Background

Currently, most of the University’s human brain imaging data is created on MR (Magnetic Resonance) scanners. This data is then processed, linked to non-imaging clinical and biological data, analysed and re-analysed, (often for years after the original collection), using many rapidly changing research tools.

Collecting this data is expensive and hence it is of high value. The university has extensive imaging assets (>100TB, ~£100 million), some of them very ‘rare’, generated and analysed over the past 16-20 years. Curating this data is difficult as it is the responsibility of multiple groups throughout the university which mostly rely on ‘human infrastructure’ for linking to non-imaging data, provenance support and documentation (Whyte A. et al., 2008, Digital Curation Centre - http://www.dcc.ac.uk/).

Due to the difficulties in curating this data, and our reliance on 'Human infrastructure', it is essential that researchers adhere to good data management practices.

Approach

Edinburgh Imaging and other organisational units support much of the Data Management and Planning process.

Our projects are best approached in two stages, and all data should be recorded at each step. It is essential to follow this division, even if there is a time line overlap between these stages. Stage 1, the Service Stage, often involves Person Identifiable Data (PID). Stage 2, the Analysis Stage, should not involve PID, unless specifically required and agreed in ethics and consent documents.

For each step in each stage all information should be kept for future reference. It is advisable to maintain an index and catalogue to this information.

1) Service Stage: Data collection of 'raw data'.
   a. Application. See figure 1 for a diagram of stage 1.a:
      i. Formulate idea for study
      ii. Ethics, R & D approval, IRAS, ERI, funding approval, cost implications, NHS co-/Sponsorship
      iii. Imaging approval
      iv. CRF Imaging Core application
      v. Formal approvals: Ethics/R&D/Sponsor & Imaging CMT
      vi. Service Level Agreement (SLA)
   b. Specify Principal Investigators (PI):
      i. Specify Delegation list - tasks to be done, and individuals/position names to delegate tasks to (as much as is known, maintain and update when available).
      ii. Consider any essential training requirements; identify Standard Operating Procedures (SOPs), Good Clinical Practice (GCP) etc. Record these in individual’s Training Records.
      iii. On-line Data Management training http://datalib.edina.ac.uk/mantra/
iv. Apply for relevant Research Passports, and honorary NHS contracts.

c. Now read the university Data Management Policy:
   i. This policy for managing research data was approved by the University Court on 16 May, 2011. It is an aspirational policy: [http://www.ed.ac.uk/schools-departments/information-services/about/policies-and-regulations/research-data-policy](http://www.ed.ac.uk/schools-departments/information-services/about/policies-and-regulations/research-data-policy).

d. Complete the Data Management Plan (DMP) for your sponsor (e.g. MRC), or DCC DMP Online, (see the University of Edinburgh defaults):
   i. [http://dmponline.dcc.ac.uk/projects](http://dmponline.dcc.ac.uk/projects)
      1. Data Capture: what data will be collected, imaging/non-imaging?
      2. What data will be generated or reused in this research? Outline the volume, type, format etc.
      3. How much data will be generated?
      4. How will the data be documented to ensure it can be understood?
      5. Where will the data be stored and backed-up?
      6. Integrity: How will you assure the quality of your data?
      7. Confidentiality, PID and IPR: How will you manage any ethical and IPR issues?
      8. How will the data be preserved: Retention & Preservation?
      9. Sharing & Publication: Which data will be shared and how?
   ii. resources: [http://www.dcc.ac.uk/resources/how-guides/develop-data-plan](http://www.dcc.ac.uk/resources/how-guides/develop-data-plan)

e. Make sure that consent is given and carefully recorded for:
   i. Imaging.
   ii. Other instruments (e.g. cognitive tests, blood pressure measurements)
   iii. Data linking, Use and Reuse.

f. Data linking & Quality control.

g. De-identification, IT/data security, confidentiality of Person Identifiable Data (PID).

h. Are other sites/ departments/ 3rd parties involved? Does the data need to be transferred somewhere else? Is all or part of the data collected off-site, e.g. home visits?
   i. Does this data feedback to patient care in any way?

j. Review with Data Management team.

2) Analysis Stage: Documentation of processing, pipelines, results, publishing and sharing.
   b. Use University of Edinburgh - Versioning services, for code, documents, and wikis.
   c. Declare and use standard widely used data types, e.g. PDF, txt, csv.
   d. Standardised provenance templates (e.g. [http://www.sbirc.ed.ac.uk/documents/templateREADME.pdf](http://www.sbirc.ed.ac.uk/documents/templateREADME.pdf)).

   e. Plan your projects area, folder structures, and naming conventions in advance.
   f. Understand your risks, how does your plan affect data integrity, storage, backup?
   g. Plan for registration, depositing and retention of research data assets, sharing and publication, e.g. [http://www.ed.ac.uk/schools-departments/information-services/research-support/data-management/data-sharing](http://www.ed.ac.uk/schools-departments/information-services/research-support/data-management/data-sharing)

   http://www.ed.ac.uk/schools-departments/information-services/research-support/data-management/data-storage

   h. Check data sharing policies and data use agreements if necessary, e.g. [http://www.mrc.ac.uk/research/research-policy-ethics/data-sharing/policy/](http://www.mrc.ac.uk/research/research-policy-ethics/data-sharing/policy/)

   i. Review with Data Management team.
Acknowledgements
Elizabeth McDowell, Julian Sparrow, WTCRF & CRIC

References

Investigator formulates idea for study

Investigator starts to complete IRAS [link to IRAS site]

Investigator contacts ACCORD office to discuss Sponsorship, R+D, Ethics and grant application details

Investigator completes application for grant funding as required including relevant Imaging collaborators (ERI input if required)

Idea developed and cost implications considered with Imaging core scientific input [link to Edinburgh imaging]

Ongoing discussion on study design with Imaging Scientific Contact

Sponsorship in principle letter produced by ACCORD
NHS Sponsorship OR Co-Sponsorship (University/NHS)

Ethics and R&D approval required via completion and submission of relevant documents using IRAS

Imaging management can review and feedback on initial enquiry at Scientific Project meeting

Completion of online CRF Imaging Core application ([link] forms
Imaging Management team review relevant parts of Ethics (e.g. SSI form)
Copies of Locked Ethics form, Patient Information Sheet and Consent form sent to Imaging Core

Formal Application to Ethics/ R&D/Sponsor

Formal Approval from Ethics /R&D/Sponsor

Formal approval by Imaging Project meeting

Service Level Agreement (SLA) sent to Investigator for signature

STUDY COMMENCES subject to all appropriate documents being received by Imaging

Figure 1, Imaging Core CRF application process 2015.