**Data Protection Impact Assessment Procedure**

|  |  |
| --- | --- |
| Author | Senior IG Specialist |
| Owner | IG ERY CCG |
| Date approved |  |
| Committee | Information Governance Steering Group |
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**Version history**

|  |  |  |  |
| --- | --- | --- | --- |
| Version | Date | Reviewer | Description |
| 0.1 | 12 September 2014 | WSYBCSU | Initial Draft |
| 2 | 12 August 2015 | YHCS | Minor revisions and clarifications added |
| 2.1d | 30 September 2016 | Embed | Revisions throughout to:  Structure  Grammar  Prompts  Language  Development of DPIA suite of supporting documents to assist organisations when completing a DPIA. |
| 2.1e | 7 November 2016 | Embed | Minor revisions to wording for screening contact details. |
| 3 | 1 December 2017 | Embed | Minor corrections and revisions to structure, grammar, terminology.  Updated to reference requirements under General Data Protection Regulation. |
| 3.1 | 1 July 2018 | Embed | Further amendments to reflect CCG GDPR structure |
| 4.0 | 29 October 2018 | Embed | Reviewed against ICO guidance – amendments made to screening questions |
| 5.0 | 31 October 2018 | eMBED | Minor formatting |
| 6.0 | October 2019 | eMBED | Addition of National opt-out question |
| 7.0 | June 2020 | IG | Removal of reference to eMBED Health Consortium |

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# Introduction

Data Protection Impact Assessments (DPIAs)[[1]](#footnote-1) are required under the General Data Protection Regulation (EU) 2016/679, where health data is being used in a manner that it either is identifiable or there is a risk of an individuals’ identity being revealed. A DPIA should also be considered where other personal data, for example data about individual staff, is being used in a way that could poses a high level of risk regarding the privacy of those individuals.

DPIAs aid organisations in determining how a particular project, process or system may affect the privacy of the individual. This procedure consists of DPIA Screening Questions and Data Protection Impact Assessment which are designed to enable an assessment *prior to* new services or new data processing/sharing systems being introduced. A DPIA is not effective when key decisions have already been taken. If an assessment is suggested, it should be seen as dynamic and subject to review with any significant change.

DPIAs identify the most effective way to comply with data protection obligations and meet individuals’ expectations of privacy. An effective DPIA will allow for the identification and remedy problems at an early stage, reducing potential distress, subsequent complaints and the associated costs and damage to reputation that might otherwise occur.

It is important to consider whether a DPIA is required as soon as the objectives/aims of the project are identified to examine what is required to successfully meet these and how it is envisaged this will happen, whilst ensuring privacy of individuals to which the data relates.

Conducting a DPIA should not be complex or time consuming, if it is given due regard at an early stage.

# Data Protection Impact Assessments

DPIAs identify privacy risks, foresee problems and bring forward solutions. A successful DPIA will:

* identify and manage risks in respect of privacy of personal information(see Appendix A for examples)
* avoid inadequate solutions to privacy risks
* avoid unnecessary costs
* avoid loss of trust and reputation
* inform the organisation’s communication strategy
* meet or exceed legal requirements

The Information Commissioners Office (ICO) has produced guidance materials on which this procedure is based (see Appendix D).

DPIAs should demonstrate that privacy concerns have been considered and serve to assure the organisation regarding the security and confidentiality of the personal identifiable data.

# Purpose of a DPIA

A DPIA should serve to:

* identify privacy risks to individuals
* identify privacy and Data Protection compliance liabilities
* protect the organisations reputation
* instil public trust and confidence in your project/product
* avoid expensive, inadequate “bolt-on” solutions
* inform your communications strategy

# Responsibilities

Responsibility for ensuring that a Data Protection Impact Assessment is considered and, where appropriate, completed resides with the manager(s) leading the introduction of new systems, data sharing or projects. Completion of the [Screening Questions](#ScreeningQuestions) also serves to evidence that this has been considered.

Line Managers are responsible for ensuring that permanent and temporary staff and contractors are aware of the Data Protection Impact Assessment procedure.

There is an expectation that partner organisations/third parties involved in supplying/providing services contribute the necessary technical information for the Data Protection Impact Assessment.

This guidance therefore applies to all staff and all types of information held by the organisation. This procedure should be read in conjunction with the organisation’s Information Governance (IG) policies:

* Data Protection and Access to Health Records Policy
* Business Continuity Plan
* Confidentiality Code of Conduct
* Email Policy
* Freedom of Information and EIR Policy
* Freedom of Information Procedures
* IG Policy and Management Framework
* Incident Reporting Policy
* Information Security Policy
* Internet Acceptable Use Policy
* Records Management Policy
* Portable Data Security and Smartphone and Tablet Policy
* Risk Management Policy
* Safe Haven Policy

# Is a DPIA required for every project?

Are you implementing a new system/data sharing arrangement/project or service, or changing the way you work?

Complete DPIA [Screening Questions](#ScreeningQuestions)

No need to conduct a Data Protection Impact Assessment

Retain completed DPIA Screening Questions as part of project documentation.

Does this project involve the processing of personally identifiable or other high risk data?

A [Data Protection Impact Assessment](#PIA) is required

Supporting information, such as contracts, system specifications and consent forms may be required (see Appendices)

Yes

Yes

No

No

*Figure 1*

DPIAs should be completed where a system/data sharing/project includes the use of personal data, where there is otherwise a risk to the privacy of the individual, utilisation of new or intrusive technology, or where private or sensitive data which was originally collected for a limited purpose will be reused in a new and ‘unexpected’ way.

# When should I start a DPIA?

DPIAs are most effective when they are started at an early stage of a project, when:

* the project is being designed
* you know what you want to do
* you know how you want to do it
* you know who else is involved

It **must** be completed before:

* decisions are set in stone
* you have procured systems/services
* you have signed contracts/Memorandum of Understanding/agreements

Following the review of the [Screening Questions](#ScreeningQuestions) it should be determined that a DPIA is required. Where it is thought that a DPIA is required, The [DPIA Sections 1-4](#PIA) should be completed and submitted to the Information Governance team for a preliminary review. It is recommended that the IG review is sought prior to the final DPIA being submitted to the Data Protection Officer, and Caldicott Guardian (if involving patient identifiable data) or [SIRO](#SIRO) (if staff data is included). Please note the controller is required under GDPR to contact the Information Commissioner’s Office if processing would result in a high risk in the absence of measures taken to mitigate the risk[[2]](#footnote-2).

# Publishing DPIAs

All DPIA’s are to be included within the organisation’s Publication Scheme and must therefore be presented to the INSERT ROLE HERE once they have received approval.

It is acknowledged that DPIA’s may contain commercial sensitive information such as security measures or intended product development. It is acceptable for such items to be redacted but as much of the document should be published as possible.

# Data Protection Impact Assessment (DPIA) Screening Questions

The below screening questions should be used inform whether a DPIA is necessary. This is not an exhaustive list therefore in the event of uncertainty, completion of a DPIA is recommended.

|  |  |
| --- | --- |
| **Title** | Click here to enter text. |
| **Brief description** | Click here to enter text. |

*Screening completed by*

|  |  |
| --- | --- |
| **Name** | Click here to enter text. |
| **Title** | Click here to enter text. |
| **Department** | Click here to enter text. |
| **Email** | Click here to enter text. |
| **Date** | Click here to enter text. |

Marking any of these questions is an indication that a DPIA is required:

|  |  |  |
| --- | --- | --- |
| **Screening Questions** | | **Tick** |
| 1 | Will the project involve the collection of new identifiable or potentially identifiable data about individuals? |  |
| 2 | Will the project compel individuals to provide data about themselves or involve the processing of personal data not obtained directly from the individual?  i.e. where they will have little awareness or choice or where it is impossible, or would involve disproportionate effort, to inform the individuals that the processing is taking place |  |
| 3 | Will identifiable data about individuals be shared with other organisations or people who have not previously had routine access to the data? |  |
| 4 | Are you using data about individuals for a purpose it is not currently used for or in a new way?  i.e. using data collected to provide care for a service evaluation; data matching where data obtained from multiple sources is combined, compared or matched. |  |
| 5 | Where data about individuals is being used, would this be likely to raise privacy concerns or expectations?  i.e. will it include health records, genetic data, criminal records or other information that people may consider to be sensitive and private and may cause them concern or distress. |  |
| 6 | Will the project require you to contact individuals in ways which they may find intrusive?  i.e. telephoning or emailing them without their prior consent. |  |
| 7 | Will the project result in you making decisions in ways which can have a significant impact on individuals?  i.e. will it affect the care a person receives? Is it based on automated decision making (including profiling)? |  |
| 8 | Does the project involve you using new technology which might be perceived as being privacy intrusive?  i.e. using biometrics, facial recognition, Artificial Intelligence or tracking (such as tracking an individual’s geolocation or behaviour) |  |
| 9. | Is a service/processing activity being transferred to a new supplier/organisation (or re-contracted) at the end of an existing contract |  |
| 10. | Will the project involve systematic monitoring of a publicly accessible area on a large scale?  i.e. use of CCTV |  |
| 11. | Will the project involve the targeting of children or other vulnerable individuals?  i.e. for marketing purposes, profiling or other automated decision making |  |

***Please retain a copy of this questionnaire within your project/system documentation.***

***Please note that once completed the following sections (1 to 4) should be extracted from the rest of this document prior to being included within the Publication Scheme.***

# 

# Data Protection Impact Assessment (DPIA)

Please complete all questions with as much detail as possible (liaising with partners/third parties) and then contact the IG Team prior to seeking approval.

**Section 1: System/Project General Details**

|  |  |  |
| --- | --- | --- |
| **System/project/process (referred to thereafter as ‘project’) title:** | Click here to enter text. | |
| **Objective:** | Click here to enter text. | |
| **Detail:** Why is the new system/change in system required? Is there an approved business case? | Click here to enter text. | |
| **Stakeholders/Relationships/Partners:** Please outline the nature of such relationships and the corresponding roles of other organisations. | Click here to enter text. | |
| **Other related projects:** | Click here to enter text. | |
| **Project lead:** | Name: | Click here to enter text. |
| Title: | Click here to enter text. |
| Department: | Click here to enter text. |
| Telephone: | Click here to enter text. |
| Email | Click here to enter text. |
| **Information Asset Owner:**  All information systems/assets must have an [Information Asset Owner (IAO).](#IAO) IAO’s should normally be a Head of Department/Service. | Name: | Click here to enter text. |
| Title: | Click here to enter text. |
| Department: | Click here to enter text. |
| Telephone: | Click here to enter text. |
| Email | Click here to enter text. |
| **Information Asset Administrator:**  Information systems/assets may have an [Information Asset Administrator (IAA)](#IAA) who reports the IAO. IAA’s are normally System Managers/Project Leads. | Name: | Click here to enter text. |
| Title: | Click here to enter text. |
| Department: | Click here to enter text. |
| Telephone: | Click here to enter text. |
| Email | Click here to enter text. |

**Section 2: Data Protection Impact Assessment Key Questions**

|  | **Question** | **Response** |
| --- | --- | --- |
| **Data Items** | | |
|  | **Will the project use identifiable or potentially identifiable data in any way?**  If answered ‘No’ then a DPIA is not normally suggested. | Yes  No  If yes, who will this data relate to:  Patient  Staff  Other: Click here to enter text. |
|  | **Please state purpose for the processing of the data:**  For example, patient care, commissioning, research, audit, evaluation. | Click here to enter text. |
|  | **Please tick the data items that are held in the system**  **Personal**    **Special categories**  **of personal data**  **(sensitive data)** | Name  Address  Post Code  Date of Birth  GP Practice  Date of Death  NHS Number  NI Number  Passport Number  Pseudonymised Data  Online Identifiers (e.g. IP Number, Mobile Device ID)  Health Data  Trade Union membership  Political opinions  Religion  Racial or Ethnic Origin  Sex life and sexual orientation  Biometric Data  Genetic Data    Other: |
|  | **What consultation/checks have been made regarding the adequacy, relevance and necessity for the processing of the data for this project?** | Click here to enter text. |
|  | **How will the data be kept up to date and checked for accuracy and completeness?** | Click here to enter text. |
| **Data processing** | | |
|  | **Will a third party be processing data on the CCG or one of its contractors?** | Yes  No  If no, please go to the Confidentiality section. |
|  | **Is the third party contract/supplier of the project registered with the Information Commissioner?**  This was required until 25 May 2018. | Yes  No  Organisation: Click here to enter text.  Data Protection Registration Number: Click here to enter text. |
|  | **Has the third party supplier completed and published a satisfactory** [**Data Security and Protection Toolkit submission**](https://www.dsptoolkit.nhs.uk/)**?**  Please note that the Data Security and Protection Toolkit replaced the IG Toolkit from 1 April 2018. | Yes  No  If yes, please give organisation code and percentage score:  Click here to enter text.  *IG Toolkit Score:*  Satisfactory  Not satisfactory  Satisfactory with Improvement Plan  If satisfactory with an improvement plan, please request a copy of the plan and enclose it with this assessment.  If not satisfactory, please explain how the service has been procured:  Click here to enter text. |
|  | **Does the third party/supplier contract(s) include all the necessary Information Governance clauses regarding Data Protection and Freedom of Information?** See [Contract and Commissioning Information Governance Assurance](#SupportingDocs) checklist. | Yes  No  Is the contract based on or utilise the NHS standard contract?  Yes  No |
|  | **Will other third parties (not already identified) have access to the data?** Include any external organisations. | Yes  No  If so, for what purpose?  Click here to enter text.  Please list organisations and by what means of transfer:  Click here to enter text. |
| **Confidentiality** | | |
|  | **Please outline how individuals will be informed and kept informed about how their data will be processed.**  A copy of the [privacy notice and/or leaflets](https://ico.org.uk/for-organisations/guide-to-the-general-data-protection-regulation-gdpr/individual-rights/right-to-be-informed/) must be provided. | Click here to enter text. |
|  | **Does the project involve the collection of data that may be unclear or intrusive?** Are all data items clearly defined? Is the data collected limited to a specific set of predefined categories? | Yes  No  If yes, please explain:  Click here to enter text. |
|  | **Are you relying on individuals (patients/staff) to explicit consent to the processing of personal identifiable or sensitive data?**  Please provide copies of any consent documentation that will be used, including patient information leaflets | Yes  No (Go to next question)  How will consent be obtained and by whom?  Click here to enter text.  Will the consent cover all proposed processing and sharing/disclosures?  Yes  No  If no, please detail:  Click here to enter text. |
|  | **If explicit consent is not being sought, what legal basis enables this data processing?**  For more information about conditions for processing, please see the [ICO’s GDPR website](https://ico.org.uk/for-organisations/guide-to-the-general-data-protection-regulation-gdpr/). | Personal data (identifiers and potentially identifiable data):  Relating to a contract: Click here to enter text.  Legal obligation: Click here to enter text.  Vital interests: Click here to enter text.  Public task: Click here to enter text.  Other: Click here to enter text.  Special categories of personal data (sensitive data), *if applicable*:  Medical related: Click here to enter text.  Public Health: Click here to enter text.  Employment related: Click here to enter text.  Vital interests: Click here to enter text.  Already public: Click here to enter text.  Legal claim related: Click here to enter text.  Substantial public interest: Click here to enter text.  Other: Click here to enter text. |
|  | **Will identifiable data only be handled within the patients’ direct care team (in accordance with the** [**Common Law Duty of Confidentiality**](#CommonLaw)**)?** | Yes  No  If no, please detail:  Click here to enter text. |
|  | **How will consent, non-consent, objections or opt-outs be recorded and respected?** | Click here to enter text. |
|  | **What arrangements are in place to process Subject Access Requests?** What would happen if such a request were made? | Click here to enter text. |
|  | **Will the processing of data be automated?** Will the proposed processing of data involved automated means of processing to determine an outcome for the individual? | Yes  No  Not applicable  If yes, please outline what arrangements are available to enable the individual access and to extract data (in a standard file format). Please also detail any profiling that may take place as part through automated processing:  Click here to enter text. |
|  | **What process is in place for rectifying/blocking data?** What would happen if such a request were made? | Click here to enter text. |
| **Engagement** | | |
|  | **Has stakeholder engagement taken place?** | Yes  No  If yes, how have any issues identified by stakeholders been considered?  Click here to enter text.  If no, please outline any plans in the near future to seek stakeholder feedback:  Click here to enter text. |
| **Data Sharing** | | |
|  | **Does the project involve any new data sharing between stakeholder organisations?**  **Is this use or disclosure of data in scope for the national data opt- out to be applied?**  ***(contact your IG lead if you need more information about this)*** | Yes  No  If yes, please describe:  Click here to enter text.  Please provide a high level data flow diagram showing how identifiable information would flow.  Yes  No |
| **Data Linkage** | | |
|  | **Does the project involve linkage of personal data with data in other collections, or significant change in data linkages?**  The degree of concern is higher where data is transferred out of its original context (e.g. the sharing and merging of datasets can allow for a collection of a much wider set of information than needed and identifiers might be collected/linked which prevents personal data being kept anonymously) | Yes  No  If yes, please provide a data flow diagram showing how identifiable information would flow and ensure this is added to the CCG Information Asset and Data Flow Register (see Information Assets and Data Flows section). |
| **Information Security** | | |
|  | **Who will have access to the data within the project?**  Please refer to roles/job titles/organisations. | Click here to enter text. |
|  | **Is there a useable audit trail in place for the project?**  For example, to identify who has accessed a record? | Yes  No  Not applicable  If yes, please outline the audit plan: Click here to enter text. |
|  | **Where will the data be kept/stored/accessed?**  Where applicable, please refer to data flow diagram. | Click here to enter text. |
|  | **Please indicate all methods in which data will be transferred** | Fax  Email (Unsecure/Personal)  Email (Secure/nhs.net)  Internet (unsecure – e.g. http)  Telephone  Internet (secure – e.g. https)  By hand  Courier  Post – track/traceable  Post – normal  Software  Mobile app  Other: Click here to enter text. |
|  | **Does the project involve privacy enhancing technologies?**  *New forms* of encryption, two factor authentication and/or pseudonymisation. | Yes  No  If yes, please give details: Click here to enter text. |
|  | **Is there a documented System Level Security Policy (SLSP) or process for this project?**  A [SLSP](#SupportingDocs) is required for new *systems* – this is likely to need to be completed by the supplier. | Yes  No  Not applicable  If yes, please provide a copy. |
| **Privacy and Electronic Communications Regulations** | | |
|  | **Will the project involve the sending of unsolicited marketing messages electronically such as telephone, fax, email and text?**  [Please note that seeking to influence an individual is considered to be marketing.](#PECR) | Yes  No  If yes, what communications will be sent?  Click here to enter text.  Will consent be sought prior to this?  Yes  No  If no, please explain why consent is not being sought first:  Click here to enter text. |
| **Records Management** | | |
|  | **What are the specific retention periods for this data?**  Please refer to the [Records Management Code of Practice for Health and Social Care 2016](https://digital.nhs.uk/data-and-information/looking-after-information/data-security-and-information-governance/codes-of-practice-for-handling-information-in-health-and-care/records-management-code-of-practice-for-health-and-social-care-2016) and list the retention period for identifiable project datasets. | Click here to enter text. |
|  | **Will the data be securely destroyed when it is no longer required?** | Yes  No  If no, please detail: Click here to enter text. |
| **Information Assets and Data Flows** | | |
|  | **Has an** [**Information Asset Owner**](#IAO) **been identified and does the** [**Information Asset**](#InfoAssets) **and Data Flow Register require updating?**  Please see the [Information Asset Register and Data Flow Mapping Form](#SupportingDocs). | Yes  No  If yes, include the completed Information Asset Register New Entry Form.  Does this project constitute a change to existing Information Asset(s) or is this a new Information Asset?  Yes  No  If yes, include the completed Information Asset Register and Data Flow Mapping Form for risk review. |
| **Business Continuity** | | |
|  | **Have the business continuity requirements been considered?** | Yes  No  Business Continuity is not applicable  Please explain and either reference how such plans link with the organisational plan or why there are no business continuity considerations that are applicable for this project: Click here to enter text. |
| **Open Data** | | |
|  | **Will identifiable/potentially identifiable from the project be released as Open Data (placed in to the public domain)?** | Yes  No  If yes, please describe: Click here to enter text. |
| **Data Processing Outside of the UK and European Union (EU)** | | |
|  | **Will any personal and/or sensitive data be transferred to a country outside the UK?** | Yes  No  If yes, which data and to which country?  Click here to enter text. |

**Section 3: Data Protection Impact Assessment Information Governance Review**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Information Governance Review (for completion by IG)** | | | | **Response (for completion by project lead)** | |
| **Issue** | | **Potential Risk** | **Recommendation** | **Agreed Action** | **Completion (Date and Initials)** |
| **1** |  |  |  |  |  |
| **2** |  |  |  |  |  |
| **3** |  |  |  |  |  |
| **4** |  |  |  |  |  |
| **5** |  |  |  |  |  |

*For completion by IG:*

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Residual Risk** | | **Main Risk Sources** | **Main Threats** | **Main Potential Impacts** | **Main Controls Reducing the Severity and Likelihood** | **Severity** | **Likelihood** |
| **1** |  |  |  |  |  |  |  |
| **2** |  |  |  |  |  |  |  |
| **3** |  |  |  |  |  |  |  |

**IG review completed by:**  Click here to enter text. **Review date:**  Click here to enter text.

**Date complete and risk assessed:** Click here to enter text. **Consultation with ICO required? Yes/No (delete as appropriate)**

**Section 4: Review and Approval**

**Assessment completed by**

|  |  |
| --- | --- |
| **Name:** | Click here to enter text. |
| **Title:** | Click here to enter text. |
| **Date:** | Click here to enter text. |

**Data Protection Officer Approval**

|  |  |
| --- | --- |
| **Name:** |  |
| **Title:** |  |
| **DPO advice:**  DPO should advise on compliance, risks identified and whether processing can proceed.  If accepting any residual high risk, consult the ICO before going ahead |  |
| **Approved** |  |
| **Date:** |  |

The DPO should also review ongoing compliance with DPIA

**SIRO/Caldicott Guardian Approval**

|  |  |
| --- | --- |
| **Name:** |  |
| **Title:** |  |
| **DPO advice accepted or overruled:**  If overruled, you must explain your reasons |  |
| **Approved:** |  |
| **Date:** |  |

|  |  |
| --- | --- |
| This DPIA will be kept under review by: |  |

# Appendix A - Example risks

**Risks to individuals**

1. Inadequate disclosure controls increase the likelihood of information being shared inappropriately.
2. The context in which information is used or disclosed can change over time, leading to it being used for different purposes without people’s knowledge.
3. New surveillance methods may be an unjustified intrusion on their privacy.
4. Measures taken against individuals as a result of collecting information about them might be seen as intrusive.
5. The sharing and merging of datasets can allow organisations to collect a much wider set of information than individuals might expect.
6. Identifiers might be collected and linked which prevent people from using a service anonymously.
7. Vulnerable people may be particularly concerned about the risks of identification or the disclosure of information.
8. Collecting information and linking identifiers might mean that an organisation is no longer using information which is safely anonymised.
9. Information which is collected and stored unnecessarily, or is not properly managed so that duplicate records are created, presents a greater security risk.
10. If a retention period is not established information might be used for longer than necessary.

**Corporate risks**

1. Non-compliance with the data protection legislation can lead to sanctions, fines and reputational damage.
2. Problems which are only identified after the project has launched are more likely to require expensive fixes.
3. The use of biometric information or potentially intrusive tracking technologies may cause increased concern and cause people to avoid engaging with the organisation.
4. Information which is collected and stored unnecessarily, or is not properly managed so that duplicate records are created, is less useful to the business.
5. Public distrust about how information is used can damage an organisation’s reputation and lead to loss of business.
6. Data losses which damage individuals could lead to claims for compensation.

**Compliance risks**

1. Non-compliance with the Data Protection Act/General Data Protection Regulation (EU) 2016/679.
2. Non-compliance with the Common Law Duty of Confidentiality.
3. Non-compliance with the Privacy and Electronic Communications Regulations (PECR).
4. Non-compliance with sector specific legislation or standards.
5. Non-compliance with Human Rights Act 1998 and Equality Act 2010.

# Appendix B – Supporting Documents

**Provider Contract and Commissioning Information Governance Assurance**

This guidance should be followed when entering into a contract, which must be present if any personal data is flowing/being transferred/processed:

****

**Information Asset and Data Flow Register Entry Form and Handbook**

Should be completed for any data corresponding to the activity that will be held either by the organisation or on behalf of it (that the organisation would have access to) and any transfers/flows of personal data must be documented:

****

**System Level Security Policy Template**

Should be completed by the provider/supplier of any system/product where personal data will be stored/flow through:



**Data Sharing Agreement Template** (Appendix III of the regional [Inter-Agency information Sharing Protocol](http://www.this.nhs.uk/fileadmin/IG/interagency-information-sharing-protocol.pdf))

**Standard Contract Clauses** (General Condition 21 of the [NHS Standard Contract](https://www.england.nhs.uk/nhs-standard-contract/))

This text covers Patient Confidentiality, Data Protection, Freedom of Information and Transparency. Text must be reviewed to suit individual contracts unless the whole NHS Standard Contract is being used.

# Appendix C - Glossary

|  |  |
| --- | --- |
| ***Item*** | ***Definition*** |
| **Anonymised Data** | Information may be used more freely if the subject of the information is not identifiable in any way – this is anonymised data. However, even where such obvious identifiers are missing, rare diseases, drug treatments or statistical analyses which may have very small numbers within a small population may allow individuals to be identified. A combination of items increases the chances of patient identification. When anonymised data will serve the purpose, health professionals must anonymise data and whilst it is not necessary to seek consent, general information about when anonymised data will be used should be made available to patients. |
| **Authentication Requirements** | An identifier enables organisations to collate data about an individual. There are increasingly onerous registration processes and document production requirements imposed to ensure the correct person can have, for example, the correct access to a system or have a smartcard. These are warning signs of potential privacy risks. |
| **Caldicott** | Seven Caldicott Principles were established following the original reviewed in 1997 and further development in 2013. The principles include:   1. justify the purpose(s) 2. don't use patient identifiable information unless it is necessary 3. use the minimum necessary patient-identifiable information 4. access to patient identifiable information should be on a strict need-to-know basis 5. everyone with access to patient identifiable information should be aware of their responsibilities 6. understand and comply with the law 7. the duty to share information can be as important as the duty to protect patient confidentiality |
| **Common Law Duty of Confidentiality** | This duty is derived from case law and a series of court judgements based on the key principle that information given or obtained in confidence should not be used or disclosed further except in certain circumstances:   * Where the individual to whom the information relates has consented * Where disclosure is in the overriding public interest; and * Where there is a legal duty to do so, for example a court order * The common law applies to information of both living and deceased patients.   The Common Law Duty of Confidentiality persists through the changes to data protection legislation in 2018. |
| **Data Protection Act 2018** | The 2018 Act is secondary to the requirements of the GDPR, which means the Act covers national derogations and otherwise supplements the Regulations.  The Act specifies the age of 13 years as sufficient to seek consent for the processing of personal data and also identified the Information Commissioner’s Office as the national supervisory authority. |
| **Explicit consent** | Express or explicit consent is given by a patient agreeing actively, usually orally (which must be documented in the patients case notes) or in writing, to a particular use of disclosure of information.  GDPR only recognises explicit consent. |
| **General Data Protection Regulation (EU) 2016/679 Principles of Lawful Processing of Personal Identifiable Information** | The GDPR requires that data controllers ensure personal data shall be:   1. processed lawfully, fairly and in a transparent manner in relation to individuals 2. collected for specified, explicit and legitimate purposes and not further processed in a manner that is incompatible with those purposes; further processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes shall not be considered to be incompatible with the initial purposes 3. adequate, relevant and limited to what is necessary in relation to the purposes for which they are processed 4. 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 5. 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; personal data may be stored for longer periods insofar as the personal data will be processed solely for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes subject to implementation of the appropriate technical and organisational measures required by the GDPR in order to safeguard the rights and freedoms of individuals 6. 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   The implementation of the Regulation completed by 25 May 2018. |
| **Information Asset Administrator (****IAA)** | There are individuals who ensure that policies and procedures are followed, recognise actual or potential security incidents, consult their IAO on incident management and ensure that information asset registers are accurate and up to date. These roles tend to be system managers |
| **Information Asset Owner (****IAO)** | These are senior individuals involved in running the relevant service/department. Their role is to understand and address risks to the information assets they ‘own’ and to provide assurance to the SIRO on the security and use of those assets. They are responsible for providing regular reports regarding information risks and incidents pertaining to the assets under their control/area. |
| **Implied Consent** | **Implied consent is unique to the health sector and *is no longer recognised* under the GDPR (from 25 May 2018).** Implied consent is given when an individual takes some other action in the knowledge that in doing so he or she has incidentally agreed to a particular use or disclosure of information, for example, a patient who visits the hospital may be taken to imply consent to a consultant consulting his or her medical records in order to assist diagnosis. Patients must be informed about this and the purposes of disclosure and also have the right to object to the disclosure. |
| **Information Assets** | Information assets are records, information of any kind, data of any kind and any format which we use to support our roles and responsibilities. Examples of Information Assets are databases, systems, manual and electronic records, archived data, libraries, operations and support procedures, manual and training materials, contracts and agreements, business continuity plans, software and hardware. |
| **Information Risk** | An identified risk to any information asset that the organisation holds. Please see the Risk Policy for further information. |
| **Personal Data** | This means data which relates to a living individual which can be identified:   1. from those data, or 2. from those data and any other information which is in the possession of, or is likely to come into the possession of, the data controller.   It also includes any expression of opinion about the individual and any indication of the intentions of the data controller or any other person in respect of the individual. |
| **Privacy and Electronic Communications Regulations 2003** | These regulations apply to sending unsolicited marketing messages electronically such as telephone, fax, email and text. Unsolicited marketing material should only be sent if the requester has opted in to receive this information. |
| **Privacy Invasive Technologies** | Examples of such technologies include, but are not limited to, smart cards, radio frequency identification (RFID) tags, biometrics, locator technologies (including mobile phone location, applications of global positioning systems (GPS) and intelligent transportation systems), visual surveillance, digital image and video recording, profiling, data mining and logging of electronic traffic. Technologies that are inherently intrusive, new and sound threatening are a concern and hence represent a risk |
| **Pseudonymisation** | Where patient identifiers such as name, address, date of birth are substituted with a pseudonym, code or other unique reference so that the data will only be identifiable to those who have the code or reference.  GDPR recognises pseudonymised data as personal data with mitigation in place, if implemented correctly, to protect individuals’ privacy and confidentiality. |
| **Records Management Code of Practice for Health and Social Care 2016** | Is a guide to the required standards of practice in the management of records for those who work within or under contract to NHS organisations in England. It is based on current legal requirements and professional best practice. The code of practice contains an annex with a health records retention schedule and a Business and Corporate (non-health) records retention schedule. |
| **Retention Periods** | Records are required to be kept for a certain period either because of statutory requirement or because they may be needed for administrative purposes during this time. If an organisation decides that it needs to keep records longer than the recommended minimum period, it can vary the period accordingly and record the decision and the reasons behind. The retention period should be calculated from the beginning of the year after the last date on the record. Any decision to keep records longer than 30 years must obtain approval from The National Archives. |
| **Special categories of personal data (sensitive data)** | This means personal data consisting of information as to the:   1. Concerning health, sex life or sexual orientation 2. Racial or ethnic origins 3. Trade union membership 4. Political opinions 5. Religious or philosophical beliefs 6. Genetic data 7. Biometric data   Most of these categories were previously referred to as “sensitive data” under the Data Protection Act 1998. |
| **SIRO (Senior Information Risk Owner)** | This person is an executive who takes ownership of the organisation’s information risk policy and acts as advocate for information risk on the Board. |

# Appendix D - Further information

*Relevant statutory legislation and law:*

[Common Law Duty of Confidentiality](file:///Z:/Documents/Downloads/NHS-information-governance-legal-professional-obligations.pdf)

[Data Protection Act 2018](https://ico.org.uk/for-organisations/data-protection-act-2018/)

[Freedom of Information Act 2000](https://ico.org.uk/for-organisations/guide-to-freedom-of-information/)

[General Data Protection Regulation (EU) 2016/679](https://ico.org.uk/for-organisations/guide-to-the-general-data-protection-regulation-gdpr/what-is-personal-data/)

[Human Rights Act 1998](https://www.legislation.gov.uk/ukpga/1998/42/contents)

[Privacy and Electronic Communications Regulations 2003](https://ico.org.uk/for-organisations/guide-to-pecr/)

*Further reading and guidance:*

[Caldicott 2 Review Report and Recommendations](https://www.gov.uk/government/publications/the-information-governance-review)

[Confidentiality Code of Practice](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/200146/Confidentiality_-_NHS_Code_of_Practice.pdf)

HSCIC [Code of practice on confidential information](http://systems.hscic.gov.uk/infogov/codes/cop)

[Information Security Code of Practice](http://systems.hscic.gov.uk/infogov/codes/securitycode.pdf)

[Records Management Code of Practice](https://digital.nhs.uk/data-and-information/looking-after-information/data-security-and-information-governance/codes-of-practice-for-handling-information-in-health-and-care/records-management-code-of-practice-for-health-and-social-care-2016) for Health and Social Care 2016

ICO [Anonymisation: managing data protection risk code of practice](https://ico.org.uk/for-organisations/guide-to-data-protection/anonymisation/) may help identify privacy risks associated with the use of anonymised personal data

ICO [Data sharing: code of practice](https://ico.org.uk/for-organisations/guide-to-data-protection/data-sharing/) may help to identify privacy risks associated with sharing personal data with other organisations

ICO [Guidance on Data Protection Impact Assessments](https://ico.org.uk/for-organisations/guide-to-the-general-data-protection-regulation-gdpr/data-protection-impact-assessments-dpias/)

1. DPIAs were previously known as Privacy Impact Assessments under the Data Protection Act 1998. [↑](#footnote-ref-1)
2. Article 36, General Data Protection Regulation (EU) 2006/679. [↑](#footnote-ref-2)