**National Haemoglobinopathy Registry Data Sharing Policy**

**Introduction**

The National Haemoglobinopathy Register (NHR) is a database holding demographic, clinical care, and health outcome data on people with Sickle cell disease, Thalassaemia and other rare inherited anaemias. Data are entered onto a secure web-based platform by clinical care teams in all specialist Haemoglobinopathy centres across the UK. NHS England and NHS Improvement is the data controller of the NHR. More information, including Annual Data Reports, can be found at <https://nhr.mdsas.com/>

**NHR Steering Committee**

The NHR Steering Committee members and Terms of Reference are available on the NHR website. Its role is to provide advice, governance and on the strategic direction of the NHR for the registry development, in consultation with the NHSE Haemoglobinopathies Clinical Reference Group and Haemoglobinopathy community**.** The NHR steering group and NHR DARG are not decision-making bodies. As outlined in the NHR governance documentation, NHS England, as the custodian of the NHR is the decision-making body.

**Data Analysis and Research Group**.

The NHR Data Analysis and Research Group (DARG) is a sub-committee of the NHR Steering Committee. It is responsible for receiving and reviewing most requests for data held in the Registry. It assesses whether the purpose for the data request complies with UK data sharing laws, the governance requirements of the NHR steering group and whether it meets the NHR Data Sharing Criteria. Following review of the data request DARG will recommend that the request is approved, recommend approval is deferred as further information is needed, or recommend that the request is declined. Where the request is recommended to be declined the reason for this will be given.

In certain circumstances organisations, for example, other ‘executive agencies of the Department of Health and Social Care’ or ‘Arm’s Length Bodies,’ may contact NHSE directly regarding a request for data from the NHR. In those circumstances the same data access criteria and access request application forms will apply. Following assessment within NHSE if access is agreed this will be added to the ‘live’ log of approved NHR data requests, held on NHS England’s behalf by MDSAS Ltd.

**Purpose**

This policy is designed to ensure fair, transparent and ethical access to NHR data for high quality commissioning, service planning, research, service evaluation and audit use for the purpose of improving care, quality of life and clinical outcomes of people with Haemoglobinopathy disorders. Registry data requests are only granted if they:

* meet the NHR Data Sharing Criteria (see Appendix1)
* are recommended for approval following DARG, NHR Steering Group request or NHSE direct assessment processes
* have final approval by NHSE, (as the Data Controller of NHR data).

The purpose for using the NHR data must comply with relevant Data Protection Legislation, including the Data Protection Act 1998. 4 Version 1.0, 23 May 2018 and UK GDPR 2021.

Where the data is requested for research purposes, appropriate permission to access the data via the Health Research Authority (HRA) must be obtained.

**Scope**

• This policy applies to all parties requesting data with the exception of NHS England (NHSE), which is both the custodian of the NHR and the Data Controller of NHR data. NHSE is also the organisation accountable for Haemoglobinopathy services in England and has a statutory right to obtain data in order to fulfil this role.

• The policy is applicable to all data requests from third parties, with the exception of NHSE, or Haemoglobinopathy services accessing their own service data held in the Registry.

**Data Access Request Process**

**Submitting a request**

All requests must be submitted using the NHR Data Access Request Form available for download from <https://nhr.mdsas.com> , and emailed to [support@MDSAS.com](mailto:support@MDSAS.com). DARG will acknowledge receipt of the request. Requests will be submitted for review by the committee at monthly intervals.

**Quality control**

The designated Data Request leads will screen the request for missing or unclear information prior to it going out to the NHR DARG for evaluation. This includes whether the following information is present:

• The requestor has provided details of specific data items required and why

• The requestor has specified the cohort required and why

• The requestor has specified the data range required and why

• Whether the project has been granted funding support, and if so, where from

• The lead research team members are listed including their role and institution, it is expected that the team will include a healthcare professional with experience in haemoglobinopathies.

**Evaluation**

The NHR DARG will consider requests for data against a set of published criteria (see Appendix 1).

The NHR DARG does not perform a research peer review function; it is anticipated that this will be performed by the editorial/scientific committee involved in reviewing conference and journal submissions, prior to the publication of any research. It is expected that researchers will register individual Registry-research projects with their local Research and Development departments.

The NHR DARG committee does not evaluate the scientific validity of the research question, or dictate the research question, research team, collaborators, or analysis methodology. The UK Forum for haemoglobin disorders (UKFHD) Research Committee may provide advice and make suggestions regarding the research study proposal to support a more robust application prior to the application being submitted, but these are not binding and will not affect the recommendation of the request.

**Summary and decision-making**

Data requests will be shared with members of the NHR DARG who will provide a recommendation on the data request before or at the next scheduled meeting. The NHR DARG Chair will agree a written response, regarding the DARG’s decision will communicate this to the data Requestor.

If NHR DARG supports the data request this recommendation will then taken to the NHR Steering Committee for ratification. Following ratification of the Steering Group, this is passed to made to NHS England and NHS Improvement for approval of the data request.

The chair of the NHR DARG will report back on approved and rejected data requests to the NHR Steering Committee on a quarterly basis.

In certain circumstances organisations, for example, other ‘executive agencies of the Department of Health and Social Care’ or ‘Arm’s Length Bodies,’ may contact NHSE directly regarding a request for data from the NHR. In those circumstances, NHSE will communicate directly with the data requestors but will inform the NHR DARG of the outcome of the data request and ask MDSAS Ltd to add those approved to be added to the ‘live’ log.

**Turnaround time**

The NHR DARG and NHSE will endeavour to provide the requestor with a decision within eight weeks of receipt of an accepted completed data access request form. Data will be provided eight weeks after the original request as a minimum. The resources of the Registry team are finite, and requestors should plan ahead to allow the maximum possible time for processing data requests. In periods of increased workload for the team, this timeline may be subject to change however, the requester will be informed on any delays.

**Data sharing agreement**

Once approval has been given, the requestor(s) and the lead named requestor on the access request form will be asked to sign a data sharing agreement. Data will not be extracted until a signed copy of this agreement has been returned to NHSE.

**Steering Committee requests**

Where a member of the Steering Committee, NHR DARG or NHR is a member of the Research team, they must be named on the Data Request form. This member(s) will not be included in the evaluation process, and the final decision will be communicated as per the usual process for external requesters.

**Data Controller and Chair’s action**

NHSE will assess requests for aggregated data. The Chair of the NHR DARG may forward resubmission as a result of feedback from the NHR NARG that now clearly meets the requirements directly to NHSE for approval. Amendment to a request previously recommended by the NHR DARG and approved by NHSE may also be assessed by the chair and forward this directly to NHSE for approval. All decisions will be documented and reported back to the NHR DARG as part of the Data Request Overview standing agenda item and MDSAS Ltd will be asked to update the ‘live’ log as appropriate. Where the Chair is a member of the requesting research team, Chair’s action will not be taken, the requests will be dealt with directly by NHSE.

**Interpretation of data, publication and project completion**

Terms and conditions for the usage of data, their interpretation, intention to publish data and destruction of data will be covered in the Terms and Conditions of each Data Sharing Agreement (DSA). These will be set prior to signing the DSA and any release of data.

**Appendix 1**



**Criteria for Assessing Requests for data from the National Haemoglobinopathy Registry**

1. **Criteria for assessing data requests for NHR data for non-research purposes:**

Data requests must clearly set out the purpose for which the data requested will be used and these must have a recognised legal basis.

NHSE may specify certain terms and conditions in any data sharing agreement

1. **Criteria for assessing data requests for NHR data for research purposes:**

* Data requests must clearly set out in detail what the expected benefit of the research will be:

for people living with of affected by Sickle Cell Disease, Thalassaemia or other rare anaemias,

for the treatment and care of people living with or affected by of Sickle Cell Disease, Thalassaemia or other rare anaemias,

for the existing body of knowledge regarding Sickle Cell Disease, Thalassaemia or other rare anaemias,

* Personal identifiers will not be given to researchers unless they have appropriate ethics and NHS Health Research Authority approval (Confidentiality Approval Panel (CAG) S251 for Research
* Patient Identifiable data will not be shared with most organisations including commercial entities. In most instances they will receive reports created by NHSE using aggregated data
* Patient Individual-level data will not to be given to non-UK based entities. Any pseudonymised data will only be shared with countries outside UK which are on the UK GDPR ‘safe list.’
* Additional terms and conditions for data usage or analysis will be specified in the Data Sharing Agreement
* There will also be a number of technical criteria which must be met and these will be assessed as part of the data access request process. These will include: Data storage and data security arrangements (these must be fully described in the data access request and show that the requesting organisation has completed the NHSD DSP Toolkit, meets GDPR, data security and data protection legislation).