INTERREG VA CHITIN HEALTHCARE INTERVENTION TRIALS FUNDING CALL

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CV Section

34. *The CV states "Recent publications". Is there any definition of "recent" – how many years are anticipated?*

35. *Do the CVs have to adhere to a specific length or number of pages, within the format specified in Annex A? Or is any length fine, so long as the format is adhered to?*

36. *Do Collaborators need to complete CVs?*

INTERREG Programme – NEW 21.09.17

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Intention to Submit

1. What is the purpose of the Intention to Submit stage?

One purpose of the Intention to Submit stage is to allow for the early identification of peer reviewers for the applications being submitted. The aim of this is to allow peer reviewers to be identified ahead of the submission of full applications, thus reducing the time lines for the review process. No eligibility checks or evaluation of the Intention to Submit form will be undertaken.

To be considered at the full application stage, applicants must complete the Intention to Submit stage. Given that it is anticipated that further guidance and advice may be necessary ahead of full submission, a further purpose of the Intention to Submit stage is to collate applicants' contact details so that the CHITIN partners can provide updates between the Intention to Submit stage and Full Application submission. All applicants who complete and send in the Intention to Submit form by the deadline should continue to work on their full application in line with the guidance document and/or any other additional guidance provided.

2. Is there a word limit for the Sections of the Intention to Submit form?

The word limit for the abstract is 500 words. There is no limit to the research methods, but it is not expected that full protocol details are provided here. Please provide a brief indication of the techniques and expertise needed to carry out the research. Similarly, section 2e should be used to provide an indication of the peer review expertise that is appropriate to your proposal.

3. What happens after the Intention to Submit stage?

Once the Intention to Submit stage closes, you should continue to work on your full application for 29 September. The Referees that you have nominated will be contacted and their willingness to undertake a peer review **of your full application** confirmed. Up to two more independent peer reviewers will be identified based on the information you have provided within the Intention to Submit form. All those who agree to undertake a peer review will then complete a Confidentiality Agreement and be provided with dates on which they will receive your application for review after the full application deadline. They will also be given a date for return of their review so that this can be considered by the Expert Panel as part of their evaluation.

The CHITIN Partners may be in touch to provide further information to applicants between the closes of the Intention to Submit and the full application.

Documentation Queries

4. ***A new full Application Form and supplementary document has been issued – what do I need to complete?***

Given the simplified position with the budget, the relevant sections have been amended to make them easier to populate. A new version of the application form with new versions of the budget and signatory sections has been made available. The version is otherwise unchanged to allow ease of migration to this form. A supplement to the original application for has also been made available. If you have completed significant work on the original version and do not wish to migrate to the new version, you should complete the supplementary document for the relevant sections. To summarise, you should submit:

- **PERFERRED OPTION: CHITIN Full Application AMENDED Sept 2017** (please use the most recent version issued to you by email or download it from the CHITIN project homepage).

OR

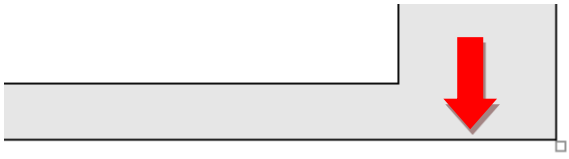
- **CHITIN Full Application form July 2017** omitting sections 14, 15 and 17
  AND CHITIN Full Application SECTIONS 14,15 & 17 REVISED

5. ***My text is within the word limit but does not fit in the box – what should I do?***

If your text does not fit in the box, you can either extend or duplicate the box:

To extend the box,

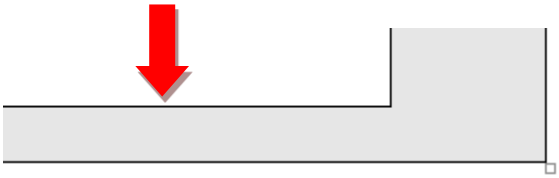
- Hover over the line beneath the grey section of the form and drag downwards:



ıment Division of the Public Health Agency

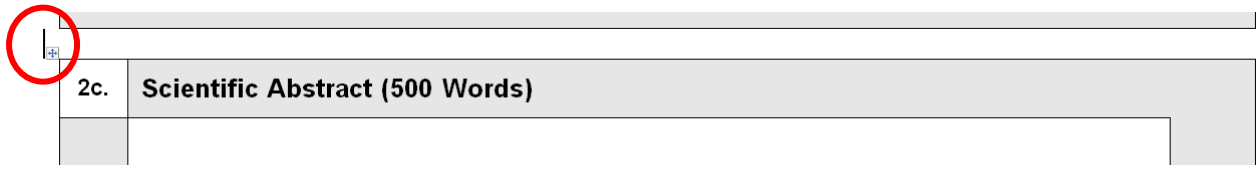
- Then do the same with the same with the white section of the box:

Back to index



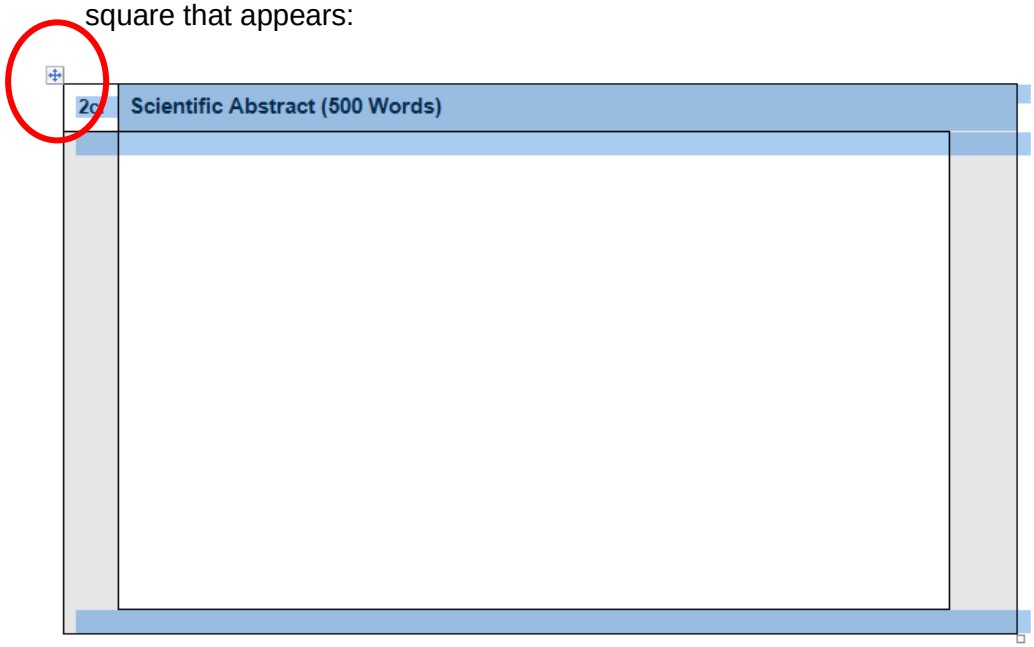
ıment Division of the Public Health Agency

- The box will move onto the next page. If the title section remains on the previous page, click in the space above and outside the box. The cursor will be a vertical bar. Use the Return key to push the box onto the next page:



To duplicate the box:

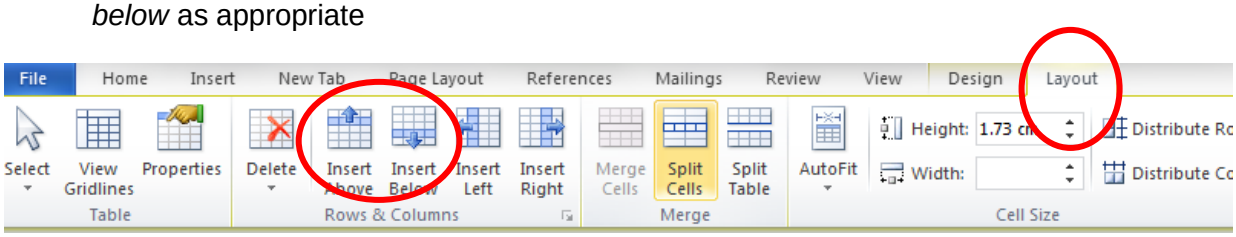
- Select the entire box by hovering over the top left corner and clicking on the small square that appears:



- Hold down Control and press “c” to copy

- Click in the space between box 2c and Box 2d
- Hold down Control and press “v” to paste

6. ***How do I add rows to the tables in the new Finance and Declaration document?***
   - Left click inside the table in any cell of the row below or above which you want to insert a row
   - In the head of Word, click on the *Layout* tab, then click on *Insert above* or *Insert below* as appropriate



7. ***Can I include a Gantt chart or flowchart with my Research Plan?***

The Research Plan/Protocol should be appended separately, must not exceed 8 pages and must adhere to the font requirements (**ARIAL SIZE 11 OR GREATER; ARIAL NARROW IS NOT ACCEPTABLE)**. A one-page GANTT chart and/or a one-page flowchart **can** be included **in addition** to the 8-page plan. If included, these charts are exempt from the font size restrictions.

- If you are including a flowchart with your Research Plan, the font size restriction does not apply.

8. ***Do the projects need to include full clinical trials and do the projects need to cover the cost of carrying out the trials?***

Projects may, but are not required to include full randomised controlled trials. Projects where costs for some of the project activities have been secured from another funding source are eligible provided that no other EU funding source is involved. Evidence of the funding commitment will need to be included with the application. The trial must be fully funded through the funds secured from other sources and the funds requested through the application to this call.

9. ***Does my proposal have to be a full trial or can pilot trials be proposed?***

Where a benefit to participants can be demonstrated, pilot and feasibility studies are welcome i.e. the work should normally involve recruitment of participants who should receive an intervention aimed at an improvement in their health or wellbeing. Proposals should not include pilot studies and trials of definitive interventions, but could include pilot and feasibility studies.

10. Do the projects need to include a CTU and the cost of a CTU?

If CTU expertise is required, the costs of and evidence of support from a suitable CTU or equivalent organisation should be included in the application, or evidence of an alternative funding source provided as per Question 6. If expertise appropriate to the requirements of the proposed study can be demonstrated within the team, then a CTU may not be required.

11. Do I need to involve the existing research infrastructure?

Applicants are encouraged to consider if their study could be supported or adopted by the existing research infrastructure, and discussions should be initiated with these organisations as early as possible. Details of some HSC R&D Division/HRB-funded infrastructure are provided in the ***Useful Information*** document. A linked diagram of the NI infrastructure can also be found here. If, following discussions with representatives of the infrastructure an agreement of involvement is reached, evidence of support should be included with full application submissions (e.g. email or letter indicating willingness to adopt or support delivery of the project).

12. Can there be more than one Lead Applicant?

Applications should identify a single Lead Applicant who takes overall responsibility for the management and oversight of the project. If opportunities exist within the team for mentorship and development of future Lead Applicants, then these should be identified within the application and CVs.

13. How should I present any bibliographical references in support of my application?

If you wish to include references you are free to do so. References can be included at the end of the relevant section and will not be included in the word count for that section. References in support of your Research Plan/Protocol should be included as part of the Plan/Protocol in addition to the permitted page count.

Intervention Queries

14. In terms of e-health, how well developed does the e-health element need to be – i.e. Does the e-health intervention need to be fully finished or can this be an health intervention which is in the process of being developed?

Proof of concept for the core component should have been attained, and a benefit to participants should be demonstrable i.e. the intervention should be at a stage of development that participants receiving the intervention could be perceived to benefit from that participation. This call will not pay for the costs of development of an intervention that is at an early stage of development. See also Question 14.

15. How is an "intervention under development" being defined?

The intervention should have proof of concept and some evidence supporting its readiness for trial by the method and/or in the population that you propose. The peer review process will allow standalone assessment and scoring of your proposal. The expert panel will take these assessments into consideration when reviewing your application alongside other applications selected for review. This is a competitive process and the ten proposals of highest quality will be funded. As such, if you feel you can present a compelling justification for the intervention's completeness and readiness for trial as above, then you are encouraged to apply.

16. Will these awards allow for app development?

These awards cannot fund the development of a new app. They may only be used to inform small refinements required for adaptation of elements of the intervention to the research setting, and to test the feasibility of an intervention or to trial a definitive intervention.

17. In terms of what the funding will not support, can you clarify what is meant by 'the cost of providing the service or the intervention itself'.

The call will not fund applications which are solely or predominantly health service developments or implementation of an intervention without a predominant research element. The call will not fund the cost of providing the service or intervention itself, only the research element. This means that the call will not fund 'usual care' but will fund anything over and above usual care that is part of the research and core to answering the research question.

Interoperability

18. Can you explain the question about interoperability?

It is clear that the CHITIN project represents an opportunity to look at delivery of interventions in more than one healthcare system and on a cross-border basis. There is therefore the potential to gather information and insights into how systems, processes and services could be impacted or improved through the implementation of a novel intervention or approach in more than one jurisdiction/healthcare system. Within the call, a broad interpretation of interoperability is therefore being applied. The delivery of a fully interoperable intervention is not a requirement of the call, but consideration should be given to maximising the opportunity to collect relevant information about future implementation of your intervention.

Your study may have a primary focus on interoperability, e.g. putting the changes in place to facilitate new systems and processes, as long as there is a clear research question involved. Alternatively, your study may have another primary aim, but elements of your proposal could gather evidence that would inform the future optimisation of your intervention in a larger study or implementation project in terms of system, process and/or service changes.

Interoperability will be considered as part of the review of your proposal; however, no proposal will be rejected on this element. Expert assessment of opportunities for additionality will be undertaken during the review process. If identified in an application that is deemed eligible for funding, these will be discussed with the Lead Applicant in advance of the issue of a Letter of Offer.

19. I'm not sure whether my project can include any aspects of interoperability – what types of things could be considered?

You will undertake an evaluation as part of your overall project, and it is likely that your standard approach to evaluation will involve the collection of information around aspects relevant to the interoperability question. In planning your evaluation, you are asked to consider how you can add value to your project by incorporating the collection of data that might inform future commissioning and operationalisation of your intervention.

Interoperability could be considered at various levels:

- It could be that there are legal, legislative or governance differences that would affect implementation of your intervention if it was commissioned as a service in one or both jurisdictions. Your research study could in part be used to identify the actions or changes that would be required, what systems and processes would be impacted, what resource implications would exist etc.
- Your study may involve some level of "exchange" or parallel operation in different setting, e.g. **data** (between systems, across jurisdictions), **messaging** (between computer networks/systems in one or both directions), **people** (crossing the border to receive an intervention where they wouldn't otherwise do so) etc.
- Delivery of a research study of an intervention in two jurisdictions may in itself highlight **legal** and **governance** differences e.g.
    - is there different legislation between the two jurisdictions that might affect how the intervention would be delivered?
    - Are the clinical governance arrangements in different healthcare organisations different for your target participant group? If so, what impact might this have on delivery?
- Other general considerations might be:
    - are measures in place to ensure the data is secure in storage, exchange and transit?

- Are datasets equivalent, or is there a need for coding, mapping or translation? Is new technology being implemented, and will it "talk" to legacy systems in both jurisdictions etc.
- Are Health Industry standard messaging protocols being used?

A number of examples are given below:

i. Your study requires the collection of data in healthcare delivery organisations in Northern Ireland and in the Republic of Ireland. Do you need to take different approaches to data collection? Do you need different levels of approval/regulation for data collection, movement and storage? Can the datasets be easily aggregated or do you require mapping? What are the impacts of these aspects? If systems were harmonised would the intervention run more efficiently? What would harmonisation require?

ii. Your study involves the movement of data in one or more direction between systems that don't currently exchange data (this could be on a cross-border basis). How is this being managed in the study? Would there be a better way to manage it? If so, could you collect information to help describe what would need to happen in order to put a better way in place? Are there any commercial implications, e.g. do legacy systems developed by different companies require new elements or modules?

iii. You are using routinely collected data on a particular condition in both jurisdictions, but the routinely collected datasets are different. What needs to be or could be done to map or harmonise the datasets? Would this be beneficial to the service? What would the implications be for future service delivery that involved your intervention?

iv. Your project involves recruiting participants, and the optimal process for recruitment in the NI sites differs from the RoI sites (e.g. recruitment through primary care versus secondary care or a charitable organisation). What are the implications of this? Was collection of demographic information about the participants easier through one of the processes? Did the participants like the setting in which they were recruited? Could changes be made to the system such that processes could be optimised for future studies or operationalisation of an intervention?

v. Your project involves a piece of technology that needs to integrate with existing systems. Is the technology bespoke? Will the developers of the existing systems in both jurisdictions (e.g. general practice systems) support the integration? Are any necessary futureproofing strategies possible?

Eligibility – NEW 21.09.17

20. I am a Lead Applicant based in an institution in the Republic of Ireland which does not hold HRB Host Institution status – am I eligible to apply as Lead Applicant?

If your organisation does not currently hold HRB Host Institution (HI) status, you are still eligible to apply as Lead Applicant under this call. Any such applicant whose proposal is deemed eligible for funding will be expected to achieve recognised HRB Host Institution status prior to the start of an award. In the event that this cannot be achieved, the award will be made to another Partner involved in the application, either based in Northern Ireland or based in the Republic of Ireland and holding HI status. A list of current HRB-approved Host Institutions and details on how to apply for Host Institution status can be found at http://www.hrb.ie/research-strategy-funding/policies-guidelines-and-grant-conditions/policies-and-position-statements/approval-of-host-institutions/.

Budget and Finance

21. What are the eligible cost categories?

The cost categories available through the INTERREG programme are:

- Staff Costs; staff costs can be claimed on the award on a full-time, or part-time basis. Individuals employed on the award on a full-time basis will be paid actual salaries based on evidence provided in employment documentation and payslips. Individuals working on the award on any part-time basis will be paid based on evidence provided in a working time registration system.

- Office and Administration Costs; these costs equate to an Overhead payment to cover the costs of administration and general running costs e.g. utilities, general office supplies, security, IT systems. These costs are paid at 15% of staff costs only.

- External Expertise and Service Costs/Training: expenditure on external expertise and services including but not limited to training associated with delivery of the HIT. Please note that a core training programme will be available for all HITs to access; this will include general training in management and delivery of R&D.

- Travel and Accommodation Costs: costs of public transport, mileage, meals, overnight accommodation for individuals working on the research. Proof of costs will need to be provided.

- Equipment Expenditure. large and small equipment; consumables associated with delivery of the HIT, office equipment, IT hardware/software; laboratory equipment, instruments, tools and devices and their associated consumables required for

delivery of the HIT. An inventory or asset register must be maintained for assets purchased on the award.

Please also refer to the INTERREG Programme Rules for further details of the cost categories and eligible costs. **Ineligible costs will not be paid and eligibility checks will be undertaken for each quarterly claim submitted.**

22. What do I do if my project requires spend that doesn't align with the maximum values indicated?

The restrictions to the budget categories indicated in previous correspondence have been **relaxed**. You should cost your study with itemisation of expenditure to a maximum of €700,000, inclusive of Office and Administration Costs calculated at 15% of Staff Costs. Costs should be broken down for each organisation. Allocation of expenditure items to cost categories will be discussed and agreed for successful applications after funding decisions have been made. New documentation has been issued to reflect the change in budget requirements and you should ensure that you complete **EITHER**: **A new Application Form and a new version of the budget and declaration sections of the Application Form are now available (Sections 14, 15 and 17).** You should transfer the

- **Application Form (version July 2017)** ***PLUS*** the supplement **CHITIN Full Application SECTIONS 14, 15 & 17 REVISED** OR
- **Application Form (version September 2017)** (**PREFERRED**)

These documents can be found on the CHITIN project page: http://www.research.hscni.net/cross-border-healthcare-intervention-trials-ireland-network-chitin-0

All spend must be fully justifiable to assure the evaluation panel of Value for Money.

23. What proportion of the budget can be spent outside the Defined Area?

At a Programme level, the INTERREG programme must reach a target of a minimum of 80% spend within its Eligible Area. However, there is no longer a requirement for individual HITs funded under this call to adhere to that requirement. As such, you may therefore include reasonable costs for input from institutions based **outside** of the Defined Area in excess of 20% of the total budget. In all cases, all costs must be fully justified.

24. What is the Office and Administration budget line and why is it 15% of staff costs?

The Office and Administration budget is 15% of the staff costs and is the overhead rate payable on INTERREG awards at a project level by the INTERREG program.

25. How should I include and cost the input of organisations from which I need expertise for my project?

If you will require specific expertise from an organisation in the delivery of your project (e.g. company expertise, Clinical Trials Unit, statistical support, network staff time), you should include an appropriate representative of this organisation as a **Co-Applicant** or **Collaborator** in line with the definitions provided. Once an individual within that organisation is assigned to deliver the expertise required by your project, their time will be recorded and claimed on the award as **Staff Costs**. If specific expertise is required to deliver your project and an organisation is not named on your application, then it would be expected that EU procurement rules would be followed in the acquisition of that expertise.

26. How should I present the employment/staff costs for NI and RoI institutions?

Please refer to section 4.2 (pp 30-32) of the INTERREG Programme rules for details of how staff costs can be presented and claimed. Given the legal differences between the two jurisdictions, please present the employment costs for staff employed in each jurisdiction separately within the relevant tables of the new budget document.

27. Can the funding be used to support PhD students?

If PhD students are to be used by an organisation delivering a HIT then the costs, such as fees and stipends payments, **are eligible** to be claimed.

Please note that eligible costs should be based on the eligible stipend payment applicable in each jurisdiction. In addition, a rate of €1,800 per month per PhD student, based on the Marie Sklodowska-Curie Action Horizon 2020 Work Programme, is eligible to be claimed. The 15% flat rate overhead cannot be claimed for PhD students.

These costs will be categorised as External Expertise and Services once itemised costs are allocated to cost categories post-award.

It is imperative that the suitability of the work for PhD study, and completion of the work to PhD level within the project timeframe is demonstrated.

28. If there are costs associated with healthcare research infrastructure, e.g. a research network, how should they be presented? What do the

You should present costs associated with support from research infrastructure in Section 14b of the application form.

29. Is each Co-Applicant expected to have an associated cost?

It is not a requirement that each Co-Applicant has an associated cost; contributions in kind are acceptable. Confirmation that Co-Applicants have capacity to contribute to the project as described may be sought.

30. What exchange rate should I use when converting sterling elements of the budget to Euros? – NEW 26.09.17

The recommended exchange rate is the European Commission monthly accounting rate of the euro which can be found here:
http://ec.europa.eu/budget/contracts_grants/info_contracts/inforeuro/index_en.cfm
Budgets will be agreed and finalised in line with this rate once funding decisions have been made.

Sign-off and Submission – UPDATED 26.09.17

31. What sign-off is required by the closing date?

The Partners have been made aware of some concerns around the completion of all signatures by the closing date of 12:00 on 29 September. In respect of this, the Partners have revised the requirements for sign-off by the closing date as follows:

- **Host Institutions** must complete electronic sign-off of **Section 17a** of the application **by the closing date** (Lead Applicant, Head of Department and Research Office).

- Applicants will then have a period of **one week** beyond the closing date to secure signatures from appropriate representatives of all organisations for **Section 17b, c and d** (as appropriate) and **Section 14a, b, c and d** as appropriate. All signatures should therefore be submitted by **12:00 on 6 October 2017. *If you are unclear regarding the required signatures, please contact Julie McCarroll at Julie.mccarroll@hscni.net in the first instance.***

PLEASE ENSURE THAT YOU AND YOUR CO-APPLICANTS ARE PROGRESSING DISCUSSIONS WITH RELEVANT INDIVIDUALS IN PARTNER ORGANISATIONS E.G. SERVICE LEADS, GENERAL MANAGERS, DISCIPLINE/CLINICAL LEADS, FINANCE LEADS, RESEARCH MANAGEMENT LEADS ETC.

32. Some of the organisations involved do not have a research office – what should I do about sign-off? What do the declarations mean? – NEW 21.09.17

Where an organisation does not have research office, an alternative signatory, such as a Clinical Director or Service Lead should be asked to sign Section 17 b, c or d (depending on the type of organisation).

Section 14 b, c or d (depending on the type of organisation) should be signed by an appropriate individual such as a Business Manager or Finance Lead who can confirm that they agree with the costs being provided and, if the application is successful, that the funds that the organisation would receive can be managed and the organisation's financial obligations under the terms and conditions of award upheld *in principle*.

The declarations in Section 17 are explained below.

17b Healthcare Delivery Body:

"I can confirm that this application has been approved in accordance with the requirements of the Research Management System"

Whilst it is recognised that applications will **not** have undergone a formal governance review at this point, this declaration confirms that the individual, acting on behalf of the organisation, is aware of, supports in principle the proposed participation in the project, and has made a record of such. In the absence of a research management function within the organisation, this record could be held in a system within the clinical section or directorate. This declaration could be completed by a Clinical Director or Service Lead.

17c: Academic institution:

"I confirm that I have read this application and that, if awarded, the work will be accommodated in the named Department."

The **Head of Department** or equivalent of the Co-Applicant should sign this declaration to confirm that the Co-Applicant has capacity within their workplan to make the proposed contribution to the project.

"I confirm that the University Research Office has a record of this application for this commissioned research award."

An officer from the **Research Office** of the institution should sign this declaration to confirm that the application has been recorded in their management system.

17d: Voluntary Sector:

"I confirm that I have read this application and that, if awarded, the work will be accommodated in the named organisation."

A Senior Representative such as a Managing Director, Chief Executive or other senior responsible office of the Co-Applicant should sign this declaration to confirm that the Co-Applicant and voluntary sector organisation have capacity to make the contribution to the project.

In the event that an application is deemed eligible for funding, all budgets, cost categories and approvals will be confirmed with appropriate individuals within each partner organisation prior to issue of a Letter of Offer.

33. Staff time for employees of a Health Service organisation is included in my application, and the organisation in question is named as a Collaborator, as opposed having a named Co-Applicant – what paperwork should I use to record the costs and signatures?

Where employees of healthcare organisations are involved in the delivery of projects, it is imperative that time spent in the care of patients is not impacted, and that the time to deliver the research has been approved and accounted for. If a healthcare organisation is included as a collaborator, you should complete the budget details in **Section 14b** and declarations in **Section 17b** of the Application Form. In such circumstances, you do not need to complete a Collaborator Form for healthcare organisations.

CV Section

34. The CV states "Recent publications". Is there any definition of "recent" – how many years are anticipated?

Whilst there is no formal restriction on the timeframe of your publications, please include what you consider to be your ten most recent publications that are of **most relevance to your application** in chronological order, starting with the most recent.

35. Do the CVs have to adhere to a specific length or number of pages, within the format specified in Annex A? Or is any length fine, so long as the format is adhered to?

No restrictions on length have been specified, and so any reasonable length is acceptable.

36. Do Collaborators need to complete CVs?

No. Lead Applicants and Co-Applicants should complete CVs; Collaborators will be asked to complete a short Collaborator form prior to the closing date for full applications. The form will be made available shortly.

INTERREG Programme – NEW 21.09.17

35. Where could I find information about the INTERREG Programme and Health Priority axis?

The project Partners, HSC R&D Division of the Public Health Agency and HRB, will need to demonstrate that the trials funded under this call contribute to what the INTERREG programme aims to achieve (cross-border, equality, creating opportunities for better healthcare, enablement etc).

The following links may be of use in the completion of Section **8b** of the Application Form (please search the pages/documents for "health" or "priority axis 4").

- General **INTERREG** homepage: https://www.interregeurope.eu/about-us/what-is-interreg-europe/

- **Output Indicators**: http://www.seupb.eu/iva-%26-piv-how-do-i-manage-my-funding (4.1 Health)

- **SEUPB** homepage (SEUPB are the Managing Authority for the INTERREG funding for this region (Scotland, Northern Ireland and Ireland): http://www.seupb.eu/

- **SEUPB** overview of INTERREG VA: http://www.seupb.eu/iva-overview

- **SEUPB's** Implementation Update overview of INTERREG VA (see page 12): https://www.seupb.eu/sites/default/files/INTERREG%20PMC/IMC_05_Paper_1_UpdateOnImplementation.pdf