Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

Quality and Patient Safety Division

Tús Áite do Shábháilteacht Othar
Patient Safety First

National Consent Policy
Part Three
Research

Part Three—Research

1. Introduction

Research has the potential to promote scientific advances, improve health services and contribute to the wellbeing of individuals and society as a whole. It allows policymakers and service providers to prepare for and respond to the risks posed by e.g. disease or environmental hazards and to verify that drugs and medical devices etc. are safe and effective. It has the potential to feed into the formation of policy and is concerned with a range of human experiences, perspectives and needs e.g. health, education, housing, family and community services as well as the social institutions created to meet those needs. Research is a regular part of the work undertaken by many HSE staff. There are various types of research which cover a range of activities, from laboratory research, clinical trials, observational studies and epidemiological investigations to surveys and interviews. Research can also assist the HSE with organising and providing services.

A number of international codes and standards as well as national and international legal instruments aimed at protecting research participants and ensuring high quality research have been developed in recent decades and these have been taken into account in formulating this policy[25].

Participation in research has the potential to offer participants direct benefits (e.g. improvements in health and well-being) and indirect benefits (e.g. greater access to professional care and support). The potential benefits of research can never be guaranteed. Therefore, it is important to ensure that any possible benefits of research are not overstated in order to avoid unrealistic expectations by prospective participants. Research, by its nature, also holds out the prospect of risk and it is essential that the risks of research be reasonable in light of any expected benefits.

A number of principles govern the ethical conduct of research, which aim to protect the wellbeing and rights of research participants. They include:

- **Beneficence** - maximising the potential benefits of the research and minimising the risks;
- **Justice** - the duty to neither neglect nor discriminate against individuals or groups who may benefit from research and to avoid placing an unfair burden of research participation on particular groups; and

[25] These documents are referred to in the bibliography

- **Respect for persons** – the notion that individuals should be treated as autonomous agents and that individuals with diminished autonomy should be protected.

Respect for persons is most commonly manifested through the exercise of informed consent (hereafter referred to as consent), which requires that people's beliefs and opinions be valued, and that they be allowed to choose for themselves whether or not to participate in research.

All modern codes of ethics concerning research with human participants affirm the importance of consent. The goal of consent is to ensure that participants have sufficient information to be able to make decisions about research participation which are compatible with their individual interests and values.

Special consideration must also be given to the timing of the consent process. Prospective research participants should be given enough time to fully consider their participation and to ask questions.

2. General principles of consent for research

2.1 Content of the information to be provided

When preparing consent documentation, researchers must provide all of the information necessary for making an informed decision. Prospective research participants should be provided with the information in the following list, as appropriate. Not all of the listed information will be required for all research. However, in certain circumstances additional information may be required.

The proposed information should be submitted to a research ethics committee (REC)[26] for a consideration of whether it is adequate to achieve consent.

[26] The Department of Health intends to designate the Health, Information and Quality Authority (HIQA) as the supervisory body for recognising and monitoring REC's. To this end, HIQA has established a Research Ethics Advisory Group with the aim of preparing national standards for RECs based on best international practice

2.1.1 Explanation of the research study

- The purpose of the study should be explained to research participants. They should be informed of the types of material/data required, the methods used to collect it and how the material/data will be utilised during the course of the study.
- Research participants should be told how long their material/data will be retained and how it will be disposed of. They should also be informed how long/often they will be expected to attend the trial centre. Researchers should give a description of any other aspects of the study, e.g. whether questionnaires or diary cards will be used.
- Participants should be informed whether or not they will be given feedback e.g. study results or any incidental findings see Section 8) as the study progresses. In instances where the material/data will be anonymous it should be made clear to prospective participants that feedback will not be possible.
- It is important that consent be sought from research participants should there be secondary uses planned for the material/data e.g. future research studies.

2.1.2 Explanation of the risks and benefits

- Prospective research participants should be given an account of the foreseeable risks and benefits associated with participating in the research study. They should be assured that they can withdraw from the research study at any time and that their decision will not have any negative repercussions.

(For more information see Section 10 on Withdrawal of Consent). The contact details of researchers should be provided to the research participant should s/he require clarification on any issue relating to the research.

2.1.3 Confidentiality

- Participants should be informed what information will be collected and for what purposes.
- Participants should also be told in what form the data will be stored (e.g. de-identified) and what measures the researchers will put in place to ensure confidentiality for the full life-cycle of the study.
- Research participants should be told which persons will have access to their data including third parties outside the jurisdiction.
- Participants should be advised in relation to the fate of their data at the end of the study.
- Participants should be advised of the risks of re-identification in the event of data security breaches.

2.1.4 Commercialisation

- Researchers should clearly explain to research participants whether or not they will receive payment (either financial or non-financial) for participating in the research project or have their expenses covered.
- Research participants should be made aware that they will not be entitled to a share of any profits that may arise from use of their material/data or products derived from it.
- Researchers should disclose any conflict of interest they may have e.g. a financial interest in the study.

(See Figure 1 for a list of sample information which might be included in a consent form)

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Figure 1.

- A statement that the study involves research participants and an explanation of the purposes of the research.
- The expected duration of the participant's involvement.
- A description of the procedures to be followed/drug to be tested, and an identification of any procedures which are experimental.
- A statement that participation is voluntary including a statement offering the participant the opportunity to ask questions and to withdraw at any time from the research without consequences. In the case of withdrawal, information regarding what will happen to material/data should be provided.
- Information about who is organising and funding the research.
- A description of any reasonably foreseeable risk, discomfort or disadvantages.
- A description of any benefits to the participant or to others which may reasonably be expected from the research, avoiding inappropriate expectations.
- A disclosure of appropriate alternative procedures for treatment/diagnosis, if any, that might be advantageous to the participant.
- A statement describing the procedures adopted for ensuring data protection/ confidentiality/privacy including duration of storage of personal data.
- A description of how incidental findings are to be handled.
- A description of any planned genetic tests, including whether results will be disseminated to research participants.
- An explanation as to whether there are any treatments or compensation if injury occurs (where relevant) and, if so, what they consist of, or where further information may be obtained. Insurance coverage should be mentioned.
- Contact details to access information about the research and research participants' rights.
- An explanation of what will happen with the material/data at the end of the research and if the material/data are retained or sent/sold to a third party for further research.
- Information about what will happen to the results of the research.
- A statement regarding the potential commercialisation of the research (where applicable).

2.2 Who should seek consent?

The person obtaining consent should have sufficient knowledge about the research and be capable of answering questions from prospective participants.

Depending on the circumstances, prospective research participants may be approached directly (e.g. by advertisement) or indirectly (e.g. by the individual's GP). Where researchers are not also the service provider, best practice and data protection considerations require that the service provider should act as a gatekeeper and make the initial contact with the prospective participant and provide him/her with the contact details of the research team.

There may be situations where the researcher is also directly involved in providing care or support to the individual. Where this is the case, it is essential that any conflict of interest that might arise as a result of the original relationship be acknowledged and that any possibility that the individual might feel obliged to participate be averted. This might be achieved by having the consent either obtained or witnessed by a person who is independent of the research.

2.3 How should consent be documented?

For the majority of cases, prospective research participants should provide written consent. However, in cases where decision-making capacity is lacking, the research team should seek consent from the person's legal representative (for a more in–depth discussion see Section 4 on Adults lacking decision-making capacity and consent for research).

There may be certain circumstances where it is not possible for a prospective participant to provide written consent due to e.g. literacy levels or physical inability. In such cases a witness who is independent of the research should be present during the entire consent process and should sign the consent form. By signing the consent form, the witness acknowledges that the information provided to the individual was explained and that the consent was freely given. A video/audio tape recording of the consent interview might also be made with the permission of the research participant, however, researchers using this method must be mindful of their obligations to protect the confidentiality of the participant.

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3. Children

Children should not be denied the possible benefits of research participation but instead should be afforded the opportunity to participate in research on matters that might affect them. Neither should children be exploited or inappropriately enrolled in research because they lack the capacity to consent to participation[27].

For the purposes of participation in clinical trials, anyone over the age of 16 years can consent on his/her own behalf[28]. For all other research, the person must be over the age of 18 years in order to provide consent.

The following principles should be adhered to when conducting research involving children:

- The research should only include children where the relevant knowledge cannot be obtained by conducting research involving adults
- The purpose of the research is to generate knowledge about the health or social care needs of children
- The research does not pose more than minimal risk unless there is a prospect of direct benefit for the participants
- The research has been designed to minimise pain, discomfort, fear and any other foreseeable risk to the child or his/her stage of development
- Consent to the child's participation must be obtained from a parent/legal guardian
- Whenever s/he has sufficient competence to provide it, the child's assent must be sought in a child-appropriate manner; and
- A child's refusal to participate or continue in research should be respected.

[27] Researchers should refer to the Department of Children and Youth Affairs document *Guidance for Developing Research Projects Involving Children* which was published in April 2012

[28] *European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations, 2004, SI no 190 of 2004*, section 4

There is an international consensus that children should not be exposed to more than minimal risk in the absence of direct benefit to the participants themselves. The standard of minimal risk requires that the probability and magnitude of the possible harms posed by participating in research are no greater than those encountered by participants in their everyday life or during the performance of routine physical or psychological examinations or tests.

Where the research entails only minimal risk, it is sufficient if the research offers the prospect of benefits either to the participants directly or to the group which is the focus of the research and to which the participants belong.

Where the research poses more than minimal risk, it should aim to generate new knowledge of sufficient importance for addressing the participants' conditions/needs. Such research should offer the prospect of direct benefits for the participants themselves and be commensurate with the level of foreseeable risk. The benefit-to-risk ratio presented by the research should be at least as favourable to participants as that presented by available alternative approaches.

It is sufficient for one parent/legal guardian to provide consent for a child's participation in research unless the REC has found that the risks involved in participation require the consent of both parent(s)/legal guardian(s). A parent or legal guardian who provides consent on a child's behalf should be given the opportunity, to a reasonable extent, to observe the research as it proceeds.

Researchers must respect the developing capacity of children to be involved in decisions about their participation in research and, where appropriate, the child's assent to participation must be sought. It is important to note that a child's capacity and/or vulnerability may fluctuate depending on age, maturity and the type and complexity of the research being proposed.

Older children, who are more capable of giving assent (i.e. children over the age of 7 years)[29], should be selected before younger children, unless there are valid scientific, age-related reasons for involving younger children first.

[29] The Department of Children and Youth Affairs' document *Guidance for Developing Research Projects Involving Children* makes reference to the US National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research's report *Research Involving Children* (1977), which recommends seeking assent from children seven years or older

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In order to assist children to make decisions, they should be informed as fully as possible, given their age and competence, about the nature of the study and the methods to be employed from the outset. Information for children five years and under should be predominantly pictorial. For older children, information sheets should be provided that explain briefly and in simple terms the background and aim of the study, so they can consider assent.

It should also contain an explanation that their parent(s)/legal guardian(s) will be asked for consent. The information should be written in clear and simple language and should be read to them. It should be explained to children that they may choose to withdraw from the study if they are uncomfortable with continuing.

The objection of a child to participate in research should be considered and adhered to unless the intervention being tested were to offer an important direct benefit to the child.

Parent(s)/legal guardian(s) who enroll their child in a study might believe that the research is designed to provide a direct therapeutic benefit to the child, as opposed to contributing to medical knowledge for the benefit of individuals in the future. This is commonly referred to as therapeutic misconception. Therefore, it is essential that researchers should be aware of the possibility of parental therapeutic misconceptions when determining how to explain the potential benefits and risks of research participation during the consent process.

In certain circumstances, it will not be possible for the researcher to guarantee confidentiality to the child due to mandatory reporting obligations. For instance, if a child reveals that they or others are at significant risk of harm, or the researcher observes or receives evidence of incidents likely to cause serious harm, the researcher must divulge this information to the appropriate authorities. This should occur only following discussion with the child. The child and his/her parent(s)/legal guardian(s) should be informed of this obligation during the consent/assent process and it should be highlighted in participant information leaflets. A strategy for information disclosure should be submitted to and approved by the REC in advance of the research being commenced.

3.1 Healthy children as participants

In certain types of research it may be necessary to involve healthy child participants to act as a control group. In such instances, healthy volunteers should be treated in the same manner as other child participants. The risks posed to healthy child participants should be no more than minimal in the absence of any direct benefit for this cohort.

3.2 Children in care

Research involving children in care is permitted once the criteria listed above are adhered to. In order to conduct research involving a child in care, researchers should first get consent from the responsible legal guardians e.g. a parent and/or the child's health/social care providers or someone with a duty of care to the child. This consent must be supplemented with the child's assent.

Given the vulnerability of children in care, researchers should consider appointing an advocate, agreed by the child. The task of the advocate would be to ensure that the child is not exploited, coerced or subjected to undue influence or harm during the course of the research and that the child has freely given his/her assent to participation.

3.3 Neonates

Research involving full-term or pre-term neonates is, in principle, similar to research involving children as the decision-making power rests with their parent(s)/legal guardian(s) and, in general, the same rules apply. However, this type of research raises additional issues relating to consent, as the parent(s)/legal guardian(s) may be distressed following a difficult or premature birth. Nevertheless, because of the important benefits that might accrue from such research, if consent can be obtained from a parent/legal guardian of the child then, providing conditions in relation to levels of risk (as set out in the criteria above) are met and the research can be justified to a REC, the research can proceed.

4. Adults lacking decision-making capacity and consent for research

In accordance with the functional approach to capacity (see Part One), there may be instances where a person might have limited capacity and may require assistance in deciding whether or not to participate in research. In such cases, researchers must ensure that efforts are made to assist people in reaching their decision and that they are provided with the appropriate tools to maximise their decision-making ability.

The objectives as well as the potential risks and benefits of the research should be explained as fully as possible to the prospective participant given their level of understanding. The information should be provided using easily comprehensible language and the prospective participant should be informed of the right to withdraw from the study at any time without there being any negative repercussions.

There may be some instances where the capacity to consent to research participation is lacking. Adults who lack decision-making capacity must neither be unfairly excluded from the potential benefits of research participation, nor may their lack of capacity to consent be used to inappropriately include them in research. However, special measures should be taken to protect their rights and interests.

The following principles should be adhered to when conducting research involving adults lacking decision-making capacity:

- The research should only be undertaken if the required knowledge cannot be obtained by conducting research involving adults with decision-making capacity
- The research is expected to provide a direct benefit to the participants or to provide knowledge about the cause or treatment of the impairing or similar condition. Where there is no prospect of direct benefit for participants, the risks involved should be no more than minimal (For more information on minimal risk see Section 3 on Children)
- Consent for participation must be sought from the person's legal representative
- A REC must approve the participation of adults lacking decision-making capacity in research taking all of the above factors into consideration
- The explicit wish of a participant to refuse participation in or to be withdrawn from the study should be respected.

Where a prospective research participant lacks decision-making capacity but has some ability to understand the significance of the research, the researcher should ascertain the wishes of that individual with respect to his/her participation.

Under the European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004[30,31], consent for research participation on behalf of an adult lacking decision-making capacity must be obtained from the person's legal representative. A legal representative has been defined as a person not connected with the conduct of the trial who by virtue of his/her family relationship with that adult, is suitable to act as the legal representative and is willing and able to do so or (if there is no such individual) a person who is not connected with the conduct of the trial, who is a solicitor nominated by the relevant health care provider.

Outside of clinical trials, there is currently no legal framework for a person who lacks decision-making capacity to participate in research. In the absence of any such legal regulations, it is recommended that as a matter of best practice the same principles should apply to both clinical trials and other forms of research. This means that consent for participation in any form of research on behalf of an adult lacking decision-making capacity must be obtained from the person's legal representative, as defined above.

Refusal to participate in a research project by an individual lacking decision-making capacity should be respected.

[30] In July 2012 the European Commission published a proposal to repeal the Clinical Trials Directive 2001/20/EC and for new legislation relating to the conduct of clinical trials on Medicinal Products for Human Use. The new legislation, which is expected to come into effect in 2016, will take the form of a Regulation which will ensure that, in the main, the rules governing clinical trials will be identical throughout Europe . Other aspects, such as the structure and function of RECs and eligibility for the role of legal representative will be decided at a national level

[31] It is also important to note that the European Commission is in the process of reviewing EU legal frameworks relating to medical devices and on the protection of personal data

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5. Vulnerable research participants

It is important to recognise that research involving human participants requires special justification in the case of potentially vulnerable people. Certain groups may continually be sought as research subjects, owing to their ready availability in settings where research is conducted, or the conditions they suffer from. Such groups should be protected against the danger of being involved in research solely for administrative convenience, or because they are easy to manipulate as a result of their illness or socioeconomic condition. Vulnerability is sensitive to context and individuals may be vulnerable in one situation but not in another.

5.1 Research in emergency situations

Research in emergency situations involves individuals who have a life-threatening medical condition that necessitates urgent intervention (for which available treatments are unproven or unsatisfactory), and who, because of their condition (e.g. traumatic brain injury) cannot provide consent. In emergency situations, when it is not possible to obtain the consent of the prospective participant, then the consent of the participant's legal representative should be sought. (See Section 4 on Adults lacking decision-making capacity and consent for research.) If there is no legal representative present then the individual can only be enrolled in research if the following criteria are met:

- the research addresses the emergency needs of the individual involved;
- the experimental interventions have a realistic probability of benefit equal to or greater than standard interventions; and
- the risks associated with the research are reasonable in view of the critical nature of the condition and the risks associated with standard interventions.

Participants who regain capacity (or their legal representatives once located) should be given all the relevant information and their consent to continued participation should be obtained as soon as is reasonably possible. The option to withdraw and to seek the destruction of any biological material or data collected as part of the study should also be given.

5.2 People highly dependent on medical care

While research involving people who are highly dependent on medical care (e.g. people in intensive care or the terminally ill) is valuable, their reliance on medical treatment may impact on their willingness to consent to research participation and this raises significant ethical issues. Therefore, such research should only be undertaken when:

- it is likely that the research will lead to an increased understanding of, or an improvement in, the care of that population; and
- any risk or burden of the proposed research to a particular participant is justified by the potential benefits that might accrue to him/her.

There should be an explicit recorded explanation that not participating in or withdrawing from the research will not adversely affect either the quality of care received or the relationship with the medical team.

When undertaking studies involving people highly dependent on medical care, researchers must be mindful of the potential for unrealistic expectations of benefits and must ensure that the prospect of benefit from research participation is not exaggerated. Where the research involves terminally ill people, their needs and wishes to spend time as they choose, particularly with family members, must be respected.

For research involving people who are highly dependent on medical care:

- steps should be taken to minimise the risk that stress or emotional factors may have on the person's understanding of the research or his/her decision to participate; and
- researchers must ensure that the dependency of prospective participants on the medical personnel providing treatment does not compromise the voluntariness of their consent.

People who are highly dependent on medical care may have impaired capability for verbal or written communication. Provision should be made for them to receive information and to express their wishes, in other ways.

Where the researcher is also the service provider, it should be considered whether a person who is independent of the research should make the initial approach and/or seek consent from potential participants.

In cases where people who are highly dependent on medical care lack the decision-making capacity required for consent the criteria listed in Section 4 should be adhered to.

5.3 People in dependent or unequal relationships

Dependent or unequal relationships might include those between: health and social care professionals and residents in care; teachers and students; penal institutions and prisoners; employers and employees; or governments and refugees.

Being in a dependent or unequal relationship may influence a person's decision to participate in research. While this influence does not necessarily invalidate the decision, it necessitates close inspection of the process through which consent is negotiated. In the consent process, researchers should, wherever possible, invite prospective participants to discuss their participation with someone who is able to support them in making their decision. Where prospective participants are especially vulnerable or powerless, consideration should be given to the appointment of a participant advocate (see Section on Children in Care 3.2). It may also be appropriate that consent is obtained by a person who is independent of the research. People in dependent or unequal relationships might be vulnerable to being over-researched because of the relative ease of access to them as research populations.

Researchers should take account of this vulnerability in deciding whether to seek out members of these populations as research participants.

A person who wishes to decline an invitation to participate in research or withdraw from a study should not suffer any negative consequences such as discrimination, reduction in care, dismissal from employment, exam penalties or any other disadvantage. Researchers must protect the confidentiality of participants, especially in settings such as shared workplaces, educational institutions, hospitals or prisons.

Researchers should be mindful that in some relationships of dependency, participants may have an unrealistic expectation of the benefits of research and must ensure that the prospect of benefit from research participation is not exaggerated.

6. Categories of research

6.1 Genetic research

The Disability Act 2005 (part 4) states that consent for the processing of any genetic data to be derived from testing must be obtained.

The act also stipulates that a person shall not process genetic data unless all reasonable steps have been taken to provide the data subject with all of the appropriate information concerning:

- the purpose and possible outcomes of the proposed processing; and
- any potential implications for the health of the data subject which may become known as a result of the processing.

As a result of the highly sensitive nature of genetic data, it is important that researchers formulate a strategy regarding third party disclosure, in particular to family members. The results of genetic research might create a need for alternative life decisions, including those concerning reproductive choices or those with the potential to improve health e.g. dietary modification or career choices.

When participants or their relatives are to be informed about genetic data that may be important for their health or lifestyle choices, the disclosure strategy should provide access to genetic and clinical advice/counselling, or clearly recommend to participants that they seek these services. Advice about the results of genetic research needs to include a clear explanation of the difference between research and clinical testing, and to clarify any need for the clinical confirmation of research results by an accredited laboratory.

Where people are asked to consent to the collection of their genetic material or data for research, they should be advised:

- That, by its nature, genetic material is in principle identifiable, even if personal identifiers are not collected or are removed
- That they are free to decline participation without giving reasons
- About arrangements to ensure the privacy and confidentiality of their genetic data with regard to both family members and others

- Whether the research may reveal information of potential importance to their future health, or the future health of their blood relatives
- That a genetic test may reveal unexpected relationships, such as non-paternity (i.e. a different biological father); and
- That, if it is proposed to approach blood relatives, consent to do so will first be sought from the participant.

Identifiers of genetic material or related data:

- Should not be removed without the consent of participants, if removal would make it difficult to communicate personal results; and
- Should be removed if participants request it, provided they have been informed that the material or data would remain potentially identifiable
- Researchers should not transfer genetic material or related data to any researcher not engaged in the research project unless:
  - ◊ where the material or data is identifiable, participants have been informed about the transfer and have explicitly consented to it; or
  - ◊ a REC has judged that the conditions for transfer have been met (for more information on consent and controlling access to data see Section 9).

6.2 Epidemiological research

A REC may waive the requirement for consent if the expected benefit of the research is real and substantial. Such waivers may also be approved when the existence of a signed consent form would be an unjustified threat to the subject's confidentiality.

Categories of epidemiological research for which consent might be waived include:

- The use of anonymous material/data
- Studies using health-related registries that are authorised for such use; and

- Cluster randomised trials (i.e. where groups are randomised as opposed to individuals). For example, villages, hospitals, families or classrooms may be randomised. Reasons for performing cluster randomised trials vary. Sometimes the intervention can only be administered to a group, for example an addition to the water supply (fluoride) or a public education campaign.

6.3 Covert research

Covert research cannot, by definition, involve obtaining consent in advance because informing potential participants would render the research overt and may change its outcome e.g. observation of teenagers' drinking habits. A distinction should be made between covert research and deception. Covert research refers to studies undertaken without the knowledge of the research subjects e.g. where a researcher observes the routine actions of others. Deception, on the other hand, refers to situations where the researcher deliberately misrepresents his/her intentions to the research participants.

There is consensus that covert research should not be undertaken routinely, rather it should occur only where it can provide a unique form of evidence that cannot be gathered in any other way or where important issues of sociological significance are being addressed. While serious ethical and legal issues arise in relation to covert research, the use of covert methods may be justified in certain circumstances. For example, difficulties arise when research participants change their behaviour because they know they are being observed.

Where consent has not been obtained prior to the research it should, where possible, be obtained at a later time. In cases where participants who are asked to give retrospective consent express concerns about their inclusion in a project, the researcher should give them the option of removing their data from the study.

For research where identifiable data (e.g. images, video recordings) is being collected, then the consent of prospective research participants must be sought.

6.4 Research in public health emergencies

The requirement for consent might be waived in public health emergencies, where a health threat and possible treatments/alleviations must be identified as quickly as possible. For instance, a waiver may be permissible, where a delay caused by the time needed to obtain consent from a person suffering from a new strain of pandemic influenza or other biological, chemical, radiological or nuclear agent, might not only jeopardise his/her health but also the health of others within the population.

6.5 Multi-jurisdictional research

When multi-jurisdiction research is being undertaken, additional ethical considerations might arise. While researchers should be cognisant of the local research ethics requirements, they should comply with this policy and act in accordance with Irish legislation.

When multi-jurisdictional research is to be conducted, local cultural values should be acknowledged in the design and conduct of the research. Irrespective of cultural traditions, consent must always be given by the prospective research participant. In certain cases it may be appropriate to seek the agreement of a person(s) invested with a certain authority within the community.

Researchers must do their utmost to communicate information accurately and in a comprehensible and appropriate way. Where formal written consent from the participant is not possible, the following should be observed:

- a community representative trained by the research team should be made available; and
- the oral approval should be witnessed by the trained and independent community representative. S/he will verify that the purpose of the research has been explained to the participant and that that the consent was freely given.

Researchers should be mindful that in some countries, participating in research may be the only way that individuals can access healthcare and they must ensure that this circumstance does not act as an undue inducement to research participation.

6.6 Research involving archival material

Researchers may want to use biological material or data that was previously accumulated for clinical purposes or that was collected by other researchers. This raises privacy issues, such as whether the archival material or data contains personal identifiers, or whether it can be linked to such identifiers and, if so, by whom. If consent was required for the original collection or use of the archival material or data then secondary uses may be constrained by the conditions specified in the initial consent. Consequently, it is essential that the consent process anticipate, where feasible, any foreseeable plans for future research using the material or data.

There are, however, certain circumstances under which archival biological material or data may be used for research purposes where consent is not required. For instance, where archival biological material or data was obtained from persons for research or clinical purposes, where the material or data is not individually identifiable (i.e. anonymous), and where there are no potential harms to the person from whom the material or data was obtained, consent requirements may be waived.

Where existing material or data is individually identifiable, researchers should make every reasonable effort to obtain consent from individuals for the use of their archival biological material or data. A REC may waive the consent requirement subject to conditions outlined below.

Researchers who have not obtained consent from participants for secondary use of their archival material or data should only use such material or data if they can satisfy a REC that:

- The use of the material/data without the participants' consent is unlikely to adversely affect the welfare of individuals involved
- The researchers will take appropriate measures to protect the privacy of individuals, and to safeguard the material/data
- The researchers will comply with any known preferences previously expressed by individuals about any use of their material/data
- It is impossible or impracticable to seek consent from individuals to whom the material/data relates; and

It is important to note that the word "impracticable" refers to excessive difficulty or onerousness that jeopardises the conduct of the research as opposed to inconvenience.

As a condition of access, archival biological material or data should be de-identified by the data controller (for more information see Section 9 Consent and controlling access to data).

6.7 Research involving deceased people

Human biological material obtained during the course of a post-mortem examination can prove extremely valuable for research purposes. An individual may provide prior consent for the use of his/her biological material for research that will be carried out after his/her death. However, this scenario is uncommon, therefore, the consent form furnished to the next-of-kin prior to a post-mortem examination should include a section which allows relatives of the deceased to give or refuse consent for the use of any retained tissue and/or organs for research purposes.

A designated person with training in bereavement should be made available to speak to relatives and explain the procedures involved in an understandable and sympathetic manner. Families must be assured that their decision will be respected.

7. Consent for future uses

It is important that consent documentation allows prospective participants to make a decision whether or not to allow their material or data to be used in the future. In order for such decisions to be as fully informed as possible, prospective research participants should be presented with a multiple choice or layered consent form. Layering the consent form allows individuals to select from a graduated set of consent options with respect to the storage and future use of their material or data.

A Layered consent form might include options such as:

- Permission for material/data to be stored for possible future research *related* to the current study *only* if consent is obtained at the time of the future research
- Permission for material/data to be stored for possible future research *related* to the current study *without* further consent being required

- Permission for material/data to be stored for possible future research *unrelated* to the current study *only* if consent is obtained at the time of the future research; or
- Permission for material/data to be stored for possible future research *unrelated* to the current study *without* further consent being required.

Where prospective research participants are to be recruited in a clinical setting, a clear distinction should be made between consent for any clinical procedures or tests and consent to research participation. In practice, this means separate discussions should take place and separate consent documentation should be provided.

Research participants should be informed of the extent to which confidentiality will reasonably be maintained during future research. If prospective research participants refuse to consent to the biobanking or future use of their material or data, then the material or data should be destroyed on completion of the planned research project.

In order to protect the interests of research participants whose material or data might be stored, institutions and researchers that maintain biobanks must:

- ensure that they have or use appropriate facilities, equipment, policies and procedures to store human biological materials safely and securely; and
- establish appropriate physical, administrative and technical safeguards to protect human biological materials and any information about participants from unauthorised access.

Biobank custodians have an obligation to respect an individual's expressed preferences. Where an individual does not want biological materials used for future research, custodians should remove these biological materials and/or data from any collections used or made available for research.

Research participants whose biological material is (or is intended to be) stored in a biobank must be informed of their right to withdraw their material and/or data without any negative repercussions. It is recommended that researchers offer prospective research participants a set of graded options for withdrawal, such as, no further contact from researchers or complete withdrawal.

- **No further contact**: participants would no longer be contacted by the researchers or data controllers but their previously provided biological material/data would still be available for use in the current research and/or future research.

- **Limited further use:** participants' biological material would be destroyed but the previously collected data derived from that material would be available for further use in the current research and/or future research. Participants might also be given the option to identify the types of research they would or would not want their material/data to be used for.
- **No further use:** all biological material/data previously collected could no longer be used by researchers but would instead be destroyed.

Whatever option is selected by an individual should be adhered to. It is important to note that the subsequent use of biological material or data collected for a specified purpose may not proceed without first receiving REC approval.

In the case of longitudinal studies, children who are recruited as research participants should be asked for consent to their continued participation in research on reaching the age of maturity (i.e. 18 years). (For more information on Reconsent see Section 11).

8. Consent and incidental findings

The term "incidental findings" refers to the unanticipated discoveries made in the course of research but that are outside the scope of the research. Medically relevant incidental findings are findings that have been interpreted as having significant implications for the participant, whether health-related, psychological or social.

As part of the consent process, prospective research participants should be provided with the option of whether or not they wish to have medically relevant incidental findings disclosed to them. Should prospective participants indicate a desire not to be given medically relevant information, then this decision should be documented and respected.

When medically relevant incidental findings are likely, researchers should develop a plan indicating how they will disclose such findings to participants and submit this plan for REC review.

The plan should identify the circumstances under which research results would warrant disclosure, a strategy for managing such disclosure, and include arrangements for appropriate medical advice or referral when disclosure is made. Disclosure of research results should be done in a sensitive manner with the consent of the participant. Incidental findings and/or research results (especially in the case of genetic research) should be confirmed by an accredited laboratory.

In cases where incidental findings are regarded to be of vital and immediate clinical significance (e.g. tumours, blood clots, aneurysms), the researcher involved has a duty of care to that individual. Prospective research participants must be advised that such a duty of care exists during the consent process.

Researchers should be especially aware of their obligations to protect the confidentiality of research participants when releasing data to third parties. For instance, in the case of genetic research, family members may need to be informed of potential genetic risks. Similarly, data may be of interest to other researchers or biobanks.

Provided that consent is in place, transfer of identifiable data to such third parties is permissible and provided a comparable level of security and protection of privacy can be ensured. (For more information on Consent and controlling access to data see Section 9).

The Disability Act 2005 (Part 4) provides that insurers cannot request, take into account or process the results of genetic tests (for a more in-depth discussion of genetic research see Section 6.1).

Certain types of information may be made available to public health officials for important purposes, for example, the reporting of infectious diseases, without the explicit consent of the individual.

9. Consent and controlling access to data

Research participants who have given appropriate consent have a right to expect that identifiable data about themselves, either provided or discovered in the course of research, will not be shared with others without their consent.

Anonymous data is beyond the scope of the Data Protection Acts, therefore, consent is not required in order to conduct research using this form of data. However, use of anonymous data is not always possible, or indeed desirable, in a research context.

De-identifying data (i.e. where identifiable information is substituted with a code to which only the data controller would have the key) is another way of protecting confidentiality. In order to safeguard a research participant's rights to privacy, data should be de-identified by the data controller as early as possible. In the case of HSE-run facilities, the HSE is the data controller.

In cases where research is to be undertaken by external third parties (e.g. researchers who are not directly involved in the care of the prospective research participants), where identifiable information will be used then the explicit consent of the prospective research participants must be obtained.

In cases where research is to be undertaken by external third parties and the data has been de-identified, prior to being transferred, the consent of the research participant for such a transfer is not required.

10. Withdrawal of consent

Prospective research participants must be informed from the outset that they can withdraw from a study at any time, that they need not offer any explanation for wishing to withdraw and that their decision will not impact on the services being provided to them.

Where an individual wishes to have his/her biological material or data withdrawn from a study, every effort should be made to respect his/her wishes. However, it is recognised that this might not always be feasible e.g. once the research results have been published or disseminated in other ways, such as by being deposited in a publicly accessible database.

Therefore, consent documentation should clearly indicate what circumstances would prohibit the withdrawal of biological material or personal data.

In the case of anonymous biological material/data, prospective research participants should be informed during the consent process that it will not be possible to withdraw their material and/ or data.

11. Reconsent

The consent process should consist of a continued exchange of information for the duration of a study. When substantial changes occur in the conditions or the procedures of a study, researchers should once again seek the consent of the participants. It is imperative that research participants be informed when there is new information that might affect their willingness to continue participation. There are a number of reasons why reconsent may be required which include but are not limited to cases where:

- the research protocol has been substantially altered;
- new safety information has come to light;
- alternative treatments have become available;
- a child participant reaches legal maturity (i.e. 18 years or 16 years in the case of clinical trials);
- a formerly incapacitated adult has regained capacity; or
- a substantial period of time has elapsed since the original consent was obtained (e.g. longitudinal study).

A strategy for reconsenting participants should be presented to the REC responsible for reviewing and approving the study.

12. Research where consent may not be required

As noted above, certain types of research may not require the consent of the research participant by virtue of a legal basis (e.g. research in public health emergencies) or because a REC has waived the requirement for consent (e.g. population based research). It should be noted that in the latter case, the waiver applies only to de-identified material/data.

Waiver of consent is to be regarded as an exception to the rule and studies seeking waiver of consent must receive REC approval. Before a waiver of consent may be granted the researcher must satisfy the REC that:

- the overall benefit to research is real and substantial
- the benefits from the research justify any risks of harm associated with not seeking consent;
- it is impracticable to obtain consent (for example, due to the quantity, age or accessibility of records);
- there is no known or likely reason for thinking that participants would not have consented if they had been asked;
- there is sufficient protection of their privacy; and
- there is an adequate plan to protect the confidentiality of data.

It is important to note that the word "impracticable" refers to excessive difficulty or onerousness that jeopardises the conduct of the research as opposed to inconvenience.

13. Remuneration of research participants

13.1 Reimbursement

Research participants may be reimbursed for lost earnings, travel costs and other expenses incurred. Another acceptable form of reimbursement might be the provision of free medical services. Compensation for the time and inconvenience involved in research participation (e.g. payment at minimum wage levels) might also be permissible as research participants should not be expected to bear the costs that relate to taking part in a study. However, it is important to note that compensation is understood to mean a recompense for losses sustained e.g. time away from work.

Any reimbursements or compensation that might be offered to prospective participants should first be approved by a REC in order to ensure that they are reasonable and do not reflect any undue inducement by encouraging people to act against their better judgment or take unnecessary risks.

13.2 Payment

There may be instances where research participants will be paid for any inconvenience and time given to the study. Payment may be financial (not limited to reimbursement, compensation or nominal levels) or non-financial e.g. entry into prize draws, gift vouchers, book tokens. Payment that is disproportionate to the time involved or is likely to encourage participants to take risks, is ethically unacceptable. The timing of payments must be such that they do not constitute undue inducement.

Where researchers wish to offer payment to prospective research participants, they must justify to a REC their reasons as well as the amount/reward being offered. Payments or rewards that undermine a person's ability to exercise free choice would be deemed to invalidate his/her consent.

14. Audit

In general, audit does not require informed consent. If audit is to be conducted by those involved in the care of the individual or their support staff (e.g. clinical audit staff) then explicit consent is not required provided that the individual:

- has access to information outlining the possibility that their personal data may be disclosed for local clinical audit; and
- has been given an opportunity to opt out.

Where clinical audit is to be conducted by an external third party, then the data must be de-identified (therefore no consent would be required). In cases where identifiable data is necessary for clinical audit purposes, the data may only be disclosed to third parties with the explicit consent of the individuals concerned.

Part Three—Research

There are a number of key differences between audit and research:

	Research	Audit
Purpose	To provide new knowledge e.g. to set or change clinical standards.	To measure practice against evidence-based standards.
Methodology	Addresses clearly defined questions/hypotheses using systematic and rigorous processes. Designed so that it can be replicated and results can be generalised to other groups.	Addresses clearly defined audit questions using a robust methodology, usually asking whether a specific standard has been met. Results are specific and local.
Data Analysis	Requires data analysis (i.e. quantitative/ qualitative) to make inferences.	Simple statistics (e.g. means, frequencies) to compare audit cycles.
Ethical Approval	Required.	May not be required.
New Treatments	May involve a completely new treatment or practice.	Will never involve a completely new treatment or practice.
Randomisation	May involve allocating individuals randomly to different treatment groups.	Will never involve allocating individuals randomly to different treatment groups.
Sample Size	Statistically powered calculation.	Sufficient number of cases to influence practice based on findings.
Outcome	Improved knowledge.	Strategies in place to improve clinical practice.