IMPARTS Research Governance Summary January 2016

By generating a systematically collected database of consecutive patients to medical clinics, IMPARTS provides considerable scope for research. IMPARTS welcomes applications to utilise data captured through routine screening for research projects. This document summarises the research governance framework that applies to all research involving IMPARTS data.

1.1 Data ownership

Data collected via the IMPARTS process becomes part of the electronic patient record and is owned by the NHS trust where screening took place e.g. KCH/GSTT.

1.2 Ethical approval

Ethical approval has been granted for use of IMPARTS data for research purposes. This approval is conditional upon:

- *The investigator having an honorary or substantive contract with King's College Hospital NHS Foundation Trust or Guy's and St Thomas' NHS Foundation Trust.* Applicants are therefore required to adhere to Trust policies regarding confidentiality and data protection.

- *A Research Application Form being approved by the IMPARTS Research Database Oversight Committee.* This committee is responsible for overseeing and monitoring use of IMPARTS data for research. It is chaired by a patient and includes senior KHP clinicians and researchers and a representative of the KHP Caldicott Guardian Committee. The Committee will review whether the submitted application is (i) feasible, (ii) ethical; (iii) has demonstrable research and clinical importance, (iv) will not unduly compromise patient confidentiality.

- *Exclusion of personal identifiable information (PII).* Researchers will be granted access to de-identified datasets comprising structured fields from the IMPARTS database, the Electronic Patient Record, or one of the hospital specialty systems. Researchers may apply to the Research Database Oversight Committee for permission to de-anonymise patient data in order to recruit research participants or to extract clinical data to which they have routine access. This is conditional upon the applicant (i) having an honorary or substantive contract with King's College Hospital NHS Foundation Trust or Guy's and St Thomas' NHS Foundation Trust, (ii) being employed by one of the organisations forming King's Health Partners (KCH/GSTT/SLAM/KCL), (iii) having document evidence of an enhanced CRB check, (iv) having existing permission to access patient health records, (v) having received REC approval for the proposed research. **De-anonymisation of patient data will only be possible where patients have given prior consent to be contacted by a researcher.**

- The researcher signing a Research Data Transfer and Confidentiality Agreement prior to release of the dataset.

1.3 Procedure for accessing pseudonymised IMPARTS datasets at KCH

1. Download a Research Application Form from the IMPARTS website: http://www.kcl.ac.uk/iop/depts/pm/research/imparts/Research.aspx
2. Complete the application form and send to a member the IMPARTS team, who will submit your application to the Research Oversight Committee. In the application form you must state the rationale for your analysis and the variables you require from either the IMPARTS database, the Electronic Patient Record, or one of the hospital specialty systems.
3. A member of the IMPARTS team will inform you when the Research Oversight Committee has reviewed your application.
4. If your application is not approved, you may be invited to submit a revised proposal.
5. The research database will be compiled by the IMPARTS Database Administrator. All patient identifiable information will be removed. Hospital Number will be replaced with a unique study pseudonym, and date of birth, postcode and ethnic category will be truncated in accordance with the IMPARTS Data Security Model (see the IMPARTS website for further details).
6. The table linking study pseudonym with the Hospital number will be held behind the KCH firewall on a secure server, separate from the KCH Research Data Store or any IMPARTS datasets.
7. A member of the IMPARTS team will send you a Research Data Transfer and Confidentiality Agreement, which must be signed prior to release of the research dataset.
8. Upon receipt of the signed Agreement, you will be given an excel spreadsheet comprising your pseudonymised research dataset.
9. Access to IMPARTS research datasets will be granted for one year only and will be subject to review. Researchers may be asked to report to the Research Oversight Committee at any point during their project's lifespan, and permission to use the dataset may be withdrawn, with justification, by the committee at any point.

1.4 Reporting policy

There is an expectation that researchers using IMPARTS data will provide the IMPARTS team and oversight committee with at least study report at the end of the study, copies of any abstracts written (including student dissertations). Copies of these will be published on our website unless you stipulate a reason to exclude your report from the website, for example, unpublished data

1.5 Publication policy

There is an expectation that researchers using IMPARTS data will recognise the contribution of the IMPARTS team through academic collaboration. At least one member of the IMPARTS core team should be listed as an author on papers arising from IMPARTS data or research infrastructure.

1.6 Acknowledgements

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