**Research Proposal Submission to the NHS Genomic Medicine Service Research Collaborative**

This form is to be used to provide full details of a research proposal to be reviewed by the NHS Genomic Medicine Service Research Collaborative. Any research proposals which wish to be supported by the NHS Genomic Medicine Service and its services should be made via this process.

This process is not to be used for requesting access to existing data held in the National Genomic Research Library. Applications to this process should be made to Genomics England: <https://www.genomicsengland.co.uk/about-genomics-england/research-environment/>.

By submitting this form, you are confirming that you have provided the full details requested (including any relevant additional information or attachments) and that the application meets the requirements outlined in Appendix 1.

The NHS Genomic Medicine Service Research Collaborative Steering Committee will review complete applications which meet the requirements outlined in Appendix 1. You will be contacted to confirm next steps and timelines for the process following submission.

Please submit this form and any relevant attachments via email to [ENGLAND.genomics@nhs.net](mailto:ENGLAND.genomics@nhs.net). Please provide any references used in the body of this submission in a separate attachment.

**Contact Information**

|  |  |
| --- | --- |
| **Named contact for research proposal** |  |
| **Organisation** |  |
| **Email address** |  |
| **Telephone number** |  |

**Research Proposal**

|  |
| --- |
| **Research Title [20 words max]** |
|  |

|  |  |
| --- | --- |
| **Proposed start date** |  |
| **Research duration** |  |
| **Estimated end date** |  |

|  |  |
| --- | --- |
| **Please confirm that you agree to all data generated as part of this research being made available to the National Genomic Research Library** | [Y/N] |

**Lay Summary**

|  |
| --- |
| **Research Lay Summary [250 words max]**  Please provide a lay summary of your proposed research. Please ensure this is a plain language summary stand-alone summary of the proposed research project aimed at an audience with no knowledge of the research. |
|  |

**Rationale**

|  |
| --- |
| **What is the scientific rationale for the proposal (e.g. how does the existing literature or existing data you have support this proposal) [200 words max]** Please provide an overview of the rationale that justifies the proposed research, and shows that it will add distinct value to what is already known |
|  |

**Research Overview**

|  |
| --- |
| **Aims and Objectives [150 words max]** Detail the overarching aims and objectives of the research including the clinical and/or scientific questions the research will address |
|  |

|  |
| --- |
| **Research Plan [500 words max]** Describe the proposed research plan and the work that will be undertaken (including patient recruitment, sample acquisition, methodology etc) to achieve the project’s aims/objectives.  **As part of this section, please provide a timeline including key milestones and deliverables** |
|  |

|  |
| --- |
| **Provide an overview of the intended outputs and impact of the research, including plans for adoption and implementation of these outputs and impact on/benefit to patients and the NHS [250 words max]** |
|  |

|  |
| --- |
| **Collaborators [150 words max]** List and explain the role of key collaborators involved in the research. Collaboration with other stakeholders such as Clinical Trials Units should also be described. |
|  |

|  |
| --- |
| **Patient and Public Involvement [150 words max]** Describe how patients and the public, as well as other relevant stakeholders, have been involved in the development of the application and plans for involvement in the proposed research |
|  |

|  |
| --- |
| **Provide an overview of the approach to patient consent that will be undertaken for this research [150 words max]** |
|  |

**Additional Information**

|  |  |
| --- | --- |
| **This proposal has undergone or will undergo independent peer review** | [Y/N] |
| **Provide brief details [50 words max]** | |
|  | |
| **This proposal has appropriate ethical approval or has been submitted for approval** | [Y/N] |
| **Provide brief details and ethical approval number/reference [50 words max]** | |
|  | |
| **This proposal has been submitted to the NIHR Clinical Research Network (CRN) portfolio** | [Y/N] |
| **Provide brief details and CRN reference, including if the proposal has been accepted and funding secured via CRN [50 words max]** | |
|  | |

**Finance and Contracts**

|  |
| --- |
| **Estimated Research Costs [150 words]** Detail the estimated research costs, including the cost to the NHS, funding requirements for NHS activities and reimbursement for NHS participation |
|  |

|  |  |
| --- | --- |
| **This proposal has the following sponsorship arrangements**  Please provide evidence of the sponsorship arrangements as an attachment to this proposal if arrangements are already in place | Commercial contract sponsorship [Y/N]  Commercial collaborative sponsorship [Y/N]  Non-commercial sponsorship [Y/N]  No sponsorship [Y/N]  Sponsorship not yet agreed [Y/N] |

|  |  |
| --- | --- |
| **Please confirm the proposed model contract approach that will be used for this research if it has been identified**  Further information can be found at <https://www.nihr.ac.uk/documents/model-site-agreements-model-contracts-standard-research-agreements/11612> | Commercial contract [Y/N]  Commercial collaborative contract [Y/N]  Non-commercial contract [Y/N]  Contract not yet agreed [Y/N] |

|  |  |
| --- | --- |
| **Please attach a draft of the appropriate costing template and evidence, based on contact model approach**  See appendix 1 for further information on template requirements | Draft documents attached [Y/N] |

**Attachments**

|  |
| --- |
| **Please list all attachments provided with this submission (e.g. high level research plan, supporting diagrams, costing template etc)** |
|  |

|  |  |
| --- | --- |
| **Signed** | **Date** |
|  |  |

**Appendix 1**

Research proposals must meet the following criteria prior to review by the NHS Genomic Medicine Service Research Collaborative Steering Committee.

It is acknowledged that not all processes or applications will be complete at the point of submission to the Steering Committee for review and that they may be reviewed through other governance mechanisms in advance.

|  |  |  |
| --- | --- | --- |
| **Criteria** | **Further information** | |
| **Details of independent peer review** | Additional support to conduct can be provided by the Committee if necessary | |
| **Details of consent approach provided** | NHS GMS - consent captured through national patient choice framework  Other studies/research - consent materials as approved by or submitted to the REC provided by researchers for review by the Steering Committee | |
| **Ethical approval evidenced**  Further information - <https://www.hra.nhs.uk/planning-and-improving-research/research-planning/> | REC approval evidenced appropriate ethical review  HRA UK Local Information Pack completed for NHS sites for all research (commercial contract, commercial collaborative and non-commercial research) | |
| **Sponsorship details provided**  Further information - <https://www.hra.nhs.uk/planning-and-improving-research/research-planning/> | Commercial contract sponsorship | Sponsorship from commercial companies to be evidenced |
| Commercial collaborative sponsorship | Sponsorship agreement to be evidenced |
| Non-commercial sponsorship | Sponsorship agreement to be evidenced |
| **Details of approach to Model Contracts provided**  Further information - <https://www.nihr.ac.uk/documents/model-site-agreements-model-contracts-standard-research-agreements/11612> | Commercial contract | Suite of Model Clinical Trial Agreements (including clinical trials of investigational medicinal products, medical technology investigations, primary care and contract research organisations) |
| Commercial collaboration | Model industry collaborative research agreement |
| Non-commercial | Model Non-Commercial Agreement (mNCA) template |
| **Costing methodology and reimbursement information detailed, including how much NHS is paid to participate or funding requirements for NHS activities**  **Draft costing templates and evidence provided.** | Commercial contract | Industry Costing Template and CPMS based interactive Costing Tool (iCT) and final cost agreement |
| Commercial collaborative | SoECAT template and evidence of funding for research costs as per ACcoRD |
| Non-commercial | SoECAT template and evidence of funding for research costs as per ACcoRD |
| **Evidence of appropriate IP requirements in place** | Standard IP recitals to be reviewed | |
| **Confirmation of data availability to National Genomic Research Library** |  | |