Trusted Research Plan

Accelerating Impact of Community HealthCarE in Tayside (AICCET)

1. The Project

1.1 Team

This project has the following collaborators:

- Heriot-Watt University
- University of Dundee
- Edinburgh Napier University
- University of Glasgow
- University of St Andrews
- NHS Tayside

1.2 Scope

The project is a multi-party Place-Based Impact Acceleration Account, funded by EPSRC and lead by Heriot-Watt University.

The main goal of AICCET is to develop, commercialise, adopt and promote innovative and equitable community healthcare technological solutions with benefits to the health and prosperity of the Tayside region of Scotland, UK.

To satisfy this aim the following objectives, laid out as work packages, will be implemented:

1) Confirmation of the technological and process barriers and challenges preventing greater innovation in the Tayside region and co-creation of solutions involving all stakeholders within and outside the Place. This includes public, patients, NHS organisations, civic bodies and university providers of technological solutions.

2) Creation of an A-to-Z pathway to innovation. This will be implemented by strengthening existing infrastructure and improving access to facilities and to processes critical to the acceleration of impact in healthcare. This includes patient and public involvement/engagement (PPIE) facilitators and data related to health characteristics of the population of the place.

3) Building of an effective regulatory environment for NHS adoption of innovative technologies through a series of measures improving knowledge of stakeholders in medical device regulations, mentoring companies in regulatory affairs and setting up accredited facilities enabling compliant manufacturing.

4) Growing an inclusive innovation ecosystem mindful of patients' needs by systematically implementing PPIE activities and inviting additional expertise through the Collaborative funds.

2. Trusted Research Principles

This document outlines the considerations of trusted research relating to AICCET. The project is based in Scotland, the project partners are based in Scotland; Heriot-Watt University has international campuses in Dubai and Malaysia.

2.1 Assessment of Partner Suitability

Financial collaborators on this project are Heriot-Watt University, University of Dundee, University of Glasgow, Edinburgh Napier University, University of St Andrews and NHS Tayside.

The project will from time to time collaborate with non-financial collaborators, such as civic organisations, namely Dundee City Council but we reserve the right to extend the non-financial collaborators with the agreement of the AICCET Steering Board with due consideration to this Plan.

A signed Collaboration Agreement is in place between the collaborators, that has been assessed by each collaborator's Legal team.

2.1.1 Collaborative Fund

Through the AICCET Collaborative Fund there is scope for involvement of international organisations, as while applicants to the fund will need to be based in the UK, they may have international activities or collaborators.

Recipients of the Collaborative Funds for PBIAA projects must undertake due diligence on any collaborative partners prior to submitting proposals, adhering to their own organisation's policies relating to Trusted Research & Innovation. As part of the process for awarding Collaborative Funds, project leads will be required to demonstrate adherence to their institution's policies relating to Trusted Research & Innovation. Where institutional policies are not yet available, AICCET will provide a list of minimum expectations in relation to Trusted Research considerations and signpost to further guidance. AICCET will explore possibilities for providing training to potential applicants to the Collaborative Fund.

If any potential areas of concern are raised, project leads will report on how these risks are being managed in line with their own institutional processes.

If a project lead identifies that their activities may require an Export Control licence or there are considerations related to the 17 Sensitive Areas of the economy as listed in the National Security and Investments Act this will be reported to the AICCET Project Manager. AICCET will provide signposting to expert guidance such as that available through the Higher Education Export Control Association to support project leads in ascertaining where these considerations may be a factor.

Sub-contracts will be required for each project awarded under the Collaborative Fund. The terms of the sub-contracts will include a requirement for proportionate due diligence to be carried out, in line with institutional processes, in relation to Trusted Research requirements.

Trusted Research considerations do not happen at a fixed point in time. Project teams should continue to be aware of the requirements of Trusted Research throughout their project and should alert the Project Manager to any project changes that affect their initial Trusted Research assessment.

2.2 Managing Information and Knowledge Sharing

All individuals involved with the project are required to use the information systems put in place by their organisations. As a multi-partner project across two regions of Scotland, the primary communication methods will be online and cloud-based. Online activity will take place using the Microsoft Office suite, with file storage provided on both MS Teams and organisation-held OneDrive. This ensures that AICCET collaborators are using the collaborator's Information Security protocols and systems.

Access to the project MS Teams space is restricted to AICCET Steering Board members and key staff at the lead organisation (Heriot-Watt University). It is the responsibility of the AICCET Project Manager to ensure the access list to the MS Teams site is kept up to date and that a business case is agreed for non-Steering Committee members to be part of the MS Teams site.

This project will work directly with the public and patients, but no personal information data will be shared with the project team. Where AICCET needs to communicate with the public and patients, this will be done using SHARE – the Scottish Health Research Register and Biobank: a secure database of patients who have signed up to be involved in research projects. Participants of SHARE have agreed to use the coded data in their various secure NHS computer records to identify when they may be suitable for health research studies. At no time will collaborators outside of NHS Tayside have access to this patient health data. Individuals within the SHARE coordination team will contact patients on behalf of AICCET; those who then agree to participate in AICCET activities will then agree to be contacted by the AICCET project team, with their data stored on Heriot-Watt systems, following Heriot-Watt Information Security protocols and policies.

Participants of public and patient workshops will be asked to agree to their views being recorded and/or noted. Analysis of the workshop discussions will be carried out by the AICCET PPIE Officer with data anonymised before any further discussion with a wider group of collaborators.

2.3 Commercial Application

A Collaboration Agreement is in place between all financial collaborators. A separate Data Sharing Agreement will be in place within the first 6 months of the project.

Clause 8 of the Collaboration Agreement outlines the steps that will be taken relating to "Intellectual Property".

As per Clause 9.3 of the Collaboration Agreement, publications are not expected specific to AICCET (but may be for individual PBIAA Projects stemming from the Collaborative Funds and Grand Challenges fund). If any publications regarding the Project specifically are identified, the Steering Board shall discuss how to proceed, including as regards to any confidentiality issues. In no event shall a Party publish information relating to the Project without consulting the Steering Board prior to such publication.

Publications relating to individual PBIAA projects will be the responsibility of the individual and their organisation to follow necessary legislation.

3. Responsible Research & Innovation

We will require that activities funded through AICCET follow the principles of our partner's research ethics policy, helping to embed a culture based on best practice principles, strengthening commitment to high-quality, transparent, and accountable research practices.

We will embed a culture of RI through our AICCET activities and funding streams by:

i. Offering relevant training to AICCET members, explaining RRI and how they can embed RRI into their own research,
ii. Requiring PIs applying for AICCET funding to explain how they will address RRI in their projects,
iii. Promoting RRI online learning resources available from AICCET collaborator partners, including development from current EPSRC IAA activity,
iv. Encouraging those applying for AICCET funding to access RRI online learning resources and training, prior to making their application,
v. Including an RRI Champion in our Steering Board to support the application review panel, to assess how EDI and RRI are embedded in projects.

The AICCET project has further considered the AREA Framework in the following ways.

3.1 Anticipate

The aims of AICCET are to better understand the challenges and barriers to innovation in healthcare, and how community healthcare and medical technology can be used to overcome these challenges. Impacts will be felt in community healthcare, in lived experience of patients and their support networks, and in the MedTech sector.

Supporting MedTech has economic benefits to business and employment. Supporting patients in their communities will have complex impacts on the NHS system as patient engagement may shift from hospitals to more local care. This in turn introduces environmental benefits with patients travelling less distance.

A large element of this project is considering demographics and the inequalities that come with that: where particular groups of people are, where particular health complaints are. We will understand these issues further as we move through the project with the support of our Citizen's Assembly and NHS Tayside data analysis.

3.2 Reflect

The AICCET project team includes a Patient and Public Involvement and Engagement (PPIE) Officer. The PPIE Officer's experience together with colleagues in NHS Tayside, SHARE and the Health Informatics Centre (University of Dundee), can ensure that our communication with the public and patients is effective, accessible, open, transparent and informed. The purpose of the collaboration partners we have, the patient workshops, and Citizen's Assembly are all to challenge and reduce assumptions and areas of ignorance, and to maximise the social transformations that could follow the project.

3.3 Engage

The project has been created to provide solutions for issues experienced by NHS Tayside and those reported by the MedTech sector relating to regulatory pathways for innovation.

We will explore the background of the region from different perspectives: from the viewpoint of the healthcare sector, for example what interventions they have previously implemented and their levels of success; but also seek background information on the region from an alternative perspective such as social science.

The embedding of public and patient involvement and engagement (PPIE) in healthcare research and commercialisation is of critical importance to accelerate acceptance and adoption of technologies. We will proactively work with patients and the public to develop the areas of need in combination with the needs of the NHS, through workshops feeding into a Citizen's Assembly.

3.4 Act

The Citizens' Assembly will be set up in collaboration with SHARE, Dundee City Council and Angus Council, to understand how to engage with LGBTQIA+, neurodiverse, additional needs, disabilities, and ethnic populations - working with charities and community stakeholders to understand the needs of the communities and the barriers to engagement. We will provide training courses to academics, PDRAs and company's employees in patient and public engagement in trusted research, responsible research innovation, and inclusive research design.

For challenges identified in the first work package that will benefit from additional expertise outside the AICCET, theme sandpit style events will take place with external invited academics and companies. These sandpit events will involve researchers, clinicians, patients and end users, industry, and regulators. Projects coming out of these sandpits will be invited to bid for funding from the Collaborative Fund. Patient/end user involvement will be a requirement for project acceptance. An annual conference of AICCET will take place to highlight the work and activities happening in the Place. This will include two public/patient led sessions whereby the audience will have the opportunity to ask questions in all matters related to activities presented and set challenges to researchers and industry. Members of the public will equally be invited to attend free of charge the conference to ensure wider participation.