**SUPPORT FOR USE OF CONFIDENTIAL PATIENT INFORMATION WITHOUT CONSENT**

#### Non-research application form

*Applicants are advised that processing for research purposes cannot be considered via this form. A separate form must be completed in IRAS if intending to process confidential patient information without consent for research purposes.*

*Please give full answers, expanding where necessary and attaching relevant supporting documents set out in Annex A.*

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| **SECTION 1: REGISTER DETAILS (if supported, this information in section 1 and 2 will be published on the Register of Approved Applications)** | |
| 1. **Full Application Title:** | Disclosure of combined commissioning data sets and GP data for risk stratification purposes to Integrated Care Boards and Data Processors. |
| 1. **Application Summary:**   *Provide a summary of the purpose the activity is designed to achieve, why it is being undertaken, why confidential patient information is required, and an overview of the data flows.*  *Applicants will be asked to provide more detail in section 2, question(m)* | The purpose is to stratify the populations data to identify high service users, at risk, and would benefit from pro-active interventions through GPs. In addition, GPs have the ability to review available interventions and verifying appropriateness.  Risk stratification has a profound impact on the delivery of health services across the developed world. The risk stratification tools use relationships in historic population data to estimate the use of health care services for each population member. The tools are useful for both populations planning purposes, health activities evaluations and identifying which patients should be offered targeted, preventative support. Confidential patient information is required from multiple sources to populate risk stratification tools to accurately identify patients that could benefit from targeted intervention. The amalgamation of specific data sets provides timely and accurate understanding of the population’s health needs.  The Integrated Care Board (ICB) can receive data on its populations via Secondary Use Services (SUS) and Mental Health Services Dataset under s261(4) of Health and Social Care Act 2012 Act in pseudonymised form to support commissioning activities. ICBs through their appointed risk stratification suppliers or tools, will provide the linkage and risk profiling analysis of the data sets.  The GP data is linked and stratified with the above data sets for case finding, re-identification and where relevant intervention. |
| 1. **Applying Organisation:**   *This is the full name of the organisation making the application. This may be different from the controller for the application e.g. if the applying organisation is a processor operating on behalf of the controller*  \* | Please refer to the supplementary information document, section Administrative Details the detailed ICB response. |
| 1. Controller   *This is the entity responsible for determining the purpose and manner of this application detail (under GDPR/DPA 2018 definitions). This may differ from the details in question 1 (c) and (f).*  *Please provide work-based contacts only* | *Organisation:* \*For Local Completion\* |
| *Full Name and Role:* |
| *Address (Work):* |
| *Email:* |
| *Telephone:* |
| 1. Processor (s)   *List all processors handling confidential patient information. Note these will need to provide evidence of adequate security assurances* | Please refer to the supplementary information document, section Administrative Details the detailed ICB response. |
| 1. Contact Name & Role:   *Person who will be responsible for responding to queries as the application is processed* \* | Name: \*For Local Completion\*  Role:  Telephone:  Email: |
| 1. Address for correspondence:   Postcode:  Email: | \*For Local Completion\* |
| 1. Name of Sponsor Organisation:   *(Sponsor’s written recommendation to be attached including approval from local Caldicott guardian(s))* | \*For Local Completion\* |
| 1. Cohort/Population being studied:   *Give details of numbers, characteristics of population, inclusion and exclusion criteria* | The population will be all GP registered patients within the Integrated Care Board footprint. |
| 1. List/description of confidential patient information intended to be processed under support:   *Please list the key identifiers to be processed*  *Please attach a full dataset or other additional information as necessary.* | The datasets and data items will vary depending upon the risk stratification tools being used.  All the national datasets utilised for risk stratification purposes will be listed within the ICB’s data sharing agreement within NHS England.  As minimum these datasets will include:  The Secondary Use Service (SUS) datasets which include the following:   * Patient Demographics * Admitted Patient Care Commissioning Datasets (120-170) * Outpatient Commissioning Datasets (020) * Community Services * Emergency Care Data Set (011) * Mental Health Services Dataset * Improving Access to Psychological Therapies dataset   (The full list of data items for these datasets can be found within the NHS Data Dictionary [NHS Data Model and Dictionary](https://www.datadictionary.nhs.uk/about/about.html) - https://www.datadictionary.nhs.uk/about/about.html)  The GP dataset including   * Patient data * Event data * Referral data * Prescriptions * Conditions / diagnosis groups * Health groups * Interventions group * Exclusions group * Practice data – ID * Registered patient list   There may also be local datasets required, which may include:   * Ambulance service data * 111 dataset   The legally restricted codes will be excluded. National Data Opt Outs will be applied.  Identifiers required for linkage:  NHS number |
| Identifiers required for analysis:  Please refer to the supplementary information document, section Informing the Patient Population for the detailed ICB response |
| 1. Classes of support   *Please mark required general purposes with X.*  *Class VI is pre-selected as it applies to all applicants* \* | □ Class I Support : the process of extracting and anonymising the information  □ Class IV Support : To link patient identifiable information obtained from more than one source  □ Class V Support : for auditing, monitoring and analysing patient care and treatment  x Class VI Support : to allow access to an authorised user for one or more of the above purposes  □ Specific Support required (Regulation 2 – cancer registration purposes) |

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| SECTION 2: JUSTIFICATION OF PURPOSE & PUBLIC INTEREST | | | |
| 1. Detailed Description of purpose:   *Provide a detailed description of the purpose of the proposed activity for which support is sought. Set out the anticipated benefits the unconsented processing will bring.*  *Must also include the precise medical purpose as defined within the* [s251 (12) of the NHS Act 2006.](http://www.legislation.gov.uk/ukpga/2006/41/section/251) | | Risk stratification is a tool for identifying and predicting which patients are high risk (of health deterioration and using multiple services) or are likely to be at high risk. Prioritising the management of their care to reduce and prevent poor outcomes.  To conduct risk stratification, national datasets are linked with GP data via the NHS Number and an algorithm is applied to produce risk scores. Risk Stratification provides focus for future demands by enabling Commissioners to prepare plans for both individual and groups of vulnerable patients who may require high levels of care. Risk Stratification also enables General Practitioners (GPs) to better target intervention in Primary Care.  The main objectives are:-   * Improving the physical, mental health outcomes and wellbeing of people, whilst reducing health inequalities within and across the region / locality. * Reducing re-occurrence of ill-health, including addressing wider determinants of health, and working with communities and partner agencies. * Addressing the wider determinants of health to early intervention, primary, secondary and tertiary disease prevention. * Producing trajectories, changes in variation over a period of time, including the impact on the economy at region and locality level   The use of risk stratified data, enables the targeting of “at risk” patients and communities at risk of deteriorating health, through:   1. Improved planning by better understanding the patient flows through the healthcare system. Allowing Commissioners to design appropriate pathways to improve patient flow and identify priorities / plans to address 2. Reduce emergency readmissions, especially avoidable emergency admissions by improving quality of services. This is achieved through the mapping of frequent users of emergency services and supporting early intervention 3. Improved access to services by identifying which may be in demand but have limited accessibility. Then from this identify areas where improvement is required 4. Supports the Commissioner to meet its requirement to reduce premature mortality in line with the ICB Outcome Framework by allowing for more targeted intervention in Primary Care 5. Better understanding of local population characteristics through analysis of their health and healthcare outcomes   All of the above lead to improved patient experience and health outcomes through more effective commissioning of services.  Ultimately, the aim is to create an appropriate information sharing environment that helps our health and care services continually improve the treatments that are used. To ensure that care is tailored to the needs of each individual, empowering people to look after themselves better and make informed choices about their own health and care. | |
| 1. **Describe how the proposed use of information without consent will improve patient care and serve the wider public interest?**   ***Expand as necessary as this is a critical section.*** | | There is an opportunity to utilise information better from patients health and care records. To understand more about health and diseases, improve public health for the population identified as high risk, develop new treatments, monitor safety, and plan / deliver health care services more effectively.  The proposed approach is informed by:   * an analysis of patient flows across local communities, with the goal of holding information close to where care is provided; * an aim to collate information at a size and scale that helps build trustworthiness in the eyes of the public; * having sufficient flexibility and agility to meet local service needs, whilst delivering a sustainable service that represents good value for money   The risk stratification data will allow the:-   1. Identification of patient groups at risk of deterioration and providing effective care 2. Identification of health determinants that are a risk of admission to hospital, and / or other adverse care outcomes 3. Monitoring of vulnerable groups of patients, including but not limited to risks of frailty, COPD, diabetes 4. Health needs assessments identifying the number of patients with specific health conditions or a combination of conditions 5. Classifying vulnerable groups based on disease profiles, conditions currently being treated, current service use, pharmacy use and risk of future overall cost 6. Specific disease based analysis 7. Aggregate reporting population found to be at risk by number and percentage   Please refer to the supplementary information document, section Patient Benefits for the detailed ICB response. | |
| 1. **Data flows**   **Provide a narrative description of the data flows for which support is sought. This must include:**   * **The data sources** * **Relevant organisations** * **Identifiers to be processed** * **Stages where information is pseudonymised**   Applicants should also provide a simple graphical data flow diagram that shows the flow of information, who is involved in processing, the stages at which it is pseudonymised/anonymised. | | As part of the risk stratification processing activity detailed above, GPs have access to the risk stratification tool which highlights patients for whom the GP is responsible and have been classed as at risk. The only identifier available to GPs is the NHS numbers of their own patients. Any further identification of the patients will be completed by the GP on their own systems.  GP Practices will be able to view the risk scores for individual patients with the ability to display the underlying data for the individual patients when it is required for direct care purposes by someone who has a legitimate relationship with the patient.   1. GP data will be extracted or sent to the approved risk stratification supplier (data processor), through either route a or b below.    1. Data is pseudonymised prior to being received / processed by the risk stratification supplier, section 251 support is not required as pseudonymised data used.    2. Data is pseudonymised after being received by the risk stratification supplier (**Section 251 support required)** 2. The national commissioning data sets will be sent to the approved risk stratification supplier, section 251 support is not required as pseudonymised data used. 3. The risk stratification supplier will link together the GP and national commissioning datasets via the NHS number **(Section 251 required)** 4. These linked datasets will be made available to the GP through the risk stratification suppliers tools enabling them to re-identify their patients via the NHS number to provide direct intervention, s251 support is not required as re-identification is for direct care.   Please refer to the supplementary information document, section Informing the patient population for the detailed ICB response. | |
| 1. Please list each of the data items you will hold in relation to each patient, and describe against each why the data item is required. | | The data items will be extracted from commissioning and GP data sets as per section j of the application.  Please refer to the supplementary information document, section Informing the patient population for the detailed ICB response. | |
| 1. Are you seeking specific support or class support?   If class support, detail which of the purposes that may be covered do you need support for? | | □ Class I Support : the process of extracting and anonymising the information  □ Class IV Support : To link patient identifiable information obtained from more than one source  □ Class V Support : for auditing, monitoring and analysing patient care and treatment  x Class VI Support : to allow access to an authorised user for one or more of the above purposes | |
| **SECTION 3: practicable alternatives and** | | | |
| 1. i. Why is it not practicable for the current holder of the information you require to seek or obtain patient consent for the proposed use of patient identifiable information on your behalf?   ii. Why is it impracticable to use anonymised or pseudonymised information? | | CONSENT:  Obtaining patient consent for risk stratification is not a practical option, as to effectively identify a small number of patients for targeted interventions the total registered population data is stratified.  The activity would require obtaining explicit consent for the whole registered population. Typically, a significant proportion and possibly the majority of patients will not reply to the communication. Potentially worsen health inequalities, if patients in more deprived areas or patients with greater health needs are less likely to respond (a phenomenon known a s the inverse equity hypothesis – (reference – Victora, CG, Vaughan, JP, Barros, FC, Silva AC, Tomasi E. Explaining trends in inequalities: evidence from Brazilian child health studies. Lancet 2000:356:1093).  PRACTICABLE ALTERNATIVES:  It is currently impractical and costly to replace all the existing tools for risk stratification to work with only pseudonymised or de-identified data only. The main reasons are:   * Widespread adoption of tools using identifiable data in the clear. For changes to be implemented would require time for commercial organisations to develop, change, and test new software to work effectively with pseudonymised data. * Commercial contracts would need to be changed and potentially annulled if those organisations are unable to adapt their tools to use pseudonymised data. Without the ability to allow ICBs to select external providers, this action would be seen as being anti-competitive. * NHS England would need to build additional capacity and capability in year without clear funding to handle bespoke data specifications for different risk stratification software. The alternative would be for NHS England to host these applications, but as many of these tools are currently contracted as managed services, this would be difficult without impacting the revenue and business models of a number of international and small companies. | |
| 1. Where support is in place, applicants are usually required to take reasonable steps to inform their cohort of the activity, and to allow for a right of objection.   *Provide clear details on what steps will be taken to provide information on this activity, where this will be placed, and how you will manage any patient objection*.: | | **Approach to informing the relevant population of the activity:**  Each ICB will ensure through privacy notices that individuals have been informed that their personal data is used in a way that is fair. Ensuring patients are informed that the processing of data in a way that could be unduly detrimental, unexpected or misleading to the individuals concerned.  Fair Processing Notices transparently advise the public through the ICB / GP websites:   * + Overall description of risk stratification data processing   + A list of all the datasets used for risk stratification   + Legal basis for risk stratification processing   + Risk stratification data processors   + Individuals’ rights and opt out details   + Record of Processing Activities   **What mechanism will be used to manage and respect objections:**  The national data opt outs are applied to the data sets provided for ICBs commissioning purposes that are utilised for risk stratification.  The type 1 objections are applied at source to GP data prior to extraction and therefore the data of those patients will not leave the practice.  A risk stratification opt out mechanism have been implemented and communicated through various patient notification techniques.  Please refer to the supplementary information document, section Informing the Patient Population for the detailed ICB response | |
| 1. How have you involved patients and the public in the development of the activity for which you seek support?   Governance  What changes have been made in response to their input? | | Please refer to the supplementary information document, section Public Involvement for the detailed ICB response | |
| **SECTION 4: JUSTIFICATION AND COMPLIANCE** | | | |
| 1. What is the justification for using confidential patient information?   *Explain the necessity of processing each relevant identifier e.g. for linkage/identify duplication, analysis etc* | | The NHS number is the only unique identifier in health that is consistently utilised across all settings. Therefore, making it the most accurate identifier for linkage and negating the need for further data items to support validation. The NHS number is also utilised by the GPs to re-identify their particular patients through their own clinical systems to offer interventions.  Use of other data items for analysis purposes, when combined, may be sufficient to produce information that relates to and identifies a particular individual.  Please refer to the supplementary information document, section Informing the Patient Population for the detailed ICB response | |
| 1. **Provide details on how this activity is compliant with the principles of data protection legislation**   Due to legal requirement, support cannot be provided unless the application demonstrates it is operating within the provisions of data protection legislation. | **Under each of the principles below, clearly demonstrate how the specific activity is operating in compliance with the principles of the GDPR and Data Protection Act 2018. Please seek specialist advice from your information governance advisors.**   1. Uniform **Principle (a): information is processed lawfully, fairly and in a transparent manner in relation to individuals (‘lawfulness, fairness and transparency’)**   Every ICB has published a Privacy Notice that includes a separate section relating to risk stratification and as a minimum will cover:     * + Overall description of risk stratification data processing   + A list of all the datasets used for risk stratification   + Legal basis for risk stratification processing   *Processing of personal data*  GDPR 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  *Processing of special category data*  GDPR Article 9(2)h – processing is necessary for the purposes of preventive or occupational medicine, for the assessment of the working capacity of the employee, medical diagnosis, the provision of health or social care or treatment or the management of health or social care systems and services on the basis of Union or Member State law or pursuant to contract with a health professional and subject to the conditions and safeguards referred to in paragraph 3  DPA 2018, Schedule 1- Special categories of personal data and criminal convictions etc data, Part 1 - Conditions relating to employment, health and research etc (2) – health and social care purposes.  *Processing of confidential patient information*  Exemption under the NHS Act 2006, section 251 – control of patient information     * + Risk stratification data processors   + Individuals’ rights and opt out details   + Record of Processing Activities   Please refer to the supplementary information document, section Informing the Patient Population for the detailed ICB response   1. Uniform **Principle (b): information is collected for specified, explicit and legitimate purposes and not further processed in a manner that is incompatible with those purposes;**   The Health and Care Act 2022 requires the ICB to commission certain health services and support discharging of the Secretary of State and NHS England duties to promote a comprehensive health service.  The information related to risk stratification is collected to support identification and prediction of which patients are high risk (of health deterioration and using multiple services) or are likely to be at high risk. Prioritising the management of their care to reduce and prevent poor outcomes.   1. **Principle (c) information is adequate, relevant and limited to what is necessary in relation to the purposes for which they are processed (‘data minimisation’);**   Data must only be used for the purposes stipulated within the application and boundaries detailed within the ICBs privacy notice.  The ICB keeps a record of locations the data is processed, stored and these addresses are within the UK. The ICB must also minimise the number of processing and storage locations to prevent excessive processing. All access to data is managed under Role-Based Access Controls. Users can only access data authorised by their role and the tasks that they are required to undertake. Data may only be processed and held as long as is required to carry out the risk stratification purposes.  Only confidential patient information within the datasets specifically detailed within the application will be collected and linked for risk stratification purposes.   1. **Tailored Principle (d): information is accurate and, where necessary, kept up to date; every reasonable step must be taken to ensure that personal data that are inaccurate, having regard to the purposes for which they are processed, are erased or rectified without delay (‘accuracy’);**   Assurance of this principle is obtained through the ICBs Data Security & Protection Toolkit – standards met. Please refer to the supplementary information document, section Administrative detail for the detailed ICB response   1. **Tailored Principle (e): information is kept in a form which permits identification of data subjects for no longer than is necessary for the purposes for which the personal data are processed;**   Please refer to the supplementary information document, section Informing the Patient Population for the detailed ICB response.   1. **Tailored Principle (f): information is processed in a manner that ensures appropriate security of the personal data, including protection against unauthorised or unlawful processing and against accidental loss, destruction or damage, using appropriate technical or organisational measures (‘integrity and confidentiality’).”**   Assurance of this principle is obtained through the ICBs Data Security & Protection Toolkit – standards met. Please refer to the supplementary information document, section Administrative detail for the detailed ICB response.   1. **Uniform – The controller shall be responsible for, and be able to demonstrate compliance with, paragraph 1 (‘accountability’). The accountability principle requires you to take responsibility for what you do with personal data and how you comply with the other principles. You must have appropriate measures and records in place to be able to demonstrate your compliance**   The following controls will be implemented by the ICB as a minimum:  The ICB has conducted a Data Protection Impact Assessment on the risks to processing personal and special category data for risk stratification. Where applicable, risk assessments are in place with mitigation and treatment plans. There are data processing contracts are in place with the risk stratification suppliers. Where relevant, Data Sharing Agreements and joint data controllership documentation is drafted, signed by relevant parties and reviewed annually. An audit plan and review documentation, including compliance with the Data Security and Protection Toolkit (DSPT). | | |
| **SECTION 5: MEASURES TO PREVENT DISCLOSURE OF CONFIDENTIAL PATIENT INFORMATION** | | | |
| 1. What security and audit measures have been implemented to secure access to, and limit use of, patient identifiable information within your organisation? | | It has been agreed with the Confidentiality Advisory Team that this section does not require completion. | |
| 1. Please provide details of your processing sites 2. Please provide details of your security assurance evidence | | It has been agreed with the Confidentiality Advisory Team that this section does not require completion. | |
| 1. Provide written confirmation that the organisation’s data security policy is fully implemented (and complies with the management and control guidelines contained in the ISO/IEC 17799:2005 & ISO/IEC 27001:2005, as replacements for Parts 1 & 2 of the BS7799 “Code of Practice for Information Security Management” | | It has been agreed with the Confidentiality Advisory Team that this section does not require completion. | |
| 1. Provide confirm that the organisations processing confidential patient information organisation have registered with the Information Commissioner’s Office. | | It has been agreed with the Confidentiality Advisory Team that this section does not require completion. | |
| 1. Describe the physical security arrangements for the location where patient identifiable data is to be: 2. Processed; and   ii) Stored (if these are different) | | It has been agreed with the Confidentiality Advisory Team that this section does not require completion. | |
| 1. System Information:   Identify the type of system and application to be used for information processing including product version numbers where known (e.g. desktop PC, Laptop PC, MS Access, etc) | | It has been agreed with the Confidentiality Advisory Team that this section does not require completion. | |
| Confirm if the computer system will be entirely standalone or connected to a LAN or WAN network, or be otherwise accessible remotely by another means such as dial-up modem. If so please confirm which networks these are and what they are used for, and provide a copy of the Network Security Policy. | | It has been agreed with the Confidentiality Advisory Team that this section does not require completion. | |
| Provide details of access and/or firewall controls implemented on:   1. This system; and 2. Any LAN or WAN to which it is connected   Please also identify who is responsible for the management of these arrangements. | | It has been agreed with the Confidentiality Advisory Team that this section does not require completion. | |
| 1. System-level Security:   Is there a system level security policy for this system? If yes, please supply a reference copy and confirm its status. | | It has been agreed with the Confidentiality Advisory Team that this section does not require completion. | |
| Has the system ever been the subject of a security risk review? If so, please provide details and confirm whether all the necessary recommendations have been implemented. | | It has been agreed with the Confidentiality Advisory Team that this section does not require completion. | |
| Please provide details of the arrangements you have implemented to routinely monitor and audit the security of this system for potential misuse or abuse. | | It has been agreed with the Confidentiality Advisory Team that this section does not require completion. | |
| 1. Data Retention & Destruction:   How long will the information be retained? If longer than 12 months please provide justification. | | It has been agreed with the Confidentiality Advisory Team that this section does not require completion. | |
| Describe the method of data destruction you will employ when you have completed your work using patient identifiable data. | | It has been agreed with the Confidentiality Advisory Team that this section does not require completion. | |
| **SECTION 6 SIGNATURES** | | | |
| This form should be signed and dated by the **controller** of the application as per section (1) (D)  Declaration: I confirm that the application is accurate, and I support and take responsibility for this application to process confidential patient information without consent | | | |
| SIGNED: | | | DATE: |
| **Return completed application and supporting information to:**  [**cag@hra.nhs.uk**](mailto:cag@hra.nhs.uk)  **Confidentiality Advisory Group**  **Health Research Authority**  **Ground floor, Skipton House**  **80 London Road**  **London SE1 6LH**  **The Confidentiality Advice Team can be contacted via 0207 104 8100 in the first instance** | | | |

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# Annex A

## Application Checklist

* Have you correctly identified the controllers and processors for the activity within the application?
* Have you addressed in full how the application meets each element of the principles of data protection legislation? Have the responses been checked by persons with the relevant expertise?
* Have you provided a copy of the information to be provided to the relevant population? Is there a mechanism to respect objection clearly set out in this material?
* Have you had a colleague check through your application form so that it is complete and conforms with actual practice?
* Are all acronyms explained and is the application understandable to a lay reader?

Have you included the following with your application form (where relevant):

* Data flow diagram setting out the flows of confidential patient information
* Written recommendation from the relevant sponsor
* Copy of your organisation’s Confidentiality Policy, including staff information leaflets and example(s) of confidentiality clauses in relevant staff contracts
* Copy of your organisation’s Security Policy, covering physical and system security
* Link to the relevant organisational Data Protection registration with the ICO
* Examples of Patient Information Leaflets provided to the public