## Version History

<table>
<thead>
<tr>
<th>Date</th>
<th>Version Number</th>
<th>Description</th>
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<tbody>
<tr>
<td>15/01/2013</td>
<td>1.0</td>
<td>Document is devised to provide guidance and clarity to users.</td>
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</tbody>
</table>
Organisation

ResearchOne was developed by TPP in collaboration with the University of Leeds and the UK Government’s Technology Strategy Board via a Knowledge Transfer Partnership. The organisation operates as a not-for-profit enterprise.

Summary

ResearchOne is a pseudonymised research database consisting of data derived from the TPP SystmOne clinical database. The data is drawn from a variety of health and care settings across England, including both primary and secondary care providers. For example, General Practice, Child Health, Community Health, Palliative Hospital, Out-Of-Hours, A&É and Acute Hospital can all contribute to the research data set. In order for the data controlled by a health and care provider to be included in the ResearchOne database, the provider must opt-in to allow their data to be used; individual patients also have the opportunity to opt-out of supplying their de-identified data to the database.

ResearchOne has the potential to be one of the largest clinical research databases in the world. The data is of exceptionally high quality and offers a unique opportunity for clinical and healthcare research on a comprehensive data set, drawn from a single data source. Frequent checks are in place to ensure data quality, including comparisons with aggregated national data sources, and to ensure geographic and demographic representation.

The database is used to develop intelligent diagnostic risk algorithms, to produce enhanced decision support systems, to help stratify “at risk” patients, to assist in public health surveillance and to drive future clinical research.

The close links with TPP SystmOne allow for a dynamic research dataset - the database is updated on a weekly basis in order to ensure researchers have the most up-to-date information. Utilising the frequent SystmOne software releases also allows for new types of data to be recorded and gathered quickly. It also allows new tools to be built into the system and their impact on outcomes assessed rapidly and accurately.

Data security is of paramount importance and we have exceptionally high security protocols. A corporate level security policy and a system level security policy have been fully implemented and a risk assessment process is carried out annually. All protocols are compliant with, and driven by, the NHS security standards BS7799/ISO 27002. All database policies and research work are guided by the fundamental need for patient, clinician and provider confidentiality, as given in the NHS Confidentiality Code of Practice.

The database has received full ethical approval from the Research Ethics Committee and the National Information Governance Board.

All policy and management decisions are set by the ResearchOne Database Committee. The committee consists of representatives from all the key stakeholders in the project including, for example, patients, healthcare providers, academics, ethics, governance and data management experts, and TPP staff members. This is complemented by the ResearchOne Project Committee whose responsibility is to assess all proposed research projects to ensure that high-quality, high-impact research is carried out and that assurance of confidentiality remains paramount.
System Overview

Since the introduction of information technology into clinical environments in the 1980s the majority of general practices have adopted electronic clinical information systems and their use across other healthcare provider settings is constantly increasing. As electronic records have become more prevalent throughout the health and care estate there have been new opportunities for clinical and social research to take place on purpose-built clinical databases. The increased quality of diagnostic coding in electronic patient records has led to more powerful, accurate research being undertaken with increasingly important outcomes. For example, recent results have helped develop risk stratification tools and informed the decision support models used in many areas of healthcare. Clinical research databases have also revolutionised the potential of longitudinal studies that do not depend upon long-term contact with patients but rather consent to track patient records.

TPP SystmOne is a clinical system with modules for many different healthcare providers including General Practice, Child Health, Community Health, Prison, Out-Of-Hours, A&E and Acute Hospital. SystmOne fully supports the NHS vision for a “one patient, one record” model of healthcare. Professionals can access a single source of information, detailing a patient’s contact with the health service across a lifetime. SystmOne is centrally-hosted, fully accredited to NHS CfH hosting standards, and has a full disaster recovery solution implemented.

SystmOne is among the largest clinical databases in the world and contains the electronic records of more than 26 million patients. Of these, 60% have full, active records from General Practice and there are over 6 million patients registered at SystmOne Child Health. There are currently over 120,000 users of the system across more than 2000 GP practices, 50 Child Health units and 1800 Community units. SystmOne is also used across secondary care with the Acute Hospital, A&E and Clinical Record Viewer modules in use across many trusts throughout the UK.

ResearchOne Overview

ResearchOne is a clinical research database created from the electronic patient records held on TPP SystmOne. An overview of the database and its policies is given below:

- ResearchOne has been fully accredited by the Research Ethics Committee and the National Information Governance Board.
- Data is only extracted into ResearchOne from consenting health and care providers and only from patient records where explicit dissent has not been recorded.
- All data held on ResearchOne has been de-identified and is stored pseudonymously. For example, there are no strong identifiers (such as NHS Number), no names, no narrative data, no full postcodes and no full dates of birth or death.
- No data is stored on the database if the record contains sufficiently rare data (such as a coded clinical entry for an unusual disease) that identifiability is risked.
- The ResearchOne database resides in a secure data centre in the UK, hosted to the same CfH-accredited standards as SystmOne and subject to the same security protocols.
- As SystmOne is centrally-hosted, no physical data transfer is required in order to update ResearchOne, removing an inherent security risk from other research database models.
- The central nature of the system allows both providers and TPP to accurately record, audit and monitor the consent status for research.
The database is updated on a weekly basis so that the research data is up-to-date and so that any changes in the consent status of providers and patients are actioned within seven days.

The database is subject to periodic checks to maintain data quality and to ensure that the data set is representative of the population as a whole.

As data is recorded across care settings on SystmOne, ResearchOne contains rich research records without the need for external data linkage and with improved linkage accuracy.

Data is recorded from social, primary and secondary care sources, allowing almost real-time research to be carried out at this important boundary.

Ethics & Governance Approval

ResearchOne has been reviewed by the Research Ethics Committee and granted ethical approval. This favourable opinion is given for a 5 year period starting from October 2012. The review was carried out by the NRES Committee North East - Newcastle and North Tyneside 1 with REC reference 11/NE/0184.

The approval process included full consultation with the National Information Governance Board Ethics and Confidentiality Committee (ECC). Following consideration of the ECC advice, the Secretary of State determined the application did not require a recommendation of support; no Section 251 approval is required as the data held on ResearchOne is appropriately removed of identifiers (de-identified).

Any substantial amendments to database protocol must be approved by the REC before implementation via the NRES Notice of Substantial Amendment.

Further details of the ethical and governance and approval, along with any substantial amendments, are available upon request.

Benefits

Health and care units consenting to ResearchOne are contributing to a clinical research database with the potential to be the largest in the world. They are facilitating high-quality, ethical, clinical research in the UK, which is of benefit across the healthcare estate. Results of all research are submitted to peer-reviewed journals, presented at international conferences and summarised on the ResearchOne website. Any risk stratification algorithms and decision support tools created are published under an open-source framework and built back into SystmOne in order to enable all users to benefit from this research.

Using this iterative feedback loop between research data and the clinical system allows for the evolution of increasingly accurate tools for use by clinicians across the UK, bringing benefits to both users and patients. The benefits may both enhance patient care at a unit and improve their efficiency in delivering effective health care. Contributing units are given the opportunity to be pilot sites for any such projects and to be involved in their development.

ResearchOne also has links into public health surveillance programmes, which can be used, for example, to track the pandemic behaviour of disease. This is of clear benefit to the Department of Health nationally and an important secondary use of clinical data.
Committees

ResearchOne is overseen and governed by 2 committees, the ResearchOne Database Committee (RDC) and the ResearchOne Project Committee (RPC).

ResearchOne Project Committee

The RPC is charged with maintaining the quality and impact of all research undertaken using the data held on ResearchOne; of particular consideration is the value of any research to the patient, to the NHS and to public health.

The RPC assess each proposal from a scientific and confidentiality viewpoint, assessing any risks posed and referring any committee disputes to the RDC for advice and guidance. In the extremely unlikely event that certain combinations of the data stored on the research database might compromise patient or provider confidentiality, the RPC are obliged to prohibit access.

Membership includes representatives with a strong background in healthcare, informatics and clinical research. The committee bring a wealth of experience to the project, and includes internationally recognised academic researchers; such expertise also enables the committee to assist researchers in overcoming technical or academic issues.

Members of the following organisations are currently present on the RPC:

- Royal College of General Practitioners
- Public Health Observatories
- Yorkshire Centre for Health Informatics, University of Leeds
- School of Computing, University of Leeds
- Leeds Teaching Hospitals NHS Trust
- TPP clinical staff team

ResearchOne Database Committee

The RDC represents patients, healthcare providers, academics, researchers, ethics committees and governance experts. The committee oversees all database operations, including database access by research staff. The RDC are responsible for continually assessing risk, confidentiality and security details, granting approval for new internal research staff, authorising data linkage to external sources, resolving any research proposal issues from the RPC, overseeing the direction of all research undertaken, as well as auditing all database and research activities.

Current members have experience of the following:

- Patients
- SystmOne users
- ResearchOne staff members
- TPP staff members
- SystmOne National User Group
- Academic researchers
- Research Ethics Committee
- Chair of the RPC
The research projects we aim to support are those which drive improvements in healthcare understanding and its delivery. Amongst the current research goals are:

- The development of intelligent diagnostic risk prediction and stratification algorithms.
- The design of new decision support tools for use in clinical practice.
- Investigation into the use of the data for public health surveillance.
- Innovative prediction algorithms at the boundary of primary and secondary care.
- Validation of existing medical algorithms and knowledge derived from other data sets (such as QResearch and CPRD).
- Driving and informing new clinical trials and research using retrospective analysis on existing data.

A list of all research projects which have utilised ResearchOne is fully audited and is available on the organisation website. An annual report is provided to the Research Ethics Committee listing all projects for which data has been released in the previous year and ad-hoc requests from the committee are accepted at any time.

Both internal and external researchers must submit applications for new projects to the RPC for approval and accreditation; the RPC must review the proposal in terms of its quality, impact and confidentiality aspects. The project’s principal investigator must submit the application and include the list of data items to be accessed, a research hypothesis and an overview of the potential outcomes. A panel of RPC representatives then assess the project. If there is complete agreement from the panel on whether the project should be approved or rejected, then the principal investigator and the RDC are informed of the outcome and the details are centrally audited. If there is any disagreement, then this is passed to RDC or the Research Ethics Committee for further advice.

Once a project has been approved, time-scales and an agreed plan are put in place for the electronic transfer and receipt of an encrypted minimal data extract from ResearchOne to the project team. This is discussed further in later sections of this document.

Consent

All English non-prison units using SystmOne are invited to contribute data for research analysis. In order for any pseudonymised data to be included in the ResearchOne database, the data controllers for health and care providers on SystmOne must decide to opt-in. This is done via a standard organisation preference within the clinical system. Documentation on how to set this preference is distributed to all appropriate SystmOne units and is available on the ResearchOne website. The information includes contact details for requesting additional information from TPP; providers can speak to the ResearchOne data controller directly with any queries. Note that there is high-contrast functionality and JAWS screen reading technology embedded in SystmOne to aid the visually impaired when assessing this proposal. Any requests for translation of the information into languages other than English should be made directly to the ResearchOne Support Team – the contact details are available at the end of this document.
Providers can choose to opt-in or opt-out at any time by changing this consent status; any status change will be reflected within 7 days at the next database update.

We have also included a patient opt-out mechanism into ResearchOne should an individual wish to dissent from their de-identified data been held for research purposes. An action is available for all SystmOne users (who provide data to ResearchOne) which allows this dissent to be easily recorded as a miscellaneous flag on the patient record. Should the patient change their mind, this flag can be marked in error to remove the dissent status. Again any changes to this patient status will be reflected within 7 days at the next database update.

As with other large databases derived pseudonymously from patient records (for example, CPRD or QResearch) it is not practical to seek consent from individual patients due to the number of records involved. Units who have direct contact with patients are provided with posters to display in order that patients are aware that their data is to be used pseudonymously for research purposes. Some SystmOne units do not have direct contact with patients but deal with large numbers of records for administrative purposes (for example, Child Health). It is again unfeasible for consent to be gained from individual patients in this case.

While consent for pseudonymous, de-identified data is not a legal or necessary requirement of the National Information Governance Board Ethics & Confidentiality Committee, every practicable effort is made to inform the patients and public in general about ResearchOne and an opt-out mechanism has been built into the system.

**Confidentiality**

**Pseudonymisation**

The data held on ResearchOne is all pseudonymised. No strong patient identifiers, such as NHS number, hospital number or master patient index identifier, are held on the database at all. Similarly no provider identifiers, such as Organisation Data Service (ODS) national codes, are held.

The data contains no names, titles, full postcodes, exact dates of birth, exact dates of death, or clinical / administrative reference numbers (such as Choose & Book UBRNs or spell identifiers). Postcodes are stored at sector level (e.g. LS18) and dates of birth / death with the month and year only. No clinical narrative or free text will be stored on the database to avoid any potential compromise in patient confidentiality. The only exception is the inclusion of textual drug dosage information; this has been approved by the Research Ethics Committee.

**k-Anonymity**

There is an increased risk of patient identifiability for any rare data items or combination of items (for example, a coded entry for a very unusual disease). For this reason no clinical data is stored on ResearchOne if there are fewer than 5 entries with the same value. For example, if a research record has a Read-coded diagnostic entry present for which fewer than 5 records contain the same code, then the entire record is automatically removed from the database before any researcher has access to it. This is known as k-anonymity with the anonymity level set to k=5.

**Record identifiers**
A unique research identifier is automatically assigned to each electronic research record to allow suitable intra-record data item linkage. This is created automatically during database build/update from a hard patient identifier using industry standard encryption techniques (for example, SHA-256). The process of creating this identifier is irreversible; ResearchOne staff members and researchers have no way of directly identifying patients or providers from these identifiers. Should access ever be required then a formal application to the Research Database Committee, the Research Ethics Committee and the National Information Governance Board is required. This is discussed in a later section.

Census/Demographic Indicators

ResearchOne contains important census and demographic indicators in order to facilitate quality health and social care research. For example, the indices of multiple deprivation are recorded on research records (as long as k-anonymity is passed). In order to accurately record such values, these are calculated from the full data item before it is degraded to a non-identifiable level. For example, in order to calculate deprivation scores, full postcodes are used, before the postcode is reduced to sector level for storage on the database. In order to maintain confidentiality, this is an entirely automated procedure; there is no need for any person to process or view this data and indeed access is denied to researchers during any such build/update phase.

External Data Sets

Any data sets derived from ResearchOne for supply to researchers must be effectively pseudonymised or anonymised before being supplied; the records contained in the data sets will either contain pseudonymised identifiers or no identifiers at all.

In order to avoid an increase in the risk of identifiability by the cumulative release of more data sets (potentially containing data items from the same native record) all pseudonymised identifiers are project specific. The same research record is assigned a different identifier for each different research project and there is no possibility of linkage between these identifiers.

In order to achieve this, ResearchOne has currently adopted the Openpseudonymiser software developed by QRResearch and the University of Nottingham. This utilises current industry standard encryption (SHA-256) and a project specific code in order to produce pseudonymised identifiers from the ResearchOne record identifier (see [http://www.openpseudonymisation.org/](http://www.openpseudonymisation.org/) for further details).

Section 251

Following the recommendation of the NIGB Ethics and Confidentiality Committee, support for Section 251 of the NHS Act 2006 is not formally required by ResearchOne as patient identifiable data is not included and the pseudonymisation procedure replaces the need to obtain explicit patient consent. This is the same for data linkage to external data sets; no identifiable data will be extracted at all and so no approval for Section 251 is required.

Exclusions

In addition to the confidentiality protocols above, there are some additional data exclusion policies in place on ResearchOne (following the recommendation of the Research Ethics Committee and the NIGB Ethics and Confidentiality Committee).
• No data is extracted from any prison units on SystmOne. It is not possible for the prisons to opt-in to contribute their data.
• Only data from consenting health and care units in England can be extracted into ResearchOne.
• No data items relating to the termination of pregnancies will be included on the database.
• No patient flags indicating military affiliations will be included on the database.

Custodianship

TPP are NHS accredited to manage patient data and retain custodianship over any of the de-identified data extracted from SystmOne as part of the ResearchOne project.

Security

All research data is stored on servers at a secure hosted data centre, governed by the strict TPP security protocols. The hosting solution has been fully accredited to the NHS standards. Physical access to the data centre is strictly controlled as outlined in the TPP corporate level security policy. Obstacles to physical access include identification cards, CCTV and 24-hour security guard surveillance. Only named engineering staff with authentication may gain physical access to the servers for hardware maintenance and the server racks are all locked; access is absolutely controlled by TPP.

Database creation is achieved via data extracted from a current SystmOne database backup to the ResearchOne database on a server within the data centre. There is no physical transfer of data and no data for the ResearchOne database leaves the data centre during this process.

Any access to the ResearchOne database is restricted to remote access from a small number of computers located in the TPP offices. Access, logon details and remote access details are highly restricted and governed by the corporate and system level security protocols. Only senior Technical Team members can access any of the production environments. Every staff member has been Criminal Records Bureau checked and has signed the appropriate confidentiality agreement (available in the appendix of this document). The computers are constantly monitored by CCTV, are in a securely locked room and the building guarded at all times by a security team. All network traffic is encrypted to industry-standard levels.

Database policies

Use of the ResearchOne database is in accordance with the following principles of operation:

• The ResearchOne Database Committee (RDC) oversees all development and operation of the database. This includes any development regarding ethical issues.
• Accounts of any database activity are provided to a designated member of the RDC and made transparent to all members. This includes, but is not limited to, any research database updates, any data linkage requests, any faults detected on the servers, any necessary maintenance, any hardware, software or firmware installations/upgrades and any media destruction.
• Monthly audits of database research activity are provided from each approved ResearchOne researcher to a designated individual in the RDC. These are made available to all members of
the group and are kept indefinitely. Similarly automatically generated monthly audits of all database access are to be provided by the Technical Team so that consistency can be checked if required.

- The methodology and protocols employed to create, update and use the database must be in line with the proposal approved by the Research Ethics Committee.
- The criteria and confidentiality agreement to which researchers are contractually obliged to adhere is governed by the RDC. These criteria are periodically reviewed.
- The TPP corporate level security policy and the database system level security policy should be followed all times for any database use or development.
- The database is to be held in secure centrally hosted data centres governed by the same protocols as the SystmOne production environment.
- Any access, processing or analysis of the data by the ResearchOne team must take place in this secure environment, accessed via a remote connection from the designated secure, fully monitored computers at TPP.
- No data is ever to leave the secure data centres via removable media.
- Extracts of ResearchOne data that comprises the minimum required dataset for an approved external research project will be provided in encrypted files and transferred electronically.
- Researchers must seek approval from the ResearchOne Project Committee in order to be permitted access to a data extract for any new research proposal.
- Any proposal with split approval from the RPC will be referred on to the RDC for guidance. Any subsequent dispute among the group will be taken externally to the appropriate ethics body.
- Attempts to identify patients, clinicians or healthcare providers by researchers are strictly prohibited, will result in their access to any research data being revoked and possible legal action being taken.

### ResearchOne Database Build & Update

ResearchOne is built and updated via an automatic process from a backup of the SystmOne database. The process checks unit consent status and individual patient dissent, as well as ensuring that no data is drawn from prison units or from providers outside of England. There is no manual intervention required at all during the build process and indeed all staff members are prohibited from accessing the database during a build or update phase.

The ResearchOne database is updated on a weekly basis so that:

- Any changes to organisation consent status, whether opt-in or opt-out, are quickly reflected in the research dataset.
- Research records are removed from ResearchOne for any new patient dissents recorded.
- The research data is as contemporary as possible, allowing researchers to have access to the most up-to-date clinical information.

The facility also exists for extraordinary database updates. This will only occur in full consultation with the Research Database Committee.

### Data Extracts

Approved research projects will be provided with data extracts of anonymous or pseudonymous data from ResearchOne. The extracts will consist of the minimum required dataset for the project goals to be achieved, after assessment by the RPC. The data will be electronically transferred to
researchers in the form of files encrypted to current industry standards. The arrangements for data storage, use and disposal must be provided to the RPC prior to extract. As discussed previously, each data extract will contain project-specific research identifiers; this is to prevent linkage of multiple different data extracts as an extra precaution to stop re-identification.

ResearchOne is run as a not-for-profit organisation and we aim to provide a cost-effective research data service to the academic and health communities. The cost of an extract will be assessed in terms of the scale and complexity of the data required, along with any request for consultancy. All extracts will be provided at the minimum cost required to enable the organisation to run in an entirely self-funded manner.

**Link Database**

During a ResearchOne database build an additional link database is also created. The purpose of this database is to allow for the future possibility of data linkage with external data sources, for example, the Hospital Episode Statistics provided by the NHS Health & Social Care Information Centre. It is important to note that any such linkage would require further assessment and approval by the Research Ethics Committee and the National Information Governance Board Ethics & Confidentiality Committee.

This link database contains a table linking a research record identifier from ResearchOne to a strongly encrypted hard local identifier on SystmOne. This link database is stored in a secure data centre, physically separated from the data centre which holds the ResearchOne database but hosted and managed to exactly the same standards. The transfer of this data between data centres is over an encrypted secure network.

Access to the database requires login credentials which are only held by senior members of the Technical Team; research staff can never access this data. The key used to encrypt the SystmOne hard identifier is only held by the designated senior security manager in the Technical Team. Any access to the link database can only be performed by the Technical Team, only after a formal request from the RDC and only after all the required ethical and governance approval has been received.

**Data Linkage**

TPP ResearchOne strive to extend the quality of the database as a research resource by linking non-identifiable data acquired from other approved data sources. For example, the data is linked to the Index of Multiple Deprivation (at Lower Layer Super Output Area level) as provided by the UK Government at data.gov.uk.

As stated earlier there are also future plans to link to further data sources provided by the NHS Health & Social Care Information Centre and utilising the Trusted Data Linkage Service they provide. This would need full approval from the Research Ethics Committee, the National Information Governance Board and the RDC.

All linkage is assessed in line with the NHS Code of Confidentiality and with full attention to security and confidentiality concerns. For example, it is policy that any indicators that are included on the database that are so specific as to compromise confidentiality are never to be included; this is in line with the k-anonymity concept discussed in the ‘Confidentiality’ section.
ResearchOne Staff

There are three different internal staff teams working within ResearchOne:

- **Support Team**
  
  The Support Team are involved in the day-to-day running of ResearchOne including, for example, data extraction, data quality checks, promotional activities, website maintenance, consultancy services and development.

- **Research Team**
  
  The Research Team are internal research staff who work on approved projects, guided by the ResearchOne research programme. The team are subject to the same strict protocols as external researchers.

- **Technical Team**
  
  The Technical Team are responsible for all hardware and infrastructure monitoring. They are responsible for all access and logon credentials, the storage of the link database and of all necessary encryption keys.

ResearchOne Database Access

The Research Team never have direct access to the ResearchOne database; the team receive anonymised or pseudonymised data extracts from the Support Team in exactly the same way as if they were external researchers.

In order to gain any access to ResearchOne or any data extract, all potential staff members must obtain full approval from the RDC. This firstly involves the staff member following all standard company employee protocols and training. The staff member must also have a successful Criminal Records Bureau check and sign the appropriate confidentiality agreement as given in the appendix to this document. All members of the RDC must then review this application for access, with respect to their approval criteria. They must be in total agreement before full approval is granted.

Once a Support Team staff member has been granted full approval they will be given unique database login credentials to the ResearchOne database from a senior member of the Technical Team. Note that this includes a strong individual password. These login details are to be used by staff members whenever they access the data so that the monthly access audit can be produced for the RDC.

Data Quality Checks

The data held on ResearchOne is routinely checked for integrity and for quality at an aggregate level; this is to ensure data quality is maintained and that appropriate statistics can be provided to researchers. This includes, for example, high-level prescribing trends, clinical coding prevalence and indicators of demographic representation. This work is carried out by the Support Team and all
results made available to the RPC and RDC. The results may be published, presented or supplied to researchers in order to given assurances about ResearchOne data quality.

Documentation

All units on SystmOne are provided with links to documentation regarding ResearchOne, including the database protocol, in a variety of ways. All documentation is accessible via the standard ‘F1’ help functionality in the system, on the live and training environments. Appropriate documentation will always be included in any communications to users via SystmOne, for example, via status messages or tasks. All documents are provided in a standard Adobe Acrobat pdf format. The project has been outlined in the SystmOne magazine, TPP times, and publicised at SystmOne National User Group events. A dedicated website is available for research information and all documentation is also available to download there.

Hard copies of any documentation are available upon request. In order to increase availability and accessibility of the documents, TPP will strive to facilitate any specific requests from users, for example, if translations of the documentation into languages other than English are required.

Further queries

For any enquires, queries or complaints please contact ResearchOne in any of the following ways:

ResearchOne
Mill House
Troy Road
Horsforth
Leeds
United Kingdom
LS18 5TN

Tel: 0113 2050082

Fax: 0113 2050081

Email: research@tpp-uk.com
Appendices

Stored data items

The patient data items stored on ResearchOne are as follows:

Demographic Information

- Date of birth (MM/YY)
- Date of death (MM/YY)
- Cause of Death
- Deprivation indices
- Ethnicity
- Gender
- Occupation
- Rurality indices
- Sector-level postcode
- Mid-Level Super Output Area

Clinical Information

- Acute medication
- Alert indicators
- Allergies
- Appointments
- A&E admission / event details
- Care episodes
- Care pathways
- Care plans
- Child at risk entries
- Child health appointments
- Child health scheduling suspensions
- Clinical diagnosis entries
- Clinical numeric entries
• Clinical numeric ranges
• Clinical procedure entries
• Consultation data
• Contacts
• Drug sensitivities
• Healthcare provider types
• Hospital admission / event details
• Hospital discharge details
• Medication end details
• Miscellaneous patient flags
• Out-of-hours cases
• Pathology results
• Recalls
• Referrals in
• Referrals out
• Repeat medication
• Staff roles
• Vaccinations
• Vaccination consents
• Visits
• Waiting list entries
Confidentiality Policy - Research Team

I acknowledge the following conditions under which I am permitted access to data from ResearchOne:

1. The data extract is solely for use on a project that has approval from the ResearchOne Project Committee and relevant ethics and governance bodies.
2. The ResearchOne Database Committee and TPP reserve the right to request information about the usage, storage and disposal of the dataset, and to request its deletion.
3. Changes to a research objective must be accepted by the ResearchOne Project Committee and relevant ethics and governance bodies prior to commencement of any change.
4. Copying or transferral of the data set is prohibited without the approval of the ResearchOne Project Committee and relevant ethics and governance bodies.
5. No attempt will ever be made to identify patients or healthcare providers and I am aware of the relevant legislation.
6. Should I identify any patient or healthcare provider then I shall immediately highlight this privacy breach.
7. Research findings can be freely published without interference, regardless of the nature of the findings.
8. Where the data extract contributes toward any publication or presentation the source must be acknowledged and a copy of any journal or conference publication submitted to the ResearchOne Project Committee.
9. I will provide a review of data usage and disposal and a project summary to the ResearchOne Project Committee upon completion of the project.
10. For projects of which I am the principal investigator I shall submit a review to the ResearchOne Project Committee each quarter, and at the end of the project.
11. Aggregated data in the form of anonymous graphs, figures and tables may be used for the purposes of education, presentations and publication.
12. All research I carry out will follow the strict requirements of research governance and the code of confidentiality.
13. Violation of this policy may restrict or deny me from further access to the research dataset.
14. I have read and understood the ResearchOne Information Governance Policy and ResearchOne Confidentiality Policy and had opportunity to ask questions.

Signed……………………………………………………………………………Date………………………….
Print name……………………………………………………………………

This is a copy of the part of the confidentiality policy which all ResearchOne researchers must sign as part of their accreditation for full approval from the RDC.
Confidentiality Policy - Support Team

I acknowledge the following conditions under which I am permitted access to data on ResearchOne:

1. The ResearchOne database will only be remotely accessed from within the TPP offices, using only my own unique login credentials. I will not share these details with any other person.
2. Database access is solely for data extraction for approved projects, for ongoing data quality checks or for any specific request from the ResearchOne Database Committee.
3. The ResearchOne Database Committee and TPP reserve the right to monitor and revoke user activity.
4. Changes to a research objective must be accepted by the ResearchOne Project Committee prior to any new data access.
5. Any data processing or analysis will only take place on the same secure server as the ResearchOne database. This includes any analysis using third party analytic or statistical software.
6. No attempt will ever be made to identify patients or healthcare providers and I am aware of the relevant legislation.
7. Should I identify any patient or healthcare provider then I shall immediately highlight this privacy breach.
8. Data extracts will only be transferred electronically as strongly encrypted files and only where the ResearchOne Project Committee authorises me to provide minimum data extracts for approved external projects.
9. Where authorised by the ResearchOne Project Committee I will also prepare minimum datasets for use by the Research Team.
10. Aggregated data in the form of anonymous graphs, figures and tables may be used for the purposes of education, presentations and publication.
11. Data extracts will always be prepared using project-specific unique identifiers. A secure log of project-specific codes will be maintained to ensure all such codes are unique.
12. The use of removable media to download data stored on ResearchOne is prohibited.
13. Violation of this policy may restrict or deny me from further access to the ResearchOne database.
14. I have read and understood the ResearchOne Information Governance Policy and ResearchOne Confidentiality Policy and had opportunity to ask questions.

Signed..............................................................................Date........................................
Print name..............................................................................

This is a copy of the part of the confidentiality policy which all Support Team staff must sign.
Confidentiality Policy - Technical Team

Name........................................................................................................................
Address........................................................................................................................
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I acknowledge the following conditions under which I am permitted access to data on ResearchOne

1. The data will be remotely accessed from within TPP using only my own unique login credentials. I will not share these details with any other person.
2. Access is solely for database maintenance that has approval from the ResearchOne Database Committee.
3. The ResearchOne Database Committee and TPP reserve the right to monitor and revoke user activity.
4. No attempt will ever be made to identify patients or healthcare providers and I am aware of the relevant legislation.
5. Should I identify any patient or healthcare provider then I shall immediately highlight this privacy breach.
6. The use of removable media to download data stored on ResearchOne is prohibited.
7. The link database will be stored in a physically separate data centre from the ResearchOne database.
8. I will never access the link database without an explicit request from the RDC.
9. I will securely store any encryption keys required for link database access and never make them available to research or support staff.
10. I will comply with all audit requirements of the RDC and RPC.
11. All logon credentials issued will be unique to each staff member and compliant with all security protocols.
12. Violation of this policy may restrict or deny me from further access to the ResearchOne database.
13. I have read and understood the ResearchOne Information Governance Policy and ResearchOne Confidentiality Policy and had opportunity to ask questions.

Signed..........................................................Date...........................................
Print name..............................................................

This is a copy of the part of the confidentiality policy which all Technical Team staff must sign.
Confidentiality Policy - External Researchers

I acknowledge the following conditions under which I am permitted access to a data extract from ResearchOne:

1. The data set is solely for use on a project that has approval from the ResearchOne Project Committee and relevant ethics and governance bodies.
2. The ResearchOne Database Committee and TPP reserve the right to request information about the usage, storage and disposal of the dataset, and to request its deletion.
3. Changes to a research objective must be accepted by the ResearchOne Project Committee and relevant ethics and governance bodies prior to commencement of any change.
4. Copying or transferral of the data set is prohibited without the approval of the ResearchOne Project Committee and relevant ethics and governance bodies.
5. No attempt will ever be made to identify patients or healthcare providers and I am aware of the relevant legislation.
6. Should I identify any patient or healthcare provider then I shall immediately highlight this privacy breach to ResearchOne.
7. Research findings can be freely published without interference, regardless of the nature of the findings.
8. Where the data extract contributes toward any publication or presentation the source must be acknowledged and a copy of any journal or conference publication submitted to the ResearchOne Project Committee.
9. All research I carry out will follow the strict requirements of research governance and the code of confidentiality.
10. Violation of this policy may restrict or deny me from further access to the research dataset.
11. I will provide a review of data usage and disposal and a project summary to the ResearchOne Project Committee upon completion of the project.

Signed........................................................................Date........................................

Print name........................................................................

This is a copy of the confidentiality policy which all external researchers must sign as part of their accreditation for full approval from the RDC.