Department of
Health, Social Services
and Public Safety
www.dhsspsni.gov.uk

Marie Austin
Clerk
Health, Social Services and Public Safety Committee
Parliament Buildings
Ballymiscaw
Stormont
Belfast
BT4 3XX

Our Ref: COR/1456/2015

Date: 17 September 2015

Dear Marie,

Officials have been invited to attend a meeting of the Health Committee on Wednesday 30 September at 2.00 pm to provide oral evidence on the Health and Social Care (Control of Data Processing) Bill.

Sharon Gallagher, Director of Corporate Services and Chris Matthews, former Head of Information Management Branch will represent the Department.

I attach the Department's responses to the comments made about the Bill by stakeholders in response to the Health Committee's call for evidence.

Yours sincerely

Jonathan P. Bill

Jonathan Bill
Departmental Assembly Liaison Officer

HEALTH AND SOCIAL CARE (CONTROL OF DATA PROCESSING) BILL

SUMMARY OF EVIDENCE ON CLAUSES OF THE BILL

Complete written evidence can be accessed at: http://www.niassembly.gov.uk/assembly-business/committees/health-social-services-and-public-safety/legislation/processing-of-data-control/written-submissions/

Clause 1 sets out the circumstances for which the Department may make regulations to make provision for the processing of Health and Social Care information

Stakeholder Comments	**Department's Response**
Clause 1(1) The **Privacy Advisory Committee** is of the view that Clause 1(1) (a) is redundant and that the interests are much broader than improvement. It points out that the health and social care purposes that require to be addressed by this Bill cover a range of activities directed at enabling all health and social care organisations to carry out their tasks effectively and efficiently, including improvements where necessary and possible. It suggests that Clause 1 (1)(b) is incorporated into Clause 1(1) to read: *'The Department may by regulations make such provision for and in connection with requiring or regulating the processing of prescribed information of a relevant person for medical or social care purposes and which are in the public interest.'*	The comments of the Privacy Advisory Committee are noted and the Department is currently considering the drafting of this Clause.

The **Law Centre** notes that one of the most important safeguards for the individual interests of service users is a right to opt out of any processing of their confidential health and social care information which the committee has authorised. It states that experience in England and Wales shows that opt out tends to be a rare occurrence in practice, but such a right ensures proper respect for the decisions of individual service users. The existence of a right to opt out of such processing of their confidential information would also serve to maintain and build confidence amongst service users about the proposed arrangements in the Bill. In England and Wales, a right to opt out is one of the 'Standard Conditions of Approval' of the Confidentiality Advisory Group which states that the approval of processing by the committee requires that the applicant ensure that: 'The wishes of patients who have withheld or withdrawn their consent are respected'. The Law Centre believes that this does not provide adequate protection of individual rights and interests and nor is it sufficiently apparent to service users. The right to opt out of processing authorised by the committee as proposed by the Bill should be part of primary legislation, not a policy of the committee. It therefore proposes that Clause 1 be amended as follows: *Clause 1, page 2, line 2, at end insert—* *"( ) Subsection (2)(c) does not apply for or in connection with the processing of prescribed information of a relevant person in circumstances where that person has expressly withheld or withdrawn their consent to such processing."*	Regulations will set out how the process will operate. Opt –out arrangements will be consulted upon as part of the process of developing these Regulations which will also be subject to draft affirmative procedure in the Assembly.

The **Information Commissioner's Office** is of the view that processing health and social care data without the consent of an individual where it is necessary in the interests of improving health and social care, or, where it is in the public interest, would satisfy the conditions for processing set out in Schedule 2 para 5(b) and Schedule 3, para 7(b) of the Data Protection Act 1998. However, whilst it appreciates that the proposals will provide a legal gateway for the Department to allow the disclosure of health and social care data in certain circumstances, thus satisfying a relevant condition for processing, it points out that the processing may still may not be compliant with the first data protection principle i.e. that information is processed fairly and lawfully and that certain 'conditions' are met.	This Bill does not set aside the requirements of the Data Protection Act 1998. Any processing must fully comply with the provisions of the Data Protection Act. It will be the responsibility of the requestor to evidence to the Committee that this is the case. Where individuals opt out of having their information shared their wishes will be respected. Opt –out arrangements will be consulted upon as part of the process of developing these Regulations which will also be subject to draft affirmative procedure in the Assembly.
The Information Commissioner's Office has some concerns regarding the fairness of the provisions of the Bill on the rights and freedoms of individuals. Where individuals' rights are unreasonably overridden, the processing, even though it may satisfy a Schedule 3 condition, may nonetheless be unfair. It suggests that it might be worthwhile for the Department to engage with the general public and consider their views on the re-use of their data for secondary purposes. The Information Commissioner's Office questions whether the disclosure of data for secondary uses is compliant with the second data protection principle i.e. that personal data is to be obtained only for one or more specified purposes and shall not be further processed in any manner incompatible with that purpose. It points out	The proposals were subject to a public consultation and 94% of respondees were in favour of the proposals. The Regulations will also be subject to public consultation.

that if an individual provides information about their health condition or social well-being to an organisation with the belief that it will only be used in relation to their own direct treatment/care, and that information is then processed further for secondary purposes, then it may be arguable that this is not compatible with the second principle.	
The **Belfast Health and Social Care Trust** highlights that difficulties have arisen in the past where the risk of sharing data for beneficial purposes has been refused as the public interest test is open to interpretation. The Trust would wish to ensure that the Bill adequately covers some of the sharing and processing of information that currently exists and projects which would have relied on the public interest test. It points out that the sharing of personal identifiable data with organisations such as the Cancer Registry has been of concern because of the ambiguity within the 'public interest' test.	It is the intention that all applications for access to identifiable information for secondary uses will be made to the Committee. This will ensure greater consistency in the determination of what is in the public interest.
The **Southern Health and Social Care Trust** and the **South Eastern Health and Social Care Trust** are of the view that, to provide clarity on the purpose of the Bill, the term 'health' and social care purposes should be used rather than 'medical'.	The Department is currently considering the application of these definitions within the Bill.
The **Northern Ireland Cancer Network** (lung sub-group) believes that the legislation should allow organisations such as the Northern Ireland Cancer Registry to handle, analyse and report on data. It states that the Cancer Registry is a key partner to it in the processing and analysis of audit data for the national lung cancer audit and highlights the audits' positive impact in Eng-	It is anticipated that the NI Cancer Registry will receive "specific support" under the Regulations to provide a statutory basis for its operation. This support will make provision for the handling, analysing and reporting of data.

land on improvement in survival and care. It suggests that the Bill may need some rewording to facilitate this partnership.	
The **Northern Ireland Fire and Rescue Service** (NIFRS) highlights that people who die in accidental fires in Northern Ireland are, almost without exception, known to health and social care because of existing health conditions. The NIFRS is of the view that it needs to take a risk-based approach to prevention, not a blanket one. It believes that by having access to information that tells it where vulnerable people live it can take a directed risk-based approach and take meaningful steps to reduce risks where its actions have the most effect. The NIFRS refers to the fact that colleagues in Fire Services in England can gain access to GP data to help them to direct their prevention work. It believes that access to similar data for the NIFRS would allow it to transform its prevention work and make a significant contribution to the health, safety and well-being of the public of Northern Ireland.	Noted
The **Rare Disease Partnership** believes that the Department must be obliged to make the regulations and the word “may” should be replaced with “shall”.	The Department is currently considering the drafting of this Clause.
Clause 1(1)(a) The **Southern Health and Social Care Trust** questions whether the end of Clause 1(1)(a) should read ‘and/or’.	The Department is currently considering the drafting of this Clause.
The **Royal College of Psychiatrists** was of the view	

that ‘in the interests of improving health and social care, or’ suggests processing for service development and research. In this case, the College would expect either the Code of Practice or the terms of reference for the committee to give examples of the improvements which would be likely to be considered appropriate or desirable.	It is intended that appropriate guidance will be prepared for the Committee.
The **Rare Disease Partnership** believes that if the World Health Organisation’s definition of health is used this could obviate the need for the ‘in the public interest’ phrase. Under this approach the wording in Clause 1 (1): would be replaced with: *“in the interests of improving health”* With the following definition added to Clause 5: Interpretation *“health” means a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity”.*	The current definitions reflect the general duties of the Department.
The **Law Centre** believes that while it is assumed that improving health and social care is always in the public interest, the inclusion of Clause 1(1)(a) serves to underline the emphasis that the processing must serve a medical and social care purpose.	Noted. The Department is currently considering the drafting of this Clause.

Clause 1(1)(b) The **Northern Ireland Human Rights Commission** referenced the Council of Europe Committee of Ministers Recommendation on the protection of medical data which provides that medical data may be collected and processed for specified purposes and if provided by law: • for public health reasons; or • subject to principle 4.8, the prevention of a real danger or the suppression of a specific criminal offence: or • another important public interest. The Commission is of the view that the phrase 'in the public interest' is too broad and does not meet the requirements to be specific on the other 'important public interest' being covered. The Commission believes that the Bill could be made clearer on the specific purposes provided by law enabling the collection and processing of medical data. It recommends that the Health Committee considers how to ensure that the powers are used for health and social care purposes envisaged by the Bill and not for other unrelated purposes. For example, Clause 1(1)(b) could be amended to specify "in the interests of public safety" rather than "in the public interest". This would make it clear that the provision is tied to health, social care and public safety.	The phrase "public interest" does not mean any public interest. The use of the information requested must always be for a medical or social care purpose which is necessary or expedient in the interest of improving health and social care or in the public interest. The Department is currently considering the drafting of this Clause.
The **Information Commissioner's Office** highlights that the Bill contains terms which have the potential to	The phrase "public interest" does not mean any public interest. The use of the information requested must

be interpreted quite broadly, such as the provision in Clause 1 (1)(b) which allows for the processing of personal data for medical or social care purposes where it is in the 'public interest'. Whilst it understands that the 'public interest' can be a difficult term to define, it is of the view that it would be useful for the Department to provide greater clarity i.e. what level of public interest is required and what kinds of cases this will apply to.	always be for a medical or social care purpose which is necessary or expedient in the interest of improving health and social care or in the public interest. The public interest is only one aspect to be considered in addition to Data Protection and Human Rights considerations. Public interest by its very nature is considered on a case by case basis. The Committee will have the broad skills needed to stringently test this. Existing case law will also assist.
The **Law Centre** believes that Clause 1(1)(b) is necessary and appropriate: without this condition, the Bill would permit processing which was not in the public interest. It notes that this does not mean that any public interest might be used to legitimate the processing of health and social care information without consent; the public interest must be one which is served by processing for a 'medical and social care purpose'. It highlights that many things which are in the public interest such as the prevention of crime, the interests of national security, or the economic well-being of the country are not 'medical and social care purposes' and points out that such other public interests cannot serve to access confidential information lawfully through this Bill.	Noted
The **Royal College of Nursing** (RCN) has misgivings about the inclusion of the phrase 'in the public interest'.	The phrase "public interest" does not mean any public interest. The use of the information requested must

The RCN is concerned that this phrase may be too comprehensive and non-specific in scope, potentially leaving the system open to abuse on the basis of a broad and/or subjective interpretation of what may be 'in the public interest'. The RCN notes the explanation provided by Departmental officials at the evidence session on 17 June in relation to the potential use of data by, for example, the Northern Ireland Fire and Rescue Service. However, it does not find this explanation convincing. It is of the view that the legislation should apply purely to the purpose defined at Clause 1(1)(a) and the RCN recommends that Clause 1(1)(b) is excised.	always be for a medical or social care purpose which is necessary or expedient in the interest of improving health and social care or in the public interest. The public interest is only one aspect to be considered in addition to Data Protection and Human Rights considerations. Public interest by its very nature is considered on a case by case basis. The Committee will have the broad skills needed to stringently test this. Existing case law will also assist. Clause 1(1)(b) places an evidential requirement on the requestor to clearly show the Committee how the public interest is served where Clause 1(1)(a) does not apply. Its inclusion is expected to significantly reduce the use of the current common law approach.
The **Royal College of Psychiatrists** notes that, as so often cited, "[something that is in] the interest of the public may not actually interest the public". The College has particular concerns in this regard in relation to illnesses or disorders which carry a 'stigma'. It points out that a main thrust of the forthcoming Mental Capacity Bill is to reduce stigma by putting mental and physical health on an equal footing, and this Bill does likewise. Regardless of this, it believes that some illnesses or disorders are more likely to cause harm to patients through their disclosure than others e.g. Addictions Treatment, where someone's dependence	The use of the information requested must always be for a medical or social care purpose which is necessary or expedient in the interest of improving health and social care or in the public interest. It is highly likely that, where a request involves small numbers, the requestor will be required to seek consent or to use anonymised or pseudonymised information.

on a substance (be it legal or illegal) is likely to cause issues with employment, the PSNI etc. Such information is, as such, particularly sensitive – and its disclosure likewise would require very careful consideration. It believes that another area where the public interest may conflict with the private good is that of Forensic Psychiatry; at the moment in Northern Ireland there is one Regional Secure Unit for the management of people with severe mental disorder and associated high levels of risk to others, as well as community teams undertaking care of people with these issues in the community. Again these are service users whose very involvement in these services could, if known generally, be harmful to their future health and quality of life. The College refers to the Hansard of 17 June where there is mention of the Fire and Rescue Service being interested in using this legislation to identify vulnerable people admitted during fires. The College fears that there is only a small step from this to the PSNI seeking access to people's medical records, where possibly incriminating information may be held confidentially; undoubtedly the PSNI seeking such information would see it as in the public interest. However, it would be difficult to see it as in the patient's interest. The College highlights that the legislation includes provisions for over-ruling an opt out from information sharing; the power is there effectively to not just enable but to require sharing of information on any aspect of health and social care engagement in Northern Ireland as long	

as ‘the public interest’ is served. The College notes that this seems to be well-intentioned, but points out that such legislation is open to abuse in the future by those with less pure intent. Therefore it suggests at least changing the wording of this section to ‘*in the public interest, so long as this would not subject the relevant person to risk of harm*’.	
The **Northern Ireland Local Government Association** highlights that councils may seek to obtain and use information in the public interest, and requests that councils are considered fully, within the information sharing context.	The primary purpose must be medical or social care.
Clause 1(2)	
The **Privacy Advisory Committee** believes that any refusal to process prescribed information should be respected.	Where individuals opt out of having their information shared their wishes will be respected. Regulations will set out how the process will operate. Opt –out arrangements will be consulted upon as part of the process of developing the Regulations which will also be subject to draft affirmative procedure in the Assembly.
The **Information Commissioner’s Office** points out that in the consultation document report to ‘Caring for you and your information’ (November 2014), the Department acknowledged that there was a concern amongst some respondents that an individual should	The “requirement” provision will only be used to address unforeseen emergency circumstances. The exercise of this power will require Regulations to be made by the Department which will be subject to draft affirmative procedure in the Assembly.

have the right to 'opt-out' of secondary uses. In response, the Department explained that the proposals will establish a statutory basis which will allow for the sharing of information, and will not have the power to require it to be shared. It notes however that in Clause 1(2)(a), regulations may make provision for 'requiring or authorising' the disclosure, to a relevant person involved with improving the physical or mental health of people in Northern Ireland, or, with the prevention, diagnosis or treatment of illness. This would suggest that in cases where the personal data may assist with either of these provisions that the data controller would be required to share the data.	
The **British Dental Association** seeks confirmation that the committee has no power to compel the Data Controller to disclose information.	The final decision will rest with the Data Controller
The **British Medical Association** (BMA) is very concerned, by the reference to 'requiring' disclosure. It notes that this would place a legal requirement on providers to supply data. It states that the Act should not be used as a lever to compel extractions of confidential data and this is not consistent with the Control of Patient Information Regulations 2002 applicable in England and Wales which are of a permissive nature, and which it understood the Assembly intended to replicate. It believes that the new Act should permit lawful sharing of confidential information; however, if GPs (or others who hold data) do not wish to share in particular circumstances then they must not be legally mandated to do	The NI approach is consistent with the provision in GB. The "requirement" provision will only be used to address unforeseen emergency circumstances. The exercise of this power will require Regulations to be made by the Department which will be subject to draft affirmative procedure in the Assembly

so. BMA recognises the importance of a legal framework in which clinicians and patients have confidence. Creating a statutory requirement to disclose which removes control from doctors and patients risks losing this trust which would be extremely difficult to regain. Should patients lose trust in the confidential nature of the health service they may withhold information from the clinicians who are treating them. This will not only have a detrimental impact on the care they receive but it will also reduce the quality and usefulness of the data for the purposes envisaged under the new Act.	
The **Southern Health and Social Care Trust** is of the view that the Bill does not make it clear how the balance between the committee, the Data Controller and the individual would work. It believes that the Bill should make it clear that the Data Controller has the ultimate decision about whether the information can be shared or not and that this <u>can</u> override the committee's decision.	Under the Data Protection Act the decisions as to the purpose and manner of processing rests with the Data Controller. Any processing of information under the Bill must comply with the provisions of the Data Protection Act (Clause 1(8)). Data Controllers must ensure that any processing of personal information for which they have responsibility complies with the Data Protection Act. failure to do so risks enforcement action and compensation claims from individuals. The Committee will only approve the sharing of information not compel it. The decision to share or not remains with the Data Controller.
<u>Clause 1(2)(c)</u>	
The **Law Society** points out that Clause 1(2)(c) makes possible a lawful processing of confidential information	Noted

which is not possible on the basis of the existing options The Law Centre is supportive of this as for health and social care there are significant public interests which cannot be securely and reasonably achieved using the existing options. It highlights the need for a flexible and responsive process which is independent of those who would wish to process the confidential information and avoids the need to create an explicit statutory basis for every situation which arises. It is of the view that the arrangements proposed in the Bill will provide greater protection for service user confidentiality through requiring independent scrutiny and authorisation of such uses. This would address concerns that leaving judgement about the sufficiency of the public interest basis for disclosure to individual health and social care staff (who wish to process the information) does not provide a sufficiently clear legal basis to fully meet the requirements of article 8 of the European Convention on Human Rights.	
The **Royal College of Psychiatrists** notes that one major aim of this legislation is to reduce the likelihood of public interest secondary uses being subject to legal challenge. However, it points out that this part of the Bill, read along with subsections (8) and (9) which refer to the Data Protection Act, seems almost to be a ‘get out of jail free card’, especially if there has been a breach in data security. It highlights that the information which is being shared under this legislation is both private and sensitive to the individuals being identified by it, and were such information to be inadvertently or accidentally disclosed to unauthorised third parties (such as insurance companies or other bodies whose possession of	Clause 1(2)(c) allows the Department to make regulations to enable the Common Law Duty of Confidentiality to be set aside in cases where the processing of information is authorised by the Committee. It states that any processing carried out in accordance with the Regulations will be lawful despite any obligation of confidence owed. Clause 1(8) states that these Regulations must not make any provision that would be inconsistent with the data protection Act Clause 1(9) ensures these two provisions sit alongside each other.

the information may not be in the interest of the patient) then there should be appropriate penalties.	The Information Commissioner can fine Data Controllers up to £500k for breaches of the Data Protection Act. The Bill contains a provision (clause 1(2)(d)) for the establishment of fines and penalties for failure to comply with provisions of the Regulations.
Clause 1(2)(d)	
The **Northern Ireland Human Rights Commission** welcomes the proposed enabling power to create offences to ensure protections for rights holders. It notes that Clause 1(2)(d) contains a specific indication of a sanction (up to level 5 on the standard scale). It welcomes that the Bill complies with the guidance of the Delegated Powers and Regulatory Reform Committee. However it notes that neither the Bill nor the accompanying memorandum indicates the nature of the other procedures and requests clarification.	The nature of "other procedures" will form part of the Regulations consultation process. Regulations will also be subject to draft affirmative procedure in the Assembly. In addition the Information Commissioner can fine Data Controllers up to £500k for breaches of the Data Protection Act.
The **Royal College of Psychiatrists** believes that the establishment of new offences should not overrule existing offences, or if they do they should provide similar protections.	The new offences and penalties will not overrule existing penalties.
The **Northern Ireland Local Government Association** acknowledges the importance of ensuring that contraventions of the Bill and associated regulations are prevented and discouraged through the enabling of a regulation specifying relevant offences.	Noted

<u>Clause 1(3)</u>	
The **Northern Ireland Human Rights Commission** recommends that, to be an effective safeguard in the processing of confidential information, particularly sensitive health data, Clause 1(3) should be amended to specify that regulations “must provide” for authorisation by the committee. The **Southern Health and Social Care Trust** and the **Rare Disease Partnership** share this view.	The Department is currently considering the drafting of this Clause.
<u>Clause 1(5)</u>	
The **Belfast Health and Social Care Trust** questions whether the cost and technology available will form part of the basis for requesting information via this legislation.	This provision only relates to the situation where regulations may be made to require processing of health information. It provides that regulations may not be made for this purpose if it would be reasonably practicable to achieve the objective in other ways having regard to the cost of and the technology available. Any applications will therefore have to prove that, to achieve the purpose, the regulations are required.
The **Health and Social Care Board** believes that further clarity is needed to avoid differences that could potentially arise in the application of Clause 1(5).	See above explanation
The **Royal College of Psychiatrists** believes that all reasonable steps should be taken to ensure that if anonymous or pseudonymous information can be used	Noted

that it be used, and that if the patients involved could give consent, that that option has been provided to them. It is of the view that this section of the legislation appears to achieve this and is therefore welcome.	
Clause 1(6) The **Royal College of Psychiatrists** welcomes the requirement for an annual review of any disclosures to ensure that they remain legal and that there is no other way to accomplish their aims. It believes that this is sensible and appropriate. However, it suggests that consideration should be given to tying this aspect into the work of the committee.	With regard to Clause 1(6) this provision only applies if processing is required by Regulations made by the Department. It is however intended that all applications will be subject to annual review by the Committee with a view to assessing whether support under the legislation should continue or be withdrawn. This will be considered under the process to develop regulations which will be subject to public consultation. The Regulations will be subject to draft affirmative procedure in the Assembly.
Clause 1(7) The **Rare Disease Partnership** questions the purpose of Clause 1(7). It has concerns that it may operate to inhibit or prevent the identification of individuals who could benefit from new treatments. In particular, individuals affected by rare diseases who may currently have very little treatment available and may need to be tracked down to enable them to benefit from scientific and other advances.	The output from the required disclosure of information can, under Clause 1(13)(b), be used to inform individuals about their care and treatment.

Clause 1(8) The **British Medical Association** welcomes the statement on the face of the Bill that processing must be compliant with the Data Protection Act 1998. It notes that this will encompasses the DPA principle of 'fair processing' which means that patients should be made aware when their information is being disclosed and for what purpose.	Noted
Clause 1(10) The **Northern Ireland Cancer Registry** is of the view that the definition of information should also include basic sociodemographic facts such a name, date of birth, postcode, ethnic group, gender and marital status to enable comprehensive monitoring of disease at population level.	All information which is caught within the definition of information is included in the scope of the Bill. The definition of "confidential information" is that the identity of the individual is ascertainable. Applications will detail what information is requested
Clause 1(10)(c) The **British Medical Association** believes that the intention is that all information will fall under the scope of the new Act 'whether or not the identity of the individual in question is ascertainable from the information'. The Association understands that if the information is anonymous to the extent that an individual cannot be identified then it would not subject to common law obligations of confidence or the DPA. Therefore it believes that it is unnecessarily restrictive to include such information within the scope of the Act.	The Bill deals with access to identifiable information not anonymised information.

Clause 1(11)(a)(i)	
The **Southern Health and Social Care Trust** questions whether Clause 1(11)(a)(i) should read ‘and/or’ to include both physical and mental health.	The Department is currently considering the drafting of this Clause.
Clause 1(11)(b)	
The **Southern Health and Social Care Trust** is of the view that the term ‘social well-being’ should be replaced with ‘social care’ for consistency throughout the Bill.	The Department is currently considering the use of this term.
The **South Eastern Health and Social Care Trust** is of the view that the introduction of the term social well-being is confusing and suggests reference to the definition supplied under (11) (b).	The Department is currently considering the use of this term.
The South Eastern Health and Social Care Trust suggests that Clause 1(11) could be simplified to read: *Services designed to secure improvement* *(a) Health* *(1) in the physical and/or mental health of people in Northern Ireland* *(2) medical purposes as defined in subsection (13)(a)* *(b) Social Care purposes* *(1) Services designed to secure improvement in social well-being of people in Northern Ireland as defined in subsection (14).*	
The **Rare Disease Partnership** believes that it is impossible to create an exhaustive list of groups that receive services designed to secure improvement in so-	Noted

cial care. It suggests that thought might be given to specifying the Code of Practice as a suitable vehicle to give further explanation and guidance.	
<u>Clause 1(12)</u> The **Belfast Health and Social Care Trust** notes that the Bill introduces the term ‘confidential information’ and uses a definition similar to that of personal data within the Data Protection Act. It believes that the aligning of definitions would assist with the understanding of the legislation. It notes that ‘medical purposes’ uses an extended form of words defined in the Data Protection Act.	The definition of “personal data “ in the DPA is similar to the definition in the Bill but differs in that the DPA definition is restricted to the data controller whereas the Bill definition refers to the “person processing that information” – this is important as it extends to those who seek to access the information and should therefore remain. The Bill defines confidential information as being generated in circumstances where an obligation of confidence was owed to an individual whereby tying this up with the setting aside of that obligation by clause 1(2)(c).
<u>Clause 1(13)</u> The **Southern Health and Social Care Trust** believes that the term ‘medical purposes’ needs to be clarified earlier in the Bill as it is mentioned earlier.	“Medical purposes” is defined at the end of the Clause along with other terms which are mentioned earlier – this is normal drafting protocol.
<u>Clause 1(13)(b) and Clause 1(14)(b)</u> The **Law Centre** believes that the purpose of Clauses 1(13)(b) and 1(14)(b) is not clear. It notes that these Clauses define ‘medical purposes’ and ‘social care purposes’ respectively as including provision of information to individuals:	The Bill provides, at Clause 1(13)(b) and (14)(b) for informing individual about their care and treatment. Clause 1(7) makes clear that Regulations cannot be made to determine the care and treatment of an

(13) In this section “medical purposes” means the purposes of any of— …(b) informing individuals about their physical or mental health or condition, the diagnosis of their condition or their care and treatment. (14) In this section “social care purposes” means the purposes of any of— …(b) informing individuals about their social care needs or the provision of social care services in relation to them. The Law Centre is not clear why a Bill which is essentially about facilitating the lawful secondary use of confidential information should include the possibility of ‘informing individuals’ with respect to their primary care. It also highlights that these Clauses also appear to be in contradiction to the intent of Clause 1(7): Regulations under subsection (1) may not make provision for requiring the processing of confidential information of a relevant person who is a recipient of services referred to in subsection (11)(a) solely or principally for the purpose of determining the care and treatment to be given to particular individuals. <u>Clause 1(15)</u>	individual.
The **Law Centre** points out that Clause 1(15) provides an open-ended definition of ‘processing’ which it finds unnecessary and somewhat concerning: (15) In this Act “processing”, in relation to information, means the use, disclosure or obtaining of the	The Regulations will “prescribe” what can be done with information. This will not include selling. These Regulations will be subject to public consultation and draft affirmative procedure in the Assembly.

information or the doing of such other things in relation to it as may be prescribed for the purposes of this definition. To achieve the 'medical or social care purposes' at which the Bill aims, the Law Centre finds it difficult to see what information processing would legitimately be involved that was not 'use, disclosure or obtaining'. One of obvious concern would be selling. Service users are likely to be supportive of uses which are in the public interest such as improving health and social care and the efficiency and effectiveness of health and social care services generally. However, the Law Centre believes that there is not likely to be service user and public support for confidential health and social care information being sold to the benefit of private interests. It therefore recommends that the open-ended definition of "processing" should be closed and the Clause should be amended follows: *Clause 1, page 3, line 35, leave out "or the doing of such other things in relation to it as may be prescribed for the purposes of this definition"*	
Clause 2 allows the Department to establish a body to authorise the processing of confidential information as defined in the Bill	
Stakeholder Comments	**Department's Response**
<u>Clause 2 (1)</u> The **Human Rights Commission**, **Privacy Advisory Committee,** the **Law Centre,** the **British Dental**	Noted. The Department is currently considering the drafting of this Clause

Association, the **Royal College of Psychiatrists,** the **Rare Disease Partnership** and the **Belfast, South Eastern** and **Southern Health and Social Care Trusts** all consider that the establishment of a committee to authorise the processing of confidential information should be mandatory and the wording of the Bill should be amended to reflect this.	
The **Northern Ireland Cancer Network** (lung subgroup) states that the constitution of the committee will be key to its ability to function and deliberate on the diversity of applications.	Noted
The **Health and Social Care Board** emphasises the need for an independent, suitably empowered committee not only to ensure robust decision making but also to maintain strong public confidence.	Noted
<u>Clause 2 (2)</u>	
The **Royal College of Nursing** (RCN) believes that the key issue is establishing appropriate safeguards to ensure compliance with the legislation and the safeguarding of personal information. The RCN is unclear about how the proposed committee would discharge this function. It points out that the 2014 consultation document stated (on page 17): “Under the proposals, applicants would have to demonstrate to the advisory group that the use of service user identifiable information is absolutely essential to the successful outcome of their work; that similar results could not be obtained by using anonymised or pseudonymised service user information; and that it is either impossible or impracticable to gain con-	The name of the body was changed in response to comments made during the public consultation. Consultees felt that “advisory group” was a weak description considering the Committee will make decisions on the authorisation of disclosure of information. These aims remain and will be set out in Regulations which will be subject to public consultation and draft affirmative procedure in the Assembly.

sent from every individual whose data may be used”. The RCN questions how or why the advisory group proposed in the consultation document has now evolved into the committee proposed under the Bill. More importantly, it notes that the defined purpose of the advisory group was to protect the security and interests of the service user from the non-authorised use of their personal data. It points out however that the Bill states that the purpose of the proposed committee lies in “… the processing of confidential information of a relevant person in prescribed circumstances and subject to compliance with prescribed conditions …”. It recognises that the proposed committee’s functions may well mirror those of the advisory group but, if this is the case, the RCN does not feel that this is readily apparent from the wording of the Bill. The RCN also notes a subtle change of emphasis from protecting the interests and security of the service user to ensuring compliance with the legislation. It believes that these two objectives should be synonymous but may not always be so.	
The RCN is concerned by the admission by departmental officials during the evidence session on 17 June 2015 that the proposed committee could over-ride the decision of an individual to opt-out from the disclosure of data, using the public interest criterion. It feels that whilst there was some discussion on this issue between Committee Members and departmental officials, the matter was not resolved during this evidence session. The RCN urges the Committee to seek further clarification on this issue.	There is no intention to override the decision of an individual to opt out. Where individuals opt out of having their information shared their wishes will be respected. Opt –out arrangements will be consulted upon as part of the process of developing these Regulations which will also be subject to draft affirmative procedure in the Assembly. The final decision to share or not share information rests with the Data Controller.

<u>Clause 2(3)</u>	
The **Northern Ireland Human Rights Commission** notes that the Commissioner for Public Appointments has expressed concern about the lack of diversity and specifically the underrepresentation of women, young people, persons with disabilities and ethnic minorities in public appointments in Northern Ireland. Therefore the Commission recommends that consideration be given to the concerns of the Commissioner for Public Appointments and to how best to ensure diversity on the proposed committee.	Noted
The **British Dental Association** believes that determining 'public interest' is a key responsibility and a critical aspect of the decision making process, therefore there is a need to ensure that the committee's organisational structure is effective and that the decision making processes are robust and transparent. It believes that the public interest threshold must be high and used only when disclosure is necessary to protect individuals/society. The Association also believes that greater clarity on how the committee will operate is needed and that any regulations should be subject to consultation.	Noted. Regulations will be subject to public consultation and draft affirmative procedure in the Assembly.
In relation to the committee's make-up, the **British Dental Association** believes that it should include representation of healthcare professionals, clinicians, patient representatives and those with relevant expertise including clinical research and legal.	Noted

The **Northern Ireland Cancer Registry** and **Genetic Alliance** also believe that the authorising committee should have some representation of patients.	Noted
The **British Medical Association** is of the view that it is imperative that the medical profession both from primary and secondary care, play a key role in the membership of the committee and the Association seeks a commitment in the regulations that this would be the case. It is also of the view that membership from the public health community should also be sought if the committee is to consider applications for data for public health purposes.	Noted
The **Rare Diseases Partnership** believes that the Bill should provide greater clarity on the committee's composition and powers, and its relationship with bodies with similar functions elsewhere, such as, in England, the Health Research Authority. In particular, it considers that the committee should include clinicians, ethicists and patient representatives; and that this should be made clear in the Bill itself.	The Bill contains the power to make Regulations which will make provision for Committee arrangements. These Regulations will be subject to public consultation and draft affirmative procedure in the Assembly
The **Royal College of Nursing** believes that it is important, in order to command public confidence, that the proposed committee must be truly independent in its composition, constitution and outlook, excluding anyone with a vested personal or professional interest in access to personal confidential data. It feels that it should act as a guarantor of compliance with the legislation and as an advocate for the rights of service users in this respect.	Noted.
The **Royal College of Psychiatrists** is of the view that	

the regulations discussed in Clause 2(3)(a) through (e) are sensible and appropriate. However it suggests that the make-up of the committee and the publication of its decisions should be established in this legislation, or if not then at least the hoped-for purpose of the committee should be disclosed in the legislation at this stage.	The Bill contains the power to make Regulations which will make provision for Committee arrangements. These Regulations will be subject to public consultation and draft affirmative procedure in the Assembly.
The **Northern Ireland Local Government Association** (NILGA) believes that it will be necessary for the committee consider how it will deal with applications from councils or community planning partnerships in a strategic and efficient manner. NILGA requests that full consideration is given to the potential for a senior local government representative (e.g. a Chief Executive) to have membership of the committee. It is the view of NILGA that councils should be considered a governmental partner in tackling the public health issues faced in Northern Ireland.	The use of the information requested must always be for a medical or social care purpose which is necessary or expedient in the interest of improving health and social care or in the public interest. The Bill contains the power to make Regulations which will make provision for Committee arrangements. These Regulations will be subject to public consultation and draft affirmative procedure in the Assembly
Clause 3 places an obligation on the Department to publish a Code of Practice in respect of the processing of information	
Stakeholder Comments	**Department's Response**
Clause 3(1) and 3(2)	

The **Southern Health and Social Care Trust** believes that it should be clear that the Code of Practice relates to the processing of information for 'secondary purposes'.	View noted.
The **British Dental Association** is of the view that the Code of Practice should be subject to consultation.	Agreed
The **Rare Disease Partnership** believes the clause should be revised to read: *3(1) The Department must, as soon as reasonably practicable, and in consultation with the patients, carers and relevant experts, prepare and publish a Code of Practice on the processing of information.*	The Department already has a statutory duty to consult under section 75 of the Northern Ireland Act 1998 and under section 19 of the HSC(Reform) Act (NI) 2009.
The **Belfast Health and Social Care Trust, British Medical Association, Northern Ireland Local Government Association** and **Northern Ireland Cancer Registry Council** welcome the requirement that the Department prepares a Code of Practice and the timeframe for review.	Noted
<u>Clause 3(4) to 3(5)</u>	
The **Northern Ireland Human Rights Commission** advises that in fulfilling the 'in accordance with the law' requirement, any interference with or restriction of Article 8 rights is clearly provided for in primary or secondary legislation and not left to non-binding codes of practice. In any event, the Commission also recommends that	The CoP will be fully compliant with the Data Protection Act and Human Rights Act. The CoP will be considered alongside other guidance and legislation and the use of "must comply with" would restrict consideration to the CoP only.

Clause 3 (4) and 3 (5) are amended to specify ‘must comply with’ rather than must ‘have regard’ to the Code of Practice.	
The **Privacy Advisory Committee** is of the view that health and social care bodies must consciously consider the equality duty in section 75 of the Northern Ireland Act 1998 and have ‘due regard’ to the Code of Practice.	Noted
The **Law Centre** proposes a minor amendment to Clauses 3(4) and 3(5). It considers that ‘regard’ would be better replaced by ‘due regard’ which is a standard legal phrase which means to give a fair consideration to and sufficient attention to all of the relevant material.	Noted
The **Northern Ireland Cancer Registry** and the **Northern Ireland Cancer Registry Council** point out that the Bill refers only to health and social care bodies. They both highlight that some organisations are undertaking innovative and important work providing population based information for epidemiological research on disease causation and outcomes using health and care data. They are therefore of the view that the legislation should be phrased in such a way to ensure that it does not exclude such work.	All applications will be considered provided the purpose is in line with Clause 1(1).
The **Northern Ireland Local Government Association** recommends consultation with all organisations potentially affected by requirements in the Code.	The Department has a statutory duty to consult under section 75 of the Northern Ireland Act 1998 and under section 19 of the HSC(Reform) Act (NI) 2009.
<u>Clause 3(6)</u>	.

The **Southern and South Eastern Health and Social Care Trusts** believe that this section should be included earlier in the Bill to provide clarity and to limit use to these terms rather than introduce other terms which are more open to interpretation e.g. well-being.	The Department is currently considering the drafting of this Clause.
Clause 4 relates to control of regulations made under the Bill	
Stakeholder Comments	**Department's Response**
<u>Clause 4(2)</u> The **Law Centre** and the **Rare Disease Partnership** welcome the requirement that a draft of the regulations will be laid before and approved by resolution of the Assembly. The **Northern Ireland Human Rights Commission** views this as an additional protection for Article 8 of the ECHR.	Noted
Clause 5 sets out the definitions of specific terms used within the Bill	
Stakeholder Comments	**Department's Response**
The **South Eastern Health and Social Care** Trust	The phrase "public interest" does not mean any public

believes that a definition of 'public interest' should be included.	interest. The use of the information requested must always be for a medical or social care purpose which is necessary or expedient in the interest of improving health and social care or in the public interest. The public interest is only one aspect to be considered in addition to Data Protection and Human Rights considerations. Public interest by its very nature is considered on a case by case basis. The Committee will have the broad skills needed to stringently test this. Existing case law will also assist.
The **Rare Disease Partnership** recommends that the World Health Organisation's definition of health should be included: "*health" means a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.*	The current definitions reflect the general duties of the Department.
Clauses 6 sets out the title and commencement dates	
Stakeholder Comments	**Department's Response**
The **Southern Health and Social Care Trust** is of the view that the title could be interpreted as a Bill for the control of data processing for all health and social care information in all circumstances, including the purpose	The title of the Bill does not affect its scope.

for which health and social care information is originally obtained i.e. direct care. It is of the view that the scope of the Bill could be improved by amending the title to read ‘control of data processing for secondary purposes’.	
Other Issues	
Stakeholder Comments	**Department’s Response**
Compatability with the Human Rights Act The **Northern Ireland Human Rights Commission** notes that paragraph 19 of the Explanatory and Financial Memorandum accompanying the Bill states that the provisions of the Bill are compatible with the ECHR. The Commission notes guidance from the Westminster government to departments about disclosure of views regarding Convention compatibility in the Explanatory Notes that accompany a Bill. In order to discharge the government’s commitment to provide a human rights assessment, departments should do one of the following: • state that the department does not consider that the provisions of the Bill engage convention rights; • in a case where any ECHR issues arise but are not significant, deal with the issues in a short paragraph or paragraphs in the explanatory notes;	Noted

• or where significant issues arise, state that issues arising as to the compatibility of the bill with convention rights are dealt with in a separate memorandum and provide a web address at which the memorandum can be accessed. The Commission also notes the view of the Joint Committee on Human Rights (JCHR) which highlighted the good practice of departments in supplying a detailed human rights memorandum, giving a full explanation of the view that a Bill is compatible with human rights. The JCHR emphasised: *The provision of detailed human rights memoranda to Parliament is an important means of demonstrating the Government's fulfilment of that responsibility. It also facilitates Parliament in fulfilling its responsibility in that regard.* The Commission recommends that the Department sets out for the Committee the basis for the statement of compatibility. The Commission also advises the Department to consider the applicability of the advice given by the Joint Committee on Human Rights and detail this for the Committee.	
Language	
The **Southern Health and Social Care Trust** points out that the wide scope of the language used throughout the Bill e.g. ‘public interest’ and ‘other similar circumstances’ is in contrast to the language used when the overall purpose of the Bill is described. It believes that stronger emphasis should be given to the fact that the sharing of information will only take place in limited	The Bill states that processing will only be considered for medical or social care purposes which are in the interests of improving health and social care or are in the public interest. The Committee will be responsible for scrutinising each application and processing will only be enabled if the Committee authorises it. The Data Controller will then make the final decision to share or not

and controlled circumstances and with robust checks and balances in place.	to share. Details will be set out in Regulations which will be subject to public consultation and draft affirmative procedure in the Assembly.
<u>Applications</u>	
The **Southern Health and Social Care Trust** suggests that in addition to proving that the outcome will be in the interests of health and social care or in the public interest, the Bill should state that applicants need to prove that: (i) the results cannot be obtained without the use of personal identifiable information; and (ii) it is not possible /practical to obtain consent from the individuals concerned.	The Department’s policy statement reflects this position and provision will be set out in Regulations.
<u>Opt Out</u>	
The **Southern Health and Social Care Trust** believes that consideration needs to be given to how any opt out will be managed.	Opt –out arrangements will be contained in Regulations and will be consulted upon as part of the process of developing these Regulations which will be subject to draft affirmative procedure in the Assembly.
The **British Medical Association** (BMA) states that its primary care colleagues, as the guardians of their patients’ information, take significant care to promote the highest standards of confidentiality in their practices. The BMA would therefore like to see reference made to respecting patient objections to the disclosure of confidential information; this would allow clinicians to act in accordance with their patients’ wishes.	Opt –out arrangements will be contained in Regulations and will be consulted upon as part of the process of developing these Regulations which will be subject to draft affirmative procedure in the Assembly.

The **Information Commissioner's Office** also refers to opt-out. It has some concerns regarding the fairness of the provisions of the Bill on the rights and freedoms of individuals. Where individuals' rights are unreasonably overridden, the processing, even though it may satisfy a Schedule 3 condition, may nonetheless be unfair. It suggests that it might be worthwhile for the Department to engage with the general public and consider their views on the re-use of their data for secondary purposes.	This Bill does not set aside the requirements of the Data Protection Act 1998. Any processing must fully comply with the provisions of the Data Protection Act. It will be the responsibility of the requestor to evidence to the Committee that this is the case. Where individuals opt out of having their information shared their wishes will be respected. Opt –out arrangements will be consulted upon as part of the process of developing these Regulations which will also be subject to draft affirmative procedure in the Assembly. The proposals were subject to a public consultation and 94% of respondees were in favour of the proposals. The Regulations will also be subject to public consultation
The **Law Centre** also proposes an amendment to Clause 1(1) to allow for opt-out.	Opt –out arrangements will be contained in Regulations and will be consulted upon as part of the process of developing these Regulations which will be subject to draft affirmative procedure in the Assembly.
<u>Benefits of Sharing Data</u> A number of organisations including the **Huntington's Disease Association**, **Genetic Alliance UK**, **Cancer Registry** and the **Rare Disease Partnership**	Noted

highlighted the numerous benefits of sharing data in relation to the prevention of diseases and improving the quality of life, treatment of care, and service provision for sufferers. A wide range of benefits in relation to international research, audits etc. were also outlined in detail. Handling of Information	
The **Royal College of Nursing**'s (RCN) primary concern in relation to the Bill is ensuring that any personal confidential information accessed is done so securely and genuinely for purposes related solely to the commissioning and provision of health care services, rather than for any commercial activities. It points out that it will be essential for the DHSSPS to build confidence in this principle and overcome some of the negative perceptions and doubts that have built up as a consequence of the indifferent track record of HSC organisations in respect of their capacity to manage and store confidential personal data securely.	The use of the information requested must always be for a medical or social care purpose which is necessary or expedient in the interest of improving health and social care or in the public interest. The Regulations will "prescribe" what can be done with information. This will not include selling. These Regulations will be subject to public consultation and draft affirmative procedure in the Assembly.
The RCN believes that stakeholder and public support for the Bill will be determined largely by an understanding of the controls that exist around the access and use of information and a general feeling that the Bill's primary purpose is to protect the security of confidential personal data, rather than to facilitate access to it. These controls relate to the security and confidentiality of the data, the fact that it must not be used to an individual's detriment, in either identifiable form or as a result of research conducted at the level of the group, and in relation to any potential commercial access to data. The	Noted.

RCN therefore welcomes the wording of paragraphs 8 and 9 in the Explanatory and Financial Memorandum A number of other organisations welcomed the introduction of a robust framework for sharing secondary information.	Noted
<u>Resource Implications</u> The **British Medical Association** believes that it is important that, in releasing approved information, general practitioners, who are under immense pressure in caring for their patients, are not expected to dedicate large and unfunded sections of work time to processing requests for information.	The experience in GB would strongly suggest that there is no significant impact on individual Data Controllers.
<u>Complaints Process</u> The **Northern Ireland Cancer Registry** questions whether there is a complaints process in cases of breaches.	There will be a complaints process and Clause 1(2)(d) provides for the establishment of fines and penalties in Regulations. All processing must be compliant with the Data Protection Act and the Information Commissioner can impose fines of up to £500k for breaches of the Act.
<u>Retrospective Provision</u> The **Northern Ireland Cancer Registry** and the **Northern Ireland Cancer Registry Council** are of the view that the legislation should apply retrospectively to health and social care data already collected.	It is proposed that the NI Cancer Registry will be given “specific support” under the Regulations to continue its operation.

	The legislation will not apply retrospectively to health and social care data already collected.