

Supplementary appendix 1

TRE Legal Toolkit
Patient and Public Involvement

The aim:

There are various contracts involved in health data research. These come in different forms and vary between different data custodians, resulting in a complicated process that can be confusing for researchers. The differences between contracts can also cause caution amongst contracts teams within organisations, resulting in delays and effectively acting as blocker to research projects starting. This is an area that could really benefit from streamlining and collaborative working across the four nations. With the move towards the use of Trusted Research Environments (TREs), this offers a chance to introduce best practice at a relatively early stage. TREs by nature provide data protection and security assurances that were not possible with traditional data sharing, and this should be reflected in the associated contracts. While the TRE may contain pseudonymised individual-level data, only anonymised aggregate data may be downloaded. The processing will occur within the highly secure TRE and any outputs will be subject to checks and approval prior to release from there.

The TRE Legal Toolkit group are developing the following templates:

1. A data access agreement (DAA), a contract between those that hold the data and those that want to access the data
2. A data depositing agreement (DDA), a contract between those that will have their data within the TRE and those that are responsible for the TRE
3. A data protection impact assessment (DPIA), a form that is completed to identify and mitigate potential data protection risks to an acceptable level before processing data that identifies individuals (personal data)

Guidance and a glossary will be developed alongside these documents to aid ease of use. We will also produce a tool to help with defining roles and responsibilities against General Data Protection Regulation (GDPR) for all parties involved.

The TRE Legal Toolkit Action Force includes various stakeholders, such as experts in health data research contracting across the four nations and patients and public representatives. This diverse collaboration will ensure our work is clear, accessible, and responsive to current priorities.

The overall aim is to produce templates that are trusted, fit for purpose and that ultimately result in the speeding up of contracting to facilitate research that improves and saves lives.

For further info see here: Data Access and Governance UKHDRA (ukhealthdata.org)

STEP 1: Developing a data access agreement (DAA) template

We have reviewed DAAs currently in place for established TREs as a benchmarking exercise to define key shared principles. We will use these principles as building blocks for

our DAA. The principles have been broken down into sections in the numbered list below. We have included questions that we would like you to answer but would also appreciate your reflections on any of the points listed. All comments, amendments and suggestions are welcomed, as we believe it is essential to include patient and public representatives' contributions.

1. Contractual Parties:

- The DAA should be between the 'Host Organisation' (an organisation which is accredited to host and control a TRE) and 'User Organisation' (an organisation which is responsible for individuals using a TRE service),
- with 'Approved Researchers' (people that access the data within a TRE, that have a contract with a verified User Organisation) agreeing that they have read and understood terms and conditions in the DAA around security and user requirements. For example, that they must only use data for the approved purposes.
- The User Organisation will sign a warranty that makes them responsible for the approved researcher meeting the requirements to access the TRE. The User Organisation is liable for the compliance of the researcher.

[We have found that some DAAs follow this arrangement whereas some ask a researcher to sign the full DAA and accept responsibility, where there may be little possibility of legal action against an individual unless there is criminal intent]

Q: Do you agree with this arrangement and the distribution of responsibility?

1. Access:

- The User Organisation shall only permit access to and use of the Data in the TRE by Approved Researcher(s) for the Approved Project and not by any other persons, and not for any other purpose.
- Approved Researcher should be affiliated with the User Organisation. [we still need to define affiliation – this could include those with employment contracts, those with honorary contracts and students]
- The User Organisation shall and shall procure that the Approved Researcher(s) keep confidential (i) the Data, and (ii) any access credentials to the Data.
- Restrictions on access to a defined 'safe setting': approved area of User Organisation covered by the NHS Data Security and Protection Toolkit (or equivalent)
- OR Approved researchers can access the TRE using a Virtual Private Network (VPN) from any location in the UK
- User Organisation/ Researcher access restrictions if subject to an investigation/breach.

- Requirement that Researchers have appropriate accreditation (This may vary but we are seeing the ONS accreditation frequently Become an accredited researcher - Office for National Statistics (ons.gov.uk)

Q. Have we considered everything when it comes to accessing the TRE?

Q. Would you expect an approved researcher to have a full employment contract with the organisation or would an honorary contract be acceptable?

Q. Would you be happy with students accessing the TRE if their supervisor takes responsibility for them?

3. Outputs

- Neither data nor any research output (the analyses and any resulting write-up) must be used for any purpose contrary to the Applicable Laws
- Data must not be downloaded, extracted, transmitted, transferred, removed, copied or published from the TRE.

4. Use of data

- Must not attempt to identify individuals from the data or contact any research participant
- Data shall only be used for purposes defined in the approval. Further research requires new approval. Non-compliance results in termination of access.

Q. What are your views on permitting access to the datasets for exploratory research? For example, permitting approved researchers access to some or all datasets to discover where we should be directing research by looking at trends in the data. Research projects are normally subject to data minimisation, where data fields are restricted to those that are absolutely necessary to answer the research question. Here, researchers would still need approval and the defined purpose would be for exploratory research, but the data would not be limited as there would be no set project.

5. Intellectual property

- There will be no transfer of intellectual property (IP) ownership (ownership of the data). IP shall remain the property of the data owners for each dataset.
- The TRE host organisation owns IP for any derived data (data that has been created by combining or processing data from one or more of the original datasets. The data fields are dependent on the original data for analysis but become new data in their own right).

6. Liability for data accuracy and availability

- The Host organisation makes no warranty, express or implied as to accuracy or quality of the data; and

- excludes all liability for actions, claims, proceedings, demands, losses, costs, awards, damages, and payments made by the User Organisation that may arise from their use of the data or unavailability to the data for whatever reason.

Q. Do you think there are clear reasons for all of the above? Anything else we should consider?

7. Compliance with Data Protection Legislation and Liability

- Each party shall comply with their respective obligations under Data Protection Laws.
- The User Organisation must inform the Host Organisation without delay, and in any event within 48 hours of becoming aware of:
 - any unauthorised access, disclosure, loss, damage or alteration of the Data
 - any element within the data that might permit the identification of a research participant
 - any complaints from an individual or supervisory authority in relation to the data; and
 - any request from a research participant to exercise their rights in respect of the data.
- The User Organisation (+ Approved Researcher) agree to preserve confidentiality of information.
- The User Organisation (+ Approved Researcher) agree to application of GDPR to data.
- Must access data in controlled environment and protect from onlookers.

Q. Do you think everything has been covered in terms of protecting data?

8. Commercial use

- Data must be used for public benefit. Unauthorised commercial use will result in termination
- Commercial use may be permitted if stated in the approvals granted prior to the project starting

Q. Please comment on your feelings around commercial use as part of approved projects?

9. Onward linkage

- There should be no attempt to link or combine the data with other information or data (including any information relating to an identified or identifiable natural person) available to the User Organisation.
- With express permission as part of the approval process, data may be linked to other datasets (the other datasets would need to be ingested in to the TRE)

Q. To what extent do you think it is important that data is not linked to other datasets? (Bearing in mind that only anonymised data will ever leave the TRE)

10. Open sharing of analysis, code, and derived data

- Ownership of Syntax (set of rules for analysis) and methodology remains with the User Organisation, but they shall grant a licence for use for other research and non-commercial purposes.

Q. Many feel it is important that the work that underpins research is shared so that we avoid wasting time in duplicating processes, and so that errors can be reduced along the way. Do you support the contractual obligation to share?

11. Term

- Access will be terminated at the end of the term defined in the approval. Data destruction is not applicable as no personal data can be taken out of the TRE.

Annex

There will also be an Annex to the DAA which will contain Terms and Conditions that are customisable to the individual TRE

These may include further detail on:

- The data that is available within the TRE – this would be a list of names of data fields and not actual data e.g. 'date of operation', 'length of stay', 'diagnosis code'. This would never contain actual patient data. There may also be detail of restrictions to reduce the likelihood of

identification e.g. Dates may only be available as month-year, only the first half of a postcode may be available, or you may only get access to time to death from an operation rather than date of death.

- Any further conditions specified for possible linkage to other datasets
- Restrictions on international access
- The protocol that will be followed in order to request output of anonymous data from the TRE
- Further detail on accreditation or training requirements for researchers before they can access the TRE
- The process for recovering costs associated with researcher access from their organisation
- How the host organisation of the TRE will go about monitoring who is accessing the TRE and how they will record and act upon this
- Acknowledgement/ copyright statements to include in any publications
- Further details if linkage of datasets occurs via a third party
- Length of term of access and the process for requesting extensions

Q. Do you support these being customisable terms and conditions?

