

## **International Rare Histiocytic Disorder Registry Information**

### **Introduction**

The International Rare Histiocytic Disorder Registry (IRHDR) is for patients with a non-Langerhans cell histiocytosis. This is a group of rare disorders of various types, including:

- 1) Diseases affecting the skin, such as juvenile xanthogranuloma (JXG) and reticulohistiocytoma (epithelioid histiocytoma).
- 2) Diseases mainly affecting the skin but also affecting other parts of the body, such as xanthoma disseminatum (XD) and multicentric reticulohistiocytosis (MRH).
- 3) Diseases affecting the whole body, such as systemic juvenile xanthogranuloma, Erdheim-Chester disease (ECD) and multi-system Rosai-Dorfman disease (RDD).
- 4) Malignant histiocytosis, such as Langerhans cell sarcoma and interdigitating dendritic cell sarcoma.

Since they are extremely rare, there is limited understanding of their causes and best treatment options. Patients with rare histiocytosis and their doctors and relatives frequently consult members of the Histiocyte Society regarding the best management of these disorders. Very often, no specific recommendation can be made owing to the lack of scientific studies describing the diseases or how to treat them.

The IRHDR has been set up to help with these issues, funded by the Histiocyte Society. It is being led by Dr Oussama Abla and his team at the Hospital for Sick Children, Toronto, Canada. The UKHR will submit data for patients with rare histiocytic disorders to the IRHDR using a secure online system called REDCap. REDCap is a secure and confidential way to collect information for medical research that is used all over the world (<https://www.project-redcap.org/>). The database is in English.

### **Aims of the Registry**

The IRHDR has been created to improve the consistency of diagnosis, to collect and analyse data to improve treatments, and to provide information for future clinical trials. Its objectives are:



- To collect medical, treatment, and follow up information on patients with rare histiocytic disorders, worldwide.
- To improve the scientific classification and understanding of rare histiocytic disorders to help pathologists make an accurate diagnosis by identifying distinguishing features and possible relationships between different diseases.
- To develop standard treatment protocols and to help patients to access clinical trials.

## **Information collected by the Registry**

Your or your child's year of birth, gender, and ethnicity are required because it is useful to know what group of patients are most often affected by a rare disease. For example young or old, male or female. The registry will also know that you or your child are a UK resident because we are submitting your data. Your participation is anonymous since there is almost no chance that you could be identified from this information. The information will also be treated confidentially and only released to researchers who want to make a contribution to understanding your or your child's disease. Although the fact that you or your child have a rare disorder is linked to your or your child's identity, data will only ever be published in a completely anonymous way as part of a cohort or group of patients rather than you or your child as an individual. Information about your illness needs to be as complete as possible. Most of this will come from your medical records, pathology reports and x-rays or scans. You may discuss this further with your doctor and let us know if there is anything that you do not wish to be disclosed.

## **Pathology samples**

Pathology slides made from your or your child's biopsy will be sent to a European pathology expert for review. This will be sent anonymously with only your or your child's registry ID number and the following information:

- Your or your child's diagnosis
- The site that the biopsy was taken
- A list of the material being sent.

The pathologist will perform additional tests on your samples and confirm that you or your child's diagnosis is made in the same way as for other patients around the world

## **Data Security Information**

The UK Histiocytosis Registry has a duty and responsibility for safeguarding your information and how it is used. We have reviewed the security of the International



UKHR IRHDR Info Version 1.2 1.3.19 IRAS 238319

Rare Histiocytic Disorder Registry database and are satisfied that it meets the appropriate standards. The Registry team headed by Dr. Abla uses the same REDCap Service at their hospital that we use to collect the data in the UK (you can find more information on this at <https://www.project-redcap.org/>). Details of the security measures are included at the end of this leaflet in a letter from the Director of Research Information Systems at the Hospital for Sick Children in Toronto.

## **Contact Details for the International Rare Histiocytic Disorder Registry Team**

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**Wayne Arnold,  
Director, Research I.T.**

To Whom It May Concern,

Below is an outline of the Research Information Technology (RIT) Research Electronic Data Capture (REDCap) Service at SickKids and the controls in place to ensure accessibility, security and privacy of our data.

**Physical Security**

All REDCap servers are located within the SickKids research data centre at the Peter Gilgan Centre For Research And Learning. Access to the building is monitored around the clock by on premises security staff. Access to the data centre is further controlled through a badging access system.

**Data Protection**

Backup is addressed through twice daily database dumps which are then protected through snapshots on a redundant (N+2) storage cluster. Disaster recovery is addressed through nightly backups to tape which are located on a separate floor and in a separate fire zone. Backups will also be stored offsite beginning in the second quarter of 2016.

**Availability**

The REDCap application and database servers reside on a multi-node VMware vSphere virtual cluster and data is housed on an N+2 storage array. Power redundancy is provide through an N+1 UPS which is itself backed up by dual diesel generators. In the second quarter of 2016 RIT will be able to bring up the REDCap service in a second data centre in a remote location in response to an outage in the research data centre.

All servers are monitored for uptime and availability 24/7. Support is provided by RIT server admins 8X5.

**Data Security**

The REDCap servers are monitored for security vulnerabilities and patches are applied on a schedule relating to the severity of the security alert. All access to the data and any changes is logged and auditable. All PHI containing projects reside within the SickKids firewall. Any projects that are hosted on an internet facing REDCap server are anonymized before going live. RIT monitors this process.