<<<INSERT RELEVANT UNIVERSITY ADDRESS>>>

<<<INSERT CARE HOMES ADDRESS>>>

<<<DATE>>>

Dear <<<INSERT CARE HOME CONTACT NAME>>>

Ref: your participation in **uSing rolE-substitutioN In care-homes to improve ORal health (SENIOR)**

Thank you for agreeing to participate in the SENIOR study. We really appreciate your involvement in the study and the opportunity to determine whether Dental Therapists and Dental Nurses could improve the oral health of your residents.

Given that the SENIOR study is a randomised controlled trial in a vulnerable population group and that financial payments will be made to your care-home, there are a number of legal obligations that we need to explain. Schedule A describes what you have agreed to do. We have tried to keep this as ‘light-touch’ as possible and you will be supported by your local research team during the study, if there is anything that you don’t understand.

UWB/BU/UCL \* (delete as appropriate) will forward to you £500 as a ‘golden hello’ and £50 per resident recruited at your home (maximum of 15) as a contribution to the Project. You will need to liaise with your local study team to confirm numbers of recruited residents to enable UWB/BU/UCL \* (delete as appropriate) to issue a Purchase Order.

The SENIOR trial needs to be managed in accordance with General Data Protection Regulations. This means that identifiable data should not be passed onto the study team. Instead, residents should only be identified using a unique study number, which will be provided by your local study team. This should be used on all study documents, apart from the Consent Form, which should be kept locked in a filing cabinet in the care-home manager’s office, once completed. The study team will provide a folder for each participating resident containing blank proformas to be stored in their rooms. Once any information is entered onto these documents, they should be stored in the care-home managers office (but kept separate from the Consent Form). All study documents that contain information need to be processed in this way to ensure the Sponsor complies with the General Data Protection Regulations. Equally, there is an obligation to comply to any applicable statutory requirements and mandatory codes of practice in respect of confidentiality (including medical confidentiality) in relation to participating residents.

As is standard in a study of this type, any intellectual property and know how generated in the course of the Project (“Arising IP”) will belong to Bangor University or QUB/UCL\* (\*delete where appropriate).

The Parties shall have no liability whatsoever (whether in contract, tort or otherwise) for any indirect or consequential loss (including but not limited to pure economic loss, loss of profits, loss of business or goodwill) howsoever caused. Nothing in this Letter Agreement shall limit or excludes either party’s liability for (i) death or persona injury resulting from negligence; or (ii) any fraud or for any sort of other liability which, by law, cannot be limited or excluded. Subject to the foregoing, a party’s liability under this letter agreement shall be limited to the amount you have received under this letter agreement.

Any amendment to this Agreement shall be made in writing. Nothing in this Agreement confers or purports to confer on any third party any right to enforce any term of this Agreement.

This letter agreement constitutes the entire agreement between the parties relating to the subject matter. This letter agreement will be governed by the laws of England and Wales and the parties submit to the non-exclusive jurisdiction of the English and Welsh courts.

In consideration of the mutual promises herein, which each party agrees is good and valuable consideration, please sign below on behalf of your institution and send to [INSERT NAME] at [INSERT EMAIL ADDRESS] who shall send you a fully signed agreement by e-mail.

|  |  |  |
| --- | --- | --- |
| Accepted on behalf of [INSERT LEAD UNIVERSITY] | Accepted on behalf of # |  |
| Signature: | Signature: |  |
| Name/position: | Name/position: |  |
| Date: | Date: |  |

cc: Lead PI

Co-investigator(s)

Annex 1

**Award Letter**

**(Optional: include Terms & Conditions if non-standard)**

Annex 2

**BREAKDOWN OF COSTS TO COLLABORATOR**

Funding Body Grant Ref:

Lead Collaborator Ref:

[INSERT PROJECT TITLE]

|  |  |  |  |
| --- | --- | --- | --- |
| **Summary Totals** | **Indexed fEC Total** | **Funding Body Contribution** | **Indexed Total (cash limited)** |
| **Directly Incurred Costs:**  Salaries  Consumables  Travel & Subsistence  Equipment  **TOTAL DI COSTS** |  |  |  |
| **Directly Allocated Costs:**  Investigators  Estates  Other Directly Allocated  **TOTAL DA COSTS** |  |  |  |
| **Indirect Costs** |  |  |  |
| **Exceptional items** |  |  |  |
|  |  |  |  |
| **Total** | **£** | **£** | **£** |

the Lead Collaborator’s representative for the receipt of invoices is:

[name]

[address]

**Schedule A**

**Study Conduct at the Participating Care Home**

|  |  |  |
| --- | --- | --- |
|  | **RESPONSIBLITIES** | **RESPONSIBLE PARTY** |
| 1. **STUDY PREPARATION** | 1. Ensure adequate facilities, resources and support are available to conduct SENIOR at the care-home | Care-Home Manager working with the Local Study Team |
| 1. **ROLES** | 1. Ensure relevant staff at the care-home are aware of and, where necessary, have agreed to their role in SENIOR | Care-Home Manager working with the Local Study Team |
| 1. **PROTOCOL AMENDMENTS** | 1. Ensure any amendments to SENIOR are implemented at the care-home | Care-Home Manager working with the Local Study Team |
| 1. **STUDY CONDUCT** | 1. Ensure all relevant care-home staff attend SENIOR trial training, which will include Good Clinical Practice (GCP) and General Data Protection Regulations (GDPR) | Care-Home Manager working with the Local Study Team |
| 1. Ensure SENIOR is conducted within the care-home according to the protocol, GCP and relevant legislation | Care-Home Manager working with the Local Study Team |
| 1. Submit all study data required for SENIOR in accordance with the protocol | Care-Home Manager |
| 1. Ensure Patient Identifiable Data is not used in the Case Report Forms | Care Home Manager working with the Local Study Team |
| 1. Maintain SENIOR’s Abridged Site File ensuring compliance with GCP | Local Study Team |
| 1. Ensure all study data and documentation is available for monitoring purposes | Care Home Manager working with the Local Study Team |
| 1. Respond to any requests for data clarification from the research team | Care-Home Manager |
| 1. Ensure any deviations to the protocol are reported to the study team (on behalf of the Sponsor) | Care-Home Manager working with the Local Study Team |
| 1. Ensure all study records are archived at the care-home and retained for 5 years | Care-Home Manager |
| 1. **ELIGIBILITY AND CONSENT** | 1. Confirm eligibility of residents to participate in SENIOR | Care-Home Manager |
| 1. Liaise with the research team to identify eligible residents | Care Home Manager working with the Local Study Team |
| 1. Assess capability of eligible residents to give informed consent | Care-Home Manager |
| 1. Ensure that all signed consent forms are held in a locked cabinet in the care-home | Care-Home Manager |
| 1. **RESIDENTS’ RECORDS** | 1. Maintain a weekly checklist diary of episodes of pain, number of onward referrals to dentist, episodes of unscheduled care | Care-Home Manager |
| 1. Ensure Case Report Forms (CRF) are kept up to date for each resident and held securely | Care-Home Manager working with the Local Study Team |
| 1. **ADVERSE EVENTS** | 1. Report any Adverse Events and/or Serious Adverse Events to the research team (in line with GCP) | Care Home Manager working with the Local Study Team |
| 1. Ensure clinical records are kept up to date following any Adverse Events and/or Serious Adverse Events | Care Home Manager working with the Local Study Team |