**THE PINPOINT TEST**

**Specific purpose(s) for which the data sharing is required (all intended purposes should be described, it may be appropriate to describe each one on a separate pro forma) and necessity for the sharing**

|  |
| --- |
| ***Background*** - The Pinpoint Test is a new test to identify a patient’s risk of cancer. The test uses the analysis of a range of blood results and combines them with a limited number of patient details to produce a calibrated risk score. The risk score indicates the likelihood that the patient has cancer.  The PinPoint test will be of particular benefit in the COVID recovery period. There is a backlog of patients who have not presented during the lockdown period, who are expected to re-engage with healthcare services over the coming months. Additionally, there is a significant backlog for diagnostics and due to COVID restrictions the expectation is that this backlog will continue for the foreseeable future. As a result there is a need to find effective ways to identify and progress care for high risk patients and if possible to rule out or manage low risk patients on a different non-urgent pathway.  Phase 1 of the project is a service evaluation of the test in a real world situation. Patients will be referred by their general practitioner using the normal two week wait (2WW) urgent cancer referral process and a Pinpoint test requested through the ICE system. This data sharing agreement is to support the information governance in relation to the patient identifiable information that will be shared via the ICE request. The test will run in parallel to the normal diagnostic process and the patients’ final clinical outcome will be matched to the PinPoint test ‘risk score’. At Phase 1 the PinPoint test ‘risk score’ will not be returned to the referring clinician.  Due to the need for consistency in processing and reporting, all testing in Phase 1 will be carried out through the laboratory at Mid Yorkshire Hospitals NHS Trust. This laboratory will act as a central testing hub for West Yorkshire and Harrogate.  During Phase one the clinical outcome for each patient will be matched to their PinPoint risk score. When 100 patients have been diagnosed with a confirmed cancer in an individual pathway, following the relevant PinPoint test, there will be a decision made based on this data as to whether to progress to Phase 2. The evaluation will be undertaken by an NHS expert panel, including clinicians, in collaboration with PinPoint Data Science Ltd (*it is possible that this decision may be made on fewer than 100 cancer diagnoses under certain circumstances*).  Once the Pinpoint test algorithm has satisfactorily met the clinical panel assessment during Phase 1, that it is safe and accurately predicts cancer risk, the project will move to Phase 2 and the test will be implemented and the PinPoint test ‘risk score’ will be returned to the referring clinician and made available to secondary care clinicians. It will be used by them as a decision support tool to better inform patient care.  ***Purpose*** - The purpose of this data sharing agreement is to cover the transfer of a small set of patient details from the GP Practice to the Laboratory at Mid Yorkshire Hospitals NHS Trust for the purpose of analysing the blood samples and running the PinPoint test algorithm. These details will be the patient’s name and NHS number, date of birth, sex, ethnic origin and pregnancy status. This process will take place using the normal ICE request form. The data that is shared will enable the test to run and return a PinPoint ‘risk score’ and for this risk score to then be matched to the patients clinical outcome.  In Phase 2 the PinPoint test will support the direct care of the patient. However, in Phase 1 the results will not impact on a patient’s care, necessitating this data sharing agreement. |

**Nature and scope of the processing**

|  |
| --- |
| **Identify the category of the information**  Personal Data and Special Category Data  **Set out** **why the sharing is necessary, relevant and proportionate**  The following personal data and special category data is necessary, relevant and proportionate to share with the hospital as it is the minimum required to enable the PinPoint test to be carried out: patient’s name and NHS number, date of birth, sex, ethnic origin and pregnancy status.  **Law enforcement processing - explain**  Not applicable to this data sharing agreement.  **Compatibility of data sets**  The transfer of this data will take place in the ICE request system. This system is in common use for other tests requested by primary care and contains information in a format that is designed and agreed by the recipient.  This is a standard process for requesting clinical tests by GP practices.  **How will you ensure data quality and data minimisation**?  All the data fields are required to run the PinPoint test algorithm and to match the patient details to their clinical outcome. These details have been kept to an absolute minimum and at the point of laboratory processing any personal identifiable detail will be removed and replaced with a sample ID.  The patient details will mainly be pulled directly from the GP record therefore ensuring accuracy. The only other information that will be selected from check boxes will be the suspected cancer pathway, ethnicity and for female patients pregnancy status.  All the information that is transferred is necessary to complete the test and will be transferred in the secure ICE system*.*  **Scope of Processing - Identify:**  Data collected for each individual test requested will be the patient’s name and NHS number, date of birth, sex, ethnic origin and pregnancy status.  Across the course of phase one (evaluation phase) approximately 15000 patients will have a PinPoint test. This is the number of tests that will enable 100 cancer diagnoses to be reached in each cancer pathway covered by the PinPoint test.  In Phase 1 stage 1, the test will be introduced to GP Practices within the Mid Yorkshire Hospitals NHS Trust catchment area (Wakefield and North Kirklees). In Stage 2 the test will be rolled out to the remaining areas in West Yorkshire and Harrogate. |

**Type and status of data shared**

|  |  |
| --- | --- |
| **Is the data ‘person identifiable’?** | Yes |
| **Does it include special category personal data** | Yes |
| **Does it include criminal offence data** | No |
| **Has explicit consent been given and recorded?** | Yes |
| **Has implied consent been recorded?** | No |
| **Is the subject aware that sharing will take place?** | Yes |
| **Is the data anonymised?** | No (however data will be pseudonymised for Laboratory processing using a sample ID and will be anonymised for the purposes of the evaluation of the PinPoint test by an expert NHS panel. |

**Context of the processing**

|  |
| --- |
| The individuals to whom this data sharing agreement relates will be patients of the GP practice. They will be subject to a Two Week Wait Urgent Cancer referral.  Patients will be able to refuse the PinPoint test or the use of their data as part of the service evaluation. They will also be able to withdraw their consent to the test and object to the sharing of their data at any point in the process.  Patients will expect the test as part of their treatment and will be aware that some items of data will be shared to enable this. They will also be made aware that this test will not currently impact on their care directly and informed consent will be taken.  Children and other vulnerable groups will not be offered the PinPoint test during the evaluation phase.  The PinPoint test uses an Artificial Intelligence/Machine learning algorithm to produce a calibrated risk score that indicates the likelihood that a patient has cancer. There have been recent concerns about algorithms that have become biased in their processing over time. In order to address this PinPoint Data Science Ltd will carry out ongoing audit and maintenance of the performance of the algorithm.  The concern over the use of Artificial Intelligence has been factored in and there are measures in place to address this.  This is a new test which has been CE marked to ensure that it meets relevant European Standards. |

**Legal basis for sharing where no consent is given**

|  |
| --- |
| Not applicable as the patient’s informed consent it sought and documented as part of the evaluation phase for the PinPoint test. |

**Duty of confidentiality**

|  |
| --- |
| **Does a duty of confidentiality exist?**  Yes. The data is identifiable patient information and is comprised of information that has been obtained by the NHS, in confidence. The data is therefore confidential information and subject to a duty of confidence under the common law (Duty of Confidence).  **What justification is there for overriding this?**  The explicit informed consent of the patient will be gained and documented on the 2 week wait form which forms part of their patient record. |

**Human Rights Assessment**

|  |
| --- |
| **Human Rights Act 1998**  Article 8: Right to respect for private and family life, home and correspondence. Interference is necessary in a democratic society for: Protection of health or morals. |

**Data Items shared**

This list must be comprehensive and include ALL data items that are to be shared. All data items to be shared must be justifiable as necessary for the purpose. The service user/staff member should be aware that the information will be shared and have consented to it. For the purpose of delivering care implied consent is sufficient. You should tailor this section to suit your organisations specific needs.

|  |  |  |
| --- | --- | --- |
| **Service User Data** | **Yes/No** | **Comment** |
| **Name, address, Date of Birth, Gender, GP** | Yes | The ICE request will include the patient’s name, date of birth, gender and ethnic background and will identify their referring GP |
| **Identifying numbers**  (NHS No. etc.) | Yes | NHS Number will be used for the request and to enable the patient matching to take place but this will be replaced by Sample number during testing. |
| **Next of Kin, Emergency Contact, Carer Details** | No |  |
| **Clinical Details**  (Clinical details should only be shared where there is a justifiable purpose) | No |  |
| **Basic Clinical Details**  (Condition and relevant care requirements) | Yes | The suspected cancer pathway will be identified on the ICE request along with their pregnancy status. |
| **Full Clinical Details**  (May include medical history, test results, clinical letters, reports etc.) | No |  |
| **Criminal Offence Data** | No |  |
| **Other**  (Should only be shared where there is a justifiable purpose) | No |  |
| **Risk Factors** |  |  |
| **Other (Please Explain)** | No |  |
| **Staff Information** | **Yes/No** | **Comment** |
| **Name, Job Title, Work Base, Work Team, Line Manager** | No |  |
| **Identifiers Such As Payroll No. NI Number** | No |  |
| **Home Address, Date of Birth and Next of Kin** | No |  |
| **Full Employment Record** | No |  |

**10. Protective Marking**

|  |  |
| --- | --- |
| **Is Protective marking/Classification relevant to this information?** | Yes – however the information will not be transferred via email but rather within existing systems ie ICE request system and hospital laboratory and pathology messaging systems. |
| **If yes please use the system relevant to your Organisation** | Classification of ‘OFFICIAL – SENSITIVE [PERSONAL]’ |