**Antithyroid Drug Study (ATD) Data Protection Impact assessment (DPIA)**

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

Explain broadly what project aims to achieve and what type of processing it involves.

The Royal Devon and Exeter NHS Foundation Trust Sponsor a research study: The Antithyroid Drug (ATD) Study. This is a multicenter study, currently recruiting in England and Wales, aiming to answer the following questions:

• Who is at risk of suffering an antithyroid drug related side effect?

• How are these side effects treated?

• Is management of complications different in different places

• Is one treatment better than another?

• How might we improve patient safety?

The study also asks participants to provide a blood sample to obtain DNA to use in a future study for validation of predictive testing to improve patient safety. The hope is to achieve a screening test that would tell us which patients should be treated with alternate therapies. This would take the promise of personalised medicine directly into the endocrine clinic, and advance a key NHS aim of improving patient safety.

Over a 2 year period the study will collect information from 150 adult patients who have had a severe antithyroid drug reaction. Data will be collected from their medical notes so participants will only need to visit the hospital to provide a blood sample (this part of the study is optional).

Prospective eligible patients will be approached in clinic by a member of their clinical care team. Retrospective eligible patients (those who have had a reaction in the past 10 years) will be contacted by letter if not actively receiving secondary care treatment. A concern, and the reason for this assessment (alongside applications to the Confidentiality Advisory Group (CAG) for England/Wales and the Public Benefit and Privacy Panel for Health and Social Care (PBPP) for Scotland) is access to patient records for research purposes.

The person approaching potential participants should be a health or social care professional who has a relationship with the patient, such as the clinician providing care, or a researcher who is also part of the clinical care team.

In this study, as cases can go back as far as 10 years, the clinician making the approach is unlikely to be part of the patients current clinical care team. Special approval (CAG/PBPP) is therefore required to support local clinicians accessing patient information to determine eligibility and approach patients who may not be currently receiving secondary care. Data needed to complete the study CRF, will not be accessed until the potential participant returns a completed consent form. We will also contact local Caldicott Guardians to seek their approval once generic PBPP approval has been gained.

The PBPP application for Scotland requests the applicant to submit a data protection impact assessment (DPIA) to demonstrate that privacy risk has been adequately assessed, is appropriately managed, and has been reduced to acceptably low levels.

All potential participants will be given the opportunity to ask questions and will be invited to return the consent form and attend the hospital to provide a blood sample. Anyone not wishing to provide a sample will still be able to participate in the clinical data collection part of the study. Where no reply or response is received, one telephone call will be made to check the patient received their invitation and to confirm they do not wish to participate.

Each participant will be capable of consenting for themselves. This means they will understand the purpose and nature of the research, understand what the research involves, its benefits (or lack of benefits), risks and burdens, understand the alternatives to taking part, be able to retain the information long enough to make an effective decision, be able to make a free choice, be capable of making this particular decision at the time it needs to be made. Any potential participant lacking capacity will be excluded. Since contacting the relatives of deceased patients is likely to cause distress, consent will not be sought for this small number of cases.

**Step 2: Describe the processing**

Describe the nature of the processing.

Once a patient has consented to participate, data will be entered onto paper based Case Record Forms (CRFs) by a member of the local research team. Clinical information will be extracted from the medical records. Once complete, the CRF will be sent to the study and data management team, based at the Society for Endocrinology in Bristol, for data entry into a centralised database. The data will be pseudo-anonymised locally before sending via email with password protection, to Bristol. Each study participant will be given a unique identification number and personal data will not be transferred. An electronic data capture system was not possible within the small study budget.

A pseudonymised copy of the final dataset will be sent, password protected, via encrypted data stick to the Chief Investigator Professor Bijay Vaidya, Department of Endocrinology, Royal Devon & Exeter Hospital, Exeter. The Chief Investigator will carry out descriptive statistical analyses to determine the demographics and risk factors for ATD-induced side effects and treatment outcomes.

A DNA sample will be obtained from each patient for a future study to determine genetic risk factors for these adverse effects. Samples will be sent directly to the Newcastle Institute for Genetic Medicine for DNA extraction and storage.

As the CRF will only be completed if a participant returns a consent form, we do not feel that the proposed data flow poses any high risk.

Describe the scope of the processing.

The data to be accessed PRIOR to consent is for determining eligibility and contacting participants only. This includes DOB (Age), history of treatment with an antithyroid drug and details of any reported side effects, name, address and telephone number.

The CRF will not be completed unless the patient returns a signed consent form.

The CRF records ethnicity. Ethnicity is important because it may be a risk factor for suffering drug induced side effects.

The CRF also records Mental and physical health data. This is necessary to determine capacity and eligibility and may be entered into the medical/drug history section of the CRF.

One CRF will be completed per participant on one single occasion. This will be archived for 5 years in order to comply with NHS policy for archiving clinical research.

Data will be collected for 150 individuals within the UK.

Describe the context of the processing.

The Clinicians involved in this study are likely to be a member of the participant’s current (for prospective cases) or past (for retrospective/deceased cases) clinical care team. Patients invited to take part are free to accept or decline the invitation and have full control over their participation and the data collected. Provision of a blood sample for future use is a voluntary ‘extra’ part of this study. Potential participants are provided with an information sheet that clearly details how their data will be used and by whom.

Adults with incapacity and children are excluded.

The processing of eligibility and contact data will all be done within the local hospital by the local study Principal Investigator, using hospital computer systems. This information will be destroyed if the patient does not consent to participate.

All Clinicians involved in this study have NHS contracts and will therefore be required to follow NHS policies and codes of conduct as well as research governance procedures.

As with any research study, the participants are entitled to withdraw at any time.

Describe the purposes of the processing.

Antithyroid drugs (ATDs) are the primary treatment for most patients with hyperthyroidism (a condition where the thyroid gland produces too much of the hormone thyroxine). Of the 15,000 new UK patients treated each year, 1/500 have a drug reaction causing a very low white cell count leading to inflammation of the throat, mouth and lips, fever and sepsis. If treatment is stopped quickly a patient will usually recover after 5-10 days but up to 10% of cases are fatal. Another potentially life-threatening effect is liver injury and 1/1000 patients taking the ATD Propylthiouracil will get this. Of these, 10% will have liver failure resulting in liver transplantation or death. As these side-effects are rare, each doctor will only see a small number of cases. Therefore, important patterns or information about who is affected and the best way to manage them could be being missed.

This systematic and detailed review of the rare cases of ATD-associated side effects will form an unparalleled research resource to identify individuals at risk, to identify common themes in management of their complications, and to improve patient safety. The future genetic analyses of the DNA samples collected in this study will identify a predisposing allelic variant(s) that has the potential to then enter clinical practice as a genomic screening test for high-risk individuals who could then be treated with alternative therapies. This would take the promise of personalised medicine directly into the endocrine clinic, and advance a key NHS aim in improving patient safety.

The plan to recruit 150 patients was a pragmatic calculation, based on the likely number of historical (past ten years) and prospective cases over a 2 year recruitment period. Without the inclusion of retrospective cases, no longer receiving current care, the study would need to recruit for many more years to reach a reasonable number of participants for analysis.

The proposed data processing prior to consent will enable this study to recruit eligible participants in a timely manner. The data processing activities after consent are necessary to fulfil the study aims.

Risks have been reviewed by the Health Research Authority, Research Ethics Committee, Confidentiality Advisory Group (England/Wales) and the Patient Benefit and Privacy Panel (Scotland). Caldicott Guardian approval will also be sought from Scottish health boards.

**Step 3: Consultation process**

Consider how to consult with relevant stakeholders.

Our patient partner is the founder and director of the British Thyroid Foundation and was diagnosed with Graves’ disease and thyroid eye disease in 1984. She attended the first study management meeting and has had input into the acceptability and design of this research study. She has reviewed the patient facing documents and will remain part of the management group providing the patient perspective throughout. Specifically regarding this assessment and the CAG/PBPP applications, our patient partner felt that an approach made by a local Clinical Principal Investigator would be acceptable to patients. In many cases this person would have been part of the patients historical care team whilst receiving secondary care. Once contacted, each patient can decide whether to patriciate or not.

Principal Investigators involved in this study have discussed and agreed the proposed method for approaching retrospective cases. The alternative would be to ask GPs to approach patients first but it was felt that this would increase the burden on GPs and protract the recruitment process. In addition, the clinician would still be required to screen for patients and look up their GP details. A patient poster has been designed which can be used in clinics and will be placed on the Society for Endocrinology website alongside further information about the study.

The proposal for clinicians to screen and approach potential research participants for this study has been reviewed by the England and Wales Confidentiality Advisory Group. The CAG agreed that the minimum criteria under the Regulations had been met and that there was a public interest in projects of this nature being conducted, and therefore advised recommending support to the Health Research Authority.

This assessment is being provided to all Scottish boards and Caldicott Guardian approval will be sought. PBPP approval will accompany this assessment.

**Step 4: Assess necessity and proportionality**

Describe compliance and proportionality measures, in particular: what is your lawful basis for processing.

The lawful basis for processing data in this study is:

Article 6 (1) e: processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller

Article 9 (j): processing is necessary for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes in accordance with Article 89(1) based on Union or Member State law which shall be proportionate to the aim pursued, respect the essence of the right to data protection and provide for suitable and specific measures to safeguard the fundamental rights and the interests of the data subject

CAG (England and Wales) and PBPP (Scotland) support and approval is sought to enable us to contact individuals who might be eligible to participate but who completed their Secondary care treatment some time ago, without breaching the common law duty of confidentiality.

The proposed data processing enables recruitment of participants and collection of data to fulfil the study aims. The CRF is not onerous and has been designed to capture the minimum data required. Only data that can be wholly collected from medical notes has been included in order to minimise the burden on the participant. The provision of a blood sample for future research is optional and it is therefore possible for a patient to participate without visiting the hospital on any occasion.

Individuals receive an invitation letter and information sheet and are given contact details for the research team and local Principal Investigator for any questions. Prospective cases approached in clinic are able to have a discussion with the local team face to face or later using the contact details provided.

The proposed data collection elements and patient information has been approved by a Research Ethics Committee.

All data will be managed according to the requirements of the NHS code of confidentiality, GDPR principles, the UK policy framework for health and social care research and in line with the UK Data Protection Act 2018. Personal data will only be stored where necessary and only in an area at the local site with restricted access. Filing cabinets and cupboards used for storage of CRFs will be lockable. Computers and computer files will be password protected.

Data quality will be ensured by careful checking of CRFs for completeness, validity and accuracy at the point of data receipt and entry. The central study team will issue data queries in a timely manner and will take responsibility for ensuring their resolve.

**Step 5: Identify and assess risk**

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| Describe source of risk and nature of potential impact on individuals. Include associated compliance and corporate risks as necessary. | Likelihood of harm Remote, possible or probable | Severity of harm Minimal, significant or severe | Overall risk  Low, medium or high |
| Sensitive/special category data is collected. Could cause harm or distress if accessed/shared inappropriately or was lost. Could lead to regulatory fines and reputational damage. | Possible  (is transferred) | Significant | Medium |
| Personally identifiable data is collected. Could cause harm or distress if accessed/shared inappropriately or was lost. There could be a compliance risk if the study accumulates this type of data without purpose or appropriate control. Could lead to regulatory fines and reputational damage. | Remote  (is stored locally) | Significant | Medium |
| Pseudonymised data could be accessed by unauthorized staff. Could cause harm or distress if accessed/shared inappropriately or was lost. Could lead to regulatory fines and reputational damage. | Possible  (is transferred) | Minimal – participant highly unlikely to be identified | Low |
| Pseudonymised data will be shared by email. Could cause harm or distress if accessed/shared inappropriately or was lost. Could lead to regulatory fines and reputational damage. | Possible  (data is to be shared via email) | Minimal – participant highly unlikely to be identified | Minimal – participant highly unlikely to be identified |

**Step 6: Identify measures to reduce risk**

Identify additional measures you could take to reduce or eliminate risks identified as medium or high risk in step 5

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| Risk | Options to reduce or eliminate risk | Effect on risk Eliminated reduced accepted | Residual risk | Risk |
| Sensitive data is collected. Could cause harm or distress if accessed/shared inappropriately or was lost. Could lead to regulatory fines and reputational damage. | Only data absolutely necessary to achieve the study aims is to be collected. Data will only be retained as long as is necessary and anonymised as soon as possible. | Reduced | Low | Yes |
| Personally identifiable data is collected. Could cause harm or distress if accessed/shared inappropriately or was lost. There could be a compliance risk if the study accumulates this type of data without purpose or appropriate control. Could lead to regulatory fines and reputational damage. | Forms clearly state how data should be stored and who data should be shared with and in what format. Data kept at site and not transferred with CRF. Process is in place for reporting and dealing with breaches. | reduced | low | yes |
| Pseudonymised data could be accessed by unauthorized staff. Could cause harm or distress if accessed/shared inappropriately or was lost. Could lead to regulatory fines and reputational damage. | Central team will destroy paper/email copy once data entered into the database. Original to be kept at local site. Data is stored on secure server with restricted access to study folder. Computer access requires password. | reduced | low | yes |
| Pseudonymised data will be shared by email. Could cause harm or distress if accessed/shared inappropriately or was lost. Could lead to regulatory fines and reputational damage. | All shared documents will be password protected (unique to each document) and the password sent separately. Emails are not retained. | Reduced | low | yes |