



**DPIA for data transfer to NHS Digital and the Secure anonymised Information Linkage (SAIL) Databank**

**Submitting controller details**

Name of controller	Vaccine research Trust
Subject/title of DPO	Data Protection Officer
Name of DPO	Dr Afshan Ahmad

**Step 1: Identify the need for a DPIA**

The need for this DPIA has arisen in preparation for a formal request by researchers in Cardiff university for transfer of personal and treatment data from care records that are held by the Vaccine Research Trust (VRT) to NHS Digital and the Secure Anonymised Information linkage (SAIL) Databank.

Researchers in Cardiff university have applied to the NHS Health Research Authority's Confidentiality Advisory Group for personal and care records held by VRT to be forwarded to NHS Digital and SAIL for anonymization before being made available to the researchers in anonymised form for research in the public interest.

This DPIA sets out a process plan for data transfer to NHS Digital and SAIL, pending approvals for data transfer.

**Step 2: Describe the processing**

**Nature of the Processing**

The care records of about 4000 patients are held in hard copies in the clinic premises. These hard copy records include personal and treatment data and are stored in secure and locked filing cabinets in a restricted locked room in the clinic premises. In addition, anonymized treatment data (without identifiers) are held in electronic format in a laptop with screen lock, security system and password protection on files.

## Scope of the processing:

Data consists of personal data and health care data.

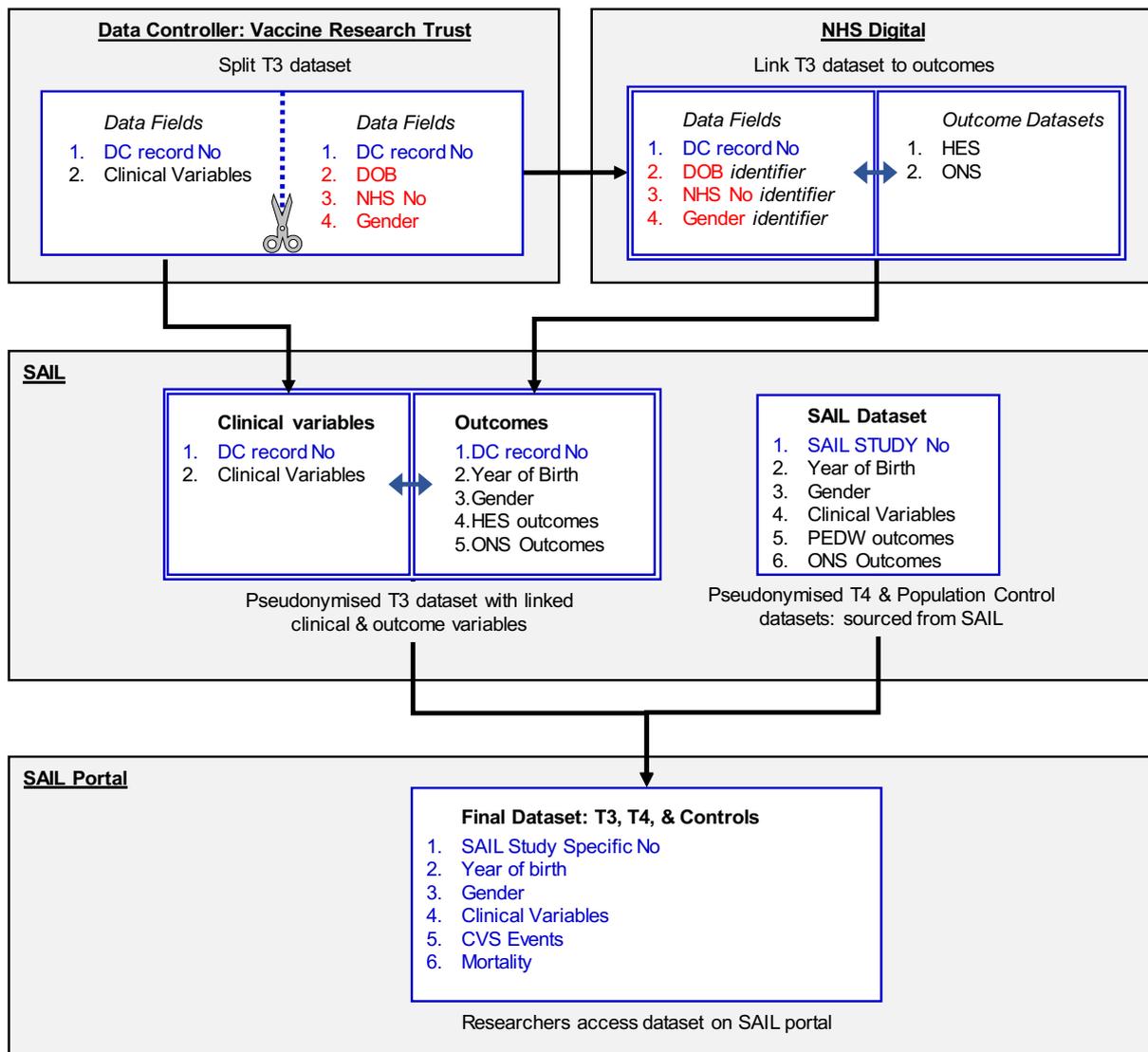
### Personal data

Personal data comprises (1) Name, (2) Gender, (3) Date of birth, (4) Address, (5) NHS no. According to the researcher's protocol the personal data will be forwarded electronically to NHS Digital using NHS Digital's secure data transfer protocol.

### Health Care Data

Health care record data comprises: (1) Diagnosis, (2) Treatment (drugs and dosages, (3) Date of diagnosis and treatment. According to the researcher's protocol, health care data with no identifiers will be forwarded electronically to SAIL using SAIL's secure data transfer protocol.

Data will be transferred as a one-off process. An anonymisation flow process created by the researchers is shown below.



**Context of the processing:**Background to the data

VRT holds care records of individuals who were treated in Dr Gordon Skinner's private medical thyroid clinic from 1996 to 2013. These records were collected to provide medical care to the patients who were treated with a thyroid drug called T3, a drug that is not widely prescribed in the NHS. Dr Skinner was the chairman of VRT until his death in 2013. Since his death, the clinic has now ceased operation, but the care records have been held under data protection by VRT who have acted as data custodian.

Proposed Research Study

Cardiff university researchers now wish to investigate the safety of the drug T3, and seek access to Dr Skinner's thyroid clinic data, in the public health interest.

Opt-out-option

VRT will publish an opt out notice on their website so that individuals who do not want their data to be used in this way will have an opportunity to opt out of the study.

**Purposes of the processing:**

The benefit of processing this data is that it will be used for research in the public health interest. The long-term safety of the drug T3 is uncertain, and the study hopes to clarify whether the drug is safe to use. This data is unlikely to be obtained elsewhere since T3 is not prescribed on a significant scale in conventional NHS clinics.

## Step 3: Consultation process

### **Consult with relevant stakeholders:**

The proposed use of these data for a research study has been discussed with many of Dr Skinner's former patients who have written letters of support and posted comments supporting the research on websites.

The proposed data transfer has also been discussed amongst the trustees who are all in agreement that the research is worthwhile.

The research has received ethical approval and CAG approval is now being sought by the researchers.

Following approval for the study, we will consult with NHS Digital and SAIL (the organisations that will receive the data) regarding the most efficient and secure way of transferring the data electronically.

## Step 4: Assess necessity and proportionality

### **Compliance and proportionality measures, in particular:**

The researchers have submitted a research application under Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002 ('section 251 support') to process confidential patient information without consent. The data will be transferred on a once only basis. The quality of the data was maintained during the life of the clinic by Dr Afshan Ahmad in line with the audit requirements imposed on the clinic by the General Medical Council during the life of the clinic. Data will be transferred securely to SAIL and NHS Digital. Both SAIL and NHS Digital are established organisations with the security assurances to handle such data.

## Step 5: Identify and assess risks

<b>Describe source of risk and nature of potential impact on individuals.</b> Include associated compliance and corporate risks as necessary.	<b>Likelihood of harm</b>	<b>Severity of harm</b>	<b>Overall risk</b>
(1) Remote risk that existing records could be breached, and patient's data viewed by unauthorized individuals.	Remote	Significant	Low
(2) Remote risk that records could be viewed by unauthorized individuals during data transfer.	Remote	Significant	Low

## Step 6: Identify measures to reduce risk

<b>Identify additional measures you could take to reduce or eliminate risks identified as medium or high risk in step 5</b>				
<b>Risk</b>	<b>Options to reduce or eliminate risk</b>	<b>Effect on risk</b>	<b>Residual risk</b>	<b>Measure approved</b>
Breach of paper records	The filing cabinet is kept locked and can only be accessed by authorised individuals. All Information handling and record keeping procedures are followed and audits are completed.	Reduced	Low	Yes
Breach of electronic records	Data is stored on a laptop which has an automatic screen lock, password protection and disc encryption In the event of theft, the laptop data will be unreadable as encrypted and a facility is also in place to enable remote wiping of the laptop.  The transfer of records will be undertaken using NHS Digital	Reduced	Low	Yes

Breach of records during electronic transfer	and SAIL secure transfer procedures.	Reduced	Low	Yes
--	--------------------------------------	---------	-----	-----

## Step 7: Sign off and record outcomes

Item	Name/position/date	Notes
Measures approved by:	Chairman of Vaccine Research Trust	Integrate actions back into project plan, with date and responsibility for completion
Residual risks approved by:	Dr Afshan Ahmad	If accepting any residual high risk, consult the ICO before going ahead
DPO advice provided:	Yes	DPO should advise on compliance, step 6 measures and whether processing can proceed
<p>Summary of DPO advice: The measures to reduce the risks are appropriate and proportionate.</p>		
DPO advice accepted or overruled by:	Chairman of vaccine Research trust Accepted	If overruled, you must explain your reasons

This DPIA will kept under review by:	Dr Afshan Ahmad	The DPO should also review ongoing compliance with DPIA
--------------------------------------	-----------------	---