management will conform to the General Data Protection Regulation and Data Protection Act 2018. The lawful basis for processing personal data in this study is Article 6(1)e 'task carried out in the public interest'. As 'special category data' will be requested from participants, an additional condition to this lawful basis will be Article 9(2)j 'processing is necessary for...research purposes'.

- Informed consent

Prior to seeking informed consent, participants will be fully informed about the study via a Patient Information Sheet (PIS) which outlines the purpose of the project, the participant's role and how their data will be protected. The PIS will clearly state that participants are free to withdraw from the study at any time. University of Manchester templates for consent and the PIS will be used to help ensure compliance with data protection laws.

- Anonymity

Data requested from participants will be minimised. For instance, age in years and not date of birth will be requested. An alphanumeric code will be assigned to each participant and used on all documents containing their personal data. The key to this code will be stored separately in a locked cabinet, accessible to the research team only. No identifiable data will be included in audio recordings. Pseudonyms will be used instead of names in all reports and publications associated with the study.

- Confidentiality

Interview and focus groups will be recorded using an encrypted University device. All data (questionnaires, assessments, demographic information, audio recordings and transcripts) will be transcribed as soon as practical and stored on the University server. The research team only will have access to this information via a secure password protected computer. If a participant exercises their right to access their personal data, advice will be sought from the University of Manchester Information Governance Office.

**24) ADDED SOCIAL VALUE: WHAT OTHER SOCIAL, ENVIRONMENTAL OR ECONOMIC BENEFIT/s WILL SALFORD RECEIVE THROUGH THIS PROJECT?**

**Quality of life/empowerment**:

- KOKU leads to improved quality of life and independence of older people. Strength and balance exercise reduces falls, and increased exercise reduces risk of hip fracture by 68%, diabetes by 40%, dementia by 30%, and depression by 30%; and improves function and mental health in older people[12]. Our user-friendly, engaging system empowers older people to actively manage their wellbeing.

**Economic contribution**:

- Falls are the largest cause of accidental death in Seniors affecting 1/3 of \>65s with direct/indirect annual costs estimated to be over £2.3bn in UK[1], $50bn in US[2]. Falls reduction would reduce healthcare costs since hip fractures cost ~£16k per patient, and falls-related hospital admissions cost ~£14k per patient in the UK. According to the Chartered Society of Physiotherapy, if everyone 65+ at risk of falling undertook falls prevention exercises, 160,000 falls would be prevented, saving the NHS £250 million every year[13].

- Providing a digital falls prevention service in Care Homes would allow therapists to be redeployed to meet increasing levels of demand for therapy within primary care; the secondary impact would be to free up time for GPs and reduce hospital admissions/ambulance call outs. This will lead to NHS productivity increases, a priority for the UK Government.

- KOKU may also create employment opportunities, initially by employing an administrator, sales and marketing lead but as our service provision expands, further positions would be created.

**Sustainable development**:

- NHS England, NHSX and NHS Digital are committed to more sustainable healthcare delivery. KOKU Health will also have an environmental benefit. Digital delivery reduces carbon emissions associated with the movement of health and social care staff, energy use will fall contributing to meeting the Climate Change Act target. This transition echoes the shift toward digitally enabled health care as part of a new service model for the 21st Century.

**Supporting national strategies**:

- KOKU will help Salford realise its' regional plans noted in this application as well as the NHS Long Term Plan to address health inequalities by making physical activity accessible to more people regardless of local resources and availability of therapists. One of the Industrial Strategy Grand Challenges aims to ensure that people can enjoy at least 5 extra healthy, independent years of life by 2030, while narrowing the gap between the experience of the richest and poorest. There are no similar systems at present for Care Home residents, this funding will further protect the product by advancing the technology so that it is years ahead in its field, enabling wider, national roll out and expansion.

Form Continues on Next Page

## SECTION SEVEN: OPERATIONAL DETAILS

### 25) REGISTERED DETAILS OF BIDDING ORGANISATION/s

| Name of Organisation | Registered Address | Organisation Type |
|---|---|---|
| University of Manchester | Office Of Director Of Finance, University Of **Manchester,** Oxford Road Manchester, M13 9PL | Charity (exemption number: XR82062) |
| | | |
| | | |

### 26) WHICH ORGANISATION WOULD THE GRANT FUNDS BE PAID TO?

*Please note that funding will only be paid to registered organisations, and not to individuals*

University of Manchester

### 27) WHO WILL BE THE INDIVIDUAL/s RESPONSIBLE FOR THIS PROJECT?

*(Please complete all sections)*

| **SENIOR LEAD** *(overall accountability and oversight of project)* | |
|---|---|
| Name | *Dr Emma Stanmore (with Drs Emma Vardy and Siobhan O'Connor)* |
| Job Title | *Reader & Healthy Ageing Research Group Lead* |
| Organisation | *University of Manchester* |
| Email Address | *Emma.stanmore@manchester.ac.uk* |
| Telephone Number | *07917 870055* |

| **OPERATIONAL LEAD** *(day-to-day delivery of project)* | |
|---|---|
| Name | *Danielle Harris* |
| Job Title | *Research Associate* |
| Organisation | *University of Manchester* |
| Email Address | *danielleharris@manchester.ac.uk* |
| Telephone Number | *0161 306 7645* |

Form Continues on Next Page

## SECTION EIGHT: APPLICANT AGREEMENT

| 28) PLEASE CONFIRM THAT IF YOUR PROPOSAL IS ACCEPTED YOU ARE AWARE OF, AND AGREE TO, THE FOLLOWING CONDITIONS: |
|---|

*Applicants must tick all boxes to indicate that they agree to all conditions*

| | |
|---|---|
| ☒ | Bidding organisation must be able to confirm a commencement date for the project within 2 months of receiving funding approval or approval may be withdrawn |
| ☒ | Completion of a 6 month (mid-point) project update report, presented to the Innovation and Research Oversight Group (IROG) and relevant Sponsoring Strategy Group |
| ☒ | Completion of a 12 month (final) evaluation report, presented to IROG and the relevant Sponsoring Strategy Group |

| 29) PLEASE CONFIRM THAT YOU HAVE READ AND ACCEPT THE TERMS AND CONDITIONS |
|---|

☑ I have read and accept the Salford Innovation & Improvement Fund Terms & Conditions

**End of Application**

**Your completed application form, along with any requested additional information, should now be submitted via email to innovation.salfordccg@nhs.net**

**You will receive confirmation of receipt within three working days, along with a unique Bid Reference for managing your application and for on-going communication regarding your proposal.**

**Applications can be withdrawn at any time, for any reason, by contacting innovation.salfordccg@nhs.net with your Bid Reference**

## MAILING LIST

***Want to be notified when we release new Innovation & Improvement funding opportunities?***

If so, please add your preferred email address/es in the box below to subscribe to the Innovation Fund Mailing List:

*All of the data you provide will be treated in accordance with the General Data Protection Regulations 2018 and will be stored securely. You may unsubscribe at any time by contacting innovation.salfordccg@nhs.net*