

# UK Heart Failure with Preserved Ejection Fraction Registry (UK HFpEF)



## Collaboration and support policy

V1.0 08/07/2022



## 1 Purpose

The purpose of this document is to describe the process by which requests to collaborate with UK HFpEF, and requests to provide support for grant applications and such like, will be managed.

## 2 Examples of requests to collaborate and provide support

Based on our experience to date, it is envisaged that collaboration requests will broadly fit into one of the following categories:

1. Support for recruitment to other studies. To identify patients who are participating in UK HFpEF that fulfil the recruitment criteria for another study.
2. Proposed additional procedures/measurements. Investigators proposing additional procedures/measurements on participants in UK HFpEF.
3. Access to the UK HFpEF data dictionary. Investigators requesting access to the UK HFpEF data dictionary so that data collection for studies in development can align with UK HFpEF.
4. Linking data with other large cohort studies. Investigators leading other large cohort studies in heart failure or allied fields requesting to link data. In the UK, this may be via a common trusted research environment.
5. Access to data for specific analyses. Requests to use UK HFpEF data for specific analyses.
6. Access to samples. Requests to use stored UK HFpEF samples for analysis.

It is expected that requests for letters of support for grant or fellowship applications will be received in relation to the categories of work described above.

## 3 General ethos

In general, we will be supportive of legitimate research in HFpEF and allied fields, for the following reasons:

- To facilitate and support better understanding of HFpEF and improvements in its management.
- UK HFpEF is itself a collaborative endeavour.
- A key metric by which UK HFpEF will be judged, for example when applying for further funding, is the ability to support, facilitate and enable other research.
- Often other studies will facilitate recruitment to UK HFpEF.
- Often other studies will enrich the UK HFpEF dataset.
- Other studies may provide the opportunity to expand UK HFpEF analyses into larger populations, or validate findings from UK HFpEF analyses in external populations.
- Other studies may provide the opportunity to understand the relationship between HFpEF and other conditions.

That said, when making decisions regarding collaborations, it is important to recognise the hard work that goes into recruitment and data collection, and this should be acknowledged in the outputs.

## 4 Procedure

- Requests will be reviewed by the Executive Steering Committee during Committee meetings.
- The Committee will evaluate:
  - The quality of the proposal
  - How the proposal aligns with the aims of UK HFpEF
  - What is being expected of UK HFpEF
  - How the proposal will contribute to UK HFpEF
  - If there is overlap with other proposals
- It is expected that data collected as part of collaborative projects will be deposited in the UK HFpEF database. UK HFpEF data will not be shared until the data generated from the collaborative analysis (e.g., the results of sample analysis) have been deposited in the UK HFpEF database.
- Data cannot be submitted for consideration of publication without agreement from the UK HFpEF Executive Steering Committee.
- Acknowledgement of UK HFpEF/authorship on outputs from collaborative projects shall be considered as part of the review and shall be expected in line with the guidance below (Section 5).
- It will be mandated to collaborators that UK HFpEF is acknowledged (via acknowledgement/authorship as detailed in Section 5 below) in all outputs utilising/arising from any form of collaboration with UK HFpEF. Failure to do so will result in restriction on future access to UK HFpEF for the collaborator and all investigators at the institution where the collaborator is based.
- A decision will be provided promptly (2 - 4 weeks).
- A standard letter of support will be agreed in line with these points.
- To inform its decision making, the Committee shall ensure it is up to date with current and proposed heart failure research in general, and research allied fields. This will be facilitated by Committee members being part of BHF Clinical Research Collaborative cardiovascular society research groups (e.g., British Society for Heart Failure Research Group).

## 5 Acknowledgment and authorship

### 1. Support for recruitment to other studies

Supporting recruitment to other studies, such as therapeutics and diagnostics trials, is a key aim of UK HFpEF. Within the General conditions listed above, the Committee will generally look to support.

It is expected that the outputs from such studies will acknowledge UK HFpEF, but authorship will not generally be expected.

### 2. Proposed additional procedures/measurements

The Committee will consider whether studies proposing additional procedures/measurements on participants in UK HFpEF are better managed as a sub-study of UK HFpEF, in which case a UK HFpEF study amendment would be required, or a standalone study that links to UK HFpEF.

In return for access to UK HFpEF data, data from the additional procedures/measurements would be expected to be deposited in the UK HFpEF database, and access would not be granted until this has happened.

Authorship would generally be expected in line with the UK HFpEF Authorship Policy.

3. Access to the UK HFpEF data dictionary

Requests for access to the UK HFpEF data dictionary will generally be supported as part of developing collaborations.

It is expected that the outputs from such studies will acknowledge the use of the UK HFpEF data dictionary.

4. Linking data with other large cohort studies

Requests from large cohort studies in heart failure or allied fields to link data will be considered on a study by study basis, both in terms of the General conditions listed above, and to determine how the collaboration would work in practice.

The Committee will generally aim to collaborate.

UK-based cohort studies utilising the BHF Data Science Centre Trusted Research Environment represent a particular collaborative opportunity, and the Committee will generally look to work with such studies to align data and sample collection in order to facilitate combined analyses.

Authorship would generally be expected in line with the UK HFpEF Authorship Policy.

5. Access to data for specific analyses

Requests to use stored UK HFpEF data for specific analyses will be considered in line with the General conditions listed above.

Authorship would generally be expected in line with the UK HFpEF Authorship Policy.

6. Access to samples

Requests to use stored UK HFpEF samples for analysis will be considered in line with the General conditions listed above.

Authorship would generally be expected in line with the UK HFpEF Authorship Policy.

## **6 Governance**

Release of data will be covered by a Data Transfer Agreement and release of samples will be covered by a Material Transfer Agreement. These Agreements are legally binding documents that will regulate the use of data or samples to that determined by the Executive Steering Committee and ensure that standards are maintained.