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| **Annex 1 – Research involving human participants** | | |
| **Does your proposal involve human participants?** If yes, you must complete all questions below | Yes/No | |
| **Aims:** Describe the aims of the project, including the below:i. What is the aim of your project, and what are you hoping to achieve?  ii What are the potential benefits of this work? | | |
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| **Study Design:** Describe the study design. This should include where relevant:  i. target population, including inclusion and exclusion criteria ii. number of participants in each arm, and how participants will be allocated to an arm where applicable  iii. type, frequency and duration of interventions iv. the proposed frequency and duration of follow up and any problems anticipated with non-compliance and/or loss to follow-up v. outline the study endpoints, and how these will be assessed.  vi. detail any risks to the safety of patients taking part in the study. Include details by which the level of risk will be assessed  vii. if applicable, details of any investigational product to be used | | |
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| **Recruitment strategy:**   1. Outline and justify the strategy for recruitment 2. Describe and justify the sample size and proposed statistical analyses to be used, including number of samples in each analysis, the associated level of statistical power, and any potential limitations or biases. 3. What do you think the likely recruitment challenges will be and how will you overcome them 4. Details of input from a statistician where received | | |
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| **Study team:** Provide details of the study team members and how the expertise of the study team will facilitate successful delivery of the proposed study. Include any infrastructure support, as well as details of any staff external to the applying organisation working/collaborating on the project. Please also describe who will be leading on the management of the project. | | |
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| **Study governance:** Describe the study governance, and if applicable, details of the Trial Steering Committee and Data Monitoring Committee. | | |
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| Does this project require formal sponsor(s)? | | Yes/No |
| If yes, which organisation(s) has/have agreed to fulfil this role? | | |
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