THE LAW SOCIETY of SCOTLAND
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Consultation Response

CSO Research Strategy 2014

The Law Society of Scotland's response

September 2014

Introduction

The Law Society of Scotland aims to lead and support a successful and respected Scottish legal profession. Not only do we act in the interest of solicitor members but we also have a clear responsibility to work in the public interest. That is why we actively engage and seek to assist in the legislative and public policy decision making processes.

To help us do this, we use our various Society committees which are made up of solicitors and non-solicitors and ensure we benefit from knowledge and expertise from both within and out with the solicitor profession.

The Mental Health and Disability Sub-Committee (the Committee) welcomes the opportunity to consider and respond to the Chief Scientific Officer's consultation on the CSO Research Strategy 2014 and, in particular, to Questions 8 and 9 (Chapter 2) of the consultation document. The Committee has the following comments to put forward:

General comments

The Committee welcomes the proposal to increase the involvement of members of the public in any health and social care research. It wishes to emphasise that such research must, of course, include individuals with mental health and capacity issues, their carers and relatives so that their interests are adequately addressed. Indeed, the requirement for participation of this category of persons in relevant research is reinforced in the general principles underlying and identified in the UN Convention on the Rights of Persons with Disabilities (CRPD) and in Articles 25 (the right to health) and 28 (the right to adequate standard of living and social protection) of the same Convention.

However, where it is proposed to that individuals with mental health and capacity issues participate in research their full, free and informed consent must be obtained, or where lawful and appropriate on their behalf, to such participation. This also applies to the use of any tissue, information and data obtained in the course of such research and already held about them. These requirements are identified in Scottish law and international human rights law.

Section 51 Adults with Incapacity (Scotland) Act 2000

Section 51 Adults with Incapacity (Scotland) Act 2000 sets out various conditions and limitations regarding the carrying out of surgical, medical, nursing, dental or psychological research where an adult lacks the capacity to give valid consent to participate in such research. In such circumstances, research may only be conducted where the research of a similar nature cannot be carried out on an adult who is so capable, and:

1. The research is to obtain knowledge about that adult's disease and/or its care and/or treatment; and
2. The research will be of real and direct benefit to that adult or, if not of real and direct benefit to that adult, it will significantly contribute to scientific understanding of that adult's incapacity to that adult's or others with the same incapacity's real and direct benefit; and
3. The adult has not indicated an unwillingness to participate. It is important to note that this applies despite the adult's incapacity;
4. Ethics Committee approval has been obtained;
5. The research involves no foreseeable, or minimal foreseeable, risk to the adult;
6. The research will involve no discomfort, or minimal discomfort, to the adult; and
7. Consent must have been obtained from the adult's guardian or welfare attorney with relevant powers to so consent or, failing this, from the adult's nearest relative.

Human Rights Requirements

In terms of research involving persons with mental health and capacity issues regard must be had, in particular, to the European Convention on Human Rights (ECHR) and CRPD.

All devolved Scottish legislation, its implementation and acts of the Scottish Ministers must be compatible with the rights identified in the ECHR[1]. Moreover, proposed devolved legislation and actions of the Scottish Ministers can be set aside if it is incompatible with the UK's international obligations which includes those under international human rights treaties that it has ratified[2]. Whilst the CRPD is not incorporated into UK law in the same manner as

[1] Sections 29(2)(d) and 57 Scotland Act 1998, and section 6 Human Rights Act 1998..
[2] Sections 29(2), 35(1) and 58 Scotland Act 1998.

the ECHR and thus does not create rights that are enforceable nationally, the UK is nevertheless obliged under international law to give effect to the rights identified in the treaty. In addition, in interpreting ECHR rights the European Court of Human Rights is also obliged to have regard to relevant UN human rights treaties and there is evidence that increasing reference is being made to CRPD rights in ECHR jurisprudence.

1. *Capacity, consent and confidentiality of information*

The requirement to ensure that full, free and informed consent of individuals with mental health and capacity issues is obtained and confidentiality in terms of access and use of medical and other data and information is affirmed in Article 8(1) ECHR (the right to private and family life) and related jurisprudence[3]. It should be noted that that a limitation of this right is only permissible where it can be justified as being lawful (in other words, authorised under the law), proportionate and for one of the reasons given in Article 8(2) ECHR, namely "in the interests of national security, public safety or the economic wellbeing of the country, for the prevention of disorder or crime, for the protection of health or morals, or for the protection of the rights and freedoms of others."

The World Health Organisation and European Court of Human Rights have both stressed that there must be a presumption of capacity in the case of persons with a functional assessment approach being adopted about all decisions concerning their lives[4]. Moreover, non-consensual involvement in medical or scientific research may even give rise to concerning the right to liberty and the prohibition of torture and of inhuman or degrading treatment (Articles 5 and 3 ECHR)[5]. Regard must also be had for the fact that Article 15 CRPD (prohibition of torture and of inhuman or degrading treatment) makes specific reference to the fact that non-consensual medical or scientific experimentation must not take place with the individual's consent. Moreover, Article 31 CRPD identifies the requirement for legally established safeguards to ensure confidentiality and respect for

[3] See, for example, *Glass v United* Kingdom (20114) 39 EHRR 15, para 82, *Storck v Germany (2006) 43 EHRR 6, para 143, and LH v Lativia* (Application No. 52019/07) judgment of 29 April 2014.
[4] World Health Organisation, *Resource Book on Mental Health, Human Rights and Legislation*, 2005, pp39-40; *Shtukaturov v* Russia 54 EHRR 27, paras 90, and 93-95.
[5] Reinforced by corresponding Articles 12 (equal recognition before the law), 14 (the right to liberty), 17 (the right to personal integrity) and 22(2) (the right to privacy, confidentiality of information and data) CRPD should also be noted. See also Council of Europe Recommendation No.R(99) 4 *on Principles concerning the Legal Protection of Incapable Adults*.

privacy and compatibility with international human rights standards and ethical principles in the collection and use of statistics.

Finally, regard must be had for the UN Committee on the Rights of Persons with Disabilities' General Comment interpreting Article 12 CRPD (the right to equal recognition before the law)[6]. The implications of this interpretation are yet to be fully realised but it undoubtedly reinforces the requirement for genuine and demonstrable respect for legal capacity, and therefore the autonomy, of all individuals with mental disorder[7].

Questions:

Question 8: Would a trial register be of benefit to patients seeking trials? Would it be an effective way to partner patients with researchers? Is there a danger that expectations of taking part could be unfairly raised?

It is noted that it is proposed that there be established a Scottish Health Research Register (SHARE), containing details of participants who are willing to be approached about taking part in research studies, and a Scottish Clinical Trial Register. In both cases, sensitive personal information will be entered and retained on, and accessed from, such databases.

In connection with SHARE, in light of the greater vulnerability of persons with mental health and capacity issues, and the human rights and legislative requirements highlighted above, it would be useful if more information can be supplied as to how and who will assess and ensure that individuals (a) have capacity to consent to their data being stored and used in this way; (b) have given full, free and informed consent; and (c) have appropriate support in making such decisions.

In regard to the Scottish Clinical Trial Register it is unclear if and how NHS patients will be required to register for this database and clarification on this and the information to be

[6] Committee on the Rights of Persons with Disabilities, General Comment No. 1(2014) *Article 12: Equal recognition before the Law*, adopted 11 April 2014 http://daccess-dds-ny.un.org/doc/UNDOC/GEN/G14/031/20/PDF/G1403120.pdf?OpenElement

[7] See also UN Committee on Economic, Social and Cultural Rights, "The right to the highest attainable standard of health (article 12 of the International Covenant on Economic, Social and Cultural Rights)" (Substantive Issues Arising in the Implementation of the International Covenant on Economic, Social and Cultural Rights, General Comment No 14, 2000) para 34 and the MI Principles, principles 1(3), 10 and 11(11)-(15).

stored on it would therefore be appreciated. Where registration is required and use of any stored information is proposed then the observations made in the above paragraph are repeated. Where a patient lacks capacity to give their full, free and informed consent the above-mentioned provisions of section 51 of the Adults with Incapacity (Scotland) Act 2000 must be applied.

Question 9: Would using electronic NHS patient records to alert GPs to research studies for which their patients may be eligible a service the NHS should offer? If so, would a process where NHS records are only accessed by identified NHS staff working in secure facilities, and only passing potential participant names to their GPs or hospital consultants for consideration, be a suitable way to proceed?

It is understood that it is proposed that NHS staff will access NHS patient records in order to alert GPs to research studies. It would appear that the individual patients concerned would not have given their consent to their data being accessed and used in this manner. It would be difficult to justify this as legitimate, proportionate and specified in terms of Article 8(2) ECHR (please see above). The Committee on the Rights of Persons with Disabilities General Comment interpretation of the right to equal recognition before the law identified in Article 12 (please see above) should also be taken into account in this context. Further, where a patient lacks capacity to give their full, free and informed consent section 51 of the Adults with Incapacity (Scotland) Act 2000 will again apply.

Note: The Society's Privacy Law Committee has also considered Question 9 above and responded separately[8].

[8] http://www.lawscot.org.uk/for-the-public/law-reform-consultations-and-bills/consultations-2014/privacy-law/

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