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Date: 30 April 2018 – Scottish Government

Consultation: *Adults with Incapacity (Scotland) Act 2000 Proposals for Reform*

Consultation response on behalf of the Scottish Council on Human Bioethics:

The **Scottish Council on Human Bioethics** (SCHB) is an independent registered Scottish charity composed of doctors, lawyers, biomedical scientists, ethicists and other professionals from disciplines associated with medical ethics.
The principles to which the Scottish Council on Human Bioethics subscribe are set out in the ***United Nations Universal Declaration of Human Rights*** which was adopted and proclaimed by the UN General Assembly resolution 217A (III) on the 10th of December 1948.
The SCHB's response can be shared internally with other Scottish Parliament policy teams who may be addressing the issues discussed. They may contact the SCHB again in the future and the SCHB gives permission to do so.
The SCHB is very grateful to the Scottish Government for this opportunity to respond to the consultation on the ***Adults with Incapacity (Scotland) Act 2000 Proposals for Reform.*** It welcomes the Government's intention to promote public consultation, understanding and discussion on this topic.

Response from the Scottish Council on Human Bioethics (SCHB)

Since some of the issues in the consultation do not related to medical ethics, not all consultation questions will be answered by the SCHB.

Note: Sometimes, this consultation was difficult to understand because of the poor English. It would have been useful for this document to be checked and edited before being sent to the lay public in order to correct and clarify its contents. If the general public does not understand the proposals in this document, because of poor English, this undermines the principles of democracy.

CHAPTER THREE – RESTRICTIONS ON A PERSON'S LIBERTY

Do you agree with the overall approach taken to address issues around significant restrictions on a person's liberty?

In particular we are suggesting that significant restrictions on liberty be defined as the following:

- **The adult is under continuous supervision and control and is not free to leave the premises;**
- **barriers are used to limit the adult to particular areas of premises;**
- **the adult's actions are controlled by physical force, the use of restraints, the administration of medication or close observation and surveillance.**

Do you agree with this approach? Please give reasons for your answers.

Are there any other issues we need to consider here?

Response from the Scottish Council on Human Bioethics

The SCHB is in general agreement with the above overall broad approach.

CHAPTER FOUR- PRINCIPLES OF THE ADULTS WITH INCAPACITY LEGISLATION (Part 1, s.1)

Article 12 of the UN *Convention on the Rights of Persons with Disabilities* (adopted in December 2006) includes the following:

"1. States Parties reaffirm that persons with disabilities have the right to recognition everywhere as persons before the law.

2. States Parties shall recognize that persons with disabilities enjoy legal capacity on an equal basis with others in all aspects of life.

3. States Parties shall take appropriate measures to provide access by persons with disabilities to the support they may require in exercising their legal capacity.

4. States Parties shall ensure that all measures that relate to the exercise of legal capacity provide for appropriate and effective safeguards to prevent abuse in accordance with international human rights law. Such safeguards shall ensure that measures relating to the exercise of legal capacity respect the rights, will and preferences of the person, are free of conflict of interest and undue influence, are proportional and tailored to the person's circumstances, apply for the shortest time possible and are subject to regular review by a competent, independent and impartial authority or judicial body. The safeguards shall be proportional to the degree to which such measures affect the person's rights and interests."

Do you agree that we need to amend the principles of the AWI legislation to reflect Article 12 of the UN Convention on the Rights of Persons with Disabilities?

Response from the Scottish Council on Human Bioethics

The SCHB agrees that Scottish legislation should be aligned with Article 12 of the UN Convention on the Rights of Persons with Disabilities.

Does our proposed new principle achieve that?

Response from the Scottish Council on Human Bioethics

The proposed new principle from the Scottish Government states: "*There shall be no intervention in the affairs of an adult unless it can be demonstrated that all practical help and support to help the adult make a decision about the matter requiring intervention has been given without success*."

The SCHB supports this proposal but believes it could have been presented in a clearer way.

CHAPTER FIVE – POWERS OF ATTORNEY AND OFFICIAL SUPPORTER

Do you agree that there is a need to clarify the use of powers of attorney in situations that might give rise to restrictions on a person's liberty?

If so, do you consider that the proposal for advance consent provisions will address the issue?

Please give reasons for your answers.

Response from the Scottish Council on Human Bioethics

The SCHB agrees that advance directive conditions would need to follow specific wording and meet criteria to be set out in regulations. These advance directive conditions would enable the adult to consent to specified arrangements enabling his/her care and treatment to be put in place at a later time, which, if the person did not consent to them would give rise to a significant restriction on their liberty. Regular reviews of the arrangements would be required and such arrangements should benefit from the right of appeal.
A general declaration would not suffice since there would then be a danger that a person could forego his/her article 5 protections for an unknown period of time in unforeseen circumstances.

Is there a need to clarify how and when a power of attorney should be activated?

If you have and answered yes and have views on how this should be done, please comment here.

Response from the Scottish Council on Human Bioethics

The SCHB agree that there is a need to clarify how and when a power of attorney should be activated

Do you think there would be value in creating a role of official supporter?
If you have answered yes, please give us your views on how an official supporter might be appointed.

Countries that have created a role of supported decision maker have used different names, such as supportive attorney in Australia. We have suggested 'official supporter'. Do you think this is the right term or is another term preferred?

Response from the Scottish Council on Human Bioethics

The SCHB supports the proposal that a person who has capacity to understand the consequences of a decision can appoint an official supporter, who can help the person understand situations and make decisions but does not have the authority to make decisions on behalf of the adult.
The supporter would have access to as much information as the adult would wish but unless a point is reached where the adult no longer has capacity to understand the implications of a decision, the adult would always still make the last decision. The supporter could become an attorney for the adult, if the adult so wished, but someone else could also be appointed as an attorney.

A power of attorney would need to contain an appointment of a supporter, and for the supporter to be registered in the same way as an attorney is at present.

CHAPTER SEVEN - GRADED GUARDIANSHIP

Do you agree with the proposal for a 3 grade guardianship system? Please give reasons for your answer.

Our intention at grade 1 is to create a system that is easy to use and provides enough flexibility to cover a wide range of situations with appropriate safeguards. Do you think the proposal achieves this? Please give reasons for your answer.

Are the powers available at each grade appropriate for the level of scrutiny given?

We are suggesting that there is a financial threshold for Grade 1 guardianships to be set by regulations. Do you have views on what level this should be set at? For example the Public Guardian requires that financial guardians have to seek financial advice on the management of

the adult's estate where the level is above £50,000. Would this be an appropriate level, or should it be higher or lower?

We are proposing that at every grade of application, if a party to the application requests a hearing, one should take place. Do you agree with this?

Please give reasons for your answer.

We have listed the parties that the court rules say should receive a copy of the application. One of these is 'any other person directed by the Sheriff'. What level of interest do you think should be required to be an interested party in a case?

We have categorised grade 3 cases as those where there is some disagreement between interested parties about the application. There are some cases where all parties agree, however there is a severe restriction on the adult's liberty. For instance very isolated and low stimulus care settings for people with autism, or regular use of restraint and seclusion for people with challenging behaviour. Do you think it is enough to rely on the decision of the Sheriff/tribunal at grade 2 (including a decision to refer to grade 3) or should these cases automatically be at grade 3?

Please add any further comments you may have on the graded guardianship proposals.

Response from the Scottish Council on Human Bioethics

At present, for guardianship orders, a registered medical practitioner and a doctor, authorised under section 22 of the *Mental Health (Care and Treatment) (Scotland) Act 2003*, are required to examine and assess the adult and report on the adult's incapacity as part of the application for guardianship, or an intervention order, where incapacity by mental disorder has been needed.

Under section 47 of the AWI Act, medical treatment for adults with incapacity can be authorised by any of the following:

- The medical practitioner primarily responsible for the medical treatment of the adult.
- A person who is a dental practitioner; ophthalmic optician; registered nurse or an individual who falls within a description of person as may be prescribed by Scottish Ministers.

Presently, guardianship cases are decided by the Sheriff Court which is the nearest to where the adult lives. Guardians are appointed by the Sheriff.
Guardianship powers should be sought only where the adult is unable to take their own decisions and should take into account the adult's will and preferences as far as they can be ascertained.

To address the concerns people have about the way guardianship works at present, the SCHB agrees to the proposal to change to a graded system of guardianship. The changes aim to create a system whereby it will be easier to seek only those guardianship powers that are absolutely necessary to safeguard the finance and welfare of an adult, leaving the adult to make many other decisions about their lives.
The SCHB supports a move to 3 grades of guardianship covering both financial and welfare matters, with the complexity of the application increasing as the level of powers sought increases.

A Grade 1 guardianship would be used for day to day welfare matters and for managing simpler financial affairs under a threshold to be set by regulations.

A Grade 2 guardianship would be used for managing property and financial affairs above the threshold set by regulations, as well as more complex welfare needs such as a move of accommodation where there might be a significant restriction on a person's liberty.

A Grade 3 guardianship would be used for all the financial and welfare powers of Grade 2 and is used where there is some disagreement between interested parties, including the adult, about the application.

CHAPTER NINE- SUPERVISION AND SUPPORT FOR GUARDIANS

Is there a need to change the way guardianships are supervised?

If your answer is yes, please give your views on our proposal to develop a model of joint working between the Office of the Public Guardian, Mental Welfare Commission and local authorities to take forward changes in supervision of guardianships.

If you consider an alternative approach would be preferable, please comment in full.

What sort of advice and support should be provided for guardians?

Do you have views on who might be best placed to provide this support and advice?

Please give reasons for your answers

Do you think there is a need to provide support for attorneys to assist them in carrying out their role?

If you answered yes, what sort of support do you think would be helpful?

Response from the Scottish Council on Human Bioethics

The SCHB is of the view that more could be done to provide advice and support to attorneys and guardians and that they should be supervised in some way.

CHAPTER TEN - ORDER FOR CESSATION OF A RESIDENTIAL PLACEMENT, CREATION OF A SHORT TERM PLACEMENT

Do you agree that an order for the cessation of a residential placement or restrictive arrangements is required in the AWI legislation?

If so does the proposal cover all the necessary matters?

Response from the Scottish Council on Human Bioethics

The SCHB agrees that an order for the cessation of a residential placement or restrictive arrangements is required in the AWI legislation.

Do you agree that there is a need for a short term placement order within the AWI legislation?

If you agree, does the above approach seem correct or are there alternative steps we should take? Please comment as appropriate.

Response from the Scottish Council on Human Bioethics

The SCHB is of the view that there is a need for a short term placement order within the AWI legislation. However, the placement should be for no longer than 14 days (and not 28 days) which can be renewed once. There seems to be too much reliance on the possibility of an appeal being made if the placement is seen as inappropriate. However, in some situations an appeal may not be made for different reasons, even though it should be made, with the result that the adult is blocked for too long a time in a placement.

CHAPTER ELEVEN - ADVANCE DIRECTIVES

Should there be clear legislative provision for advance directives in Scotland or should we continue to rely on common law and the principles of the AWI Act to ensure peoples' views are taken account of?

If we do make legislative provision for advance directives, is the AWI Act the appropriate place?

Please give reasons for your answers.

Response from the Scottish Council on Human Bioethics

The SCHB notes that significant discussion took place on this topic in the lead-up to the *Adults with Incapacity (Scotland) Act 2000.* This was in the context of an extremely contentious societal and parliamentary debate in which the SCHB played an active role. Since then, the SCHB's position has not changed in arguing that Scotland should continue to rely on common law and the principles of the AWI Act to ensure peoples' views are taken into account. Clear legislative provisions for advance directives in Scotland would be open to abuse and may even lead to passive euthanasia.

In a Green Paper, published in 1999, which preceded the Scottish Act, the Scottish Executive specifically excluded the provision of advance statements that had originally been included in the Scottish Law Commission's original draft. It summarised its position by indicating that:

> *"We [The Scottish Executive] have examined carefully a number of other proposals made by the Scottish Law Commission … and by others. Such proposals have included legislation to give clear legal force to Advance statements ("Living Wills") and to provide for the withholding or withdrawal of treatment from patients who may be in … PVS. Although such proposals have the sincere support of particular interest groups, we do not consider that they command general support. Attempts to legislate in this area will not adequately cover all situations which might arise, and could produce unintended and undesirable results in individual cases*."[1]

In addition, para. 2.50 of the Code of Practice indicated:

"During Parliamentary debate on the Act, Ministers made it absolutely clear that the Act does not permit any form of euthanasia, which remains a criminal act under Scots Law.
As the then Deputy Minister for Community Care, Iain Gray, said in the Scottish Parliament:

> *"Any health professional, like any individual, who acted by any means – whether by withholding treatment or by denying basic care, such as food and drink – with euthanasia as the objective, would be open to prosecution under the criminal law."*

All interventions under the Act (including some omissions to act) must comply with the general principles that all interventions must benefit the adult, and that any intervention must be the least restrictive option in relation to the freedom of the adult. Clearly, an intervention under Part 5 of the Act which adversely affects the well-being of an adult or causes harm or even death to that adult cannot be described as bringing a benefit to that adult.

Section 47 of the Act only allows intervention to "safeguard or promote the physical or mental health of the adult". This does not impose a duty to provide futile treatment or treatment where the burden to the patient outweighs the clinical benefit."[2]

The Code of Practice of the *Adults with Incapacity (Scotland) Act 2000* states that:

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[1] Making the Right Moves published by the Scottish Executive 1999, http//:www.scotland.gov.uk/rightmoves/docs

[2] Para. 2.50 of the Code of Practice Laid before the Scottish Parliament by the Scottish Ministers pursuant to section 13(e) of the Adults with Incapacity (Scotland) Act 2000; SE/2001/, http://www.nhslothian.scot.nhs.uk/Services/A-Z/LearningDisabilities/GuidelinesAndLegislation/Adults%20with%20Incapacity%20Act%20-%20Code%20of%20Practice.pdf
See also Para 2.66 of the Adults with Incapacity (Scotland) Act 2000: Code of Practice (Third Edition - 2010): For Practitioners Authorised to Carry Out Medical Treatment or Research Under Part 5 of the Act;
http://www.gov.scot/Publications/2010/10/20153801/2

"A competently made advance statement made orally or in writing to a medical practitioner, solicitor or other professional person would be a strong indication of a patient's past wishes about medical treatment but should not be viewed in isolation from the surrounding circumstances. The status of an advance statement should be judged in the light of the age of the statement, its relevance to the patient's current healthcare needs, medical progress since the time it was made which might affect the patient's attitude, and the patient's current wishes and feelings. An advance statement cannot bind a medical practitioner to do anything illegal or unethical. An advance [statement] directive is a document which specifically refuses particular treatments or categories of treatment. Such documents are potentially binding. When the medical practitioner contemplates overriding such a directive, appropriate guidance should be sought."[3]

The SCHB is of the opinion that advance directives may be considered if they are not legally binding

Advance directives have been increasingly considered as a response to the demand by patients for a greater amount of autonomy and control concerning decisions and responsibilities with respect to their health. This has arisen in an environment in which a growing lack of familiarity or even mutual trust may exist between patients and the providers of health care.

The SCHB recognises that competent patients are entitled to make their own decisions concerning medical interventions in order to, for example, avoid breaching their personal or religious beliefs. However, autonomy is not a simple issue, especially when another person's autonomy, rights and views are present.

Moreover, even if only a few days old, advance directives may not reflect the patient's contemporaneous wishes. People's attitudes and wishes often change with the onset of a serious disease, with time and with other personal circumstances. New medical developments may mean that novel forms of treatment may exist which were not foreseen when the advance directives were prepared.
It may also be difficult to establish, retrospectively, whether a person had capacity at the time of making an advance directive. Moreover, it is unclear what level of capacity is required in order to revoke a directive, once made.

Thus, because advance directives may not always reflect the real wishes or the specific situation of a patient when a medical decision is being envisaged, the SCHB considers that they should not be legally binding. This gives those caring for incapacitated persons essential flexibility in the provision of appropriate care and treatment.

The SCHB believes that advance directives should not be used to address quality of life matters

The fears that a person may experience concerning end-of-life issues could be significantly addressed through the application of palliative care. It has also been noted that advance directives may sometimes swing the balance against quality care and rehabilitation that would have enabled patients to live the lives that they value.

The SCHB agrees that legally binding advance directives may impose unworkable obligations upon medical professionals

Legally binding advance directives may impose upon medical professionals interventions which are in conflict with their duty of care or with the law. For example, some legally binding advance directives may amount to the enforcement of circumstances reflecting professional neglect.

In addition, some legally binding advance directives may prevent healthcare professionals giving the most appropriate treatment to the patient that is in his or her best interest. For example, patients who are not treated because of an 'end of life' advance directive may survive and become permanently harmed, bed-ridden or ill as a result, when they could have been effectively treated.

[3] Para 2.30 of the Adults with Incapacity (Scotland) Act 2000: Code of Practice (Third Edition - 2010): For Practitioners Authorised to Carry Out Medical Treatment or Research Under Part 5 of the Act; http://www.gov.scot/Publications/2010/10/20153801/2

There may also be questions over the legal validity of advance directives since they may be revoked at any time through, for example, a private conversation with a single individual and without any witness. Suicide notes could even be misconstrued as advance statements. What may have then been a cry for help could become a death warrant.

The SCHB recognises that legally binding advance directives may be abused

Legally binding advance directives could be open to abuse whereby a vulnerable person may be coerced into preparing an advance directive which is not to his or her benefit. This may happen if a person is led to believe that he or she is an "unacceptable burden" or "expensive" on relatives, carers or society in general.
Legally binding advance directives may even open the door to euthanasia which should not be accepted.

The SCHB notes that advance directives may be misinterpreted

Badly expressed advance directives may mislead or cause confusion and result in patients being treated differently from the manner in which they intended or not at all.
Moreover, they may not correspond to a real situation since the diagnosis and prognosis of a specific disease are always open to uncertainties and even mistakes.
Finally, advance directives may reduce rather than enhance the opportunities for discussion. Inhibitions about raising the matter with health professionals may, indeed, lead some persons to draft them in isolation.

CHAPTER TWELVE – AUTHORISATION FOR MEDICAL TREATMENT (s.47-50)

Do you agree that the existing s.47 should be enhanced and integrated into a single form?

Do you think that there should be provision to authorise the removal of a person to hospital for the treatment of a physical illness or diagnostic tests?

Please explain your answer.

Do you agree that a 2nd opinion (medical practitioner) should be involved in the authorisation process?
If yes, should they only become involved where the family dispute the need for detention?

Do you agree that there should be a review process every 28 days to ensure that the patient still needs to be detained under the new provisions?

How many reviews do you think would be reasonable?

Do you think the certificate should provide for an end date which allows an adult to leave the hospital after treatment for a physical illness has ended?

In chapter 6 we have asked if we should give consideration to extending the range of professionals who can carry out capacity assessments for the purpose of guardianship orders. Section 47 currently authorises medical practitioners, dental practitioners, ophthalmic opticians or registered nurses who are primarily responsible for medical treatment of the kind in question to certify that an adult is incapable in relation to a decision about the medical treatment in question. It also provides for regulations to prescribe other individuals who may be authorised to certify an adult incapable under this section.

Do you think we should give consideration to extending further the range of professionals who can carry out capacity assessments for the purposes of authorising medical treatment ?

Please give reasons for your answers.
Response from the Scottish Council on Human Bioethics

The SCHB agrees that the existing s.47 should be enhanced and integrated into a single form.

The SCHB recognised that there is a need for a short term placement order within the AWI legislation. However, the review process should be for no longer than 14 days (and not 28 days) which can be renewed once. There seems to be too much reliance on the possibility of an appeal being made if the placement is seen as inappropriate. However, in some situations an appeal may not be made for different reasons, even though it should be made, with the result that the adult is blocked for too long a time in a placement.

There should never be a situation where an adult is placed in limbo with renewal orders being prepared without an end date. Thus, the SCHB agrees that there should be a mechanism to provide for discharge with the aim of reducing the risk of an adult being kept in hospital because it is not possible to identify suitable alternative accommodation.

The SCHB does NOT agree to any widening of the list of professionals who can carry out capacity assessments for the purposes of authorising medical treatment.
Section 47 currently authorises medical practitioners, dental practitioners, ophthalmic opticians or registered nurses who are primarily responsible for medical treatment to certify that an adult is incapable in relation to a decision about the medical treatment in question. It also provides for regulations to prescribe other individuals who may be authorised to certify an adult incapable under this section.
The SCHB is concerned that other professionals may not be suitably qualified to certify that an adult is incapable in relation to a decision about the relevant medical treatment.

CHAPTER THIRTEEN – RESEARCH (s.51-52)

Where there is no appropriate guardian or nearest relative, should we move to a position where two doctors (perhaps the adult with incapacity's own GP and another doctor, at least one of whom must be independent of the trial) may authorise their participation, still only on the proviso that involvement in the trial stops immediately should the adult with incapacity show any sign of unwillingness or distress?

Response from the Scottish Council on Human Bioethics

Where there is no appropriate guardian or nearest relative, the SCHB strongly opposes the possibility of two doctors authorising their participation in research, on the proviso that involvement in the trial stops immediately should the adult with incapacity show any sign of unwillingness or distress.
This is completely unacceptable and may lead to the abuse of some of the most vulnerable people in Scottish society. Medical professionals are not sufficiently independent from the interest of medical research to undertake such a role.
Only research with the authorisation of an appropriate guardian or nearest relative should take place.

The SCHB is of the opinion that Scottish legislation relating to the protection of persons not able to consent to research should abide by all the provisions of the **Council of Europe *Convention on Human Rights and Biomedicine*** ETS - No. 164[4] (legally binding). This entered into force on 1 December 1999 (the UK has not signed nor ratified this instrument) and states:

Article 6 – Protection of persons not able to consent

"[A]n intervention may only be carried out on a person who does not have the capacity to consent, for his or her direct benefit. ...

Where, according to law, an adult does not have the capacity to consent to an intervention because of a mental disability, a disease or for similar reasons, the intervention may only be carried out with the authorisation of his or her representative or an authority or a person or body provided for by law.
The individual concerned shall as far as possible take part in the authorisation procedure.

[4] Convention on Human Rights and Biomedicine, ETS No.164, http://conventions.coe.int/Treaty/en/Treaties/Word/164.doc

Article 17 – Protection of persons not able to consent to research

1 Research on a person without the capacity to consent as stipulated in Article 5 may be undertaken only if all the following conditions are met:

i the conditions laid down in Article 16, sub-paragraphs i to iv, are fulfilled;

ii the results of the research have the potential to produce real and direct benefit to his or her health;

iii research of comparable effectiveness cannot be carried out on individuals capable of giving consent;

iv the necessary authorisation provided for under Article 6 has been given specifically and in writing; and

v the person concerned does not object.

2 Exceptionally and under the protective conditions prescribed by law, where the research has not the potential to produce results of direct benefit to the health of the person concerned, such research may be authorised subject to the conditions laid down in paragraph 1, sub-paragraphs i, iii, iv and v above, and to the following additional conditions:

i the research has the aim of contributing, through significant improvement in the scientific understanding of the individual's condition, disease or disorder, to the ultimate attainment of results capable of conferring benefit to the person concerned or to other persons in the same age category or afflicted with the same disease or disorder or having the same condition;

ii the research entails only minimal risk and minimal burden for the individual concerned.

The SCHB is also of the opinion that the Scottish Parliament should abide by all the provisions of the **Council of Europe *Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research***.

When drafting their power of attorney should individuals be encouraged to articulate whether they would wish to be involved in health research?

Response from the Scottish Council on Human Bioethics

The very important principal of informed consent is required before any research is undertaken on a patient. This includes:

1. Competence: A person's capacity for decision making or his or her representative.
2. Disclosure: The content of what a person is told during the consent negotiation.
3. Comprehension: How much given information the person understands.
4. Voluntariness: The ability for a person to make a choice without being unduly pressured or influenced to make a particular choice.
5. Permanence: The ability for a person to remember his or her decision and be able to withdraw consent in the future if he or she so wishes.

It is difficult to see how persons could know and be informed beforehand about the different kinds of research that will be undertaken on them if they give a power of attorney. It would only be acceptable if very specific research is mentioned in the advance directive.
Thus the SCHB generally opposes the possibility of encouraging individuals to articulate whether they would wish to be involved in health research through advance directives.

Should there be provision for participation in emergency research where appropriate (e.g. if the adult with incapacity has suffered from a stroke and there is a trial running which would be likely to lead to a better outcome for the patient than standard care)?

Response from the Scottish Council on Human Bioethics

The SCHB is of the view that adults with incapacity should be able to participate in emergency research as already happens with other patients. Of course, during an emergency, informed consent cannot usually be obtained beforehand. But this should then be obtained from the relevant person in charge of the adult with incapacity as soon as possible after the emergency.

Should authorisation be broadened to allow studies to include both adults with incapacity and adults with capacity in certain circumstances? (e.g. an adult with incapacity who has an existing condition not related to their incapacity may respond differently to different types of care or treatments to an adult with capacity)

Response from the Scottish Council on Human Bioethics

The SCHB is opposed to authorisation being broadened to allow studies to include both adults with incapacity and adults with capacity in certain circumstances which are not defined.
Article 17 of the *European Convention on Human Rights and Biomedicine* indicates that:
Research on a person without the capacity to consent may only be undertaken only if all the following conditions are met:

- *the results of the research have the potential to produce real and direct benefit to his or her health;*

- *research of comparable effectiveness cannot be carried out on individuals capable of giving consent.*

Should clinical trials of non-medicinal products be approached in the same way as clinical trials of medicinal products?

Response from the Scottish Council on Human Bioethics

The SCHB does not understand this question. Non-medicinal products should not be tested on adults with incapacity.

Should there be a second committee in Scotland who are able to share the workload and allow for appeals to be heard respectively by the other committee?

Response from the Scottish Council on Human Bioethics

When biomedical research is rejected by Research Ethics Committees in Scotland, the SCHB is already aware of researchers appealing and 'shopping around' to other Research Ethics Committees until their research is authorised. This is an unacceptable abuse of the system and should not be opened up to research on adults with incapacity.
Thus, the SCHB rejects the creation of a second committee in Scotland so that appeals are heard from the first. If the research is rejected by the first committee which exists specifically to address research on adults with incapacity then a possibility for an appeal should not exist.

Should part 5 of the act be made less restrictive?

Response from the Scottish Council on Human Bioethics

The SCHB does not agree that part 5 of the act should be made less restrictive.

The SCHB believes that measures should exist to enable the general public to have full confidence that the relevant committee able to consider applications for research with adults with incapacity in Scotland will not authorise research that could lead to the abuse of some of the most vulnerable persons in Scottish society.