## Register Research Panel: project change request

Please ensure all required sections are completed and sent to [register.research@hfea.gov.uk](mailto:register.research@hfea.gov.uk). Where necessary, we will use details provided in this form to update research project information on our website.

1. Applicant and organisation information

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| Applicant information | |
| **Full name:** | Click or tap here to enter text. |
| **Job title:** | Click or tap here to enter text. |
| **Email address:** | Click or tap here to enter text. |
| **Telephone number:** | Click or tap here to enter text. |
| **Research group information** | |
| **List all collaborators who are approved to access to the dataset** (please include job title, email address, organisation name and address) | Click or tap here to enter text. |
| **Applicant’s organisation** | |
| **Organisation name:** | Click or tap here to enter text. |
| **Registered organisation address:** | Click or tap here to enter text. |
| **Address of premises where data will be accessed (if different than registered organisation address)** | Click or tap here to enter text. |

2. Project information and progress

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| Project information | | |
| **Project title:** | Click or tap here to enter text. | |
| **HFEA project number:** | Click or tap here to enter text. | |
| **Classification of dataset identifiability level:** | ☐ | Anonymous |
| ☐ | De-personalised |
| ☐ | Personally identifiable |
| **Current authorisation end date and any granted extensions:** | Click or tap here to enter text. | |
| **Please attach the following documents where applicable:** | * Original completed application form * Original HFEA authorisation form * Any authorisations from the HFEA for project extension | |
| **Progress on project thus far (including linkage progress, analysis completed, publications):** | Click or tap here to enter text. | |

3. Project change request

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| Project change request | | |
| **Please tick all boxes that match the reason(s) for the project change request:** | ☐ | Change in organisation or Chief Investigator |
| ☐ | New variable(s) requested for held dataset (this may incur a fee) |
| ☐ | Change in research aims |
| ☐ | Change in collaborators |
| ☐ | More recent data requested (this may incur a fee) |
| ☐ | Other (please specify): Click or tap here to enter text. |
| **Describe the change required to the project authorisation and the reason the change is needed:** | Click or tap here to enter text. | |
| **New project end date requested (if applicable):** | Click or tap here to enter text.  If the original application required ethics approval and/or a section 251 exemption, please complete section 4 and/or 5.  All project extension requests must complete section 6. | |

4. Section 251 exemption (if applicable)

This section is necessary for all project extensions or change in project aim requests using personally identifiable information for treatments prior to 2010.

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| Legal gateway (common law) | | |
| **Section 251 exemption** |  | Please select the organisation authorising the Section 251 exemption (this will be based on the country in which the research is taking place):  [**Confidentiality Advisory Group**](https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/confidentiality-advisory-group/) **(England and Wales)**  [**Public Benefit and Privacy Panel for Health**](https://www.informationgovernance.scot.nhs.uk/pbpphsc/) **(Scotland)**  [**Privacy Advisory Committee**](http://www.privacyadvisorycommittee.hscni.net/) **(Northern Ireland)**  **Reference number:** Click or tap here to enter text.  **Date of original approval:** Click or tap here to enter text.  **Date of any renewals:** Click or tap here to enter text.  Please enclose all letters documenting that Section 251 support has been granted and remains extant, sent to you by the authority approving the S251 exemption for this project.  **I have enclosed a copy of the S251 approval, approved amendments and any renewal letters.** |

5. Ethics approval for research (if applicable)

This section is mandatory for all project extensions or change in project aim requests where the request is to process de-personalised or personally identifiable data.

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| HRA Research Ethics Service approval | | |
| **Has ethics approval been obtained and from whom?** | [**Research Ethics Committee (REC)**](https://www.hra.nhs.uk/about-us/committees-and-services/res-and-recs/) **name:** Click or tap here to enter text. |
| **REC reference number:**Click or tap here to enter text.  **I have enclosed a copy of the final REC approval letter and letters documenting any REC-approved amendments** |

6. Organisation’s information governance, data management and security assurances (if applicable)

This section is mandatory for all project extensions. The applicant must ensure anyone who has access to the data understands their responsibilities for confidentiality, data protection and information security and is left in no doubt about the consequences of misconduct. The applicant must certify the following organisational information governance requirements have been met.

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| Information governance management | | | |
| * I certify that the individual(s) who will process the data is a/are *bona fide* worker(s) at the applicant’s organisation (Section 1). | | |  |
| * I certify that the individual(s) (including permanent, temporary and locums) who will process the data has/have been subject to personnel background checks and their employment contracts include compliance with organisational information governance standards. | | |  |
| * I certify that information governance awareness and mandatory training procedures are in place and the individual(s) who will process the data is/are appropriately trained. | | |  |
| * I certify that the data can be entrusted to the organisation, in the knowledge that the individual(s) processing the data will conscientiously discharge their obligations, including with regard to confidentiality of the data. | | |  |
| * I certify that adequate breach notification arrangements are in place. | | |  |
| * I certify that the data will only be used for the purposes described in this application and will thereafter be destroyed according to HFEA destruction requirements. | | |  |
| **Fair processing assurances** | | | |
| **DPA registration (code and register organisation name):** | [Provide the organisation code and name (as registered)]  Click or tap here to enter text. | | |
| **DPA registration expiration date:** | Click or tap here to enter text. | | |
| **Name and contact details for your organisation’s Data Protection Officer:** | Click or tap here to enter text. | | |
| **Security assurance (provide one of the following)** | | | |
| **Data Security and Protection Toolkit (DSP Toolkit)** |  | **Organisation code:**  Click or tap here to enter text.  **Toolkit score:**  Click or tap here to enter text.  **Version completed:**  Click or tap here to enter text. | |
| **ISO 27001** |  | (Enclose a copy of the certificate) | |
| **SLSP** |  | (Enclose a completed system level security policy for HFEA review) | |
| **Please provide a description of the security arrangements in place at the premises, particularly with respect to de-personalised or patient identifiable information:** | | | |
| Click or tap here to enter text. | | | |

7. Declaration

I certify that the information contained in this request form is true, correct and complete and understand that any misrepresentation may invalidate my application or lead to delay.

I understand that where HFEA employees make intellectual, scientific and professional contributions for this project, their input will be acknowledged through co-authorship or by recognition as non-author contributor on all publications produced from the data.

I understand that any publications using HFEA data must acknowledge the HFEA and cite the Register Research Panel in accordance with HFEA citation directions.

I understand that the HFEA may charge a fee to cover the costs of assembling and providing any updates to project datasets.

I understand that the HFEA may refuse a request because it does not have the capacity to complete the request (eg, the request will take longer than 10 working days to prepare and provide data, or the HFEA have already approved the maximum number of requests possible given available resources).

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| **Signature:** |  |
| **Date:** | Click or tap here to enter text. |