CHEME Data Protection Impact Assessment

This document records the CHEME Data Protection Impact Assessment (DPIA) process and outcome. It follows the process set out by the Information Commissioner's Office (ICO) DPIA guidance, and should be read alongside that guidance and the Criteria for an acceptable DPIA set out in European guidelines on DPIAs.

The steps in the document should be considered at the start of any major project involving the use of personal data, or if making a significant change to an existing process. The outcomes should be integrated back into the project plan.

Step 1: Identify the need for a DPIA

Explain broadly what project aims to achieve and what type of processing it involves. You may find it helpful to refer or link to other documents, such as a project proposal. Summarise why you identified the need for a DPIA.
The Centre for Health Economics and Medicines Evaluation (CHEME), within the School of Healthcare Sciences, Bangor University undertakes health economic evaluation activities in association with clinical and research departments across the UK. This often involves processing patient-level data held by hospitals, GP practices and other academic units. The DPIA is required to ensure we process any personal data in a manner consistent with the General Data Protection Regulations (GDPR). To comply, CHEME must handle personal data using systems and procedures designed and built with consideration of the principles of GDPR. This means we must provide safeguards to protect data (for example, using pseudonymisation or full anonymisation where appropriate), and use the highest-possible privacy settings by default, so that the data is not available publicly without explicit, informed consent, and cannot be used to identify a subject without additional information stored separately. Under GDPR, CHEME has to identify a legal basis for processing personal data and, where appropriate, an additional condition for processing special category data. Some of the data we process (ethnicity and healthcare data) is in the category of special data. In line with our charter which states that we "advance and disseminate learning and knowledge by teaching and research", the University processes personal data for research purposes under Article 6 (1) (e) of the GDPR: Processing is necessary for the performance of a task carried out in the public interest. Special category data is processed under Article 9 (2) (j): Processing is necessary for archiving purposes in the public interest, or scientific and historical research purposes or statistical purposes.

Step 2: Describe the processing

Describe the nature of the processing: how will you collect, use, store and delete data? What is the source of the data? Will you be sharing data with anyone? You might find it useful to refer to a flow diagram or other way of describing data flows. What types of processing identified as likely high risk are involved?
Data will be depersonalised at source so personal identifiers such as NHS number, patient name and address will be removed and replaced with the patient trial randomisation number before coming to CHEME. Source can include for example hospitals providing Patient-linked information costing (PLICS) data, other academic units providing trial database data and NHS Digital providing HES data. CHEME will not retain any means of identifying patients (e.g. lists of patient names, NHS numbers and addresses). Data will be collected in encrypted files from source-approved sites such as vocal and sharepoint and stored in encrypted files on either the Bangor U-drive or an encrypted laptop or a flash drive. Storage on the Bangor U-drive will be using restricted-access folders available only to the project researchers whereas encrypted laptops and flash drives holding encrypted data will be stored in locked offices. Relevant data will be extracted and combined with other depersonalised patient-level data to generate an anonymous profile of the number of patient visits to inpatient, outpatient, GP and A&E departments. These are working files and retained by CHEME in restricted-access folders on the U-drive. They are used to generate aggregated data for publication in peer-reviewed journals. Source data files such as HES or PLICS are retained for the duration of the projects, archived and destroyed safely, in accordance with the Data Protection Laws and in line with our agreement with source partners governing secure data deletion methods. Since the data handled is depersonalised and the source data files are held for a minimal period, the risks are considered minimal in this assessment.

Describe the scope of the processing: what is the nature of the data, and does it include special category or criminal offence data? How much data will you be collecting and using? How often? How long will you keep it? How many individuals are affected? What geographical area does it cover?
We process patient data under Article 6 (1) (e) of the GDPR: Processing is necessary for the performance of a task carried out in the public interest. Special category data such as hospital visits are processed under Article 9 (2) (j): Processing is necessary for archiving purposes in the public interest, or scientific and historical research purposes or statistical purposes. Data is depersonalised at source so personal identifiers such as NHS number, patient name and address are removed and replaced with the patient trial randomisation number before coming to CHEME. This means our researchers working with patient data will be unable to actually identify the patients involved. Depersonalised data will be from across the UK and generally relate to healthcare resource use data such as inpatient stays in clinical trials but may from time-to-time include special category data such as date of death. Clinical trials will range in size from fewer than 10 to as many as 10,000 individuals and may cover anything from six months to ten years depending on what the trial is studying. Data collections are usually specific to a trial and may include a data request halfway through the trial but will always need a final data download at the end of the study. Datasets will be kept for a minimum period; however, UK clinical trial regulations mean we need to archive data for lengthy periods (up to 15 years). Appropriate steps will be taken to ensure the data is safe. These are specifically: 1. Patient personal details such as name, address and NHS number will not be stored alongside depersonalised records at any point in the data lifecycle at CHEME. 2. Archival will be in folders encrypted to military-grade AES 256 standard and inaccessible to the internet. 3. Source data files such as HES or PLICS will retained, archived and destroyed safely, in accordance with the Data Protection Laws and in line with our agreement with source partners governing secure data deletion methods. 4. Access to data will be restricted to staff involved 5. Where small numbers of patients (<30) are involved, or where other concerns are raised regarding the potential identifiability of the patients involved in a study then all files pertaining to the study will be retained in folders encrypted to military-grade AES 256 standard and inaccessible to the internet.

Describe the context of the processing: what is the nature of your relationship with the individuals? How much control will they have? Would they expect you to use their data in this way? Do they include children or other vulnerable groups? Are there prior concerns over this type of processing or security flaws? Is it novel in any way? What is the current state of technology in this area? Are there any current issues of public concern that you should factor in? Are you signed up to any approved code of conduct or certification scheme (once any have been approved)?
CHEME does not have any relationship with the patients and our sole purpose is to generate aggregated health economic data for clinical trials and to report the findings in peer-reviewed journals such as The Lancet or Value in Health either separately or as part of the clinical trial. We do this under Article 6 (1) (e) of the GDPR: Processing is necessary for the performance of a task carried out in the public interest. Special category data such as hospital visits are processed under Article 9 (2) (j): Processing is necessary for archiving purposes in the public interest, or scientific and historical research purposes or statistical purposes. Patient groups can include children and other vulnerable groups; however, all patients will have read the clinical trial patient information sheet and signed the trial consent form allowing us to process the data. This of course does not affect their right to withdraw from the trial at any time of their choosing and if this is the case, their randomisation details are removed from the randomisation list and their depersonalised data will not be requested. As it is patient-level data, there are many prior concerns over the way the data is processed, therefore, CHEME has completed its Data Security and Protection (DSP) Toolkit to allow us to measure and publish our performance against the National Data Guardian's data security standards.

Describe the purposes of the processing: what do you want to achieve? What is the intended effect on individuals? What are the benefits of the processing – for you, and more broadly?
CHEME carries out health economic analysis on new clinical trial interventions to see if they are cost effective. The main method used—cost–utility analysis—considers the quality of life someone will experience as well as the extra life they will gain, as a result of intervening in a particular way. The health benefits are expressed as Quality Adjusted Life Years (QALYs) – or years of good health in lay terms. In general, interventions costing less than £20 000 per QALY are considered by NICE to be cost-effective and represent effective use of resources in the NHS. Effective use of resources is fundamental to enable health and social care providers to deliver and sustain high quality services for people. Without a health economic analysis this could not be achieved.

Step 3: Consultation process

Consider how to consult with relevant stakeholders: describe when and how you will seek individuals' views – or justify why it's not appropriate to do so. Who else do you need to involve within your organisation? Do you need to ask your processors to assist? Do you plan to consult information security experts, or any other experts?
Patients are consulted right at the start of their journey within a clinical trial. They are provided with a patient information sheet which outlines why their data is needed and how it will be processed. They are also provided with a patient consent form so they can give their permission for their data to be used as well as provided with contact details should they wish to withdraw their consent at any time. At CHEME, we never underestimate the importance of data security and always consult with our partners to ensure the depersonalised data is kept in a secure manner. This means consulting with people providing the data (e.g. universities, hospitals and government bodies such as NHS Digital) and including our own in-house experts on data security to work out the best practical means of receiving, processing and destroying the data in a way consistent with current UK data protection legislation.

Step 4: Assess necessity and proportionality

Describe compliance and proportionality measures, in particular: what is your lawful basis for processing? Does the processing actually achieve your purpose? Is there another way to achieve the same outcome? How will you prevent function creep? How will you ensure data quality and data minimisation? What information will you give individuals? How will you help to support their rights? What measures do you take to ensure processors comply? How do you safeguard any international transfers?
Lawful basis is underpinned by informed patient consent to permit receipt, processing and release of data as well as public interest and research. Processing of the data at the patient level achieves the purpose because resource use costs can be derived from resource usage and aggregated into a mean with confidence intervals. Other methods can be deployed, e.g. patient questionnaires; however, these put the onus of reporting down to the patient, themselves, who might not remember all their GP, hospital and outpatient visits in a 12 month period. Function creep is prevented by ensuring no one outside the clinical trial has access to the depersonalised patient-level data and only individuals working within the trial are authorized to access it. Data quality is a task associated with the hospitals providing the data and does not fall into our remit at CHEME; however, checks will be made for example to prevent double counting of hospital stays. Individuals will be given information about their role in the clinical trial in the patient information sheet provided by the clinical trials unit and will be kept updated on the trial by other means such as newsletters, websites and

discussions with their health care professionals. At CHEME, we act outside of the clinical trials unit. We do not contact the patients themselves nor do we store any of their personal information.

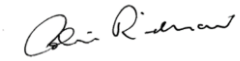
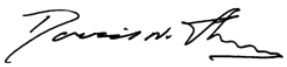
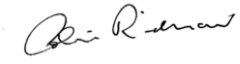
Step 5: Identify and assess risks

Describe source of risk and nature of potential impact on individuals. Include associated compliance and corporate risks as necessary.	**Likelihood of harm**	**Severity of harm**	**Overall risk**
1. Laptop gets left on a train/in a shop/on a park bench etc	remote	severe	medium
2. Excel file containing data is seen on computer or laptop screen by someone outside of study (e.g. looking over shoulder)	possible	significant	medium
3. Excel file containing data is illegally downloaded from Bangor U-drive by international / corporate / business intelligence hackers	remote	severe	medium
4. Excel file containing data is accidentally downloaded by university students	possible	significant	medium
5. Member of staff wants to access medical record of a patient on a trial	remote	significant	medium
6. Imposters phoning members of the trial study team and asking for information on a patient	possible	severe	high
7. E-mail containing patient data is accidentally forwarded on to someone outside of the trial	possible	severe	high
8. Some other identifier getting into the dataset, e.g. patient postcode, and this being used.	possible	significant	medium
9. A trial only has a few patients and some of these are named on the internet (e.g. in a news article) making them potentially identifiable to the researcher.	remote	significant	medium

Step 6: Identify measures to reduce risk

Identify additional measures you could take to reduce or eliminate risks identified as medium or high risk in step 5				
Risk	**Options to reduce or eliminate risk**	**Effect on risk**	**Residual risk**	**Measure approved**
1.	Use of encrypted laptops and encrypted folders. No patient identifiers in datasets.	Eliminated	Low	Yes
2.	No patient identifiers in datasets. Persons individualised by randomisation number. Key to randomisation number not held on site.	Eliminated	Low	Yes
3.	No patient identifiers in datasets. Persons individualised by randomisation number. Key to randomisation number not held on site. Original files removed from U-drive or laptop.	Eliminated	Low	Yes
4.	No patient identifiers in datasets. Persons individualised by randomisation number. Key to randomisation number not held on site.	Eliminated	Low	Yes
5.	No patient identifiers in datasets. Persons individualised by randomisation number. Key to randomisation number not held on site.	Eliminated	Low	Yes
6.	Internal policy of not giving patient data out over phone. No patient identifiers in datasets.	Eliminated	Low	Yes
7.	No patient identifiers in datasets. Persons individualised by randomisation number. Key to randomisation number not held on site.	Eliminated	Low	Yes
8.	Extracted datasets will be categorised, e.g. postcodes will be changed to their ranking in the index of deprivation. Original datasets will be deleted	Eliminated	Low	Yes
9.	Dataset access restricted to minimum number of authorized trained personnel. Breach of DPP a disciplinary matter. Use of AES 256 encryption.	Eliminated	Low	Yes

Step 7: Sign off and record outcomes

Item	Name/date	Notes
Measures approved by:	Colin Ridyard 5th November, 2019 	Integrate actions back into project plan, with date and responsibility for completion
Residual risks approved by:		If accepting any residual high risk, consult the ICO before going ahead
DPO advice provided:	Gwenan Hine 5th November, 2019 	DPO should advise on compliance, step 6 measures and whether processing can proceed
Summary of DPO advice: Discussions have occurred prior to the DPIA being completed, all advice followed. Section 6 measures are acceptable and have been approved between the DPO and CHEME.		
DPO advice accepted ~~or overruled~~ by:	David Thomas 5th November, 2019 	If overruled, you must explain your reasons
Comments:		
This DPIA will kept under review by:	Colin Ridyard 5th November 2019 	The DPO should also review ongoing compliance with DPIA