University of Dundee

The Five Safes

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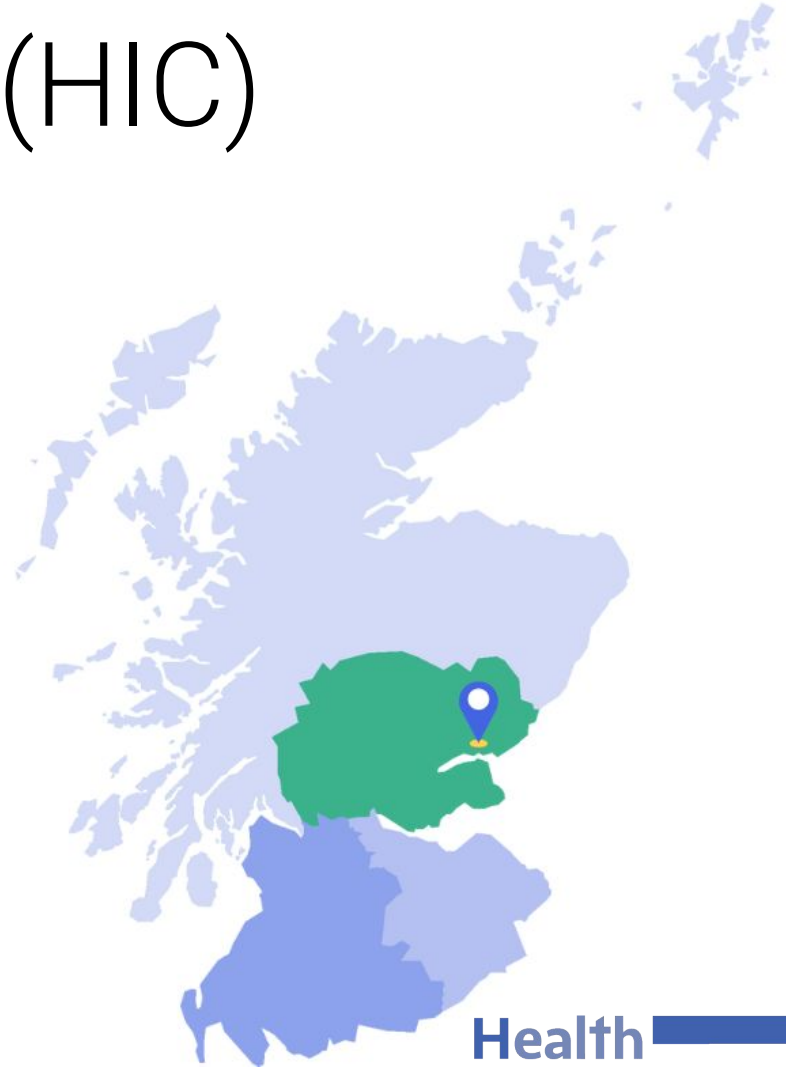
1. Health Informatics Centre (HIC)

Dr Chris Cole – Academic Co-Director

Dr Simon Li – Senior Research Infrastructure Engineer

Dr Laura Ward – Project Manager (Trusted Research Environment)

- HIC is the East of Scotland NHS Scotland node (represented in green). And 1 of 4 regional Scottish Safe Havens
- Scotland is divided into 4 regional and 1 national Safe Havens. Work together under the Scottish Safe Haven Charter
- Operated as a TRE for 12+ years delivering secure, research managed access to data under robust governance control



Health Informatics Centre

bsi ISO/IEC 27001 Information Security Management CERTIFIED

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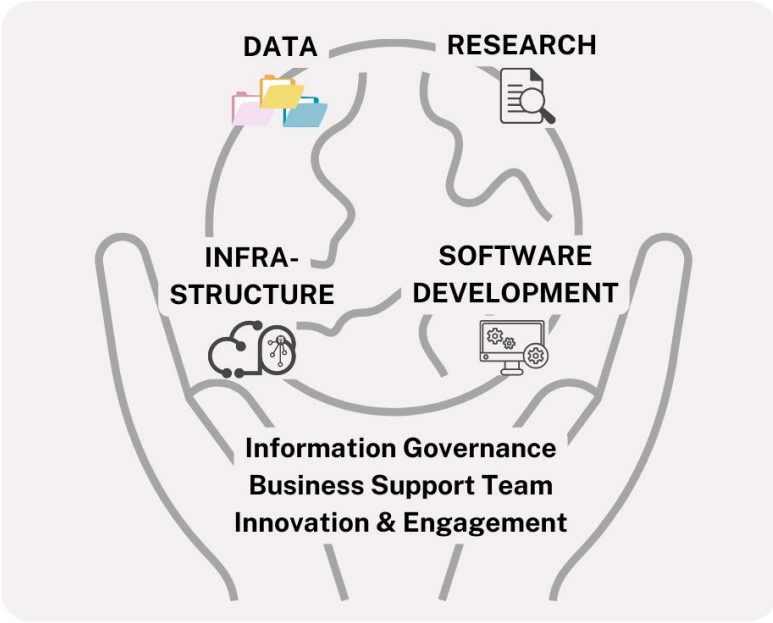
1.1 Who are we?

- Expertise across data linkage and engineering, data science research, software development, infrastructure, and information governance.
- Operate on a cost-recovery basis
- *Our TRE may be a product, but it is the wider expert team and people working here that make us a data safe haven.*
- Wide range of clinical, academic, public and private sector partners:



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Scottish Government
Riaghaltas na h-Alba

Public Health Scotland

eDRIS

HDRUK
Health Data Research UK

ADRUK

EHDEN

Alleviate
The Advanced Pain Discovery Platform (APDP) Data Hub

CHIEF SCIENTIST OFFICE

NHS SCOTLAND

Research Data Scotland

DaSH
Grampian Data Safe Haven

NHS Greater Glasgow and Clyde

DataLoch

DARE UK

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TASC
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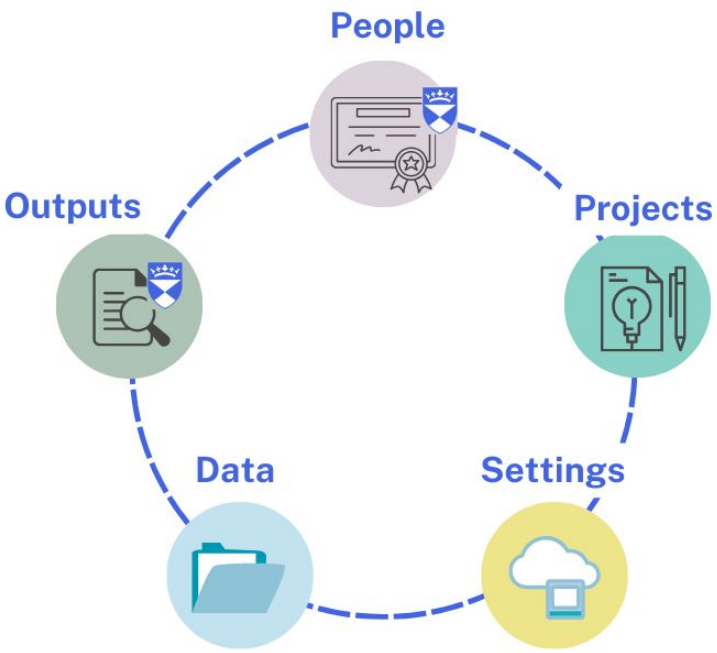
2.1 Introduction to the Five Safes

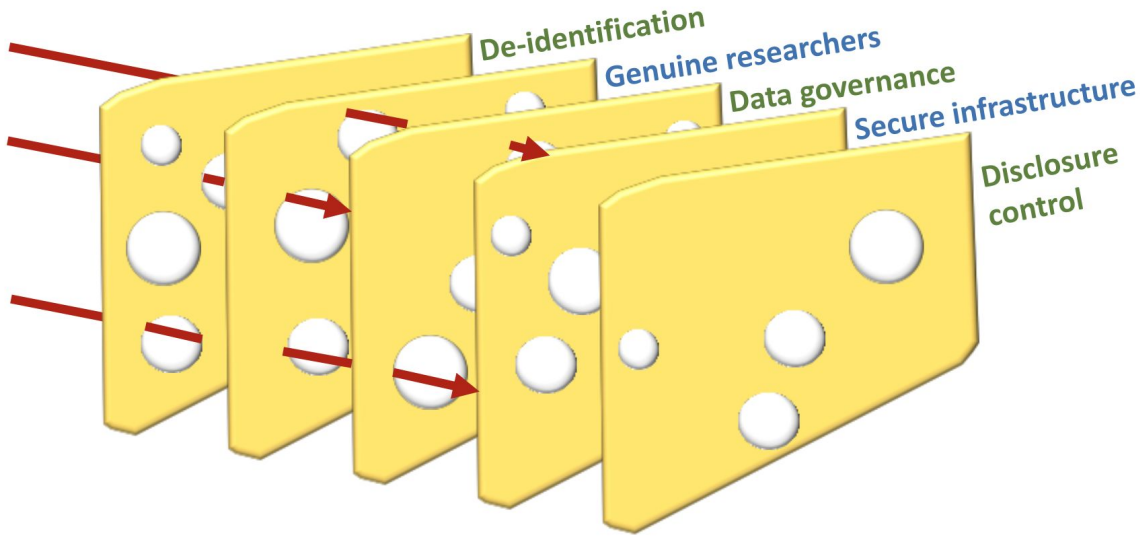


- The Five Safes are a set of principles which provide a practical and comprehensive approach to handling sensitive data in a responsible and ethical manner, while still enabling research
- Each principle is a different (but related) dimension that contributes to the overall safe use of sensitive data
- Most widely adopted since introduced by Ritchie et al. (2008), increased access to national statistics data for academic and governmental research

Ritchie, F. *Econ Lab Market Rev* **2**, 29–34 (2008). https://doi.org/10.1057/elmr.2008.73

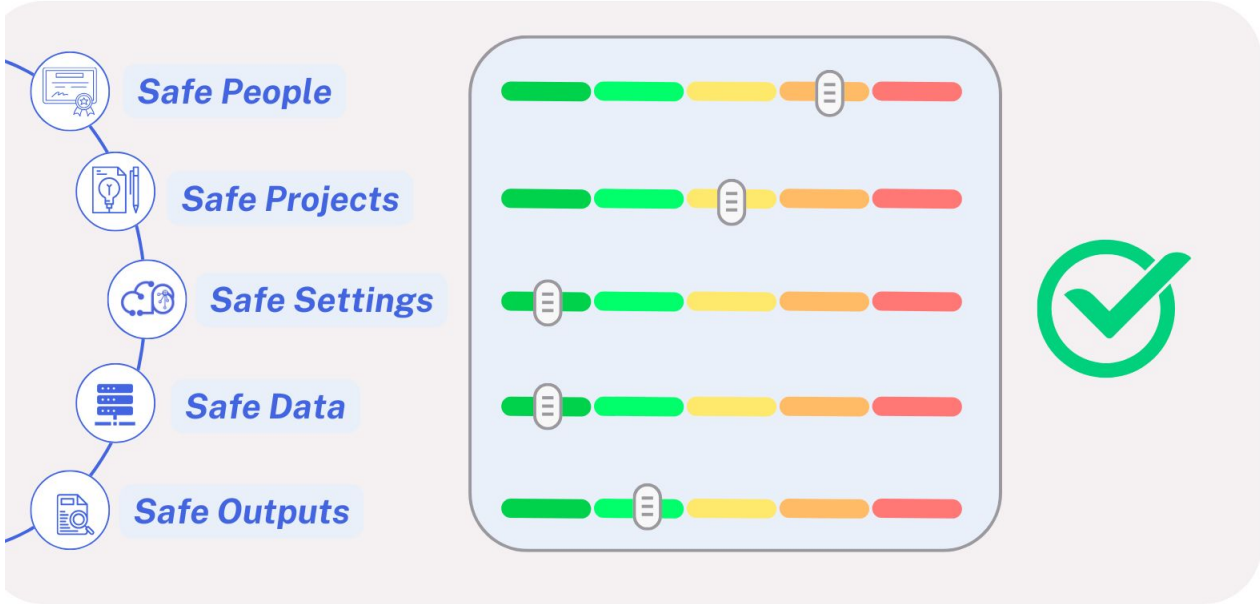
2.2 A Security Model

- A set of overlapping security controls
- Any single failure of a safe is not a disaster
  - The “Swiss cheese” model
- Designed for “thin-client” access to central data stores



2.3 The Five Safes explained

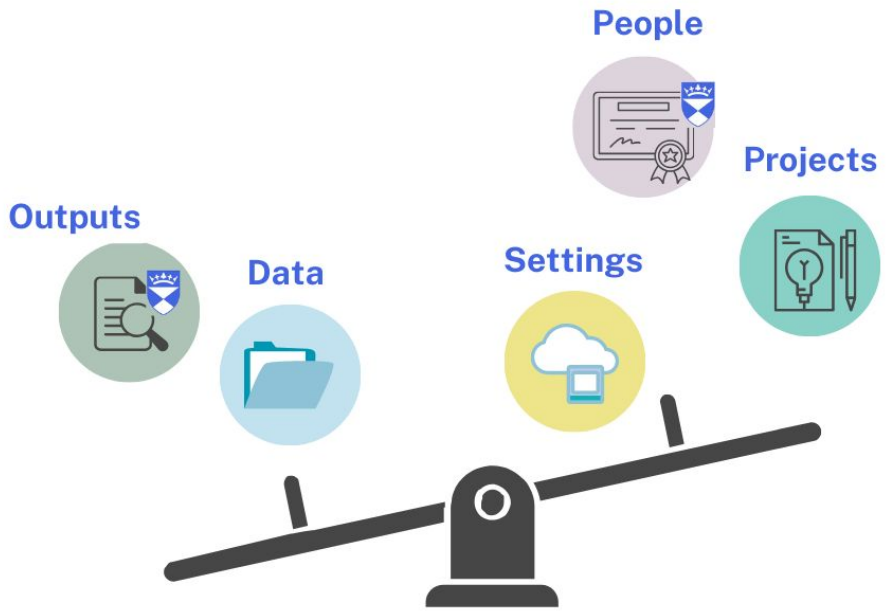
1. **Safe People** can access the TRE after training, approvals, and agreements are in place.
2. **Safe Projects** are reviewed for potential patient and public benefit.
3. **Safe Settings** (TRE) are used to access the data on secure technology systems.
4. **Safe Data** is provided as pseudonymised to protect privacy.
5. **Safe Outputs** are ensured as only summary data can be taken out of the TRE after disclosure control.



2.2 The process - application planning

- Managerial
  - Projects, People, Settings
  - Designed and implemented first

- *vs* Statistical
  - Data, Outputs
  - Implemented second



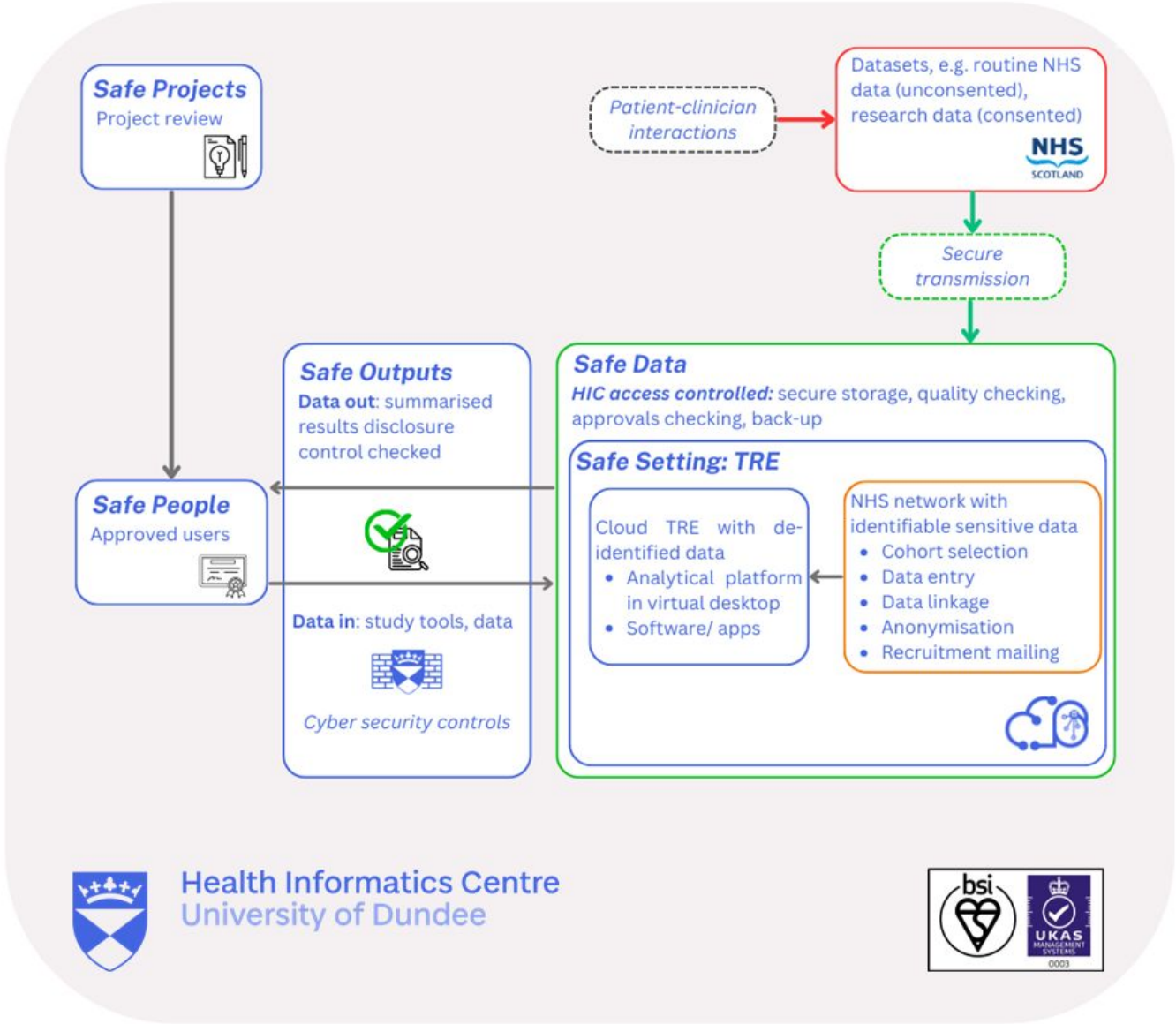
2.3 Adoption

- UK
  - ONS, UK Data Archive, HDR UK, DARE UK, NHS England, UK Stats Authority and Administrative Data Research UK
- International
  - Eurostat, Statistics New Zealand, Australian Bureau of Statistics, Statistics Canada, Mexican National Institute of Statistics & Geography

- Legislation
  - South Australian Public Sector (Data Sharing) Act 2016
  - Digital Economy Act 2017 (UK)
  - Australian Data Availability and Transparency Act 2022

3. Implementation at HIC - overview

- Representing the 5 Safes within our structure (in blue)
- We provide access to project data extract (following approvals), which is always pseudonymised and provisioned in a segregated workspace (green box for TRE)
- Diagram is colour coded traffic light system for risk



3.1 HIC: Safe People

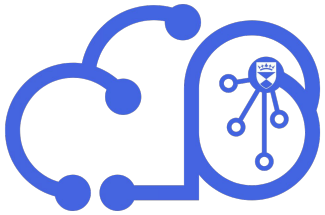
- Bona fide researcher only
- Information governance training required
  - MRC GDPR
  - E.g. no working on the TRE in a public café when individual level could be visible
- Police clearance (Disclosure Scotland)
  - HIC staff
- Unique, secure logins

3.2 HIC: Safe Projects

- HIC are the gatekeepers (not decision makers)
- Approvals required:
  - Caldicott (Data) Guardian
  - Ethics committee
  - NHS Research & Development

3.3 HIC: Safe Settings

- Trusted Research Environment (TRE) ensures security of the data analysis space, restrictive and controlled
- Physical restrictions to data team office
- HIC has
  - ISO accreditation
  - Regular audits
  - Regular cyber testing



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3.4 HIC: Safe Data

- Compliant with GDPR
  - Limited & proportionate access to data
- All individual IDs are project specific
- All NHS data de-identified (pseudonymisation)
  - Encourage data minimisation
  - Data protection impact assessments
    - Mitigates risk

3.5 HIC: Safe Outputs

- Only summary data released
- Disclosure control
  - Statistical
  - AI/ML
- All outputs checked manually

3.6 Seven Safes?

Safe Compute

- In the advent of cloud computing are the data/projects/settings “Safe?

Safe Return

- Ingesting data into a secure environment has some potential additional risks

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