

Health Informatics Centre (HIC)

Trusted Research Environment (TRE) User Agreement

Contents

1	Introduction.....	2
1.1	The Parties	2
1.2	Trusted Research Environment (TRE)	2
1.3	Project	2
1.4	Responsibilities	2
2.	Safe People	3
2.1	User responsibilities	3
2.2	User Organisation responsibilities	3
2.3	HIC Responsibilities	4
3.	Safe Setting	4
3.1	User responsibilities	4
3.2	User Organisation responsibilities	4
3.3	HIC responsibilities	5
4.	Safe Projects	5
5.	Safe Data	5
5.1	Handling of data	5
5.2	Storage and copying of data	6
6.	Safe Output	6
6.1	Release of output.....	6
6.2	Output acknowledgement	6
7.	General Provisions	7
7.1	Interpretation.....	7
7.2	Non-compliance	7
8.	Offences and penalties	7
8.1	Offences and sanctions	7
8.2	Statutory penalties.....	7
8.3	Use of generated Project data for commercial gain	8
8.4	Right of appeal	8
8.5	Claims	8
9.	Review	8
10.	Declarations and signatories	9

1. Introduction

This Agreement is the legal document that sets forth the terms and conditions governing the use of the Trusted Research Environment (TRE) service provided by the Health Informatics Centre (HIC). By engaging with the TRE, all Parties involved acknowledge and agree to adhere to the outlined conditions to ensure the security and protection of HIC data and services. Users are urged to carefully review the Agreement, including the penalties set for non-compliance (Section 8).

This document is a legal agreement, and acceptance of these terms is a prerequisite for access to and use of the TRE provided by HIC.

1.1 The Parties

Parties to this Agreement are:

- 1.1.1 The individual TRE user (referred to as “**You**”, and “**Your**”) named in Clause 10
- 1.1.2 The **User Organisation** named in Clause 10 whose registered address is [**User Organisation address**]
- 1.1.3 The host organisation The University of Dundee, established by Royal Charter dated 20th July 1967 and a registered Scottish Charity (charity number SC015096) and having its principal office at 149 Nethergate, Dundee, DD1 4HN, as represented by the University’s Health Informatics Centre, School of Medicine, Ninewells Hospital, Dundee, DD1 9SY (“**HIC**”).

1.2 Trusted Research Environment (TRE)

The Trusted Research Environment (TRE) is a service delivered by HIC. The TRE is a secure computing environment specifically designed for handling personal data in a way that protects privacy and ensures security. Whether You do or do not use HIC data, all users are responsible for upholding the highest standards of information security and management and terms of this Agreement.

HIC operates in line with several pieces of UK legislation, statutes and regulations forming the basis of “**Applicable Laws**” including the Data Protection Act 2018 implementing Data Protection Regulation, ensuring personal data is used fairly, lawfully, and transparently.

1.3 Project

This Agreement relates to the appropriate TRE project(s) which are approved to be conducted in principle within the HIC TRE. A Principal Investigator and/or User, may conduct any number of projects within the TRE, all of which are covered by this Agreement and are referred to as “**Project(s)**”. This Agreement shall commence on the date of signing and expire after 3 years, whereupon renewals will be sought when appropriate. The Agreement remains binding irrespective of the duration of the approved Project.

1.4 Responsibilities

Prior to being provided with access to the TRE and any data which HIC as agreed to provision, You must:

- 1.4.1 Demonstrate that You have completed and passed a mandatory HIC approved training course on privacy, data protection, and freedom of information (“**IG Training Course**”) and provide a certificate to HIC (“**Training Certificate**”).



- 1.4.2 Have read and understood this Agreement, being aware of the penalties for non-compliance should You compromise the security, availability, or confidentiality of the TRE.
- 1.4.3 Understand that the Project You are working on must have the approval of all relevant authorising bodies (“**Approvals**”): Research Sponsor, Ethics Committee, Research and Development Department and Data Controller, Data Custodian, Data Protection Officer and Caldicott Guardian. Where appropriate, a copy of such Approvals must be provided to HIC; (HIC will document the decision on which Approvals are not relevant).
- 1.4.4 Sign the declaration agreeing to be bound by the requirements of this Agreement and return it to HIC.

Once You have satisfied the requirements of above, You will become an approved TRE “**User**”.

Please note that behaviours conducted by Users apply regardless of whether You are a standard or view-only User. View-only Users have Approvals in place to see the project data solely through screen sharing online or in person, with a standard User. View-only Users will not have dedicated TRE accounts for login, and interactions with the data by sharing login details with standard Users are strictly prohibited. Standard Users are provided with unique TRE log ins and have approvals in place to interact and analyse the Project data. This Agreement will refer to both standard and view-only users as TRE Users.

2. Safe People

2.1 User responsibilities

As an approved TRE User, You must familiarise yourself with and comply with best practice for data protection and governance, upholding the security and confidentiality of HIC data and the TRE:

- 2.1.1 You are responsible for ensuring that the data You are working on is not read, viewed, or handled by anyone not named in the relevant Approvals for the Project. If it appears that anyone is deliberately attempting to view, read, or handle data not within their authorised duties, You must report this immediately to HICSupport@dundee.ac.uk.
- 2.1.2 If You are responsible for or are aware of the occurrence of an (un)intentional disclosure of any data within the TRE, You must report this immediately to HICSupport@dundee.ac.uk.
- 2.1.3 You should not discuss information which could breach an individual’s right to privacy in public places. In this context, a public place is anywhere where people not named in the relevant Approvals for the Project may be present.
- 2.1.4 You must satisfactorily complete another IG Training Course within 2 weeks of the expiry of the Training Certificate You last provided to HIC to retain access.

2.2 User Organisation responsibilities

The User Organisation warrants that the User is appropriately trained and skilled in data protection and governance, and to the standard specified in this Agreement. The User Organisation shall:

- 2.2.1 Ensure User compliance with the terms of this Agreement, and any breach by a User shall be a breach of the User Organisation of this Agreement.



- 2.2.2 Notify HIC within 5 working days of changes to User(s), including where a User has left the User Organisation or is no longer authorised to work on the Project.
- 2.2.3 Ensure that User(s) do not share login details or access credentials to the TRE, and do not attempt to access the TRE after they have been notified that they are no longer authorised to do so.

2.3 HIC Responsibilities

HIC as the host organisation, shall:

- 2.3.1 Suspend TRE access on termination or expiry of the Agreement.
- 2.3.2 Following notification in accordance with clause 2.2.2 above, terminate access to the TRE for the relevant Users.
- 2.3.3 In the event of a breach of suspected breach of this Agreement, immediately suspend access to the TRE for one or more User(s) to fully investigate and may apply further penalties and/ or require remediations as set out in Clause 8.

3. Safe Setting

3.1 User responsibilities

Approved TRE Users shall ensure:

- 3.1.1 You have understood this Agreement before signing, which is dependent on access to the TRE (and any provisioned data). If You have any questions about the contents of this Agreement, You should contact HICSupport@dundee.ac.uk.
- 3.1.2 You have provided HIC with all appropriate governance and Approvals.
- 3.1.3 You have provided HIC with an accurate e-mail address, allowing HIC to e-mail instructions how to log-in to the TRE using secure multi-factor authentication.
- 3.1.4 You must not leave Your screen unattended whilst using the TRE, You must either lock Your screen or log out.
- 3.1.5 All Project findings generated (“**Outputs**”) must be approved by HIC prior to release from the TRE. This output checking is crucial to ensure files do not breach an individuals’ privacy. Outputs should be limited to the minimum required for sharing results of any analyses. Under no circumstances will unapproved Outputs be released (see Clause 5).

3.2 User Organisation responsibilities

The User Organisation shall ensure that the User:

- 3.2.1 Keep HIC data and access credentials in accordance with Applicable laws.
- 3.2.2 Do not access, use, or disclose HIC data other than as permitted by this Agreement or as required by Applicable Laws.
- 3.2.3 Do not attempt to introduce or permit the introduction of any virus, software, code, file, or programme into the TRE which could compromise its security and shall ensure that the security requirements are followed by the User.

3.3 HIC responsibilities

HIC as the host organisation, shall:

- 3.3.1 Ensure that the TRE and processing arrangements implement appropriate technical and organisational measures in compliance with Applicable Laws.
- 3.3.2 Monitor and audit the use of the TRE and HIC data by the User Organisation and its User(s) to ensure compliance with the terms of this Agreement.

4. Safe Projects

- 4.1 The User Organisation shall access and use HIC data in the TRE:
 - 4.1.1 In accordance with Applicable Laws.
 - 4.1.2 For the Project only, in line with the approved Project scope for research in the public good, or where access is permitted under this Agreement for other Approved Purposes, and not for any other purposes.
 - 4.1.3 In accordance with all applicable ethical standards and Approvals.
- 4.2 HIC shall publish accurate details of the Approved Project(s) and User(s) in a publicly available data use register.

5. Safe Data

5.1 Handling of data

You are required to maintain the security and confidentiality of data in the TRE in accordance with this Agreement and *will not*:

- 5.1.1 Reuse the data for purposes outside of the scope of the Approvals.
- 5.1.2 Share the data with people not named on the Approvals.
- 5.1.3 Attempt to link the Project data extract to any other data provided in the TRE by HIC, within the scope of the Project Approvals.
- 5.1.4 Attempt to identify or re-identify any individual within the data including facial recognition reconstruction.
- 5.1.5 Share Your access credentials to login to the TRE.
- 5.1.6 Discuss information which could breach an individual's right to privacy in public places. In this context, a public place is anywhere where anyone not named in the relevant Approvals for the Project may be present. This includes members of Your household if working from home.
- 5.1.7 The User Organisation understands that HIC, acting reasonably, can delete any data at any time in the event of a breach of the Agreement, or the occurrence of an event under Clause 5.1.8, without terminating the Agreement.
- 5.1.8 The User Organisation will inform HIC within 12 hours of becoming aware of:
 - 5.1.8.1 Any unauthorised access, disclosure, loss, damage, or alteration of the data.
 - 5.1.8.2 Any element within the data that might permit the identification of an individual.
 - 5.1.8.3 Any complaints in relation to the data including complaints from an individual or supervisory authority.

5.2 Storage and copying of data

- 5.2.1 There will be no movement of data in or out of the TRE without the approval of HIC. No data can be copied or released out of the TRE without undergoing HIC disclosure control. You should not attempt any malicious activity such as taking a screen shot or re-typing/ writing information locally.
- 5.2.2 HIC will securely archive the Project data and Outputs after completion and will retain for ten years.

6. Safe Output

6.1 Release of output

- 6.1.1 You and the User Organisation may only publish, distribute, or otherwise share Project Outputs that have been approved in accordance with HIC disclosure control.
- 6.1.2 Project Outputs as standard, will not include personal or individual level data, unless prior Approvals and information governance arrangements are in place. HIC acts as the Data Processor on behalf of Data Controllers, and will only release Outputs from the TRE in line with relevant requirements. A “**Data Controller**” is a natural or legal person or organisation which, alone or jointly with others, decides on the purposes and means of processing of personal data.
- 6.1.3 Data Controllers will be Project dependent. You must request any Outputs created to be disclosure checked by HIC. HIC will review content to ensure that it does not contain any information which identifies, or which could be used in conjunction with other data, to identify an individual. If approved, HIC will send Your Outputs to You in a secure manner. Be aware that the security measures forming part of the TRE do not allow You to export any data, documents, or other files from the TRE without going through this disclosure control process.
- 6.1.4 If an Output is rejected by HIC, You will have an opportunity to demonstrate to HIC, and where appropriate, the Data Controller(s), that the Output is safe for release. However, the final decision to release any Output remains with HIC.
- 6.1.5 On request from HIC, You must provide a description of variables used, new variables/ measures/ indices created, documentation of datasets and programs used in producing Your Output. These requests are likely in the output checking of Artificial Intelligence/ Machine Learning models. This documentation will ensure that HIC have the information needed to process the request for disclosure control.

6.2 Output acknowledgement

- 6.2.1 Where generated Outputs are formally presented or published, You should acknowledge the use of HIC in supporting the Project.
- 6.2.2 Where generated Outputs from HIC data are formally presented or published, You should acknowledge the use of HIC in supporting the Project, and cite the appropriate dataset via Direct Object Identifiers (DOIs).

7. General Provisions

7.1 Interpretation

7.1.1 If You require additional information in relation to this Agreement, You should contact HICSupport@dundee.ac.uk.

7.1.2 This Agreement is not intended to constitute any transfer of Intellectual Property Rights in the TRE. Ownership of Intellectual Property in the generated Project Outputs shall belong to the User Organisation.

7.2 Non-compliance

7.2.1 Each Party shall comply with their respective obligations under all Applicable Laws, including Data Protection Laws.

7.2.2 Any breach of this Agreement may result in immediately suspending Your access to the TRE so HIC can fully investigate the event and may apply further penalties and/ or require remediations as set out in Clause 8.

7.2.3 This Agreement constitutes the entire agreement between the Parties.

8. Offences and penalties

8.1 Offences and sanctions

8.1.1 Your signing of this Agreement demonstrates that You understand the seriousness of the undertakings and the penalties that may be imposed for breaches.

8.1.2 Application of the penalties for intentional breaches of this Agreement is non-discretionary.

8.1.3 If You take full and prompt action to report an unintentional breach, You may not be penalised, but You may be asked to repeat training.

8.1.4 HIC has discretionary powers for the use of penalties for self-reported, unintentional breaches.

8.1.5 You agree to inform HIC of any errors found in the data, whilst there is no formal penalty for not informing HIC, You may be contacted to provide such information.

8.1.6 All breaches and the penalties applied will be reported in full by HIC to the HIC Executive Team and other interested parties (e.g., Data Controllers, Approvals teams, Information Commissioner's Office).

8.2 Statutory penalties

HIC believes that penalties will only effectively deter Users if they are fully understood. Additionally, it should be emphasised that HIC prioritises prevention than punishment. In relation to statutory penalties:

8.2.1 The Statistics and Registration Services Act 2007 ("**SRSA 2007**") states, in Section 39(9) that persons who contravenes subsection (1) (which states that any person who has directly or indirectly received personal information from the Statistics Board must not disclose it) "is guilty of an offence and liable – (a) on conviction of indictment, to imprisonment for a term not exceeding two years, or to a fine, or both; (b) on summary conviction, to imprisonment for a term not exceeding twelve months, or to a fine not exceeding the statutory maximum, or both".

However, this does not apply when the person making the disclosure “reasonably believes” that either personal information is not specified in the information which is disclosed, or that a person’s identity cannot be deduced from the information, or that a person’s identity cannot be deduced from the information taken together with any other published information.

- 8.2.2 Taking personal information out of the TRE except within HIC processes (as explained in Section 5), remains a breach of this Agreement, regardless of whether You had ‘reasonable belief’. You should regard only the Outputs which have been released by HIC, to be non-disclosive, and that receiving such an Output is the basis for Your ‘reasonable belief’.
- 8.2.3 HIC will seek prosecution for any breach of SRSA 2007. The only exceptions are where the disclosure was unintentional and self-reported, or the ‘reasonable belief’ defence is unambiguously relevant. However, this defence is effectively removed considered the information provided in 8.2.2.
- 8.2.4 Section 170 of the Data Protection Act 2018 criminalises “the knowing or reckless obtaining or disclosure of personal data without the consent of the controller”. HIC will inform the appropriate authorities if an offence has been committed.
- 8.2.5 Section 171 of the Data Protection Act 2018 criminalises “the re-identification of de-identified personal data without the consent of the controller”. HIC will inform the appropriate authorities if an offence has been committed. The reporting process is via Tayside Science Centre (TASC) onto the University of Dundee Data Protection Officer, who takes a decision to inform the Information Commission.

8.3 Use of generated Project data for commercial gain

- 8.3.1 Unless stated in the Approvals, You are strictly prohibited from selling or commercially exploiting the data or Outputs generated from the Project for personal financial gain, or any other commercial purposes while acting as paid ‘agents’ of business.

8.4 Right of appeal

- 8.4.1 If You consider a penalty following a self-reported, unintentional is unfair, the right of appeal is to HIC Executive team.

8.5 Claims

- 8.5.1 It should be noted that whilst HIC are not the Controllers of the data for the purposes of this Agreement, they have the right to take independent civil action against any offender who causes them harm by release of personal data.

9. Review

- 9.1 HIC reserves the right to update terms in accordance with legislative changes. Users are bound by these updates unless they terminate the Agreement within 30 days of notification. Access to the TRE will be terminated from the date the User terminates the Agreement. Otherwise, the terms shall become effective 30 days after the date of notice where the User has not opted to terminate.
- 9.2 HIC will be entitled to terminate this Agreement in the event of any Approvals being withdrawn or lapsing during the Project, and TRE access terminated.

10. Declarations and signatories

By signing below, You/ the User Organisation/Student Supervisor, confirm that You have read, understood, and agree to comply with all the terms and conditions of this Agreement. Any breach of this Agreement will result in full investigation by HIC and may lead to withdrawal of access for You/ the User Organisation and sanctions listed in Clause 8. HIC has a duty to report legal or regulatory breaches to the HIC Executive Team and appropriate authorities (e.g., Data Controllers, Approvals teams, Information Commissioner's Office).

To reiterate Clause 1.3, this Agreement shall commence on the date of signing and expire after 3 years, whereupon renewals will be sought when appropriate. The Agreement remains binding irrespective of the duration of the approved Project.

Detail	Full name printed and signed	Date
Approved TRE User		
Representative for and on behalf of User Organisation		
Student Supervisor		
Representative for and on behalf of HIC		