## Register Research Panel: Application form

Applicants are advised to read the supporting guidance before completing this form to fully understand what information should be submitted to the Register Research Panel (RRP). Details given will be used to review your application for data from us and will form part of the data sharing contract. If approved, we will publish details of the project on our website. Please complete all relevant fields and include all the required documentation.

The Human Fertilisation and Embryology (Disclosure of Information for Research Purposes) Regulations 2010 requires a written application which contains the mandatory information specified in this form by an Asterisk (\*), for your application to be submitted to the RRP. However, there is further supplementary information requested in this form which is both important and necessary for the RRP to reach a decision. Without this information it is highly likely that the Panel will adjourn until the information is provided, and if it is not provided within 56 days the RRP will refuse to grant authorisation of the research application.

Please contact [register.research@hfea.gov.uk](mailto:register.research@hfea.gov.uk) to discuss the feasibility of any planned project before completing this application and seeking any approvals from external bodies.

1. Applicant and organisation information

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| 1.1Applicant information. (This is the person designated as taking overall responsibility (Chief Investigator; CI) within the team of researchers for the design, conduct and reporting of the study. The named CI must be based in the United Kingdom | | |
| **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 Qualifications\*:** | Please attach a CV for the CI. 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. | |
| **1.1.4 List any conflicts of interest:** | Click or tap here to enter text. | |
| **1.1.5 Email address\*:** | Click or tap here to enter text. | |
| **1.1.6 Telephone number\*:** | Click or tap here to enter text. | |
| **1.2 Research group information** | | |
| **1.2.1 List all collaborators who will require access to the dataset:** (please include job title, email address, organisation name and organisation address) | Click or tap here to enter text. | |
| **1.2.2 Describe the planned involvement of trainees in the research and any specific training that will form part of your plan:** | Click or tap here to enter text. | |
| **1.2.3 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. | |
| **1.3.4 Organisation type:** | Academic institution (UK) |  |
| Commercial |  |
| Government agency |  |
| Other (please specify): Click or tap here to enter text. | |

2. Project information

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| 2.1 Project information (technical information) | |
| **2.1.1 Project title\*:** | Click or tap here to enter text. |
| **2.1.2 Links with previous studies/applications:** (if the application is part of a series of closely linked projects in a programme, give details of relevant previous or current applications, providing HFEA reference numbers where applicable): | Click or tap here to enter text. |
| **2.1.3 Describe the overall aim(s) and objectives of the project:** |  |
| **2.1.4 Explain the rationale for why this project is needed:** (provide sufficient details of past and current research which support the need for this work)**:** | Click or tap here to enter text. |
| **2.1.5 Provide a list of key references related to your project:** | Click or tap here to enter text. |
| **2.1.6 Explain the methods you will use in your project, such as how you will obtain the data, how you will analyse it and how you will draw conclusions\*: (**Where the project involves data linkage, the instruction of data processors, profiling and/or automated decision making, this must be described.) | Click or tap here to enter text. |
| **2.1.7 Describe any major challenges to the research plan and any steps to mitigate these challenges:** | Click or tap here to enter text. |
| **2.1.8 Provide a summary of the project using technical terms: (300 words max)** | Click or tap here to enter text. |
| **2.1.9 Explain how your research group and collaborators are well qualified to conduct this research:** | Click or tap here to enter text. |
| **2.2 Project information (lay terms)** | |
| **2.2.1 Provide a project title in lay terms:** | Click or tap here to enter text. |
| **2.2.2 Describe in lay terms the project aim(s):** | Click or tap here to enter text. |
| **2.2.3 Describe in lay terms the rationale for conducting the project:** | Click or tap here to enter text. |
| **2.2.4 Describe in lay terms how HFEA data will be used in the delivery of the project:** | Click or tap here to enter text. |
| **2.2.5 Provide a summary in lay terms to be published publicly by the HFEA (300 words max):** | Click or tap here to enter text. |
| **2.2.6 Describe how this research is in the public interest or in the interests of improving patient care:** | Click or tap here to enter text. |
| **2.2.7 Explain why the processing of HFEA data is necessary for the purposed of the research project and the reasons why the information cannot be otherwise obtained\*:** | Click or tap here to enter text. |
| **2.2.8 Explain the planned output of the research:** | Click or tap here to enter text. |
| **2.2.9 Estimated project start date\*:** | Click or tap here to enter text. |
| **2.2.10Estimated project duration (months)\*:** | Click or tap here to enter text. |

3. Data specification

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| 3.1 Data | | | | | | |
| **3.1.1 Classification of data requested\*** | | | | | | |
| The data is stripped of direct identifiers but contains fields which could be used to indirectly identify an individual through combinations of information, either by the people handling the data or by those who see published results (eg, ethnicity, sex, month and year of birth, admission dates, geographies or other personal characteristic). The data will be released with controls in line with the ICO Anonymisation Code of Practice. | | | | | De-personalised |  |
| The data request includes direct identifiers (eg, name, address, NHS number, date of birth), free text or is coded (pseudonymised), but would be directly identifiable in the hands of the data recipient (such as by hospital number or a cohort-specific identifier). To access identifiable data, an extant legal gateway must be presented (see Section 6). Data will be released with controls. | | | | | Personally identifiable |  |
| **3.1.2 Explain why a lower level of patient identifiability would be insufficient for your research purposes\*:** | Click or tap here to enter text. | | | | | |
| **3.1.3 Time period required for dataset\*:** (please note we can only supply data two calendar years in arear to ensure data validation is complete)**:** | Click or tap here to enter text. | | | | | |
| **3.1.4 Data specification\*:** | Please attach a completed data specification sheet. A template will be supplied by the HFEA for your use, to submit all data-fields required. Please ensure that all inclusion and exclusion criteria are indicated. Please also ensure all requested banding and/or pseudo-anonymisation are detailed in the data specification sheet. | | | | | |
| **3.1.5 Specify any data linkage requirements including the required data flows between the HFEA and the other organisations to be involved:** (Where there are multiple data linkages required, involving two or more data processors, the application must include a diagram to illustrate the proposed data flows. Please ensure each organisational boundary is clearly identified and where data is moving between organisations, those fields are also included) | | | | | | |
| Click or tap here to enter text. | | | | | | |
| **3.1.6 Data already held for this project/purpose:**  Please include the dataset name, classification of the data (eg, patient identifiable), the legal basis for processing, and the time period. | | Click or tap here to enter text. | | | | |
| **3.1.7 Please select and complete the most appropriate option for your project regarding the HFEA data retention period.** | |  | **The HFEA retaining records for my application and project for five years from the date of data transfer is satisfactory.** | | | |
|  | **I require the HFEA to retain records of my application and project for longer than five years from the date of data transfer.**  **Length of HFEA retention required (years):** Click or tap here to enter text.  **Reason for extended retention:** Click or tap here to enter text. | | | |
| **3.1.8 Does this project involve patient contact (directly or indirectly through a clinical team/service provider)? If yes, please give details.** | | Click or tap here to enter text.  **I have enclosed copies of the materials to be used by the project in the contact exercise.** | | | | |
| **3.1.9 Please confirm details of expected data transfer methods for the prepared dataset.** | |  | | **The HFEA standard secure data transfer file process.** | | |
|  | | **I require the HFEA to send the data file through another transfer system.**  **Details of the secure data transfer system to be used:** Click or tap here to enter text.  **Reason for this system to be used:** 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 duty of confidentiality) | | |
| **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 approval:** Click or tap here to enter text.  **Date of next renewal:** 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.**  Where an exemption is in place for a contact exercise, enclose all copies of patient, public or health service facing materials to be used.  **I have enclosed a copy of any materials used to inform the data subject that their data will be processed without consent (including web-based content).** |

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.  **I have enclosed a copy of the final REC approval letter and letters documenting any REC-approved amendments** |

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 is/are appropriately trained. | | |  |
| * (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. | | |  |
| **7.2 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 or more of 7.3.1/7.3.2/7.3.3, and 7.3.4 is mandatory)\*** | | | |
| **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)  **Certificate number:**  Click or tap here to enter text.  **Issue date:**  Click or tap here to enter text.  **Current expiry date:**  Click or tap here to enter text. | |
| **7.3.3 System level security policy (SLSP)** |  | (Enclose a completed system level security policy for HFEA review) | |
| **7.3.4 Please provide a description of the security arrangements in place, particularly with respect to de-personalised or patient identifiable information \*:** | Click or tap here to enter text. | | |
| **7.3.5 Please provide information on the data access and data storage methods which will be used to host the HFEA dataset,** **including encryption, password protection, multi-factor authentication, and description of how the HFEA data is processed from data transfer from HFEA up to data destruction (if a third party trusted research environment is being used please include details on how the provider meets UK GDPR and fulfils the requirement for UK only hosting):** | Click or tap here to enter text. | | |
| **7.3.6 Please specify whether users of the data will be permitted to access the dataset, from outside of the Research Establishment. If so please provide details of the security arrangements in place (e.g. home-working policy):** | Click or tap here to enter text. | | |

8. Declaration

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

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 will charge a fee to cover the costs of assembling and providing the dataset for projects and may charge a fee to cover associated legal costs.

I understand that the HFEA may refuse an application 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** (typed signatures will not be accepted)**:** |  |
| **Date:** | Click or tap here to enter text. |

9. Supporting document checklist

The below includes a list on the documents which you may be requested to submit alongside your application form. Some of these documents are referred to/requested directly in the application form, however others are intended to evidence your descriptions within the application. The specific documents required will differ between projects depending on multiple factors such as linkage with external datasets and use of third party data cloud storage. The list below is not comprehensive but should give an indication of the type of documents the Panel may require when considering your application. For additional guidance on the required documentation please contact [register.research@hfea.gov.uk](mailto:register.research@hfea.gov.uk).

**For all applications:**

Mandatory requirements:

**🞎** CV of Chief Investigator (max 2 pages)

**🞎** Data specification sheet

**🞎** REC approval letter – this can be provided after consideration of the project application by RRP, however the application for REC approval should be submitted prior to submission of this application form to the HFEA RRP.

If relevant:

**🞎** A copy of ISO 27001 certificate or System Level Security Policy

**🞎** Home working policy or relevant supporting document on data access from outside the Research Establishment

**🞎** Password policy or relevant supporting document

**🞎** A copy of the 251 approval letter

**🞎** Letter from the Caldicott Guardian in the Research Establishment

**Please tick the box(es) that applies:**

**🞎 Project that involves linkage with external data**

Mandatory requirements:

**🞎** Data flow diagram – including description of how data linkage will be managed and relevant annotations to describe how the HFEA data is processed, including how the data is managed from data transfer from HFEA up to data destruction and relationships between all people/organisations involved in processing the data.

**🞎** Information of the external data that will be linked to the HFEA data in Section 3.1.5 above and/or in a separate document - dataset name, level of identifiability of the data, data controller and list of variables in external dataset(s). This should contain list(s) of variables at each stage of data linkage including the list of variables in the final dataset the named researchers will have access to. The list can be included in additional tabs in the data specification sheet.

If relevant:

**🞎** Privacy notice or patient information leaflet if personal data are included in the external data, to demonstrate the data is collected lawfully by complying with the UK GDPR.

**🞎 Project that involves a third party (a person, public authority, agency or other body)**

This includes any bodies which touch the data in any way, including a research collaborator in an organisation outside the named research establishment, and a third party providing data storage or other data services.

Mandatory requirements:

**🞎** Information of the third party (name, registered address; ICO registration number, registered organisation name and expiration date; valid DSPT Toolkit, ISO 27001 certificate or SLSP)

If relevant:

**🞎** A copy of ISO 27001 certificate/SLSP to demonstrate data security of any third parties

**🞎** Fully executed data processing agreements/data sharing agreements from any third parties - this should align with UK GDPR (post Brexit) and with the requirements in the Human Fertilisation and Embryology (Disclosure of Information for Research Purposes) Regulations 2010

**🞎** List of staff members accessing the HFEA dataset in the third party organisation

**🞎** Home working policies of the third parties