Ethical framework for DECIPHER

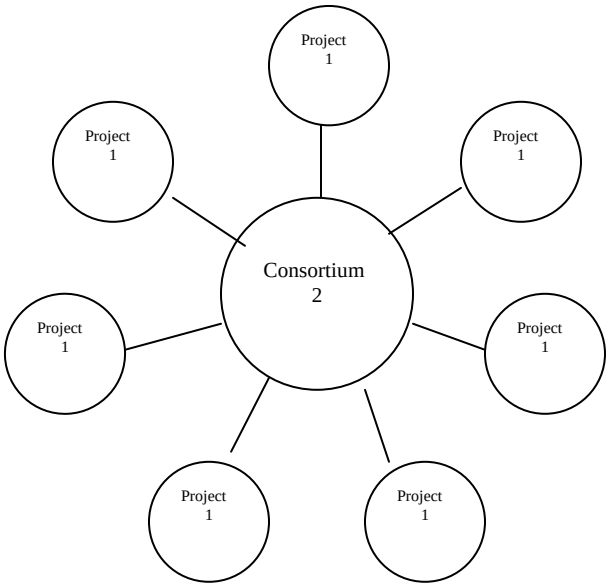
Subtle chromosomal imbalance can occur anywhere in the genome, but changes occurring at a particular locus are very rare. The DECIPHER project was conceived as a clinical and research tool to:

1. Aid in the interpretation of data from genomic microarray analysis eg. the differentiation between pathogenic and polymorphic copy number changes
2. Facilitate collaboration between clinical geneticists and cytogeneticists to accelerate progress in the delineation of new syndromes and of gene function.

Each centre using DECIPHER must consider whether they require approval from a research ethics committee in their institution/country and must abide by any laws relating to data protection/consent/confidentiality and professional ethics in their institution/country when entering data into DECIPHER. In the UK, DECIPHER has been approved by the **Eastern MREC 04/MRE05/50** and the project has also been notified to the Information Commissioner in accordance with the Data Protection Act.

Obtaining appropriate consent to enter phenotype data into DECIPHER is the responsibility of the submitting clinician. Information leaflets and sample forms drawn up for use in England & Wales may be downloaded from the homepage, but may need adaptation/translation to comply with regulations prevailing in your own institution/country. We are happy to make any leaflets/consent forms which have been adapted/translated for specific projects available via the DECIPHER homepage. Please contact: decipher@sanger.ac.uk

Structure of DECIPHER



Project (1)
In individual project domains, DECIPHER is used exclusively as a clinical tool to aid in the interpretation of a high resolution chromosome analysis eg. microarray analysis. The data is held in a linked anonymised form within the closed, password protected domain of an individual clinical genetics department which is affiliated to DECIPHER as a submitting centre. Data held within a project domain is only visible to nominated clinicians / cytogeneticists within that centre who have legitimate access to the data and are logged into DECIPHER

Consortium (2)
Fully anonymised data is released into DECIPHER-Ensembl view where it becomes visible to all projects to facilitate collaboration between clinical geneticists and cytogeneticists to accelerate progress in the delineation of new syndromes and of gene function.

The process
Guidelines for data entry and data sharing
Confidentiality and security
Great care has been taken in the design of DECIPHER to protect patient privacy. Broadly speaking, two levels of access are provided for. Parties issued a user name and password, which allows them to *log in* to the system, will have the highest level of access. They will be able to examine phenotype and array data, and identify which participating centre entered a particular phenotype. They will not be able to identify individual patients, except where it is a patient from their own clinic. Other members of the public will have low level access allowing them to *browse* phenotype and array data in DECIPHER-Ensembl view. At this level, patient information is anonymized.

Only trusted individuals in trusted centres will be issued with usernames and passwords to log into DECIPHER. This information should not be shared with persons at other participating centres, nor disclosed to persons not authorised to log into DECIPHER. DECIPHER is served over an encrypted SSL (secure socket layer) connection which is the industry standard for secure connections, similar to that used by banks and building societies to operate on-line banking systems.