

Equality and Human Rights Screening Template

The BSO is required to address the 4 questions below in relation to all its policies.

What is the likely impact on equality of opportunity for those affected by this policy, for each of the Section 75 equality categories? (minor/major/none)

Are there opportunities to better promote equality of opportunity for people within the Section 75 equality categories?

To what extent is the policy likely to impact on good relations between people of a different religious belief, political opinion or racial group? (minor/major/none)

Are there opportunities to better promote good relations between people of a different religious belief, political opinion or racial group?

As part of the audit trail documentation needs to be made available for all policies and decisions examined for equality and human rights implications. The screening template is a pro forma to document consideration of each screening question.

For information (evidence, data, research etc.) on the Section 75 equality groups see the Equality and Human Rights Information Bank on the BSO website:

<http://www.hscbusiness.hscni.net/services/1798.htm>

SCREENING TEMPLATE

See Guidance Notes for further information on the 'why' 'what' 'when', and 'who' in relation to screening, for background information on the relevant legislation and for help in answering the questions on this template.

(1) INFORMATION ABOUT THE POLICY OR DECISION

1.1 Title of policy or decision

Briefing Note Regarding Research in Northern Ireland on Adults Lacking Capacity - (Non-Drug research only)

1.2 Description of policy or decision

- **what is it trying to achieve? (aims and objectives)**

To give procedural and practical advice to Health and Social Care Research Ethics Committee members and researchers based in Northern Ireland on inclusion of adults lacking capacity (unable to consent for themselves) in non-Clinical Trials of Investigational Medicinal products, i.e. research which does not involved drug trials.

- **how will this be achieved? (key elements)**

The Guidance and example flow charts are to be used in the development of core research documents such as the research protocol and patient participating documents which will be used by researchers in non-CTIMPs involving adults who lack capacity to consent for themselves.

- **what are the key constraints? (for example financial, legislative or other)**

The Mental Capacity Act (Northern Ireland) became law on 9th May 2016 however it has not yet been implemented in Northern Ireland. The provisions of this Act therefore cannot be relied upon. The most recent timetable suggested the earliest date for implementation would be in or about 2019/2020 however, this is subject to change.

The position therefore remains that there is no specific legislation within Northern Ireland applicable to research involving adults who lack capacity except in clinical trials of investigational medicinal products (CTIMPs) which is covered by the UK clinical Trials Regulation 2004. All non CTIMP research involving adults lacking capacity must be approved by an ethics committee and must comply with common law principles (i.e. do no harm, and in the patient's best interests).

1.3 Main stakeholders affected (internal and external)

For example staff, actual or potential service users, other public sector organisations, voluntary and community groups, trade unions or professional organisations or private sector organisations or others

ORECNI Staff

Committee Members

Potential Future Committee Members

Researchers

Research participants whether patients, service users or their carers, research participants who are not service users , patients or carers (general public)

Private industry, other public bodies and charities.

1.4 Other policies or decisions with a bearing on this policy or decision

- **what are they?**
- **who owns them?**

Standard operating procedures for research ethics committee members, e learning packages for researchers and committee members, training programmes. These guidelines have been developed by the Office for Research Ethics Committees Northern Ireland (BSO) in consultation with the Department of legal Services (BSO) and the Public Health Agency HSC R and D Division.

(2) CONSIDERATION OF EQUALITY AND GOOD RELATIONS ISSUES AND EVIDENCE USED

2.1 Data gathering

What information did you use to inform this equality screening? For example previous consultations, statistics, research, Equality Impact Assessments (EQIAs), complaints. Provide details of how you involved stakeholders, views of colleagues, service users, staff side or other stakeholders.

- Census 2011.
- Carers NI.
- GIRES 2014.
- Health Survey Northern Ireland 2016-17.
- Northern Ireland Life and Times Survey 2016
- DHSSPS (2008) Delivering the Bamford Vision.
- NI Assembly Research and Information Service.
- Mid-year age population estimates. Northern Ireland Statistics and Research Agency (NISRA).
- Northern Ireland Pooled Household Surveys (NIPHS)
- ORECNI Staff Data.
- Committee member Data.
- HSC Interpreting Service data.

2.2 Quantitative Data

Who is affected by the policy or decision? Please provide a statistical profile. Note if policy affects both staff and service users, please provide profile for both. Also give consideration to multiple identities.

As the overall numbers of staff (6) and committee members (37) is small, care has to be taken in answering the questions in this section in case anyone is indirectly identifiable).

Category	<i>What is the makeup of the affected group? (%) Are there any issues or problems? For example, a lower uptake that needs to be addressed or greater involvement of a particular group?</i>
Gender	<u>Committee Members:</u> 59.5% female and 40.5% male. <u>ORECNI Staff:</u> 100% female.

	<p><u>Potential Committee Members; Potential research participants, research and other employees of Private industry, other public bodies and charities:</u></p> <ul style="list-style-type: none"> • Latest NISRA mid-year population estimates (2016; published in June 2017) that NI population is 1,862,100. • Just over half (50.9 per cent) of the population were female, with 946,900 females compared to 915,200 males. • There is a higher level of disability among adult females (23%) compared to adult males (19%). Girls (4%) are less likely to be disabled than boys (8%). <p>Transgender</p> <p>The Gender Identity Research and Education Society (GIRES) estimate the number of gender nonconforming employees and service users, based on the information that GIRES assembled for the Home Office (2011) and subsequently updated show that 1% of the population are gender variant to some degree; 0.025% have sought some medical care; and 0.015% have already undergone transition.</p> <p>Applying GIRES figures to NI population (using NISRA mid-year population estimates for June 2016) N=1,862,100:</p> <ul style="list-style-type: none"> • 18,621 people who do not identify with gender assigned to them at birth • 466 likely to have sought medical care • 279 likely to have undergone transition.
Age	<p><u>Committee Members:</u> Range 24 to 80 years.</p> <p><u>ORECNI Staff :</u>33 to 65 years</p> <p><u>Potential Committee Members; Potential research participants, research and other employees of Private industry, other public bodies and charities:</u></p> <p>The most recent published mid-year population estimates published by NISRA in 2017 show that:</p> <p>0-19 yrs (inclusive) = 483,978 (26.0% of all NI population)</p> <p>20 – 34 yrs = 366,619 (19.7%)</p>

	<p>35 – 49 yrs = 370,263 (19.9%) 50 - 64 yrs = 343,522 (18.4%) 65 – 74 yrs = 166,059 (8.9%) 75 – 89 yrs = 118,965 (6.4%) 90+ yrs = 12,731 (0.7%)</p>
Religion	<p><u>Committee Members:</u> numbers of Committee members are small, so there is the potential to identify individuals.</p> <p><u>ORECNI Staff:</u> numbers of OREC staff are small, so there is the potential to identify individuals therefore no data is reported. See Census data below.</p> <p><u>Potential Committee Members ,Potential research participants, research and other employees of Private industry, other public bodies and charities:</u></p> <ul style="list-style-type: none"> • 41.6% of population from a Catholic background • 40.8% of population from Protestant and other Christian background • 17.6% of population from other religions, no religion or religion not stated <p>(2011 Census data)</p>
Political Opinion	<p><u>Committee Members :</u> numbers of Committee members are small, so there is the potential to identify individuals.</p> <p><u>ORECNI Staff :</u> numbers of OREC staff are small, so there is the potential to identify individuals.</p> <p><u>Potential Committee Members; Potential research participants, research and other employees of Private industry, other public bodies and charities:</u></p> <p>Data from the Northern Ireland Life and Times Survey suggests that of the NI population the proportion who consider themselves to be a particular political leaning are:</p> <ul style="list-style-type: none"> • Unionist 29% • Nationalist 24% • Neither 46% • Other/ don't know 2%

<p>Marital Status</p>	<p><u>ORECNI Staff:</u> 16.7% widowed, 16.7% divorced, 16.7%, 66.6% married.</p> <p><u>Committee Members; Potential Committee Members; Potential research participants, research and other employees of Private industry, other public bodies and charities:</u></p> <p>Northern Ireland Life and Times (2016) suggests the following proportions of the NI population are:</p> <ul style="list-style-type: none"> • Single (never married) 33% • Married and living with husband/wife 50% • A civil partner in a legally-registered civil partnership <1% • Married and separated from husband/wife 3% • Divorced 6% • Widowed 8%
<p>Dependent Status</p>	<p><u>ORECNI Staff:</u> 33.3% have children under 18 years, 66.7% no caring responsibilities.</p> <p><u>Committee Members; potential Committee Members; Potential research participants, research and other employees of Private industry, other public bodies and charities:</u></p> <p>Based on information from Carers Northern Ireland, the following facts relate to carers:</p> <ul style="list-style-type: none"> • 1 in every 8 adults is a carer • There are approximately 220,000 carers in Northern Ireland • Any one person has a 6.6% chance of becoming a carer in any year • One quarter of all carers (26%) provide over 50 hours of care per week • People providing high levels of care are twice as likely to be permanently sick or disabled than the average person • Approximately 30,000 people in Northern Ireland care for more than one person • 64% of carers are women; 36% are men <p>The most recently published figures from the Health Survey NI (2016/17) showed that almost a quarter of those in the 45-54 age-group (22%) had caring responsibilities compared with 7% of those aged 16-24.</p>
<p>Disability</p>	

ORECNI Staff: 33.4% have a declared disability.

Committee Members; potential Committee Members; Potential research participants, research and other employees of Private industry, other public bodies and charities:

The term disability covers such a wide range and combination of conditions that no standard method or single source of information is available.

- It is estimated that 42% of our population have a longstanding illness (30% limiting and 12% non-limiting illness)
- Males: limiting longstanding illness 27%; non-limiting longstanding illness 12%
- Females: limiting longstanding illness 33%; non-limiting longstanding illness 12%

(Health Survey NI 2016/17)

- Prevalence of disability increases with age. Limiting longstanding illness increases from 15% among young adults aged 25 -34 years to 61% among those who are 75 plus years.

(Health Survey NI 2016/17)

Most common disabilities

Type of long – term condition	Percentage of population with condition %
Deafness or partial hearing loss	5.14%
Blindness or partial sight loss	1.7%
Communication Difficulty	1.65%
Mobility of Dexterity Difficulty	11.44%
A learning, intellectual, social or behavioural difficulty.	2.22%
An emotional, psychological or mental health condition	5.83%
Long – term pain or discomfort.	10.10%
Shortness of breath or difficulty breathing	8.72%
Frequent confusion or memory loss	1.97%
A chronic illness (such as cancer,	6.55%

	<table border="1"> <tr> <td>HIV, diabetes, heart disease or epilepsy.</td> <td></td> </tr> <tr> <td>Other condition</td> <td>5.22%</td> </tr> <tr> <td>No Condition</td> <td>68.57%</td> </tr> </table> <p>(Census 2011)</p> <p>Learning disability Currently, there is no central register detailing the actual number of people with a learning disability in Northern Ireland. Data from the DHSSPS suggests that around 26,500 people in Northern Ireland (1% to 2% prevalence rate) have a learning disability, with half of these falling into the 0-10 age group.</p> <p>Psychiatric disorder The NI Health Survey 2017 almost every 1 in 5 persons has a possible psychiatric disorder across all age groups up to 64 years old. However by sex young males in the 16-24 age group had the highest level, whereas in the female population highest levels were found in the 45-54 age group. 45% of those who had mental health concerns felt that their normal activities were affected and 22% missed time at work or school or university.</p>	HIV, diabetes, heart disease or epilepsy.		Other condition	5.22%	No Condition	68.57%
HIV, diabetes, heart disease or epilepsy.							
Other condition	5.22%						
No Condition	68.57%						
Ethnicity	<p><u>Committee Members:</u> 5.4% Non-White ethnic, 94.6% white Caucasian.</p> <p><u>ORECNI Staff :</u>100% white Caucasian</p> <p><u>Potential Committee Members; Potential research participants, research and other employees of Private industry, other public bodies and charities:</u></p> <ul style="list-style-type: none"> • Traveller population in N Ireland is estimated at 1301 (Census 2011) • 2013/14: Ethnicity White 98.2% (1,399,000); All other Ethnicities 1.6% (23,000) (No response not included) • 2014/15: Ethnicity White 98.2% (1,409,000); All other Ethnicities 1.8% (26,000) <p>(Northern Ireland Pooled Household Survey (NIPHS) (2017)</p> <ul style="list-style-type: none"> • Between 2000 and 2014, an estimated 175,000 long-term international migrants came to Northern Ireland, while 143,000 left, leaving a net total of 32,000. Local government districts in the west 						

	<p>and south-west of Northern Ireland saw the largest net inflow of new residents, in particular: Mid Ulster (9,800), Armagh, Banbridge and Craigavon (9,300) and Newry, Mourne and Down (6,000).</p> <ul style="list-style-type: none"> Poland continues to be the most popular country of origin for international migrants coming to live in Northern Ireland. <p>(International Migration in Northern Ireland: an update (2016) Research and Information Service Research Paper)</p> <p>Statistics from the HSC Interpreting Service showed a large rise in requests for interpreters from 1,850 in 2004-2005 to 10,6541 requests in 2016-2017. The most popularly requested languages are described below:</p> <ol style="list-style-type: none"> 1. Polish 31220 2. Lithuanian 15866 3. Romanian 8975 4. Portuguese 8323 5. Arabic 6203 6. Slovak 5356 7. Tetum 5319 8. Chinese - Mandarin 5103 9. Bulgarian 3421 10. Hungarian 3387 11. Chinese - Cantonese 2858 12. Russian 2541 13. Latvian 2042 14. Somali 1151 15. Czech 855 16. Chinese - Hakka 748 17. Spanish 589 18. Farsi 515 19. Bengali 369 20. Urdu 297
Sexual Orientation	<p><u>Committee Members:</u> numbers are small, so there is the potential to identify individuals.</p> <p><u>ORECNI Staff; Potential Committee Members ; Potential research participants, research and other employees of Private industry, other public bodies and charities:</u></p>

	<p>Between 2006 and 2017, there were 1202 recorded Civil Partnerships regionally. However, this is not indicative of the LGB population. There are no accurate statistics on sexual orientation in the community as a whole, it is however estimated that between 5% and 10% of the population would identify as lesbian, gay or bisexual.</p>
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2.3 Qualitative Data

What are the different needs, experiences and priorities of each of the categories in relation to this policy or decision and what equality issues emerge from this? Note if policy affects both staff and service users, please discuss issues for both. Also give consideration to multiple identities (such as single parents for example).

<i>Category</i>	<i>Needs and Experiences</i>
Gender	There is no evidence that a person's gender impacts ability to read guidance in lay language
Age	<p>There is evidence that a person's age impacts ability to read guidance in lay language.</p> <p>Adults who lack capacity are also likely to be older, as age is a contributory factor to the likelihood of having a stroke, or developing disabilities or illnesses such a stroke, dementia.</p> <p>Although the guidance clearly states that in NI a close relative/ friend cannot consent for the adult lacking capacity they can be given information sheets regarding the research. It is possible that close relatives/ friends of the Adult lacking capacity will be of a similar age range (e.g. spouse/ partner etc.) and have similar needs.</p>
Religion	There is no evidence that a person's religion impacts ability to read guidance in lay language
Political Opinion	There is no evidence that a person's political opinion impacts ability to read guidance in lay language
Marital Status	There is no evidence that a person's marital status impacts ability to read guidance in lay language.
Dependent Status	There is no evidence that a person's dependent status impacts ability to read guidance in lay language
Disability	There may be accessibility issues for all stakeholders affected by this policy with physical and/or sensory disabilities. It is also important to

	<p>note that a one size fits all approach is not appropriate. People with learning disabilities may require research documentation in easy read, depending on the level of their learning disability. Those with sight impairments may need documentation to be in large print, braille or delivered in another format (e.g. aurally).</p>
Ethnicity	<p>There is no evidence that a person's ethnicity impacts ability to read guidance in lay language.</p> <p>However, people whose first language is not English may find it more difficult to understand written or spoken information unless it is delivered in their own language. In research, interpreters and translation would be used to translate into a service user's first language where they participate in research. This is reinforced by a question in the ethics submission completed by researchers which is reviewed by ethics committees including those in Northern Ireland (see www.myresearchproject.org.uk) namely, '<i>A33-1. What arrangements have been made for persons who might not adequately understand verbal explanations or written information given in English, or who have special communication needs?(e.g. translation, use of interpreters)</i>'</p>
Sexual Orientation	<p>There is no evidence that a person's sexual orientation impacts ability to read guidance in lay language</p>

2.4 Making Changes

Based on the equality issues you identified in 2.2 and 2.3, what changes did you make or do you intend to make in relation to the policy or decision in order to promote equality of opportunity?

<i>In developing the policy or decision what did you do or change to address the equality issues you identified?</i>	<i>What do you intend to do in future to address the equality issues you identified?</i>
<p>ORECNI will liaise with the Health Authority to highlight any equality screening issues identified and to ask that these are addressed.</p> <p>Information sheets and consent forms will be developed for use in informing close relatives/close friends of the adult lacking capacity's involvement in research and to obtain consent from the adult lacking capacity should s/he regain capacity. There are equality impacts in the following respects which will be mitigated as follows:</p> <p>a) Ethnicity- the guidance will highlight the need to have documentation translated into the close relatives'/close friends' and/or adult lacking capacity's first language.</p> <p>b) Age – a significant proportion of adults lacking capacity and their close relatives or close friends will fall into an older age group with eyesight deterioration. The guidance will reference the need to produce information sheets and consent forms in easy read and large font size</p> <p>c) Disability- a significant proportion of adults lacking capacity will be classified and their close relatives or close friends as disabled. The guidance will</p>	<p>ORECNI will liaise with the Health Authority to highlight any equality screening issues identified and to ask that these are addressed.</p> <p>Also in the ethics research application form (see www.myresearchproject.org.uk) there is the following question which is considered by an ethics committee, namely, 'A33-1. <i>What arrangements have been made for persons who might not adequately understand verbal explanations or written information given in English, or who have special communication needs?(e.g. translation, use of interpreters)</i>'</p>

<p>reference the need to produce information sheets and consent forms in easy read and large font size. The information sheets/ form will also be read out, where appropriate.</p> <p>There is clear promotion of the involvement of people with a disability in research in this guidance and references the government guidance on written information and persons with learning disabilities in the document</p> <p>https://www.gov.uk/government/publications/making-written-information-easier-to-understand-for-people-with-learning-disabilities-guidance-for-people-who-commission-or-produce-easy-read-information-revised-edition-2010 .</p>	
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2.5 Good Relations

What changes to the policy or decision – if any – or what additional measures would you suggest to ensure that it promotes good relations? (refer to guidance notes for guidance on impact)

Group	Impact	Suggestions
Religion	None	
Political Opinion	None	
Ethnicity	Minor	Need for research documentation to be in a research participant’s first language is considered in all ethics submission by the ethics committees including those in Northern Ireland.

(3) SHOULD THE POLICY OR DECISION BE SUBJECT TO A FULL EQUALITY IMPACT ASSESSMENT?

A full equality impact assessment (EQIA) is usually confined to those policies or decisions considered to have major implications for equality of opportunity

How would you categorise the impacts of this decision or policy? (refer to guidance notes for guidance on impact)

Do you consider that this policy or decision needs to be subjected to a full equality impact assessment?

Please tick:

Major impact	
Minor impact	X
No further impact	

Please tick:

Yes	
No	X

Please give reasons for your decisions.

There were a number of minor impacts identified that have been mitigated.

1. The main issue in development of this guidance is that the principle was established as follows: In deciding whether to carry out non Clinical Trial of Investigative Medicinal Product (non-CTIMP) research with persons who lack capacity (ALC), the common law principle of Best Interests will apply.

Best interests in this sense should consider the subjective best interests of one person rather than the community at large. One must therefore weigh the potential positive impact on a patient against the risk to that patient, not to society as a whole.

This mitigates the risk to an adult lacking capacity as any research in this area must adhere to patient's best interest principles.

2. Information sheets and consent forms will be developed for use in informing close relatives/close friends of the adult lacking capacity's involvement in research and to obtain consent from the adult lacking capacity should s/he regain capacity. There are equality impacts in the following respects which will be mitigated as follows:
 - a) Ethnicity- the guidance will highlight the need to have documentation translated into the close relatives'/close friends' and/or adult lacking capacity's first language.

- b) Age – a significant proportion of adults lacking capacity and their close relatives or close friends will fall into an older age group with eyesight deterioration. The guidance will reference the need to produce information sheets and consent forms in easy read and large font size
- c) Disability- a significant proportion of adults lacking capacity will be classified and their close relatives or close friends as disabled. The guidance will reference the need to produce information sheets and consent forms in easy read and large font size.

(4) CONSIDERATION OF DISABILITY DUTIES

4.1 In what ways does the policy or decision encourage disabled people to participate in public life and what else could you do to do so?

<i>How does the policy or decision currently encourage disabled people to participate in public life?</i>	<i>What else could you do to encourage disabled people to participate in public life?</i>
<p>There is clear promotion of the involvement of people with a disability in research in this guidance and references the government guidance on written information and persons with learning disabilities in the document https://www.gov.uk/government/publications/making-written-information-easier-to-understand-for-people-with-learning-disabilities-guidance-for-people-who-commission-or-produce-easy-read-information-revised-edition-2010 .</p>	

4.2 In what ways does the policy or decision promote positive attitudes towards disabled people and what else could you do to do so?

<i>How does the policy or decision currently promote positive attitudes towards disabled people?</i>	<i>What else could you do to promote positive attitudes towards disabled people?</i>
<p>As section 4.1</p>	<p>As Section 4.1</p>

(5) CONSIDERATION OF HUMAN RIGHTS

5.1 Does the policy or decision affect anyone's Human Rights?

Complete for each of the articles

ARTICLE	Yes/No
Article 2 – Right to life	N
Article 3 – Right to freedom from torture, inhuman or degrading treatment or punishment	N
Article 4 – Right to freedom from slavery, servitude & forced or compulsory labour	N
Article 5 – Right to liberty & security of person	N
Article 6 – Right to a fair & public trial within a reasonable time	N
Article 7 – Right to freedom from retrospective criminal law & no punishment without law	N
Article 8 – Right to respect for private & family life, home and correspondence.	N
Article 9 – Right to freedom of thought, conscience & religion	N
Article 10 – Right to freedom of expression	N
Article 11 – Right to freedom of assembly & association	N
Article 12 – Right to marry & found a family	N
Article 14 – Prohibition of discrimination in the enjoyment of the convention rights	N
1 st protocol Article 1 – Right to a peaceful enjoyment of possessions & protection of property	N
1 st protocol Article 2 – Right of access to education	N

*If you have answered no to all of the above please move on to **Question 6** on monitoring*

5.2 If you have answered yes to any of the Articles in 5.1, does the policy or decision interfere with any of these rights? If so, what is the interference and who does it impact upon?

List the Article Number	Interfered with? Yes/No	What is the interference and who does it impact upon?	Does this raise legal issues?* Yes/No

** It is important to speak to your line manager on this and if necessary seek legal opinion to clarify this*

5.3 Outline any actions which could be taken to promote or raise awareness of human rights or to ensure compliance with the legislation in relation to the policy or decision.

(6) MONITORING

6.1 What data will you collect in the future in order to monitor the effect of the policy or decision on any of the categories (for equality of opportunity and good relations, disability duties and human rights)?

Equality & Good Relations	Disability Duties	Human Rights
Requests for alternative access arrangements on section 75 grounds Feedback log will be maintained in roll out phase		

Approved Lead Officer: Dr Siobhan McGrath

Position: Head of the Office for Research Ethics Committees Northern Ireland (ORECNI)

Date: 27.12.2018

Policy/Decision Screened by: Dr Siobhan McGrath

Please note that having completed the screening you are required by statute to publish the completed screening template, as per your organisation’s equality scheme. If a consultee, including the Equality Commission, raises a concern about a screening decision based on supporting evidence, you will need to review the screening decision.

**Please forward completed template to:
Equality.Unit@hscni.net**

Any request for the document in another format or language will be considered. Please contact the Equality Unit:

2 Franklin Street; Belfast; BT2 8DQ; Email: equality.unit@hscni.net
Phone: 028 9536 3814/ 9536 3023