Data Access Policy for the Isle of Wight Cohorts*

***** **F0 and F1 Generations (generally referred to as the IW Birth Cohort or 1989/90 Study)**
F2 Generation (generally referred to as the 3rd Generation Study)

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Summary

The Isle of Wight birth cohort (IOWBC) is a longitudinal birth cohort study which enrolled mothers (F0) and infants (F1) who were born on the Isle of Wight between January 1, 1989 and February 28th 1990. During this period, 1536 children were born and these mothers/infant pairs were recruited into the study. Parent of 1456 agreed to have their infants included for assessments in a longitudinal study. Detailed information has been collected on these children using standardised questionnaires and clinical assessments at multiple time points. Additionally, data has been extracted from medical notes and linkage to routine information systems. Ethical approval from local/national ethics committees for the study has been obtained at birth of the child and subsequently at each assessment, performed at ages 1, 2, 4, 10, 18 and 26 years.

In 2010, a new study was started which has added a 3rd generation to the Isle of Wight Cohort. The 3rd Generation Study (F2) has recruited children whose mother and/or father are part of the F1 generation of the Isle of Wight Birth Cohort. Detailed information is collected on mothers during pregnancy at 12, 20 and 28 weeks using standardised questionnaires. Clinical assessments on the mother are completed post pregnancy. Fathers are seen for collection of data and clinical assessments once during the study. Cord blood and placenta samples are collected at birth, Guthrie cards in the first week of life and the infants are seen for questionnaires and clinical assessments at 3, 12, 24, 36 and 72 months of age.

These cohorts are collectively referred to as the Isle of Wight Cohorts (IOWC).

The purpose of this document is to describe the general processes and procedures involved in accessing data that has been collected previously.

1. Data Access Procedure

1.1. The Isle of Wight Cohorts (IOWC) resource

The process for accessing data is the same for all, regardless of research area, institution, location or funding source, provided the proposed research is **not** being carried out for personal or commercial gain.

The vast majority of data are available for immediate use on request and we do not consider the issue of potential overlap between research projects. The David Hide Asthma and Allergy Research Centre website provides an up to date list of publications using data from the Isle of Wight Cohorts. The website describes the resource and summarises the types of data available and is a useful place to start to give you a good idea as to whether IOWC would be potentially valuable in addressing your research question.

Website: http://www.allergyresearch.org.uk/studies/birth-cohort/

Access to the IOWC research data must be requested using the formal procedures described in this document and is subject to eligibility, the IOWC funder's terms and conditions and the Isle of Wight NHS Trust's policies and procedures.

1.2. Requesting access to data

Researchers are required to submit a written proposal to the Isle of Wight Cohort Data Access Group. Proposals should be emailed to: iownt.allergycentre@nhs.net.

The proposal must clearly state aims, hypotheses and describe the relevant exposure, outcome and confounders that will be considered, justifying the data you require. For multiple projects you must submit multiple proposals; one per project. We will aim to get a response within 15 working days of submission to inform you of the outcome and you will receive advice on the next stages including an exact costing for your project.

Proposals for access may be refused. Reasons for refusal include the following:

- Lack of availability of data/samples;
- Applicant not being a bona fide researcher;
- The proposed work, in the view of The Data Access Group, risks bringing the study into disrepute;
- The proposed work risks disclosure of identifiable information relating to any individual participant;
- In the view of The Data Access Group, there is a conflict of interest in relation to the proposed project;
- The proposed outputs of the project are outside the scope of the IOWC ethical approval, funders terms and conditions or the Isle of Wight NHS Trust's policies and procedures.

1.3. Charges for access to existing data

IOWC receives funding from the National Institutes of Health (US) and National Institute of Health Research (UK). These funding arrangements do not extend to providing support for individual projects and researchers will be expected to meet any and all additional costs for data access and provision.

Costs will be determined on a project-by-project basis and will reflect only the true costs to IOWC of providing the resources requested. Once a proposal has been agreed in principle, an accurate costing will be provided and these costs **are non-negotiable**.

Example costings for data requests are provided (see Appendix).

Data will **not** be provided until an invoice has been settled or a purchase order number is received by our finance department.

1.4. Management of the resource

IOWC Data Access Group (IOWC DAG): The Principal Investigator of IOWC is Professor Hasan Arshad. The IOWC Data Access Group members include Professors John Holloway, Wilfried Karmaus, Hongmei Zhang, Susan Ewart, Graham Roberts and Dr Ramesh Kurukulaaratchy and a cohort participant representative.

The terms of reference of the IOWC DAG are available on the website:

http://www.allergyresearch.org.uk/document/iw-cohort-data-access-request

1.5 Intellectual property

The Isle of Wight NHS Trust is the data controller for the IOWC resource: any data generated and the bio-samples collected. The IOWC DAG will act as the delegated representative of the data controller, as such any requests to access the data must be made through the Data Access Group.

2. Types of Data and Rules Governing Access

2.1. Directly collected data

A wide range of data is available through the resource. IOWC collects data directly through questionnaires and hands-on assessment clinics. Data is also derived from biological samples. The data dictionary (meta-data) includes detailed documentation on the data collected via questionnaires and clinics and some other subsets of data and is freely available for download from the website.

2.2. Linkage data

IOWC collect data using linkage to routine health, administrative and environmental records. The rules governing access for the linkage data might be different and access restricted as there may be additional conditions on usage and sharing of these data depending on the origin and participant consent status. Participants are free to withdraw from the study, or withdraw their consent from IOWC linking to and using their routine records for research purposes at any time. IOWC provide linked data on the understanding that these are routine records being used for a secondary (i.e. research) purpose. We make no guarantees regarding the accuracy of the data and have no means of verifying the data.

The host organisation of third party researchers is required to enter a legally binding contract (Data Transfer Agreement; DTA) with the Isle of Wight NHS Trust prior to receiving linked data. This contract commits the third party researcher/host organisation to maintaining the conditions set out in the data usage agreement between IOWC and the data owner. There may be additional cost associated with receiving linked data.

2.3. Genomic data

The details of (epi)genetic data available from the IOWBC participants and their children are available on our website. This includes;

- genome-wide single nucleotide polymorphisms (SNPs) data measured in blood in a subset of the IOW birth cohort (F1) and the 3rd generation cohort (F2);
- genome-wide DNA methylation data measured in blood in a subset of the F1 cohort at birth and at ages 10, 18, and 26 years;
- genome-wide RNAseq gene expression data measured in blood in a subset of the F1 cohort at ages 21 and 26 years and measured in cord blood collected at birth in a subset of the F2 cohort.

Accessing (epi)genetic data: Provision of (epi)genetic data requires a legally-binding agreement between the Isle of Wight NHS Trust and your host institution. This agreement is called a Data Transfer Agreement (DTA). These forms differ in terms of the signatories required, not the access level received. A project specific appendix must be agreed before the agreements are signed. Genotype data cannot be released until fully completed forms have been received and an assessment has been made to evaluate the risk of confidentiality. Copies of the DTA are included on the IOWC website to show the information that is required.

2.4. Potentially identifiable data

Some of the data collected could allow study participants to be identified. These include personal details such as postcode and "free text" that could contain identifying information. In line with the ethics approval conditions, the potentially identifying variables will not be shared. Complete dates of birth and other dates (e.g. clinic date or questionnaire completion date) are not usually made available; only season of birth and age of assessment can be released as standard.

3. Data Provision

3.1. The Data support process

When The Data Access Group has approved your project, our data coordinator will provide you with your dataset and assist you with any queries. They will not provide statistical, methodological or other support without prior agreement and the relevant costs being covered. Standard datasets are prepared within two weeks of all paperwork being completed and invoices being settled (or purchase numbers being provided); however some types of data may take longer.

3.2. Confidentiality form

Protecting the confidentiality of the study families is a primary concern of the IOWC Executive and the IOWC study team. This is a particular issue as IOWC is a locally based study that recruited children born within a defined geographical area. The principal investigator and any member of their team who will directly access the data will be requested to adhere to the clauses regarding confidentiality (please see our Confidentiality Form at: http://www.allergyresearch.org.uk/document/iw-cohort-data-access-request).

3.3. Other paperwork

If a project requires any linkage or genetics data, a Data Transfer Agreement must be completed. This requires the signature of a legal signatory in the PI's institute. We will ask investigators to sign IOW cohort Data User Agreement (DUA) form.

When a paper is submitted to the IOWC Data Access Group for approval, a papers checklist must be completed and sent to with the manuscript.

Papers Checklist can be found at: http://www.allergyresearch.org.uk/document/iw-cohort-data-access-request

3.4. Unique project identifiers

For each project a unique set of identifiers is created. If a principal investigator has more than one project, separate identifiers will be attached to each dataset relative to each project, thus datasets *cannot* be combined.

3.5. Secure data transfer

All data transferred electronically must be encrypted using AES-256 encryption (this can be achieved using compression tools such as WinZip or 7-Zip). Data users will be assigned a password for a project when the first dataset is provided.

3.6. Data access

Researchers must adhere to the IOWC access policy and confidentiality form at all times. Researchers must also comply with the terms of the IOWC DTA where applicable. Current and future access is at risk if any researcher is found to be breaking these rules. In particular, data must NOT be shared with any other researchers without going through the IOWC Data Access Group. Serious breaches of data access rules will be prosecuted to the full extent of the civic or criminal law.

3.7. Confidentiality/security Breaches

Any breaches of data security must be reported immediately to the IOWC Data Access Group.
Examples of data security breaches include (but are not limited to):

- Any unauthorised person (i.e. has not signed a data access agreement for the relevant data set) gaining access to IOWC data;
- Sharing IOWC data with unauthorised persons;
- Failing to ensure data are sufficiently encrypted during transport;
- Sharing login details that permit access to IOWC data with unauthorized persons.

3.8. Derived variables

Any derived variables, created as part of any research project, must be returned to the data coordinator with appropriate documentation; these will be incorporated into the main resource and made available to all researchers.

4. Publication

4.1. Peer reviewed papers

All full papers must be sent to the IOWBC Data Access Group (DAG) for approval (iownt.allergycentre@nhs.net) along with a completed paper checklist *prior* to journal submission. The Data Access Group will process all papers within two weeks of receipt. The DAG read all papers to check that confidentiality is protected and to ensure that the paper will not bring the study into disrepute. The DAG reserves the right to require that any paper that could potentially breach the confidentiality of any IOWC participant(s) be withheld from submission for publication. The DAG will work with the authors to

overcome such breaches. If the researcher submits such publications regardless, the DAG will attempt to prevent publication.

The DAG also provide advice and feedback to authors where we feel this may be helpful but their role is not to provide formal peer review: the applicants/authors are not duty bound to follow the advice provided. Under all circumstances the IOWC DAG reserve the right to submit letters or papers for publications in response to any paper to explain study procedures or to express a coherent scientific argument.

A checklist of requirements for IOWC papers along with some accompanying notes explaining these requirements and containing appropriate text to insert is available with the papers checklist. A completed checklist must be included with each paper submitted for approval. Researchers should let the DAG know when a paper is accepted and send through an electronic copy of the final published version.

IOWC DAG fully supports the NIH policies on open access. If your research is wholly or partly funded by the **NIH** you are required to make your research paper available via the PubMed Central repository, without embargo, as soon as possible and in any event within six months of the date of publication.

A list of publications arising from the study can be found on the study website (http://www.davidhideallergyresearch.co.uk)

4.2. Theses

We request that we are provided with an electronic copy of any theses that use IOWC data as soon as possible after a degree is awarded.

4.3. Reports and other publications

We request that we are provided with an electronic copy of any reports and other publications that use IOWC data as soon as possible.

4.4. Conference Proceedings

IOWC DAG do not need to see submissions to conferences.

4.5. Acknowledgment

All peer reviewed papers, thesis and other reports are required to acknowledge IOWC's grants and the team.

Acknowledgment for funding support:

Recruitment and initial assessment for the first 4 years of age was supported by the Isle of Wight Health Authority. The 10-year follow-up of this study was funded by the National Asthma Campaign, UK (Grant No 364) and the 18-year follow-up by the National Institute of Heart, lung and Blood Institute (NHLBI) at National Institutes of Health (NIH) (R01 HL082925-01). Further grants from the

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A sample text for acknowledgment of the IOW team is;

"We are extremely grateful to all the families who took part in this study, the midwives for their help in recruiting them, and the whole IOW team, which includes interviewers, laboratory technicians, clerical workers, research scientists, managers, receptionists and nurses".

5. Appendix: Charges to be applied for data requests

Type of data request	**Charge**
Standard access fee (including individual genetic variants) - Includes up to 50 variables Every additional 100 variables	£1500 £60
Genetics data Methylation GWAS (observed data) Gene Expression Associated phenotype data (see standard fee)	£500
Text data (to be coded by applicant) – up to 5 fields Each additional field thereafter	£150 £30
Amendment Form (additional data request) - admin cost - Includes up to 50 variables Every additional 100 variables	£370 £60