## Register Research Panel: project renewal request

This form is to be completed by a Chief Investigator to renew an existing authorisation granted for access to identifiable or de-personalised Register data. A completed renewal request form should be submitted to register.research@hfea.gov.uk within 90 days before or after the expiry of the authorisation. We strongly recommend submission of a completed form 90 days prior to the expiry of the most recent authorisation, as this gives time to both the research group and the HFEA to ensure that there is continued access to the research dataset while the application is being considered by the Panel.

Please ensure all sections in the form are completed before submission. Sections in this form marked by an asterisk (\*) are details specified by the 2010 Regulations.

Any amendments should be requested separately using the Register Research Project Change Request Form before or after your project authorisation is renewed.

Where necessary, details provided in this form will be used to update research project information on our website.

1. Applicant and organisation information

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| 1.1. Applicant information |
| **1.1.1. Full name\*:**  | Click or tap here to enter text. |
| **1.1.2. Job title:** | Click or tap here to enter text. |
| **1.1.3. Qualification\*:** | Please attach an updated CV for the Chief Investigator. This should be in summary form, with only information relevant to the current application, and must include relevant qualifications. The length should be a maximum of 2 pages of A4 and should be signed and dated before it is submitted. |
| **1.1.3. Email address\*:** | Click or tap here to enter text. |
| **1.1.4. Telephone number\*:** | Click or tap here to enter text. |
| **1.2. Research group information** |
| **1.2.1. List all collaborators who have access to the dataset:** (please include job title, email address, organisation name and address) | Click or tap here to enter text. |
| **1.2.2. Name, address and reference number(s) of current or anticipated funding body/bodies:** | Click or tap here to enter text. |
| **1.3. Applicant’s organisation** |
| **1.3.1. Organisation name:** | Click or tap here to enter text. |
| **1.3.2. Registered organisation address:** | Click or tap here to enter text. |
| **1.3.3. 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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| 2.1. Project information |
| **2.1.1. Project title:** | Click or tap here to enter text. |
| **2.1.2. HFEA project number:** | Click or tap here to enter text. |
| **2.1.3. Current authorisation end date and any granted project changes or renewals (please provide a summary of any project changes along with the date that these changes were approved by RRP):** | Click or tap here to enter text. |
| **2.1.4. Please attach the following documents where applicable:** | * Original completed application form
* Original HFEA authorisation form
* Original HFEA letter of approval
* Any authorisations from the HFEA for project changes or renewals
* Any letters of approval from the HFEA for project changes or renewals
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| **2.1.5. Provide a summary in lay terms to be published publicly by the HFEA (300 words max):** | Click or tap here to enter text. |
| **2.1.6. Provide a summary of all the aspects of this renewal application, if any, which are different to the information provided by you in your existing authorisation (for example, but not limited to: change in****organisation, change in collaborators, change in aims)** | Click or tap here to enter text. |
| **2.1.7. Progress on project thus far (including linkage progress, analysis completed, publications):** | Click or tap here to enter text. |
| **2.1.8. Explain why the processing of HFEA data is necessary for the purpose of the research project and the reasons why the information cannot be otherwise obtained\*:** | Click or tap here to enter text. |

3. Project renewal request

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| 3.1. Project renewal request |
| **3.1.1. New project end date requested:** | 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. |
| **3.1.2. Describe the reason the renewal is needed:** | Click or tap here to enter text. |

4. Section 251 exemption (if applicable)

Section 251 exemptions may be required by external organisations if HFEA data is part of a data linkage. It is not required by the HFEA to obtain data for research projects.

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| 4.1. Legal gateway (common law) |
| **4.1.1. Section 251 exemption** |[ ]  Please select the organisation authorising the Section 251 exemption:[ ]  [**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 the most recent letter documenting that you still have Section 251 support from the authority. [ ]  **I have enclosed a copy of the most recent S251 renewal letters.** |

5. Legal gateway (data protection)

As controllers under the General Data Protection Regulation (GDPR), data recipients that process personal data must establish and publish the lawful basis that they are relying on for processing personal data.

The GDPR sets out conditions for lawful processing of personal data (Article 6), and further conditions for processing special categories of personal data (Article 9). As personal data concerning health is one of these special categories, data recipients requesting to process such data must be able to demonstrate that they have met a condition in both Article 6 and Article 9 of the Regulation.

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| **5.1 Legal gateway (data protection)** |
| **5.1.1 Article 6 condition** |[ ]  Please detail and reference |
| **5.1.2 Article 9 condition** |[ ]  Please detail and reference |

6. Ethics approval for research

Mandatory for all research projects where the request is to process de-personalised or personally identifiable data.

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| 6.1. HRA Research Ethics Service approval |
| **6.1.1. Has ethics approval been obtained and from whom?** (the Research Ethics Committee must be recognised or established by or on behalf of the Health Research Authority, under the Care Act 2014) | [**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. Please enclose the most recent letter documenting that REC approval remains extant. [ ]  **I have enclosed a copy of the most recent REC approval or renewal letter**  |

7. Organisation’s information governance, data management and security assurances

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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| 7.1. Information governance management  |
| * (7.1.1.) 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).
 |[ ]
| * (7.1.2.) 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.
 |[ ]
| * (7.1.3.) I certify that information governance awareness and mandatory training procedures are in place and the individual(s) who will process the data has/have undertaken Information Governance training in the past 3 years.
 |[ ]
| * (7.1.4.) 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.
 |[ ]
| * (7.1.5.) I certify that adequate breach notification arrangements are in place.
 |[ ]
| * (7.1.6.) 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.
 |[ ]
| * (7.1.7.) I certify that no aspect of this project has been changed since the last RRP authorisation, including, but not limited to, the research aims, collaborators, and research establishment\*.
 |[ ]
| **7.2. Fair processing assurances** |
| **7.2.1. DPA registration (code and register organisation name):**  | [Provide the organisation code and name (as registered)]Click or tap here to enter text. |
| **7.2.2. DPA registration expiration date:** | Click or tap here to enter text. |
| **7.2.3. Name and contact details for your organisation’s Data Protection Officer:** | Click or tap here to enter text. |
| **7.3. Security assurance (provide one of the following)** |
| **7.3.1. 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. |
| **7.3.2. ISO 27001** |[ ]  (Enclose a copy of the certificate) |
| **7.3.3. SLSP** |[ ]  (Enclose a completed system level security policy for HFEA review) |
| **7.3.4. 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. |

8. 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.

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| **Signature** (typed signatures will not be accepted)**:** |  |
| **Date:** | Click or tap here to enter text. |