GIG CYMRU NHS WALES Bwrdd Iechyd Prifysgol Caerdydd a'r Fro Cardiff and Vale University Health Board	**Reference Number:** UHB 006 **Version Number: 1** **Date of Next Review:**7TH Dec 2018 **Previous Trust/LHB Reference Number:**T218

Data Protection Guidance for Researchers

Introduction and Aim

Most clinical research involves access to and the use of patient identifiable information or, information that is capable of identifying a patient. It should be noted that the Data Protection Act 1998 (DPA) only applies to the personal information of living individuals.

The purpose of this guidance document is to familiarise researchers with key DPA issues associated with clinical research at Cardiff and Vale University Health Board (the UHB). This guidance is not intended to be a definitive guide to all Data Protection issues relating to clinical research. If researchers have specific Data Protection issues, they should contact the UHB's Information Governance Department or seek legal advice.

This guidance does not remove the requirement for researchers to contact the UHB's Information Governance Department when considering completing completed application documents. This is in line with local arrangements to ensure DPA requirements are met.

This guidance will ensure that all staff understand the requirements placed upon them in respect of managing research programmes in respect of the DPA thereby mitigating any potential risks resulting form non-compliance with legislation such as substantial fines or enforcement notices from the Information Commissioners Office (ICO).

Objectives

This guidance describes the mechanism the UHB will use to develop and maintain best practice for the data protection aspects for the management of research programmes the effective implementation of which will ensure that the requirements of the DPA are met

Scope

This procedure applies to all of our staff in all locations including those with honorary contracts

Equality Impact Assessment	An Equality Impact Assessment has been completed for the overarching IG Policy. The assessment found that there was some impact on the equality groups mentioned in relation to communication. An action plan has been developed to address those areas.
Documents to read alongside this Procedure	Guideline 146: Human Resources Arrangements for Researchers Working in the NHS Information Governance Policy Data Protection Act Policy

	Records Management Policy IT Security Policy Management of Information Asset Procedure Information Risk Management Procedure Risk Management Policy Guide to Incident Reporting Incident Management Investigation and Reporting. [Serious incidents] Freedom of Information Act Policy Data Protection Act Code Code of Confidentiality
Approved by	Information Governance Sub Committee
Accountable Executive or Clinical Board Director	Medical Director
Author(s)	Head of Information Governance and Assurance

Disclaimer

If the review date of this document has passed please ensure that the version you a using is the most up to date either by contacting the document author or the Governance Directorate.

Summary of reviews/amendments			
Version Number	**Date of Review Approved**	**Date Published**	**Summary of Amendments**
1	07/12/2015	19/05/2016	Reviewed procedure

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1. INTRODUCTION

From a data protection perspective, research can be considered under two categories;

1. Retrospective research based on information held by the UHB, where there is no communication with the patient and patient consent is not sought.

2. Research where there is patient communication or contact and, where informed patient consent is required

The term 'patient' is used throughout this Guidance; the term will also apply in most cases to subjects who are not patients, e.g. staff or healthy volunteers. The Data Protection Act requirements apply to all living subjects.

Responsibilities for the maintenance of appropriate controls will lie with the Director of Research and Development. Responsibility for implementing and managing controls may be delegated to suitably experienced senior clinical managers, although accountability must remain with the nominated owner of the information asset.

2. RETROSPECTIVE RESEARCH

2.1. Researchers

Non-UHB staff requiring access to patient identifiable information are required to have a Research Passport, honorary contract, or letter of access with the UHB as indicated. Further information on this subject can be gained from UHB Guideline 146: Human Resources Arrangements for Researchers Working in the NHS

All researchers are reminded of the Duty of Confidentiality they owe research subjects

2.2. Health Records

Researchers must only access information in a patient's health record that is relevant to their Ethics and UHB R&D approved research. General browsing of patients' health records is not permitted.

2.3. Documentation

No information capable of identifying a patient (including combinations of initials and DOB, or full postcodes) may be recorded in any research without participants consent. Information that is capable of identifying a patient must not be processed on a non-UHB owned computer.

3. RESEARCH INVOLVING PATIENT COMMUNICATION OR CONTACT

3.1. Researchers

Non-UHB staff requiring access to UHB patients or UHB resources are required to have a Research Passport, an honorary contract, honorary research contract or letter of access with the UHB (apart from pharmaceutical/medical device company monitors, covered by a research contract with the UHB). Further information on this subject can be gained from UHB Guideline 146: Human Resources Arrangements for Researchers Working in the NHS

A Research Passport is the method by which an honorary research contract or letter of access is obtained. Further information on this subject can be gained from UHB Guideline 146: Human Resources Arrangements for Researchers Working in the NHS

All researchers are reminded of the Duty of Confidentiality they owe research subjects.

3.2. Patient recruitment

Only healthcare professionals, actively involved in the care of the particular patient group being studied, can approach or contact patients identified as potential participants to recruit them for research studies or gain consent for their details to be passed to researchers. Researchers (unless involved in a patient's care) cannot be given access to patient information until the patient consents to this.

3.2.1. Consent is impracticable

Where patient consent is normally is required for a study but it is deemed impractical to obtain consent; researchers must obtain approval for their study from the Health Research Authority (HRA) Confidentiality Advisory Group under section 251 of the NHS Act 2006 - http://www.hra.nhs.uk/about-the-hra/our-committees/section-251/

3.3. Patient's family

Where researchers intend patients to provide sensitive personal information (as defined by the DPA) regarding their family or relatives, researchers will need the consent of the family member or relative before recording this information. Researchers are advised to provide information sheets and consent forms for family members or relatives that can be distributed to them by the patient.

Family members or relatives cannot automatically provide consent for an adult to be involved in research unless they have the legal ability to do so (see section 2.4 below). Consideration must be given to patients under 16 years

old, with regard to Gillick Competence and their ability to provide consent in their own right

3.4. Patients unable to consent

Where a patient is not capable of consenting to taking part in research the following may apply:

The Medicines for Human Use (Clinical Trials) Regulations 2004 (the Regulations) allow a legal representative to give consent to take part in research on behalf of incapacitated adults or minors. The legal representative must be someone unconnected with the research who is suitable to act as a legal representative by virtue of their relationship with the patient. The requirements set out in the Regulations must be followed. The Regulations can be found on the Internet:
http://www.legislation.gov.uk/uksi/2004/1031/contents/made

It should be noted that these Regulations will be replaced with a new Clinical Trials Regulation (EU No 536/2014) which was adopted in 2014 but will apply no earlier that 28 May 2016. However, the above information is not expected to change. More information on the new Regulation and updates on the date of implementation can be found on the link below or via the MRHA website:

http://ec.europa.eu/health/human-use/clinicaltrials/information/index_en.htm#ct2

Research Staff undertaking Clinical Trials of Investigational Medicines (CTIMPS) should keep updated on the new Regulations and any changes pertinent to their research.

Sections 30 – 34 of The Mental Capacity Act 2005 make provision for non-patient consent for research, not covered by the Regulations, for a purpose connected with “an impairing condition affecting the patient, or its treatment.” The requirements set out in sections 30 – 34 must be followed. The Act can be found on the Internet link below:
http://www.opsi.gov.uk/acts/acts2005/20050009.htm.

Further guidance can be found in the Act’s Code of Practice, chapter 11:
www.dca.gov.uk/legal-policy/mental-capacity/mca-cp.pdf

3.5. Disclosures of identifiable data

The inclusion of identifiers (combinations of initials, DOB, gender, postcodes, clinical information etc.) in disclosures outside of the research team can in some circumstances identify patients and as such their inclusion needs to be justified as necessary. Researchers should consider the use of age instead of DOB, partial postcodes and the necessity of disclosing initials. By doing this it is likely that anonymised, rather than identifiable data are being processed.

Unless the disclosure of identifiers can be justified as necessary for the purposes of the research, their inclusion is likely to breach the DPA 3rd Principle regarding relevance and excessiveness.

If the disclosure of identifiers can be justified, patients must be informed of the purpose of their disclosure and of the confidentiality and security arrangements regarding the disclosure (see section 3.9).

If disclosures of identifiable information are made to countries outside the European Economic Area, the consent of the patient is required (see section 3.10).

Researchers should ensure that all identifiers are removed if copies of patient clinical test results are being sent to a third party. In particular, care should be taken to remove identifiers, not only from the headings of the results, but to check that there are no identifiers present in the body of the report; e.g. Radiology reports, safety reports sent to an external sponsor.

3.6. Anonymised Specimens

The Human Tissue Act 2004 allows anonymised specimens to be used in research. The act of making a specimen anonymous involves processing the identifiable specimen and as such, this processing has to comply with the Data Protection Act 1998.

Specimens originating within the UHB can be made anonymous (processed) for the purposes of research. Specimens originating from outside the UHB (GP surgeries, other UHBs etc.) cannot be made anonymous by the UHB for research purposes. This is because the UHB is a Processor for these specimens and does not have the power, under the 7th Data Protection Principle, to make the decision to anonymise the specimens. The permission of the Data Controller (the GP surgery, other UHB etc.) is required before the UHB can anonymise their specimens for the purpose of research.

3.7. Access to Medical Records

Where those involved in a research study require access to a patient's medical record as part of the research process, the UHB 'Access to Medical Records Form' must be completed. Forms are available by contacting the Information Governance Department, The form requires that researchers provide evidence that a consent process is in place (a blank consent form) and that the researcher has Ethics and UHB R&D approval (copies of approval letters).

3.8. Use of computers

If patient identifiable information is to be processed on any computer, other than one belonging to the organisation whose name is on the top of the patient information sheet, the patient must be informed of this

unless the patient could reasonably envisage that another identifiable organisation will be processing their personal information on a computer.

Access to patient identifiable information on a computer is only permissible to those to whom the patient is aware that their information will be disclosed.

The UHB does not permit patient identifiable information to be sent by email, other than email addresses to/from the Digital All Wales Network (i.e. xxx@wales.nhs.uk). Where patient identifiable information is logged directly into a database via a web browser, the web browser link must be encrypted. Participants need to be informed of this process. Where a third party is involved consideration must be given to completing a Data Processor Agreement if they are acting as our data processors.

With regard to the DPA 7th Principle; "Appropriate technical and organisational measures shall be taken against unauthorised or unlawful processing of personal data and against accidental loss or destruction of, or damage to, personal data".

3.8.1. Encryption

Any patient identifiable data on a laptop, memory stick or other portable media device (including CD/DVDs) must be encrypted.

3.9. Patient information sheet

Information provided to patients regarding the use of their personal information must be clear and comprehensive; otherwise patient consent to the use of their information will not be valid.

In the 'Confidentiality' section of the patient information sheet, the Information Commissioner's Office recommends not using the frequently used term 'names and addresses will be removed'. They advise that, for more transparency, the term "as far as possible, information which might identify you will be removed", should be used.

Patient information sheets must not provide misleading information; for example, informing patients that they will be identified by a study number but not telling them that their initials and date of birth will also be used (if they are included for this purpose).

Researchers are advised to use the HRA guidance and templates for Patient Information Sheets (see 3.11 below).

3.10 Consent form

The patient consent form must include separate endorsable points on the key issues regarding the use of patient identifiable information. These are primarily, but not exclusively:

- Access to the patient's medical records
- Disclosures of identifiable information
- Disclosures of identifiable information outside the EEA
- The processing and further use of specimens/samples
- The retention of patient contact details regarding future research
- Informing the patient's GP of their participation

Researchers are advised to use the HRA guidance and template for Informed Consent Forms (see 3.11 below).

3.11. Health Research Authority

Information on producing Patient Information Sheets and Informed Consent forms can be found on the HRA website: http://www.hra-decisiontools.org.uk/consent/examples.html

4. Information Governance

The responsible officers for R&D will provide assurance to the SIRO and Information Governance Sub Committee (IGSC) that:

- Arrangements are in place to ensure that DPA requirements are met
- All appropriate employment requirements are met including background checks for staff not employed by the UHB.
- Appropriate training is in place and is undertaken with a record being held of compliance with training requirements
- Routine internal and external audit programme e.g. MHRA Assessment is in place to provide objective assurance mechanisms.
- Effective working arrangements with the Information Governance department are in place.

5. Training

The R&D department will adhere to the UHB training policy to meet information governance and DPA training requirements.

The responsible officers for R&D will undertake training as necessary to ensure they remain effective in their role and all staff must attend refresher training**.** All training will be recorded on the employee staff record using the UHB's ESR or equivalent for staff not employed by the UHB.

6. Audit

The R&D department will develop a routine audit programme to include internal and external audit. This will include the MRHA assessment.

The R&D department will periodically be required to report to the Information Governance Sub Committee (IGSC) on compliance with MRHA standards and any other internal information governance assessments required through the Senior information Risk Officer (SIRO)