**HSC-PBPP Amendment Request Form**

*To be completed for changes to an approved HSC-PBPP application.*

*Any amendment to an approved HSC-PBPP application should be within the scope of that approved application.*

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| **Application Control**  *Please complete all sections below.*  *Please note: the applicant named below should be the same person as that named as the main applicant (Q 1.1) in the current version of the approved HSC-PBPP application.* | | |
| Application Coordinator |  |
| Application Number |  |
| Applicant name |  |
| Applicant email address |  |
| Proposal name |  |
| Application Approval date |  |
| Version number of current approved application. |  |
| Expiry date of HSC-PBPP approval |  |
| Amendment submission date |  |
| Supporting Documents  *Please ensure that the* ***most recent approval letter*** *is attached with all submissions.* | Most recent approval letter  Updated application with version number  IG certificates (if applicable)  Other relevant documents (please detail): |

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| **Please provide full justification for all changes requested.**  *Please note that all changes in the updated version of the HSC-PBPP application form should be highlighted in yellow. This included removals which should also be ~~struck through~~.*  *Note:-Updated applications forms showing track changes will not be accepted.* |
| **Why do you need an amendment?**  *Please outline the issue you have encountered and how the changes requested will help you to achieve the original purpose of the application.* |
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| **What changes are requested under this amendment?**  *Please outline the changes to your application that are covered under this amendment. Please note that justification for changes to any questions on the checklist that have been answered as ‘YES’ should be outlined below.* |
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| **Please explain and justify how this amendment remains within the scope or purpose of the original application?**  *Please note, if the HSC-PBPP consider this amendment to be beyond the original scope or purpose of the application, they may request a new related application. While this will depend on the content and context of the original application, changes beyond the original scope might include addition of new dataset(s), new objectives, different locations for storage or access of the data, from that in the original approved proposal.* |
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| **Please tick below to indicate which sections of the application have been amended and provide the answers to the ALL checklist questions.**  *Each checklist question answered ‘Yes’ requires and explanation and must be provided in the “***What changes are requested under this amendment?”** section above*.*  *Please state which questions within the application form have the changes specified.* | | |
| *Please check the box if there are changes to this section* | **Checklist questions** |  |
| Section 1  **Safe People** | Are there any changes to personnel accessing the data (additions or removals)? | Choose an item. |
| Is the IG training up to date for all personnel mentioned in section 1, where necessary?  (Please provide evidence of any updates). | Choose an item. |
| **Which questions have been updated within section 1 of the application form?** |  |
| Section 2  **Safe Organisations** | Are there changes to the organisations involved in this proposal (additions or removals)? | Choose an item. |
| Are there any changes to funding? | Choose an item. |
| Has the Main Contact for the organisation changed? | Choose an item. |
| **Which questions have been updated within section 2 of the application form**: |  |
| Section 3  **Safe Proposals** | Is there a change in the duration of the proposal? | Choose an item. |
| Have the objectives of the application changed? | Choose an item. |
| Has the design of the proposal changed? | Choose an item. |
| Has the data flow changed? If so, please provide an updated diagram. | Choose an item. |
| Have the legal bases for processing data been updated under current data protection legislation? | Choose an item. |
| Has the DPIA been updated to reflect the changes requested here? | Choose an item. |
| Do these changes require any new, or affect any existing agreements or approvals? | Choose an item. |
| **Which questions have been updated within section 3 of the application form?** |  |
| Section 4  **Safe Data Subjects and Safe Data** | Have the proposal data subjects changed? (e.g. change in inclusion criteria, addition of matched controls?) | Choose an item. |
| Have any changes to data subjects included a vulnerable population? | Choose an item. |
| Has the requirement to contact any group of individuals changed? | Choose an item. |
| Has the time-period for data variables changed? | Choose an item. |
| Have any data variables been added? | Choose an item. |
| Have any data variables been removed? | Choose an item. |
| Are any of the added variables highly sensitive? | Choose an item. |
| Has the application be updated to reflect the establishment of Public Health Scotland and the change in data controller of many of the national datasets? | Choose an item. |
| Are there any changes to the requirement to access to NHSCR data? | Choose an item. |
| Are there any changes to the requirement to access the CHI database? | Choose an item. |
| **Which questions have been updated within section 4 of the application form?** |  |
| Section 5  **Safe Storage and Safe Outputs** | Are there any changes to the location in which the data is stored for analysis? | Choose an item. |
| Are there any changes in the location from which the researcher will access the data? | Choose an item. |
| Are there any changes to the security processes? | Choose an item. |
| Has the method for data transfer changed? | Choose an item. |
| Has the frequency of updates changed? | Choose an item. |
| Are there any changes to the publication or dissemination of results changed? | Choose an item. |
| Are there any changes to the retention time or retention location of the data? | Choose an item. |
| Are there any other changes not mentioned above? | Choose an item. |
| **Which questions have been updated within section 5 of the application form?** |  |

**Please signify below confirming that, other than the changes requested, all other information on the current approved version of the application has not changed.**

To be signified by the **APPLICANT**

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| Name (in Capitals): | Date: |