Cross-border Healthcare Intervention Trials in Ireland Network (CHITIN)

Guidance Notes For CHITIN Healthcare Intervention Trials 2017

KEY DATES

Intention to Submit deadline - 28 August 2017 (12:00)

Full Application deadline – 29 September 2017 (12:00)

Evaluation Panel meeting – w/c 20 November 2017*

Notification – w/c 4 December 2017*

**** Subject to change***

July 2017

A project supported by the European Union's INTERREG VA Programme, managed by the Special EU Programme Body

Contents

1. Introduction and Background

INTERREG VA

1.1 INTERREG (**INTER**-**REG**ional) is one of 60 cross-border EU funding programmes and is specifically designed to address challenges that arise in border regions. Borders can reduce economic development, hamper efficient management of the environment, obstruct travel and hinder the delivery of essential health and social care (H&SC) services. The INTERREG Programme has four key priority axes within which the goal is to make a significant and lasting change: Research & Innovation, the Environment; Sustainable Transport and Health and Social Care. Under each Priority Axis sits a number of objectives, all of which aim to create prosperous and sustainable cross-border regions and promote greater levels of economic, social and territorial cohesion.

The Health and Social Care Priority contributes to national, regional and local development, reducing inequalities in terms of health status, promoting social inclusion through improved access to social, cultural and recreational services and the transition from institutional to community-based services[1]. Through collaboration on a cross-border basis, this Programme Priority aims to improve the health and well-being of people living in the region by enabling them to access quality health and social care services in the most appropriate setting to their needs.

Funding of €8.8 million has been awarded under Output Indicator 4.123 ***"Develop infrastructure and deliver cross-border area health care intervention trials for novel but unproven healthcare interventions to prevent and cure illness"*** [1] to the HSC R&D Division of the Public Health Agency in Northern Ireland (HSC R&D Division; Lead Partner) and the Health Research Board in Ireland (HRB; Partner). The total includes match-funding of 15% provided by the Departments of Health in both Northern Ireland and the Republic of Ireland.

The funding award has been made by the Special EU Programmes Body (SEUPB), a North/South Implementation body sponsored by the Department of Finance in Northern Ireland and the Department of Public Expenditure and Reform in Ireland. It is responsible for managing two EU Structural Funds Programmes, PEACE IV and INTERREG VA which are designed to enhance cross-border cooperation, promote reconciliation and create a more peaceful and prosperous society.

Through this funding award, ten cross-border Healthcare Intervention Trials (HITs) in a **Defined Area**[2] that contribute to the priority Output Indicator will be funded. The teams funded will form a network wherein mentoring, training and skills development will be supported, creating a legacy for future research in the Defined Area.

1. INTERREG VA Cooperation Programme. Special EU Programmes Body. 2015.

2. The **Defined Area** consists of:
   - Northern Ireland: all counties
   - The Border Region of Ireland: counties Donegal, Leitrim, Sligo, Cavan, Monaghan and Louth

1.2 Best practice in H&SC develops through adoption of the findings of research. For continued improvement in practice, research must generate evidence to inform excellent health and social care delivery. Additionally, service users have shown enthusiasm to participate in Healthcare Intervention Trials (HITs) in health and social care (Cousins et al., 2005). However, currently on the island of Ireland, such opportunities are confined largely to cities – close to major hospitals, universities and centres of research. The CHITIN project aims to increase opportunities for intervention trials within a Defined Area of Ireland, providing citizens with more opportunities to participate in research in a broader, more local geography and wider range of settings to those which are currently available.

The Cross-Border Healthcare Intervention Trials in Ireland Network (CHITIN) will involve existing organisations, build on existing partnerships and generate new partnerships. Whilst providing citizens with access to new health and social care through intervention trials, it will also provide professionals, who may not otherwise have access in their routine roles, with an opportunity to participate in the delivery of research. As well as providing overall project management and monitoring, the central CHITIN project management team will facilitate training to support up-skilling and development of such individuals in the planning and delivery of HITs, resulting in expanded capability and capacity for the on-going network activity and delivery of HITs beyond the funding period.

As part of this initiative, HSC R&D Division and HRB wish to invite applications for high quality HITs of novel but unproven interventions to prevent and cure illness and to promote improved health and wellbeing.

2. Scope

2.1 For the purposes of this call, HITs are defined as: **trials that compare different preventive and/or treatment strategies to show the benefits and risks of specific healthcare interventions**. The types of trials include:

- Prevention trials, which test ways to prevent specific health conditions. For example, life style changes, therapies, educational tools/programmes, drugs, vitamins or other interventions may be tested.
- Treatment trials, which are designed to assess ways of managing specific health conditions. For example, these trials test educational interventions, management approaches, procedures such as surgery or physiotherapy, medical technology and devices, or drugs/combinations of drugs.
- Screening trials, which test ways to detect and diagnose health conditions and diseases.

2.2 As per INTERREG Programme Output Indicator 4.123, trials must examine ***novel but unproven*** healthcare interventions. The intervention under trial must not already be available across the Defined Area; proposals extending existing trials of interventions that are novel but unproven in all or part of the Defined Area are welcome. Unproven is

defined as where there is an insufficient body of evidence to show that an intervention is effective and/or feasible because:

- The intervention is still undergoing trial or requires further trial;
- The intervention is being trialled in a setting or manner that is significantly different from what was previously tested/applied;
- The intervention is rarely used and there is a paucity of efficacy data.

Novel is defined as:

- Not currently available as a service/treatment/approach across the Defined Area;
- Involving a new population and/or approach supported by a strong rationale based on an empirically-supported hypothesis that the new approach will significantly improve outcomes.

2.3 Pilot and/or feasibility studies of interventions are welcome but should not be proposed in conjunction with a fully scaled trial of a definitive intervention.

2.4 Applications are expected to address one of the following Key Areas, which are not mutually exclusive:

Key Area	Description
Population Health	New cross-border area interventions to support positive health and well-being and the prevention of ill health, including physical activity, medicines management, self-efficacy, self-management and screening.
Primary care and older people services	Interventions supporting caring communities and independent living, including a focus on the rural setting.
Mental Health	Interventions to promote cross-border mental/emotional resilience and recovery.
Acute Services	Trials testing new models of working both in scheduled and unscheduled care streams by better utilising scarce human, physical and financial resources.
Disability Services	Trials adopting a social equality approach to promoting social inclusion, citizenship and better life outcomes for disabled people and those with a Rare Disease.
Children's Services	Trials of early interventions particularly with vulnerable families (focusing on but not restricted to the under 5 years population).

2.5 eHealth interventions utilising information, electronic processes and technologies to improve data management, disease management or diagnosis, to support new models of care delivery or to target behaviour change, are welcome across all of the areas.

2.6 The CHITIN project represents a key opportunity to collect information relevant to the interoperability of systems, processes and services. Applications for research projects primarily focusing on interoperability are welcome, provided they address a pertinent research question and can demonstrate potential benefit to patients; in addition, all applicants should consider how to add value to their project by considering how interoperability could be incorporated as a theme of the project. All applications will be evaluated for the opportunity to gather information on data, systems, legal or other relevant cross-border interoperability issues, and recommendations may be made as to additionality for any HIT deemed suitable for funding.

2.7 Ten HITs will be funded under this call, provided that the required thresholds for quality and eligibility are reached.

2.8 Each study must have cross-border elements with evidence collected in both jurisdictions. Cross-border is defined as EITHER individual participants crossing the border as part of their participation in the HIT, OR the same trial, or different arms of the same trial being carried out on both sides of the border to gather evidence about the effectiveness of the intervention in the context of the relevant healthcare system.

2.9 HITs must recruit participants, have benefit in and incur spend within the Defined Area.

2.10 HIT teams should include investigators employed by organisations based within the Defined Area.

2.11 Spend outside the Defined Area would not be expected to exceed 20% of the total requested, and is only acceptable if fully justified (e.g. the need for specific expertise) AND the benefit of the spend is realised within the Defined Area.

2.12 The proposed research must align with relevant Northern Ireland/Republic of Ireland Government strategies and policies, and applicants should reference these in their application.

2.13 Applications are invited for HITs with a maximum funding request of €700,000, to be completed by 31 July 2021.

2.14 The call will **not** support:

- Applications involving basic biomedical research or using cell lines, animals or their tissue;
- Applications which are solely literature reviews, audits, surveys, needs assessments or technology development (although these elements may be integrated into a wider research study);
- Applications which are solely **or** predominantly health service developments or implementation of an intervention without a predominant research element - whilst the cost of adapting an experimental intervention for deployment in the novel environment may be eligible, an intervention must have proof of concept and an evidence base to support its readiness for trial in humans;
- Applications from individuals applying for, holding, or employed under a research grant from the tobacco industry;
- Research intended to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer.

2.15 For applications including clinical studies that fall within the scope of the EU Clinical Trials Directive, neither the HSC R&D Division nor the HRB can assume the role of sponsor. Plans for appropriate sponsorship arrangements must be included in the application, i.e. Letters of Support must be provided from sponsors or potential sponsors.

3. Eligibility to Apply

All applications that do not meet the eligibility criteria will be deemed ineligible and will not proceed for review.

3.1 Applications must come from teams with partners from each jurisdiction consisting of an appropriate mix of staff from across disciplines and sectors e.g. higher education institutes (universities, regional colleges, Institutes of Technology etc), healthcare delivery organisations (HSC/HSE bodies, general practices, community pharmacies etc) and/or the voluntary sector (e.g. charities, community groups etc). The inclusion of **Co-applicants** with a limited experience of undertaking research, but who can demonstrate an aspiration to do so as part of their career path, is encouraged.

3.2 All proposals must demonstrate effective and credible collaboration, with clear contributions from all partners. The **Lead Applicant** may be based in an organisation in Northern Ireland or the Republic of Ireland and must have proven experience of leading intervention studies. It should be noted that a minimum of 80% of spend should be incurred within the Defined Area. 100% of the benefits of the project **must** be realised within the Defined Area (see Section 2.11).

3.3 To facilitate skills development and the exchange of expertise and knowledge, all team members will be expected to participate in a CHITIN Training Programme.

3.4 The Lead Applicant will serve as the primary point of contact for the funders on the award and during the review process. The Lead Applicant will be responsible for the scientific and technical direction of the research programme and has primary fiduciary responsibility and accountability for carrying out the research within the funding limits awarded and in accordance with the terms and conditions of award, INTERREG VA Programme Rules and INTERREG V Standard Conditions of Grant.

The Lead Applicant must:

Hold a post as an independent investigator (permanent or a contract that covers the duration of the award) recognised by the HSC R&D Division or the HRB in a research institution in Ireland ("Host Institution"), **or**

Be a contract researcher recognised by the Host institution as an independent investigator who will have a dedicated office and research space for the duration of award, for which he/she will be fully responsible.The Lead Applicant must demonstrate that they have the skills, knowledge, experience and support necessary to direct the proposed research and to be actively engaged in carrying the research through to completion, including proven experience of leading intervention studies.

A **Host Institution** is a research-performing organisation for the purpose of receiving and administering grant funding, and is responsible for compliance with all general and specific terms and conditions of awards. The Host Institution for the award is normally that of the Lead Applicant but it may be another organisation/institution designated by the research team, where it is clearly justified.

3.5 A **Co-Applicant** has a well-defined, critical and substantial role in the conduct and steering of the proposed research. Co-Applicants from outside the island of Ireland are welcome where the nature of the research renders this necessary and the inclusion is appropriately justified.

3.6 **An official Collaborator** is an individual or an organisation with a discrete role in, or making a specific contribution to, the proposed research and is eligible to request funding from the award when properly justified. Collaborators may be based in an academic institution, private enterprise, consultancy, healthcare organisation or agency, or come from the voluntary sector. It should be noted that a minimum of 80% of spend should be incurred within the Defined Area. 100% of the benefits of the project **must** be realised within the Defined Area (see Section 2.11). Award Holders are expected to ensure that EU Procurement Regulations and INTERREG VA Programme Rules are followed for the acquisition of any eligible goods and/or services.

3.7 If access to samples, vulnerable population groups, healthy volunteers or patients, data, databases or a link to an existing national or international study (e.g. an existing cohort or longitudinal study) are an integral part of the proposed project, evidence of commitment and access must be demonstrated by having the key Gatekeeper of this data or study included as a Collaborator or Co-applicant.

3.8 Through the INTERREG Programme Rules and CHITIN Project governance, the Partners are required to report regularly on the project, to undertake a post-project evaluation and to demonstrate achievement of certain qualitative and quantitative targets. Where possible, applicants are specifically requested to consider **gender balance** in the planning, conduct, management and reporting of their study.

In order to assist the CHITIN Partners in their reporting obligations, HITs will be expected to contribute data collection, and Lead Applicants will be asked to demonstrate in their application that the following minimum dataset of variables can be collected:

- Participants (unit of participation may be an individual e.g. a patient, one or more than one service user e.g. a patient and their carer, or an organisation e.g. a GP practice)
    - Number of potential participants screened/assessed
    - Number of potential participants approached
    - Number of participants consented/recruited
    - Participant recruitment to target (%)

- Training
    - Number of individuals trained (research team members, participants, PPI representatives etc)
- Engagement
    - Number of engagement events delivered
    - Number of event attendees

High level demographic information, including gender, should be collected for individual participants where possible. A process for data collection will be agreed with each Award Holder post Award.

3.9 Definitive intervention trials must be stand-alone projects i.e. proposals should not include a definitive intervention trial and a feasibility or pilot study. Proposals involving feasibility and pilot work **are** eligible.

A **Pilot Study** is defined as a smaller version of the main study used to test whether the components of the main study can all work together. It is focused on the processes of the main study, for example to ensure that recruitment, randomisation, treatment, and follow-up assessments all run smoothly. It resembles the main study in many respects, including an assessment of the primary outcome.

A **Feasibility Study** is a piece of research done before a main study in order to answer the question "Can this study be done?". Feasibility studies are used to estimate important parameters that are needed to design the main study. For instance:

- standard deviation of the outcome measure, which is needed in some cases to estimate sample size;
- willingness of participants to be randomised;
- willingness of clinicians to recruit participants;
- number of eligible patients, carers or other appropriate participants
- characteristics of the proposed outcome measure and in some cases feasibility studies might involve designing a suitable outcome measure;
- follow-up rates, response rates to questionnaires, adherence/compliance rates, ICCs in cluster trials, etc.
- availability of data needed or the usefulness and limitations of a particular database
- time needed to collect and analyse data

A **Definitive Intervention trial** is a study where the health or social care intervention has already undergone experimental development and refinement and is being tested in a population/setting where broad impact can be assessed.

4. Eligibility of Costs

4.1 Claims will be submitted quarterly in arrears in accordance with an agreed schedule. Evidence of spend will be required and failure to meet the agreed schedule and/or provide sufficient evidence may result in non-payment of expenses.

Cost categories are as follows: Staff Costs; Office and Administration; Travel and Accommodation; Training; Equipment and Consumables. Staff costs should be based on recognised, current salary scales relevant for the jurisdiction and sector, and maximum levels as indicated in the application form must be observed.

4.2 Overheads (Office and Administration) will be paid at a flat rate of **15% of direct staff costs**.

4.3 Costs for time spent by co-applicants based outside the island of Ireland are eligible if fully justified. It should be noted that a minimum of 80% of spend should be incurred within the Defined Area. 100% of the benefits of the project **must** be realised within the Defined Area (see Section 2.11).

4.4 Costs for the development of an intervention that does not have proof of concept and sufficient evidence to support its readiness for trial in humans are **not** eligible.

4.5 Where staff are committed to the HIT at less than 1.0 WTE, evidence that the agreed time commitment has been fulfilled will be required on a quarterly basis as part of the claims process.

4.6 Applicants should identify all costs including Excess Treatment Costs associated with the research (please refer to the AcoRD guidance for more information). These costs cannot be claimed through the CHITIN funding award and need to be agreed with commissioners/service leads in the relevant delivery organisations. Evidence of agreement to fund such costs should be provided with the application. The arrangements for funding of treatment costs associated with the study will be finalised and confirmed before any offer of award is issued.

4.7 Applicants will be required to ensure that the financial claims submitted meet the INTERREG Programme Rules on eligibility of expenditure.

5. Ethical Issues

5.1 The Award Holder and Host Institution will agree to uphold the CHITIN Terms and Conditions of Awards which will be made available prior to acceptance of any Letter of Offer.

For RoI Lead Applicants

5.2 Lead applicants and their Employing Organisation based in the Republic of Ireland must ensure that, before the research commences and during the full award period, all the necessary ethical, legal and regulatory requirements in order to conduct the research are met, and all the necessary licences and approvals have been obtained. All Research Institutions are responsible for ensuring that a safe working environment is provided for all individuals associated with a research project.

Ethical and Regulatory Approvals

5.3 Ethical approval is required for all research funded in the Republic of Ireland that involves human participants and/or human material (including tissue). In addition, Clinical Trial Approval from the Health Products Regulatory Authority is required for trials involving medicinal products/medical devices within the Republic of Ireland. Necessary authorisations for trials involving medical devices differ depending on the device. Lead Applicants are responsible for ensuring that all necessary approvals are in place prior to the start of the research.

5.4 In cases where such research may not commence until a later stage of an award, submission of ethical and regulatory approvals may be permitted following the award start date but prior to commencement of the research involving human subjects.

For NI Lead Applicants

5.5 Lead Applicants and their Employing Organisation based in Northern Ireland must assure HSC R&D Division that research projects have a research Sponsor and that projects align to the Research Governance Framework for Health and Social Care. Sponsorship should be evidenced in the form of Letters of Support to be provided with the full application. HSC R&D Division assumes that if HSC Research Governance permission and/or favourable ethical opinion from an HSC Research Ethics Committee are required then these will be in place prior to the start of the research. A determination should be made as to whether a Clinical Trial Authorisation is required; MHRA advice may need to be sought.

5.6 For applications including clinical trials that fall within the scope of the EU Clinical Trials Directive, the Sponsor organisation is responsible for seeking a clinical trial authorisation.

6. Application Process

6.1 Lead Applicants will be required to complete and electronically return an **Intention to Submit** at any time until **12:00 on 28 August 2017**. Intention to Submit forms should be returned as soon as possible.

6.2 Any Intention to Submit forms received by HSC R&D Division after **12:00 on 28 August 2017** will be automatically rendered invalid.

6.3 The details provided in the Intention to Submit form will be used to initiate the process of Evaluation. In the case that further information is needed to inform this process, the CHITIN Partners reserve the right to contact Lead Applicants prior to submission of any full application.

6.4 Full applications will **not** be accepted without receipt of an Intention to Submit form by 28 August 2017.

6.5 The closing date and time for receipt of **full applications** by HSC R&D Division is **12:00 on 29 September 2017.**

6.6 Any full applications received by HSC R&D Division after **12:00 on 29 September 2017** will be automatically rendered invalid.

6.7 The Intention to Submit Form and Application Form are available from HSC R&D Division or HRB in either a paper or electronic format. Electronic forms can be supplied as an e-mail attachment. Alternatively, information can be obtained from the HSC R&D Division website: http://www.research.hscni.net or the HRB website: http://www.hrb.ie/

6.8 By the closing date, the Lead Applicant must submit the following by an email **copied to each of the signatories named within the application**:

- Electronic copies of the Lead Applicant's and Co-Applicants' current CV (included at the end of full application Annex A)
- An Electronic copy of the research protocol (included at the end of original application).
- One electronic copy of the application

The Partners may contact signatories to discuss their declarations associated with the application.

All enquiries relating to this application should be addressed to:

Mrs Kathleen Roulston
Strand Administrator
HSC Research & Development Division
Public Health Agency
12-22 Linenhall Street
Belfast
BT2 8BS

OR

Tel: (028) 9536 3464
E-mail address:
Kathleen.roulston@hscni.net

Dr Julie McCarroll
Programme Manager
HSC Research & Development Division
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12-22 Linenhall St
Belfast
BT28BS

OR

Tel. (028) 9536 3490
Email address:
julie.mccarroll@hscni.net

7. Guidance for Completion of Application Forms

General Points

- The CHITIN Partners will regard incomplete or incorrectly completed application forms as invalid. All applications can only be judged on the information contained within the application form, the research protocol and the CV(s). In order to treat all applicants equally, the CHITIN Partners must strictly enforce the prescribed format requirements including font size, font type and word limits.

- Where a word restriction is indicated, please complete and include a word count.

- Make your application clear and easy to read using Sections and bullet points where possible and appropriate.

- Intention to Submit form: Applicants must adhere to the given layout. **Applications that exceed the relevant word limit will be treated as invalid and automatically excluded.**

- Application Form: Applicants must adhere to the given layout. **Forms that exceed the relevant word limit will be treated as invalid and automatically excluded.**

- Research Protocol: Applicants must adhere to the specified page limit, page margins, line spacing and font type/font size. **Protocols that do not comply with the specified format/page limit will be treated as invalid and automatically excluded.**

- Curriculum Vitae: CVs must be completed for the **Lead Applicant** and **all Co-Applicants**. The form provided at **Annex A MUST** be used. Other versions or formats of CVs will **NOT** be accepted.

- **The Intention to Submit form, Application form, CV and research protocol must be completed in clear typescript using Arial font size 11pt or greater**. Arial Narrow font will not be accepted as an alternative to Arial. Hand written applications will not be accepted, will be treated as invalid and automatically excluded.

- In the event of an IT outage or other technological issue that results in failure to meet the submission deadline, evidence of the nature of the issue must be presented to the CHITIN partners by IT management before any dispensation would be considered. Documented technological issues in the receipt of applications will also be taken into consideration if necessary.

Guidance for completion of the Intention to Submit form

Applicants are asked to note the following instructions:

Question Number	Title	Application Section Number	Application Section Name	Notes
1	Lead Applicant Details	a	Name	Provide the full name of the Lead Applicant.
		b	Job Title	Provide a main job title for the Lead Applicant.
		c	Employment Details	Provide employment details for the main job of the Lead Applicant. This would normally be the Host Institution of the research project and should be the post/role through which the Lead Applicant will deliver the study.

Question Number	Title	Application Section Number	Application Section Name	Notes
2	HIT Details	a	Working Title	Provide a current working title for your HIT.
		b	Key Area	Indicate to which of the Key Areas your HIT aligns (see Section 2.4).
		c	Scientific Abstract	Complete a scientific abstract for your project which would be used on the CHITIN project webpage to publicise the HIT.
		d	Research Methods	Indicate the methodologies that you will use to carry out the study e.g. qualitative, quantitative, questionnaire-based, epidemiological techniques, descriptive, randomised clinical trials etc. These details will be used to identify appropriate independent peer reviewers; please be as comprehensive and specific as possible.
		e	Key Identifiers	Key Identifiers – please list five other terms that describe the expertise needed to deliver your study, e.g. application of biomarkers, harm prevention, community-based recruitment etc. It may be useful to refer to the Health Research Classification System search facility to assist with this process. These details will be used to identify appropriate independent peer reviewers; please be as comprehensive and specific as possible.
3	Nominations for referees		Applicants should provide the names of two professionals based outside the island of Ireland who may be approached to provide a scientific Peer Review of your full proposal.	Nominated referees should be made aware that they may be approached to provide a scientific Peer Review of your full proposal.

Question Number	Title	Application Section Number	Application Section Name	Notes
4	**Applicant Declaration**		The Lead Application should e-sign the declaration.	

Guidance for completion of the Full Application form

Applicants are asked to note the following instructions:

Question Number	Title	Application Section Number	Application Section Name	Notes
1	**Project Details**	a	Working Title	Provide a working title for the project.
2	**Lead Applicant Details**	a	Name	Provide the full name of the Lead Applicant.
		b	Job Title and Contract Status	Provide a main job title for the Lead Applicant and indicate the Employment Status. Please see Section 3.4 of this guidance document for more details.
		c	Employment Details	Provide employment details for the main job of the Lead Applicant. This would normally be the Host Institution of the research project and should be the post/role through which the Lead Applicant will deliver the study.

Question Number	Title	Application Section Number	Application Section Name	Notes
3	**Co-Applicant Details**		Name	Provide the name of each Co-Applicant.
			Job Title	Provide a main job title for each Co-Applicant.
			Post Held	Provide details for the main post held by each Co-Applicant. This should be the post/role through which the Co-Applicant will participate in the study.
			Organisation	Provide details for the employing organisation for this post.
4	**HIT Details**	a	Title	Provide a title for your HIT.
		b	Short Running Title	Provide a short running title of fewer than 75 characters for your HIT.
		c	Host Institution	Please name the Host Institution for the research. See Section 3.4 for more information.
		d	Key Area	Indicate to which of the Key Areas your HIT aligns.
		e	Scientific Abstract (maximum 500 words)	Complete a scientific abstract for your project which would be used on the CHITIN project webpage to publicise the HIT.
		f	Lay Summary (maximum 500 words)	Please complete a summary of your project in lay terms. Guidance from the European Medical Writers' Association on writing for lay audiences can be found here.

Question Number	Title	Application Section Number	Application Section Name	Notes
5	**Research Protocol**		Please include the following: • title of research study; • main objective and research question being addressed in the study; • envisaged outcome • background evidence to indicate the context and relevance of the proposed study; • Plan of investigation – to include details of: study design; methodologies; sample size; selection and exclusion criteria; recruitment strategies suitable for the study and the setting e.g. rural communities; the need for use of controls; data protection issues; methods of data collection and analysis; metrics to be collected (see Section 3.8 of the Guidance Notes for minimum requirements); • existing research infrastructure involvement in the project (refer to the Useful Information document) • ethical and governance approvals • study timetable/project plan; • dissemination and knowledge transfer plan • all necessary diagrams and tables.	The protocol must not exceed eight pages, excluding references, nor use less than single line spacing. All page margins (top, bottom, left & right) must be at least 2.5cms and applicants must use **Arial font size 11pt or greater**.

Question Number	Title	Application Section Number	Application Section Name	Notes
6	**Innovation and Novelty**	a	Please describe the existing knowledge base and how your study will make a relevant contribution to the body of evidence (maximum 500 words).	Provide details of any preliminary work supporting your project and how your project will increase the knowledge base/support implementation.
		b	Please describe how the intervention under consideration has gained proof of concept whilst being novel but unproven in line with the definition provided in the application guidance (300 words) (see Section 2.2 of the Guidance Notes for details).	Describe how the intervention under consideration exists with sufficient evidence to justify its trial in humans i.e. it has gained a proof of concept.
				Demonstrate how the experimental intervention in question is novel but unproven in the chosen setting.
7	**Interoperability**	a	Please describe how your study will or could inform aspects of interoperability (see Section 2.6 of the Guidance Notes for more information) (maximum 300 words).	Describe what types of information would be collected or what aspects could be considered that might provide evidence about interoperability aspects, or provide direction for a future study of interoperability aspects.
8	**Strategic Importance and Alignment**	a	Relevance to HSC/HSE priorities/ alignment with health department strategies/policies in Northern Ireland and the Republic of Ireland (maximum 500 words).	Clearly demonstrate the relevance to HSC/HSE service users and to the policy aims of health and/or other governmental departments. If the study will inform specific strategies/policies/guidelines, the potential contribution should be clearly stated.
		b	Alignment with the Health and Social Care theme of the INTERREG Programme (maximum 300 words).	Demonstrate how the proposal aligns to the Health and Social Care theme of the INTERREG programme[1].

Question Number	Title	Application Section Number	Application Section Name	Notes
9	**Cross-Border elements**		Please describe the nature and value of the cross-border elements of the project in terms of planning, delivery and collaborations (maximum 500 words).	Please describe how the application and team demonstrate cross-border planning and delivery. The value of the cross-border element should be clearly articulated.
10	**Team**	a	Please describe the role of each Co-applicant/Collaborator and provide details of their experience relevant to that role (maximum 500 words).	Describe the contribution that each team member will make and how their experience to date supports their role.
		b	Please describe the research environment that will support the team to undertake the research (maximum 500 words).	Provide details of the academic environment(s) where the team will be based and any support that will be provided; also describe the environment for delivery of the research and provide evidence of support of the study from, for example, service delivery leads.
		c	Please describe the opportunities and plans for mentoring within the team (maximum 300 words).	Central training will be provided through the CHITIN project; however, opportunities for development and upskilling of team members should also be optimised by the team. Details of such plans should be included.
		d	Please justify inclusion of any Co-Applicants or Collaborators based outside of the Defined Area (maximum 300 words).	Full justification for the inclusion of team members based outside of the Defined Area should be provided, for example, in terms of specific expertise that is unavailable within the Defined Area, existing networks, collaborations or working partnerships etc.

Question Number	Title	Application Section Number	Application Section Name	Notes
11	**Impacts and Metrics**	a	Please provide details of the metrics you plan to use the in the evaluation and reporting of your HIT (please refer to Section 3.8 of the Guidance Notes) (maximum 300 words).	In order to contribute to the overall CHITIN project evaluation, you are required to collect metrics related to your study. Please use this section to confirm that you will collect the minimum required dataset; including gender data. Please include details of any other data that you plan to collect and use in evaluation of the proposed HIT.
		b	Please provide details of how you will evaluate the success of your HIT (maximum 300 words; please refer to the Guidance Notes).	You must complete a final evaluation of the HIT which will be used to inform the overall evaluation of the CHITIN project. In addition to reporting of the metrics detailed herein, please highlight the nature and value of any additional appraisal that you would propose.
12	**PPI**		Please describe the PPI activities that have informed the development of the HIT **AND** the plans for PPI in the delivery of the HIT (maximum 750 words)	Use this section to demonstrate how you have included service users and the public in the entire research process (e.g. activities to date, planning, delivery, governance, reporting, dissemination). You should include names of individuals, groups and/or organisations, and provide appropriate detail of their involvement. You must make a distinction between research participant and PPI contributors, and demonstrate an understanding of the value and benefits of PPI.

Question Number	Title	Application Section Number	Application Section Name	Notes
13	**Research Governance**	13a		You are expected to identify an organisation willing to sponsor the research. Confirmation of this support should be provided with the application and the sponsorship confirmed after any award is made. Please also refer to Section 5 of this Application Guidance for further details about Sponsorship in Northern Ireland and the Republic of Ireland.
		13b		Provide details of Care Organisations involved in the study.
14	**Finance**	14		14a should be an overall financial summary of the project; please ensure totals for each category are within the maximum permitted as indicated within the table; 14b should be used to record costs for each individual healthcare delivery organisation involved in the study; 14c should be used to record costs for each individual higher education organisation involved in the study; 14d should be used to record costs for each individual voluntary sector organisation involved in the study; in each case (14b-14d), please duplicate the page as many times as is necessary. For each organisation, a representative from the finance department should e-sign to confirm their approval of the costs.

Question Number	Title	Application Section Number	Application Section Name	Notes
15	**Justification of resource requirements**	15	Applicants must provide a detailed justification for each of the costs identified in Section 14.	Justify the level of cost in each of the budget categories; where appropriate, express staff time in hours/week. In the case of goods and services, assurance of Value for Money should be provided
16	**Nominations for referees**		Applicants should provide the names of two professionals who may be approached.	Nominated referees should be made aware that they may be approached to provide a Peer Review. Both referees must reside outside Northern Ireland and the Republic of Ireland.
17	**Declarations**	17a	The **Lead Applicant** is required to e-sign the application. This section should also be e-signed on behalf of the Host Institution's **Head of Department** / School / Faculty / Research Centre Director / Head of Research Institute confirming that the University supports the application and can accommodate its delivery. This section should also be e-signed on behalf of the Host Institution's **Research Office** to confirm that they are aware of the application.	e-signatures should be used by each signatory to complete the declaration. Lead Applicants should ensure that each signatory is copied to the submission email. The Partners may contact signatories to confirm their role in the application.
		17b	Each HSC/HSE/**Healthcare delivery body** involved in the application should complete a copy of this page. A senior representative from the **Research Office** should e-sign this declaration to confirm that the application has been reviewed and approved.	

Question Number	Title	Application Section Number	Application Section Name	Notes
17	**Declarations**	17c	Each **University/Higher Education** Institute involved in the application should complete a copy of this page. It should be e-signed on behalf of the healthcare delivery organisation by the relevant **Head of Department** / Service Lead confirming that the application is supported and the project can be accommodated. This section should also be e-signed on behalf of the higher education organisation's **Research Office** to confirm that they are aware of the application.	e-signatures should be used by each signatory to complete the declaration. Lead Applicants should ensure that each signatory is copied to the submission email. The Partners may contact signatories to confirm their role in the application.
		17d	Each **Voluntary sector organisation** involved in the application should complete a copy of this page. A senior representative from the **Research Office or equivalent** should e-sign this declaration to confirm that the organisation has reviewed the application and that the project can be accommodated in the named organisation.	

1. ***Extract from the INTERREG Health and Social Care Funding Call. Special EU Programmes Body, 2015:***

What is the theme "Health and Social Care" going to achieve? The Programme will invest in a number of health and care sectors where there is greatest need and where the value of cross-border cooperation can deliver greatest results. The specific objective is, through collaboration on a cross-border basis, to improve health and well-being of people living in the region by maximising community assets and enabling citizens to access quality health and social care services in the most appropriate setting to their needs, and to enable greater self-management and a focus on prevention. The programme will invest in programmes that reflect and support current strategic priorities within the jurisdictions of the region. These include, but are not restricted to 'Transforming Your Care' and 'Making Life Better' in Northern Ireland; 'Future Health' and 'Healthy Ireland' and 'eHealth Strategy for Ireland' in Ireland and; Achieving Sustainable Quality in Scotland's Healthcare: A '20:20' Vision", The Healthcare Quality Strategy for NHS Scotland and Renewing Scotland's Public Services: Priorities for Reform. Applicants will therefore need to demonstrate how proposals fit with the relevant strategies across the jurisdictions the project will serve.

8. Eligibility and Evaluation

8.1 Applications will be validated by HSC R&D Division and HRB to ensure they meet the appropriate format. **An invalid application will not go forward for further evaluation**. The Lead Applicant will be notified in writing if their application is deemed invalid.

8.2 Applications will undergo independent Peer Review and independent Expert Panel review.

8.3 Research proposals will be evaluated against the following criteria:

	Criterion	Purpose	Details	Primary Source of Information for Evaluation
1	**Project must end by 31 July 2021.**	Eligibility		Application Form, Section 1.
2	**Total funding value requested must be under €700,000.**	Eligibility		Application Form, Sections 1 & 14.
3	**Lead Applicant must be based in an institution on the island of Ireland.**	Eligibility		Application Form, Section 2.
4	**Lead Applicant must meet the stated contract requirements.**	Eligibility	Contract requirements are stated in Section 3.4 of this document.	Application Form, Section 2.

	Criterion	Purpose	Details	Primary Source of Information for Evaluation
5	**Teams must have Co-Applicants from both jurisdictions.**	Eligibility		Application Form, Section 3.
6	**The Research Protocol must meet the stated parameters**	Eligibility		Application Form, Section 5.
1	**The proposal must reach scientific and methodological quality thresholds.**	Evaluation	-Are the aims and objectives of the research clear? -Is the proposed methodology adequate and appropriate? -Is the envisaged outcome likely to be achieved? Have the dissemination and implementation of results been fully addressed? -Has a suitable knowledge transfer plan been developed?	Application Form, Sections 5 (Research Protocol)
2	**The proposal must demonstrate sufficient novelty and innovation.**	Evaluation	-Has the existing knowledge base been clearly and adequately presented?	Application Form, Section 6a.
			-Will the study make a relevant and valuable contribution to the existing knowledge base?	Application Form, Section 6a.
			Is the intervention at an appropriate stage of development?	Application Form, Section 6b.

	Criterion	Purpose	Details	Primary Source of Information for Evaluation
3	**Interoperability aspects must be identified.**	Evaluation	-Has the proposal identified ways in which the theme of interoperability will be addressed or informed? -Do opportunities exist to include aspects of interoperability that have not been identified? -Are the proposed activities appropriate?	Application Form, Section 7.
4	**The proposal must show Strategic Alignment.**	Evaluation	-Does the proposal study align to priorities of the Health Departments in Northern Ireland and the Republic of Ireland? -Does the proposed study demonstrate alignment with the Health and Social Care theme of the INTERREG VA Programme?	Application Form, Section 8a. Application Form, Section 8b.
5	**The proposal must demonstrate a cross-border approach.**	Evaluation	-Is the team an appropriate mix of researchers from both jurisdictions? -Does the proposal involve cross-border delivery activities? -Is clear value in the cross-border elements demonstrated?	Application Form, Section 9a.

	Criterion	Purpose	Details	Primary Source of Information for Evaluation
6	**The research team and environment must be appropriate for delivery of the proposed activities.**	Evaluation	-Has an appropriate role been identified for each team member and collaborator? -Is there appropriate experience within the team and the identified Collaborators to achieve the stated aims?	Application Form, Section 10a; CV.
			-Does the application demonstrate appropriate collaborations between sectors and organisations?	Application Form, Section 3.
			-Is the research environment appropriate to support delivery of the research?	Application Form, Section 10b.
			-Does the proposal maximise opportunities for mentoring and development of Co-Applicants and team members?	Application Form, Section 10c.
			-Has the inclusion of any Co-Applicants based outside the Defined Area been justified?	Application Form, Section 10d.
7	**The proposal must include confirmation of data collection for monitoring purposes.**	Evaluation	-Does the proposal confirm that the minimum data set described in Section 3.9 can be collected?	Application Form, Section 11a.
			-Has the applicant described how they will evaluate their project?	Application Form, Section 11b.

	Criterion	Purpose	Details	Primary Source of Information for Evaluation
8	**Personal and Public Involvement**	Evaluation	-Have the applicants demonstrated that they have sought to include service users and the public in a partnership role in the research process rather than solely as research participants? -Is the level of PPI appropriate and justified? -Does the proposal demonstrate an understanding of the benefits of PPI? -Do the applicants aim to incorporate PPI in the reporting/dissemination of the study?	Application Form, Section 12.
9	**Research Governance**	Evaluation	-Have the applicants identified an appropriate Sponsor organisation? -Has evidence been provided of support for the research from the Sponsor Organisation?	Application Form, Section 13.
10	**The proposal must demonstrate Value for Money**	Evaluation	-Does the proposal represent good Value for Money?	Application Form, Sections 14 & 15.

In the event of a high number of applications, a shortlisting process may be undertaken by the Expert Panel through more stringent application of the criteria.

Criteria subject to refinement.

9. Notification

7.1 The Chief Investigator will be notified of the outcome of the application in writing, at the address specified on the application form.

7.2 If unsuccessful, the Chief Investigator may request feedback **in writing** as to why the application failed. Applicants should note that such feedback will be limited to points of significance raised by the Evaluation Panel.

10. Successful Applicants

Financial Issues

8.1 Awards must be accepted by an appropriate designated organisation (normally the employing organisation of the Lead Applicant) which will manage the award on behalf of HSC R&D Division.

8.2 No payments under the awards will be made before the HSC R&D Division has received:

- written acceptance of the award on the terms and conditions offered
- a completed HSC R&D Division start certificate
- completed staff certificate(s)
- signed agreements as required by Research Governance – confirmation of sponsor

8.3 HSC R&D Division will make appropriate arrangements with the relevant organisation(s) for claiming the grant.

8.4 The applicants must inform HSC R&D Division or HRB immediately if funding for their research becomes available from another source.

8.5 A Project Management Plan for use in the monitoring and management of the project will be agreed with the Lead Applicant post-award.

Responsibility

8.6 All relevant codes of practice should be observed including data protection and health & safety at work.

8.7 HSC R&D Division has an obligation to monitor and evaluate the outputs and impacts of the research it funds. The CHITIN Project Partners are also required by SEUPB to monitor and evaluate the CHITIN project in line with an agreed monitoring and evaluation plan. Award holders will be required to adhere to reporting requirements as detailed in the terms and conditions of award and Letter of Offer.

8.8 Award Holders will be expected to support the HSC R&D Division and HRB in their compliance with the INTERREG Programme Rules and Standard Conditions of Grant.

8.9 Neither HSC R&D Division nor HRB will be responsible for claims under any statute or common law, nor will they indemnify the employing or care organisation(s) against any claim for compensation or any claim for which these organisations may be liable.

8.10 In order to meet their obligations under the Freedom of Information legislation, HSC R&D Division and HRB will publish details of all awards made on the HSC R&D Division and HRB websites. This will include name of awardee, research title, abstract and total value of award.

8.11 Successful applicants will be asked to supply an electronic copy of their abstract, which will be publically available

Termination of an Award

8.12 All parties, the applicants, HSC R&D Division, HRB and the relevant organisation(s) should endeavour to resolve any difficulties which arise that are likely to jeopardise a project grant. If personal difficulties arise the Chief Investigator should inform HSC R&D Division. HSC R&D Division reserves the right to terminate a project grant if no progress can be made to complete the research programme within the agreed period.