Privacy Impact Assessment (PIA):

Healthy Wirral: Wirral Care Record

VERSION 1.2

Table of Contents

Supplementary is available as a stand-alone document.

Privacy impact assessment (PIA)

1. Why do we need a PIA?

Wirral Partners are developing a new model of care. The model aims to meet the needs of the whole population of Wirral using integrated approaches to care delivery.

The new model will:

- Enable people to live well and stay well for longer
- Create a person-centred integrated system that will respond quickly, safely and appropriately when needed
- Drive technology to enable proactive approaches to integrated care
- Provide information to ensure services are developed to meet the needs of the population

Critical to the success of delivering new care models is the use of informatics to ensure instant and reliable availability of complete information. It will create a shared record will ensure that staff have access to the best information to support patients care, and also provide care planning and decision support tools that promote the delivery of evidenced based care pathways across organisational boundaries. This shared system will not replace existing systems, but will integrate tightly with them.
Whilst no new information is being collected about individuals, it will be shared with services that have not previously had access to it. The information will be used in a new way to introduce population medicine within Wirral; leading to better care that should have a significant impact on health and health resources. However, this level of information sharing may raise privacy concerns for some people.
Wirral Partners include:

- Wirral Clinical Commissioning Group (cornerstone partner in the delivery of reformed commissioning, contracting and payment models and GP member lead organisation)

The information governance model will be Data Controllers in Common

- Wirral University Hospital NHS Foundation Trust (cornerstone partner in the delivery of home facing specialist acute care)
- Cheshire and Wirral Partnership NHS Foundation Trust (cornerstone partner in the delivery of integrated mental health services)
- Wirral Community NHS Trust (cornerstone partner in the delivery of integrated community services)
- Wirral Metropolitan Borough Council (cornerstone partner in the delivery of integrated social care services and reformed commissioning, contracting and payment models)
- Wirral GP practices

Data Processor:

- Cerner UK Ltd (cornerstone partner in the delivery of informatics solutions and promotion population health management)
- Other data processors including GP supplier systems

(Wirral Care Record (WCR) is an ongoing development and there is an expectation that other processors will be joining the system as it develops; the PIA will need to be updated as this occurs.

2. The Information Flows:

The development of the Wirral Care Record (WCR) will be in phases.

April 2016 onwards, Phase 1 will be creating the records from participating general practices and Wirral University Teaching Hospital NHSFT (WUTH). Records from Wirral Community Trust, Cheshire & Wirral Partnership Trust and Local Authority coming on line in Phase 2, commencing September 2016.

An initial data upload is extracted and processed for inclusion in the solution and this will be retained as a 'delta' feed. Changes to that data are replaced through near real-time or subsequent (time scheduled) data feeds. Data is linked on NHS number (and with other identifiers such as date of birth and postcode), then cleaned to form a new record, providing a longitudinal view of patient care. These data will also feed the data registries.

The registries are condition specific views of a GP's patients that support preventative and evidence based care, enabling more holistic treatment during the consultation. They also enable the GP to monitor the uptake of preventative care in their patient groups. For example, whether a diabetic patient has undergone an eye examination and whether all diabetic patients on their list have been screened at the appropriate time. They can then arrange follow up for those in need. The first registries will include Diabetes (Paediatric and Adult), Asthma (Paediatric & Adult), Chronic Obstructive Pulmonary Disease, with more to be rolled out as they are developed. *HealtheIntent*™ is the platform through which clinicians will access the registries.

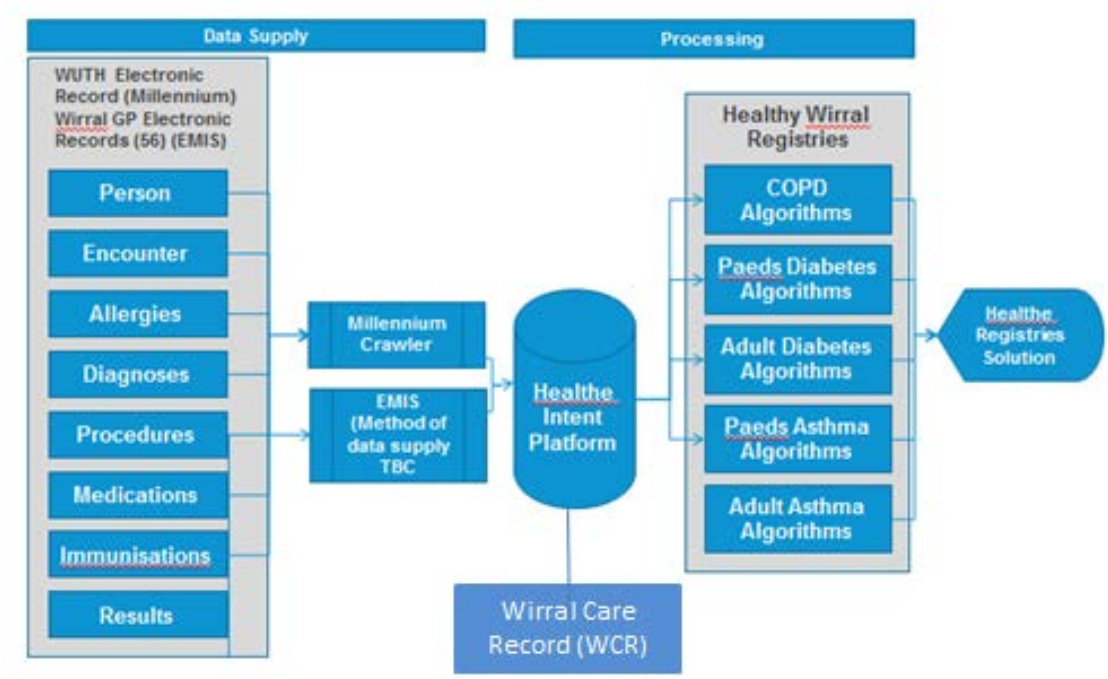
Clinicians will be able to access the WCR and the registries for direct patient care where there is a legitimate relationship established i.e. there is the relationship between a provider and a person, which indicates that the provider plays a role in the provision of care of the person and contributes to the person's health outcomes. It is also possible to release access to the WCR with certain roles prior to a legitimate relationship being established, however that will be granted on very unique circumstances should there be a clinical and operational need.

Who will be affected by this development?

Whilst the exact number of individuals who are likely to be affected by this project is difficult to assess, the community within the scope of this project is estimated to be in the region of 330,000 citizens representing Wirral residents (postcode dependent) who are registered with Wirral GPs.

What information will be shared and how often?

Any information that is shared as part of the WCR will be relevant to the aims of this Agreement. For example, data from the structured fields below will processed via the *HealtheIntent*™ Platform (WCR) to support the registries:



Examples of data that may be shared include;

- Name of subject (child, young person or adult) and other family members, their carers and other persons whose presence and/or relationship with the subject is relevant to identifying and assessing the risks to that person.
- Age/date of birth of subject and other family members, carers, other persons detailed.
- Ethnic origin of family members.
- School and educational information (to include family members where appropriate and relevant)
- GP and health records (to include family members where appropriate and relevant)
- Relevant data from any signatory to this Agreement
- Housing and other partnership data relevant to the child and family which may affect the welfare of that child

Not all of the above information will be applicable in every case.

Arrangements for who will review the personal identifiable data held will be led by WUTH and reviewed on an annual basis through a "data controller in common" agreement. The WCR Registries will go through a yearly review cycle as part of the clinical safety and governance process to ensure they remain clinically relevant.

Personal data records held on the Solution will be overwritten every time a record is received (generally in an overnight batch) and matches an existing record using the NHS Number. These feeds are deleted once the data load is completed successfully.
If patients opt out after their data is within the Solution, data submission from the GP systems will stop, the data already loaded until this point remains, but no population record (WCR) is created for that person and therefore it is not displayed on any front-end application.

How long will data be retained?

WCR is refreshed on a near real time basis depending on activity within the source systems. Each organisation must have a data retention policy that accords to the legitimate purposes of that, and a policy document will make clear the organisations approach to the retention, storage and disposal of

records, only keeping information for as long as is necessary in relation to the original purpose(s) for which it was collected. Anonymised data may be legally stored indefinitely.

The WCR is the longitudinal record and will no longer be visible for patients after their death, migration to a none Wirral GP practice or upon opting out as the result of a deletion flag being sent onto the platform from the source record. An audit log will be retained indefinitely. The deletion flag will relate to the patient's deceased date, transfer date or withdrawal of consent within the GP source system. Removal from the front end visible record will be undertaken by the data processor.

The Solution will hold the audit trail of use by staff member and by citizens whilst the WCR is held. Data that is stored and generated within the WCR, including audit trails, access logs, etc., are retained in accordance with the General Medical Council and British Medical Association guidance as well as the NHS Records Management Code of Practice.

How will patients Opt Out of the WCR?

If a patient chooses to opt out, the GP Partner Organisation can flag their record for exclusion and the data is not onboarded in to the HealtheIntent system. The WCR will build each record based on the GP record i.e. if there is no GP record then no WCR record will be created. If the patient opts back in a new bulk upload for that patient occurs and adds any data from the date that the patient was removed back into the delta feed. This provides flexibility to quickly reinstate the record if the patient should change their mind.

If an entire organisation opts out after its data is onboarded, data submission from the that organisation will stop, the data already onboarded up until this point remains in the system, but the population record (WCR) doesn't include any data produced by that organisation and data is therefore not displayed on any front-end application.

How will patient data be protected?

Data is processed in accordance with Data Processor Supplier and DPA 1998 requirements. When data are abstracted they are encrypted in transit and held in a high security level environment to enable processing. It is encrypted at rest and cannot leave this area. The Information is isolated from other systems within the processor environment.

There are two categories of filtering sensitive data: Highly Sensitive and Regular Sensitive filtering. During data acquisition, 'Highly Sensitive' data is filtered out at the very first stage of the process, with no downstream further processing. Regular Sensitive data is instead filtered out a step later in the process so that is prevented from being seen on front end application, however, it is retained to support algorithms and programs running in the background. The Highly Sensitive and Regular Sensitive filtering parameters will be defined during the system design phase through the inputs of HWP.

Access is tightly controlled based on 'The Principle of Least Privilege'. Organisations will determine what users can see and the level of access. However, they can only see patient level data where there is a legitimate relationship established and /or administrative roles are in place to enable and users have undergone IG training. The system will default to lock out after an agreed period of inactivity and supports a single log out system. All access is monitored and audited as above.

3. Consultation:

Extensive consultation and engagement is already underway on the developing proposals with key stakeholder groups. Information about the WCR has been distributed to:

- Patients; through existing networks and also via email to over 40,000 addresses, GP surgeries and other health and social care facilities
- GPs, clinicians and health and social care staff; through existing email and postal networks
- Partners; through the Vanguard board and Wirral Partnership arrangements
- MPs and Elected Members; through stakeholder briefings

Based on information provided in the initial proposal, people were invited to provide their views through a questionnaire. The results of this feedback will be used on an ongoing basis to inform the design of the WCR system.

The engagement methods vary for each stakeholder and during the timeline, however in principle there are three stages of engagement:

Phase 1 (August 2016 onwards) Initiation: a range of publicity materials including an online survey have been issued to all stakeholders. The feedback from this will inform the development of the registries and information governance documentation.

Phase 2 (October 2016 onwards) Design: the outputs from phase 1 engagement will also inform a series of events and more detailed publicity for stakeholders in which insights will be shared along with case studies detailing what this means to them and give the opportunity for questions and further informing the development.

Phase 3 (January 2017 onwards) Mobilisation: In advance of the implementation of the registries all stakeholders will be informed of how they and or their patients can opt out of the WCR and be given the opportunity to discuss any concerns or raise any questions.

4. Privacy and related risks:

This includes key privacy risks, with impact on the individual, the organisations and compliance with the Data Protection Act (DPA).

This section includes the solutions currently in progress and the impact this is likely to have in terms of mitigating the risks noted.

The risk scoring is based on the WUTH model (see Appendix 1). Where “C” is the consequence of the risk occurring based on different domains such as harm or finance, and “L” is the likelihood:

PRIVACY RISK	Risk to individuals C*L	Compliance risk C*L	Associated organisation / corporate risk	Solution(s)	Result:	**Evaluation:** is the final impact on individuals after implementing each solution a justified, compliant and proportionate response to the aims of the project?
Failure to engage with the public /partners effectively	2*1 Low Harm Individuals may be concerned about the content and spread of data sharing leading to anxiety Individuals may decide to opt out; care may be less informed. Individuals may not be included because the GP or other partner organisations have not engaged in the process; care may be less informed.	4*1 Financial ICO monetary penalty if fair processing not in place.	3*3 Objectives Partners may not agree to or delay the sharing of data; disrupt project time scales or halt project	Robust communication plan in place; monitoring and public involvement Meetings to enhance partners knowledge and engage support eg Solution demonstrations for GPs/Consultants GPs – involvement of LMC; FAQ for staff –including screenshots Awareness raising Engage all SIROs and Caldicott Guardians	Reduction 4*1	Yes

Failure to have an effective mechanism to opt out	2*1 Harm Loss of trust between individual and care organisations; failure to seek care in the future	4*1 Finance ICO monetary penalty if breach of Principle 1	4*1 Finance/ Statutory duty Breach of human rights/DPA	Opt out through the GP practices only SOP for Solution	Reduction 3*1	Yes
Organisational data will be abstracted into WCR even if patient has opted out	2*1 Harm Loss of trust between individual and care organisations; failure to seek care in the future Data seen will be out of date/ incomplete	4*1 Finance ICO monetary penalty if fair processing not in place.	4*1 Finance/ Statutory duty Breach of human rights/DPA Clinical harm to patient	No WCR to be visible unless associated with a GP record ie data is processed but not accessed Patients made aware removal takes 5-7days from request.	2*1	Only solution currently available
Failure of partners to have adequate information security standards in place	2*1 Harm Loss of trust between individual and care organisations; failure to seek care in the future	4*1 Finance ICO monetary penalty if breach of Principle 7	3*4 Objectives Partners do not have assurance that processes are in place to enable safe sharing; dependent on scale this could hamper delivery of the project	No sharing with partners who have not self –assessed against IGT and achieved level 2. Data controllers organisational processes to maintain data security Process to ensure data controllers are compliant with	Reduction 3*2	Yes

				DPA registration and IG toolkit.		
Poor quality or inaccurate data within the WCR	5*1 Harm Patient could receive wrong or inadequate treatment	4*1 Finance ICO monetary penalty if breach of Principle 4	4*1 Finance/ Statutory duty ICO monetary penalty if breach of Principle 4 Reputational effect	Data controllers in common so each organisation responsible for own data ISA – cannot share data without being IGT level 2 compliant Only coded data uploaded for WCR – no free text HWP are putting in place a Data Quality Group	No change 4*1 If found in breach of law	Yes No significant difference to current situation
Failure to recognise patients who have opted out so visible in WCR	2*1 Harm Loss of trust between individual and care organisations; failure to seek care in the future	4*1 Finance ICO monetary penalty if breach of Principle 1 and/or 6	4*1 Finance/ Statutory duty Reputational effect Breach of Human Rights Act and DPA	Robust opt out system via primary care Data processors systems to stop processing of recognised patients Audit & monitoring of the system	No change 4*1 If found in breach of law	Yes Once coding applied opt out should follow via the processing.
Inclusion of sensitive/ ultra sensitive data without opt-in consent	2*1 Harm Loss of trust between individual and care organisations; failure to seek	4*1 Finance ICO monetary penalty if breach of	4*1 Finance/ Statutory duty Reputational effect Breach of Human	Phased approach – no sensitive data shared in phase 1 Clinical discussion about value of sensitive data	No change 4*1 If found in breach of	Needs clinical review – Impact on opt out Clinical implications

	care in the future	Principle 1 or 3	Rights Act and DPA		law	
Sharing of third party information – this will be next of kin data without their consent	4*1 Harm Impact on family and social relationships could lead to significant harm	4*2 Finance ICO monetary penalty if breach of Principle 1 or 3	4*2 Finance/ Statutory duty Reputational effect Breach of Human Rights Act and DPA Finance	Ensure fair processing Limit to next of kin/ carer No free text uploaded.	Reduce 4*1	Yes Unable to consent all next of kin/carers
Failure of security systems/ inappropriate access	4*1 Harm Loss of trust between individual and care organisations; failure to seek care in the future/ provide important details	4*2 Finance ICO monetary penalty if breach of Principle 7	4*2 Finance/Statutory duty Reputational effect Breach of Human Rights Act and DPA Finance	Contractual obligation with Processor. ISA in place IG training compliance for users IG toolkit level 2 compliance Access levels Attribution algorithms in place Organisational affiliation Audit and monitoring	Reduce 4*1	Yes
	1*3	4*3	4*3	Clarity in communication about the purpose and use of the	Reduce	Yes but will need to be further

Use of data for purpose other than direct patient care	Harm Loss of trust between individual and care organisations; failure to seek care in the future/ provide important details	Finance ICO monetary penalty if breach of Principle 1	Finance/Statutory duty Reputational effect. Breach of Human Rights Act and DPA Finance	data- patient identifiable data for direct care only ISA for direct patient care PIA for direct patient care Pseudo-anonymised and anonymous data use permissible Review above annually and consider need to expand use	4*1	developed as potential for epidemiological research and needs assessment for service provision and other commissioning functions will be considerable.
Failure to delete records for patients who have moved out of area	1*4 Harm Loss of trust between individual and care organisations; failure to seek care in the future/ provide important details	4*3 Finance ICO monetary penalty if breach of Principle 5	4*3 Finance/Statutory duty Reputational effect. Breach of Human Rights Act and DPA Finance	Daily refresh from organisations will identify patients no longer on the practice register/ no update in condition. Unable to view record ISA stipulation regarding compliance with principle 5	No Change 4*3	Yes but will need to be reviewed by HWP.

5. Sign off and PIA outcomes

This section documents who has approved the privacy risks involved in the project and the solutions required.

Risk	Approved solution	Approved by
Lack of authorisation of the PIA through the correct governance route. Healthy Wirral does not exist as an organisation, therefore each member of the HW programme needs to have developed their own approval processes with their respective SIRO, Caldicott Guardian and IG lead.	1. Establish IG Task and Finish Group 2. Established Caldicott Guardian and IG Network 3. Documented timeline for approval processes 4. Engagement and inclusion of all Caldicott Guardians and IG leads in each Wirral Partner organisation. 5. Healthy Wirral Partnership Board – Data Controllers sign off of the Information sharing agreement	1.Sponsoring Lead for Healthy Wirral: Mr J Develing Accountable Office for Wirral CCG Signature: 2 SIRO: Mr M Bakewell Executive Director, Wirral CCG Signature: 3 SIRO: Mr M Blakeman Executive Director. Wirral University Teaching Hospital NHS FT Signature:

6. Integrating the PIA outcomes back into the project plan

This section documents who is responsible for integrating the PIA outcomes back into the project plan and updating any project management paperwork. Also who is responsible for implementing the solutions that have been approved and who is the contact for any privacy concerns that may arise in the future.

Action to be taken	Date for completion of actions	Responsibility for action
Establish Programme Management Office for Healthy Wirral	Programme Management Office established 1.9.15. Accountable Officer identified Recruitment of Programme Director, Finance Director and Head of PMO completed 21.9.15.	Wirral Partners Board Wirral Partners Board Accountable Officer
Head of PMO to integrate PIA outcomes back into Healthy Wirral Programme plan	31st December 2015	Natalie Armes, Head of PMO (commences in post 30.11.15.) James Barclay Programme Manager
Contact point for future privacy concerns:		
Mr Mark Blakeman Executive Director & SIRO WUTH Dr Melanie Maxwell Associate Medical Director & Caldicott Guardian WUTH Mrs Suzanne Crutchley Senior Governance Manager (Information Governance), Midlands and Lancashire Commissioning Support Unit (MLCSU)		

7. Legal Basis to Operate Within

It is worth setting out the related but separate types of ***legal basis*** upon which to rely, for processing data for the WCR. The partner organisations are all legally registered Data Controllers in their own right. That is the starting point.

The Data Controllers could in effect be described as a Multi-Disciplinary Team (MDT) collectively **providing health/social care** for their patients/clients/Service Users. There are no Information Governance concerns in this respect, as they all have a **legitimate relationship** with the patients/clients, in providing their care and treatment.

There are two distinct stages to this **Sharing of Personal Records** work programme for the WCR:

1) ***bringing data together*** held in each electronic system by each partner organisation into the WCR
2) ***accessing data*** held by one or more of the partner organisations in the WCR

For ***bringing data together*** please see the table below: Data Protection Act 1998 Conditions, which are met.

For ***accessing data***, by involving the patients/clients in their care and treatment. And by **integrating this with the provision of their health/social care**, then again there are no Information Governance concerns in this respect, as you have **informed consent** from the patients/clients. Consent should be documented on the system(s) used.

Where consent cannot be given e.g. the patient is unconscious, lacks capacity, etc, there is still provision under the DPA to access the data. For ***accessing data*** in this way, please see the table below: Data Protection Act 1998 Conditions, which are met:

For bringing data together:	**For accessing data:**
SCHEDULE 2 Conditions relevant for purposes of the first principle: processing of any personal data	
3 The processing is necessary for compliance with any legal obligation to which the data controller is subject, other than an obligation imposed by contract. 5 The processing is necessary— (b) for the exercise of any functions conferred on any person by or under any enactment. 6 (1) The processing is necessary for the purposes of legitimate interests pursued by the data controller or by the third party or parties to whom the data are disclosed, except where the processing is unwarranted in any particular case by reason of prejudice to the rights and freedoms or legitimate interests of the data subject.	3 The processing is necessary for compliance with any legal obligation to which the data controller is subject, other than an obligation imposed by contract. 5 The processing is necessary— (b) for the exercise of any functions conferred on any person by or under any enactment. 6 (1) The processing is necessary for the purposes of legitimate interests pursued by the data controller or by the third party or parties to whom the data are disclosed, except where the processing is unwarranted in any particular case by reason of prejudice to the rights and freedoms or legitimate interests of the data subject.
SCHEDULE 3 Conditions relevant for purposes of the first principle: processing of sensitive personal data	
7 (1) The processing is necessary— (b) for the exercise of any functions conferred on any person by or under an enactment, or 8 (1) The processing is necessary for medical purposes and is undertaken by— (a) a health professional, or (b) a person who in the circumstances owes a duty of confidentiality which is equivalent* to that which would arise if that person were a health professional. (2) In this paragraph “medical purposes” includes the purposes of preventative medicine, medical diagnosis, medical research, the provision of care and treatment and the management of healthcare services. * this includes registered Social Workers.	7 (1) The processing is necessary— (b) for the exercise of any functions conferred on any person by or under an enactment, or 8 (1) The processing is necessary for medical purposes and is undertaken by— (a) a health professional, or (b) a person who in the circumstances owes a duty of confidentiality which is equivalent* to that which would arise if that person were a health professional. (2) In this paragraph “medical purposes” includes the purposes of preventative medicine, medical diagnosis, medical research, the provision of care and treatment and the management of healthcare services. * this includes registered Social Workers.

8. Data Protection Act 1998 Compliance – Sign Off

This is a summary of the conclusions that have been reached in relation to this project's overall compliance with the Data Protection Act 199 Following discussion with the ICO.

Compliant

Principle 1: Robust communication plan across Wirral. Opt out system needs to be robustly implemented. Opt out means all organisations data. Need to make patients aware data is abstracted from systems but then not visible to H&SC workers from within the WCR. Data are abstracted from the source systems without consent. To view the system the user will ask patient's consent unless there is an emergency where consent cannot be obtained. Consent should be noted. Next of kin data can be incorporated.

Principle 2: For individualised care; no secondary use at this point for patient identifiable data. PIA will need to be reviewed regularly to ensure remains compliant

Principle 3: Data set will grow as registries come on board. PIA will need to be reviewed regularly to ensure remains compliant

Principle 4: Reliance on the source data; organisations are controllers in common and are responsible for the source data

Principle 6: System will be put in place for subject access. Likely to make this easier

Principle 7: System is secure as determined by IGT and provider IG systems; sharing more secure than current practice. Contractual obligation with the data processors.

Issues:

Principle 5: storage – source data will be compliant. WCR requires a retention policy within the legal framework. Currently deletion 8 years after death. If data required for secondary use in the future consider holding in an anonymised record.

Principle 8: Cerner UK will hold the data; global company and desire for 24/7 service means will want to use US/India under contract for maintenance and repair purposes. Following discussion it has been agreed that Cerner staff outside the UK will not have access to any patient identifiable data.

Hierarchy of sign off and where been in advance of sign off

In advance:	**Hierarchy of sign off**
Healthy Wirral IG Task & Finish Team	NHS Wirral Clinical Commissioning Group
Healthy Wirral IG Group	Wirral University Teaching Hospital NHSFT
Healthy Wirral Partnership	Wirral Community NHS Trust
	Cheshire and Wirral Partnership NHSFT
	Wirral Metropolitan Borough Council
	Wirral GP Practices

9. Sign off for Data Protection Act 1998 Compliance:

Proponent for the Project for the Clinical Commissioning Group	**Proponent for Information Governance for the Commissioning Support Unit**
Name: [redacted] Job Title: Lead Sponsor & Accountable Officer for NHS Wirral Clinical Commissioning Group Signature: [redacted] Date: 29 April 2016	Name: [redacted] Job Title: Senior Governance Manager (Information Governance) Midlands and Lancashire Commissioning Support Unit (MLCSU) Signature: [redacted] Date: 29 April 2016
Proponent for the Project for Wirral University Teaching Hospital NHSFT Name: Mr M Blakeman Job Title: SIRO and Executive Director Wirral University Teaching Hospital NHSFT Signature:  Date: 29 April 2016	

Appendix 1 Risk Scoring Matrix

The Risk Scoring Method should be applied to all incidents, complaints, claims

and risks identified through proactive risk assessments.

1. **Consequence:** Use **Table 1** to determine the Consequence Score(s) **C**. In the case of incidents, complaints and claims, this is the **actual** consequence (i.e. what actually happened). In the case of proactive risk assessments, it is the potential consequence (i.e. what could potentially happen). All events, actual or future, may have one consequence or several consequences (e.g. affecting patient care, financial impact, adverse publicity, etc). **The score used to calculate the overall consequence is the row from which the highest numerical score is achieved.**
2. **Likelihood:** Use **Table 2** to determine the Likelihood Score **L**. This is the chance that the consequence described above will occur (or recur) to that identified group.
3. **Risk Score:** See **Table 3**. Multiply the Consequence Score **C** with the Likelihood Score **L** to obtain the Risk Rating, which should be a score between 1 and 25.
4. **Near Miss:** Please tick the Near Miss box if applicable. All 'near miss' incidents are to be scored twice; Once for what actually happened and then for what would have happened had intervention not taken place.
5. Orange and Red incidents must be reported to Risk Management on ext. 2611 immediately

Table 1 – Consequence

Actual Severity = Incidents / Complaints / Claims Potential Severity = Risk Assessments/Near Miss

	1	2	3	4	5
Descriptor	**No Harm / insignificant**	**Very low harm / minor**	**Low harm**	**Moderate**	**Severe/Death**
Clinical impact on the safety of patients (physical/ psychological harm)	No harm: Impact prevented- any patient safety incident that had the potential to cause harm but was prevented, resulting in no harm to people receiving NHS-funded care. Minimal injury requiring no/minimal intervention or treatment No time off work	Impact not prevented any patient safety incident that ran to completion but no harm occurred to people receiving NHS funded care. Minor injury or illness, requiring minor intervention, will probably resolve within one month Staff injury requiring time off work or light duties for 6 days or less Hospital acquired **colonisation** affecting one or more patients, member of staff or the	Any patient safety incident that required extra observation or minor treatment and caused minimal harm, to one or more persons receiving NHS funded care. Staff injury requiring time off work or light duties for 7 – 35 days Hospital acquired **infection** affecting one or more patients, members of staff/the public or where a bay closure occurs	Any patient safety incident that resulted in moderate increase in treatment and which caused significant but not permanent harm to one or more persons receiving NHS funded care Moderate increase in treatment is defined as return to surgery, an unplanned readmission, prolonged episode of care, extra time in hospital or as and outpatient , cancelling of treatment or transfer to another area such as ITU as a result of the incident Moderate/ major injuries/Dangerous Occurrences reportable	Severe: any patient safety incident that appears to have resulted in permanent harm to one or more persons receiving NHS funded care. Death: any patient safety incident that directly resulted in the death of one or more persons receiving NHS funded care. Unexpected death or significant permanent disability where outcome is directly attributable to a safety incident

		public		under RIDDOR Requiring time off work or light duties for >36 days with eventual recovery Unexpected admission to critical care area with eventual recovery MRSA Bacteraemia with eventual recovery Hospital acquired **infection** affecting > 1 bay	All Never Events* (See list below) Part 1 of death certificate stating hospital acquired infection Hospital acquired **infection** affecting > 1 ward
Health & Safety / Non clinical impact on the safety of patients, staff or public (physical/psychological harm)	Minimal injury requiring no/minimal intervention or treatment No time off work	Minor injury or illness, requiring minor intervention, will resolve in 6 days or less Staff injury requiring time off work or light duties for 6 days or less	Injury or illness, requiring intervention, is expected to resolve within one month Staff injury requiring time off work or light duties for 7-35 days	Major injuries / dangerous occurrences reportable under RIDDOR Staff injury requiring time off work or light duties for >36 days with eventual recovery	An accident at work resulting in a fatality Significant permanent disability where outcome is directly attributable to a health and safety incident
Objectives / Projects	Insignificant project slippage Barely noticeable reduction in scope or quality	Minor project slippage Minor reduction in scope or quality	Serious overrun on project Reduction in scope or quality	Project in danger of not being delivered Failure to meet secondary objectives	Unable to deliver project Failure to meet primary objectives
Service / Business Interruption **Environmental Impact**	Loss / Interruption of service Up to 1 hour Minimal or no impact on the environment including contamination, not directly coming into contact with patients, staff or members of the public	Loss / Interruption of service 1 to 4 hours Minor impact on the environment	Loss / Interruption of service 4 to 8 hours Moderate impact on the environment	Loss / Interruption of service 8 hours to 2 days Major impact on the environment including ward closure	Loss / Interruption of service More than 2 days Catastrophic impact on the environment including multiple ward or hospital closure
Human resources/ organisation	Short-term low staffing level that temporarily reduces service quality (< 1 day)	Low staffing level that reduces the service quality	Late delivery of key objective/ service due to lack of staff Unsafe staffing level or	Uncertain delivery of key objective/service due to lack of staff Unsafe staffing level or	Non-delivery of key objective/service due to lack of staff Ongoing unsafe staffing

al development/ staffing/ competence			competence (>1 day) Low staff morale Poor staff attendance for mandatory/key training	competence (>5 days) Loss of key staff Very low staff morale No staff attending mandatory/ key training	levels or competence Loss of several key staff No staff attending mandatory training on an ongoing basis
Finance including claims	No obvious / small loss < £5k	£6k - £99k	£100k to £250k	£251k to £999k	Over £1m
Statutory duty/ inspections	No or minimal impact or breach of guidance/statutory guidance	Breach of statutory legislation reduced performance rating if unresolved	Single breach in statutory duty Challenging external recommendations/ improvement notice	Enforcement action Multiple breaches in statutory duty Improvement notices low performance rating. Critical report	Multiple breaches in statutory duty Prosecution Complete system change required Zero performance rating. Severely critical report
Adverse Publicity / Reputation	Rumours Potential for public concern	Local media coverage – short-term reduction in public confidence Element of public expectation not being met	Local media coverage – long term reduction in public confidence	National media coverage with <3 days service well below reasonable public expectation	National media coverage with >3 days service well below reasonable public expectation. MP concerned (questions in the house). Total loss of public confidence
Quality/ Complaints	Unsatisfactory patient experience not directly related to patient care Locally resolved concern	Overall treatment or service suboptimal Justified formal complaint peripheral to patient care	Treatment or service has significantly reduced effectiveness Justified formal complaint involving lack of appropriate clinical care, short term effects	Non-compliance with national standards with significant risk to patients if unresolved Justified multiple formal complaints. Serious mismanagement of care, long term effects	Totally unacceptable level or quality of treatment/service Ombudsman Inquiry Legal Claim
Information Governance	Less than 5 people affected or risk assessed as low e.g. files were encrypted	Serious potential breach & risk assessed high e.g. unencrypted clinical records lost. Up to 20 people affected.	Serious breach of confidentiality e.g. up to 100 people affected.	Serious breach with either particular sensitivity e.g. sexual health details, or up to 1000 people affected.	Serious breach with potential for ID theft or over 1000

Table 2 – Likelihood

	1	2	3	4	5
Likelihood reflects how likely the consequence described will occur; either frequency or probability. **% chance of recurrence of consequence in identified group.**	This will probably never happen/recur Not expected to occur for years (1 – 5%)	Do not expect it to happen/recur but it is possible it may do so Expected to occur at least annually (6 – 25%)	Might happen or recur occasionally Expected to occur at least monthly (26 – 50%)	Will probably happen/recur, but it is not a persisting issue/ circumstances Expected to occur at least weekly (51 – 75%)	Will undoubtedly happen/recur, possibly frequently Expected to occur at least daily (76 – 100%)

Consequence	Likelihood				
	1	**2**	**3**	**4**	**5**
1	1	2	3	4	5
2	2	4	6	8	10
3	3	6	9	12	15
4	4	8	12	16	20
5	5	10	15	20	25

Document Cross-Reference

The table below includes other controlled content relevant to this document.

Reference	Title
2.2	**INFORMATION SHARING: CODE OF PRACTICE** **(Tier Two) Operational Guidance for Staff**
2.4	**INFORMATION SHARING: CODE OF PRACTICE** **(Tier Two) Operational Guidance for Staff**
2.8	**INFORMATION SHARING: CODE OF PRACTICE** **(Tier Two) Operational Guidance for Staff**

Document History

Revision History

Date	Version	Description of Changes to Document (including changed section number(s))
21/09/2015	0.1	New document: collation of information from a number of sources
01/10/2015	0.2	Amended most sections in light of further information from the group (EO/JG/CT/SC). Highlighting areas for further discussion.
14/10/2015	0.3	Amended to clarify sections with input from Healthy Wirral IG Group and T&F Group (JG/CT/EO/SC/MM/SW). Comments to be discussed with ICO
20/10/2015	0.4	Amended following discussion with the ICO. Simplify document so readable to lay person; remove duplication; align with ISA; Additional Information now within a supplement.
03/11/2015	0.6	Amended following feedback from the group/ Caldicott and IG Leads and Cerner; factual accuracy/ additional appendix with risk matrix reinstated
06/11/2015	1.0	Final approved document; version control within PMO
25/04/2016	1.1	Clarification of consent model; update of privacy risks; insertion of potential secondary use of data.
26/04/2016	1.2	Updated in line with comments/factual accuracy checks made by Cerner UK, and Suzanne Crutchley.

Reviewers

Date	Version	Reviewer	Client Organisation
10/09/2015	0.1	Task & Finish Group	WUTH/WCT/CERNER/WCP/WCCG
24/09/2015	0.2	Task & Finish Group	WUTH/WCT/CERNER/WCP/WCCG
16/10/2015	0.3	Discussion with ICO	ICO/WUTH/WCCG
25/10/2015	0.4	Task & Finish Group; Caldicott Guardian and IG managers group; Healthy Wirral	WUTH/CWP/WCT/WCCG/CERNER/

Date	Version	Reviewer	Client Organisation
		IG/IT Group	HOSPICE
25/04/2016	1.2	Task & Finish Group;	WUTH/CWP/WCT/WCCG/CERNER/ HOSPICE