



UNIVERSITY OF  
**STIRLING**

# **Code of Good Research Practice**

## **Chapter 6: Research Involving Human Participants**

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# RESEARCH INVOLVING HUMAN PARTICIPANTS

The University supports research in a broad range of subject areas. Research may, from time to time, require the involvement of human participants and this may generate ethical issues which are complex and multi-fold. Human participants are an essential part of research activities carried at the University and it is, by no means, restricted to medical and healthcare-related disciplines. Research in the Arts and Humanities often necessitate an input from human participants in the context of surveys or interviews. It is essential that research projects, at the proposal development stage address ethical issues which may arise during and from the research, in particular when vulnerable groups of individuals (e.g.: children or incompetent adults) are involved. This is not only a legal requirement but also a moral one on which the success of the University's research is reliant.

Issues include, but are not limited to:

- The conduct of surveys and interviews;
- Informing subjects appropriately of the study aims and the risks which they face, if taking part in the study;
- Taking informed consent seriously
- Respecting the safety, dignity, beliefs and privacy of participants;
- Taking into consideration the involvement of kin, families, relations and carers of participants;
- Confidentiality; data handling and storage.

## ***Ethical Considerations***

### **Ethics review and Approval**

"Local" ethical review of research involving human participants is required to fulfil the University ethical committee process which ensures that all research carried out at the University is scientifically sound and ethical but also to comply with the funders' requirements. For example, it is a standard condition required by Research Councils and most funders to have in place an ethics review process in institutions hosting research. All research staff and postgraduate research students must familiarise themselves with their departmental research ethics procedures and are encourage to contribute by bringing matters to the attention of their research ethics committee. No research must be commenced prior to appropriate ethics approval.

## **University Ethical Approval**

Research proposals should be submitted to the Departmental Research Ethics Committee (DREC) for approval before the research can start. DRECs report to the University Research Ethics Committee and can refer specific research projects for consideration if this is deemed necessary, for example in the case of contentious issues.

## ***Considerations and requirements in research involving human participants***

It is essential that researchers consider the dignity, rights, safety and well being of participants as their primary concern in any research projects. For the sake of clarity, information below refers to the requirements of the main funders of research hosted by the University. Reference to other societies and charities can be found in Annex 2. The Policy and Graduate Team is happy to respond to queries and to provide information on funders' ethical requirements. Obligations towards study participants are based on the same principles regardless of the research area:

- Non-maleficence,
- Beneficence,
- Justice and,
- Autonomy.

## **Economic and Social Research Council**

The ESRC is one of the University of Stirling's main Research Council funding streams, and therefore compliance with their ethics requirements is crucial to the University's research activities and eligibility for Research Councils' funding.

The ESRC ethics definition is: *"Ethics are about respecting and protecting rights and dignity of people, moral principles of right or wrong but they are not absolute and may vary by person, by time and by place and principles may conflicts with each other. Research can be defined as a disciplined enquiry that aims to contribute to a body of knowledge or theory. Hence, research ethics are about incorporating ethical principles into research. They may involve a balance between and within principles and practices and at all stages, includes all those involved from inception of research through to completion and publications of research and beyond."*

To support the implementation of the ESRC's ethical principles for Social Research, the Research Ethics Framework was published in 2005 [\[Link to ESRC REF\]](#). The reasons for launching such a detailed document were:

- A change in the policy (and political) context which has seen the development of governance and ethics review (e.g.: Department of Health and the Cabinet Office),
- Development of new procedures for NHS ethics,
- Changes in public attitudes and expectations notably for openness and accountability,
- Changes in social science research methods,
- Changes in the social context (e.g. globalisation) and increase in multidisciplinary and collaborative work and,
- Need for ethical approach appropriate to social science.

What are the implications for social science research ethics review?

- Social science research encompasses a variety of different disciplines often linked to applied areas,
- There is a large number of diverse research methods which must be taken into account,
- The work generated by social science research may have a strong impact on society as it may be relevant to policy and,
- It may involve human participants including vulnerable groups.

ESRC's main ethical principles are:

- Research should be designed, reviewed and undertaken to ensure integrity and quality,
- Research staff and subjects must be informed fully about the purpose, methods and intended possible uses of the research, what their participation in the research entails and what risks if any, are involved,
- The confidentiality of the information supplied by research subjects and the anonymity of respondents must be respected,
- Research participants must participate in a voluntary way, free from coercion (unless covert research and deception has been deemed necessary),
- Harm to participants must be avoided and this extends to the family, kin or community groups of the participants and,
- The independence of the research must be clear; any conflict of interest or partiality must be explicit.

The ethical review must consider the risks to the rights and dignities of people. This is not restricted to physical harm and includes privacy, respect for personal values and beliefs, links with the wider community, the subject's occupation and social personal standing as well as implications of revealing illegal, sexual or deviant behaviour.

Breaches of good ethical practice in ESRC funded research will be treated as a very serious matter by the Council. Universities, the ESRC and the research community have a shared interest in good ethical practice. The ESRC wants to ensure that appropriate reviews take place during the project but does not want to know outcomes of the reviews. Appropriate reviews can be done by raising all the potential issues in high risk projects before the research starts or sending regular e-mails asking “have issues arisen since the last.....?”. This may also be done through the UK Research Integrity Office.

The Research Councils can, also, undertake dipstick testing and do conduct annual questionnaire surveys. Sanctions are a last resort and the ESRC’s position is that “*prevention is better than the cure*”. Iterative reviews should be carried out because research can develop in a way which may raise unforeseen ethical implications and in exceptional cases additional costs may be claimed.

Specialist issues for careful examination include, but are not limited to:

- Where risk of harm may be legitimate
- Informed consent
- Covert research
- Secondary use of data

## **NHS**

All research (including student projects) which involves engagement with NHS staff/patients/records and/or associated carers must be conducted in line with the NHS Research Governance Framework (RGF). The parameters of the framework, which seeks to safeguard the robustness of research and to protect the interests of all parties involved in a collaborative project, can be found at [\[Link to RGF\]](#). The framework puts a particular responsibility on each partner in a research project to vouch for the integrity of the conduct and management of their contribution to the research activity. In particular, the framework requires that all projects have a “Research Sponsor”. The “research sponsor” plays a critical role in assuring the quality of the research and its responsibilities are far-reaching. It is different from those of a funder. A detailed list of these responsibilities is set out in the framework.

Ethical review of research is a devolved matter within the UK. Policy responsibility for research ethics systems in each part of the UK is as follows:

- England Department of Health (Research & Development Directorate)
- Northern Ireland Department of Health, Social Services and Public Safety (Research & Development Office)
- Scottish Government (Chief Scientist Office)

- Wales National Assembly for Wales (Welsh Office for Research and Development)

**Both NHS ethics and R&D approvals ARE REQUIRED before the study can start.** These processes should be carried out in parallel to avoid any delay. A significant element of the RGF is the requirement for prior ethical approval, under the procedures established by the National Research Ethics Service (NRES) or, at local level, Local Research Ethics Committee (LREC). R&D management approval is done to ensure that the NHS organisations involved in the study have the capacity and the infrastructure to allow the study to be done. It will also check the costs incurred by the NHS (staff time, rooms and equipment) are covered by the proposal (and the proposed funding stream).

NRES was launched on 1 April 2007 superseding COREC. NRES will continue to work with colleagues in Scotland, Wales and Northern Ireland to maintain the established UK-wide framework for ethical review of research. This ethics approval process is independent from the R&D management approval. Applications for ethics approval are done through an online form. Advice is available from the academic department's designated Business Development Manager. Courses are also available (for example the Wellcome Trust Clinical Research Facility in Edinburgh runs regular sessions on how to fill ethics forms - Email: [WTCRF.education@ed.ac.uk](mailto:WTCRF.education@ed.ac.uk)).

Research proposals are submitted to a central ethics service. In order to avoid delay and having to wait for the Local Research Ethics Committee to meet (which happens on a monthly basis), the proposal can be sent to a possible 3 LRECs. For the University of Stirling, this can be Forth Valley, Tayside or Perth. For a multi-site study, the proposal will be referred to an MREC. Once agreement on the research proposal is reached between the Department and R&D, allow at least 60 days for Ethical Approval (See diagram below). Provisional approval may be granted pending minor changes to the proposal. A flow chart covering NHS Forth valley procedures for R&D and ethics approval is provided below.

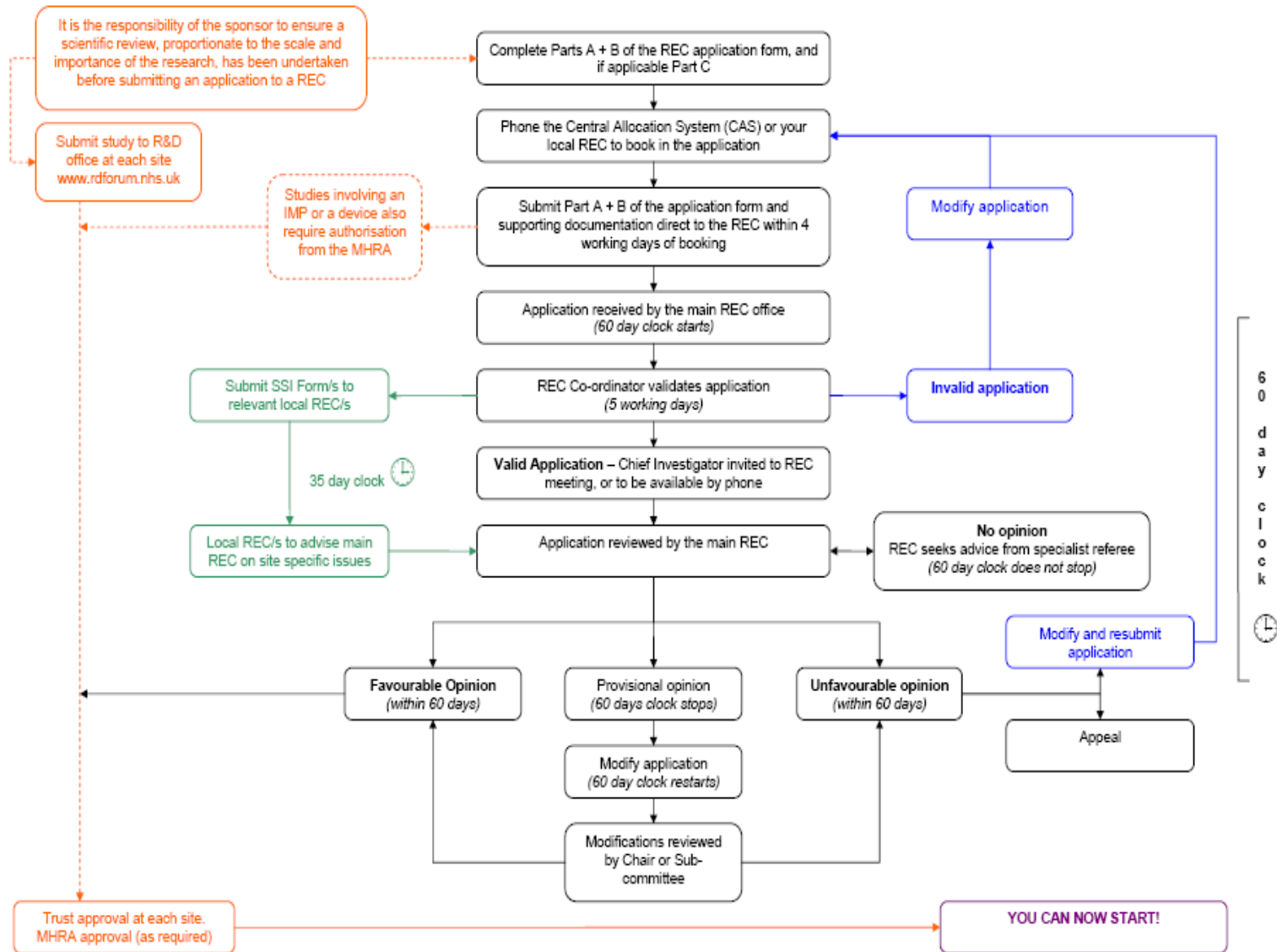
Research Ethics Committees (RECs) are convened to provide independent advice on the extent to which proposals for research comply with ethical standards. The purpose of a REC in reviewing the proposed study is to protect the dignity, rights, safety and well being of all actual or potential research subjects.

NRES ethical approval is required for any research proposal involving:

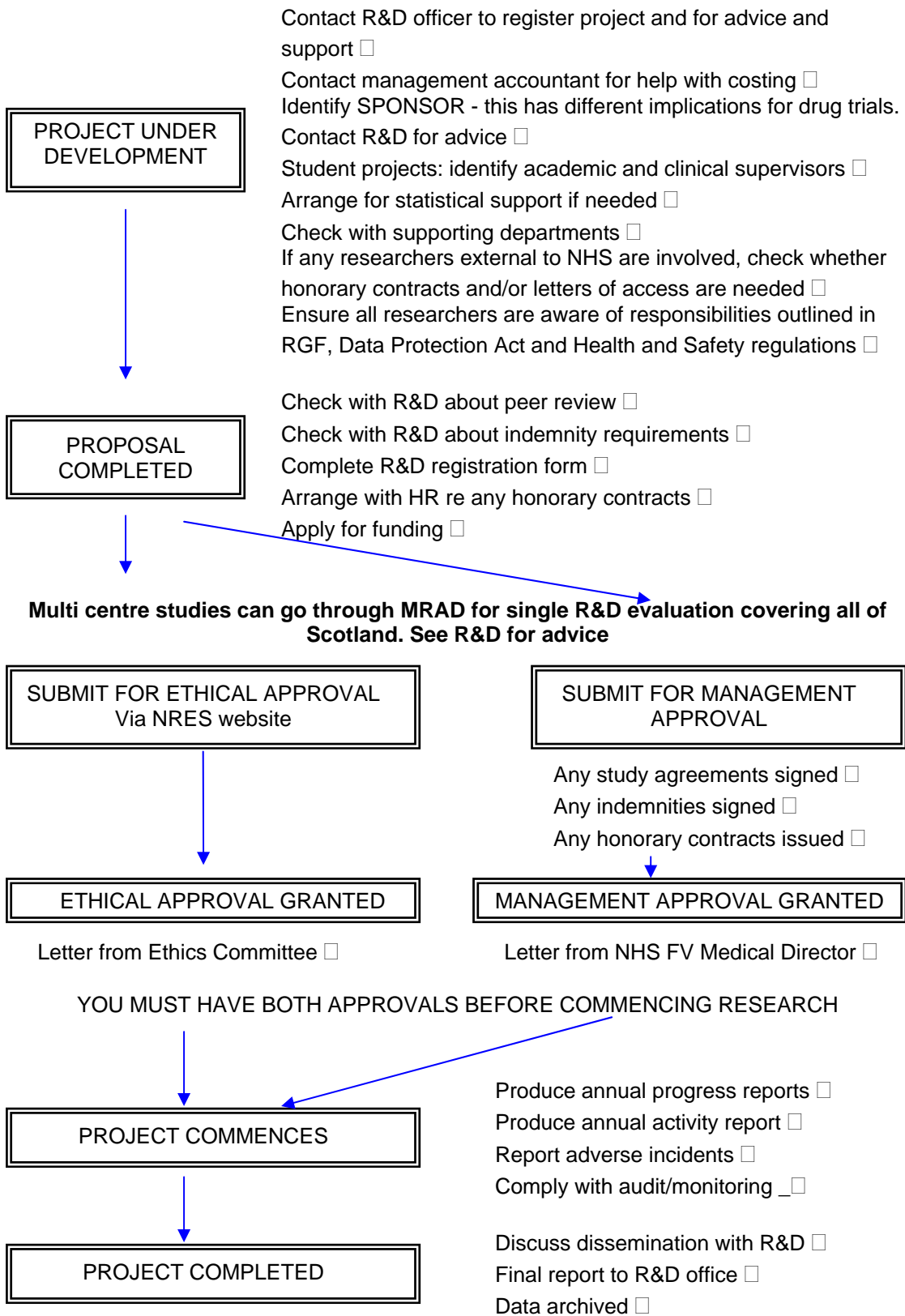
- patients and users of the NHS, including all potential research participants recruited through the NHS or because they are receiving NHS treatment. It also includes NHS patients treated within private health organisations,

- individuals identified as potential research participants because of their status as relatives or carers of patients and users of the NHS,
- access to data, organs or other bodily material of past/present NHS patients,
- foetal material and IVF involving NHS patients,
- the recently deceased in NHS premises,
- the use of, or potential access to, NHS premises or facilities,
- NHS staff recruited as research participants in their NHS staff capacity.

## QUICK GUIDE FOR APPLICANTS



**NHS FORTH VALLEY**  
**RESEARCH MANAGEMENT FLOWCHART AND CHECKLIST**  
 Tick each appropriate instruction when completed



Unfortunately, what often happens is that investigators submit their ethics application and the R&D officers are notified of the study when the letter of ethics approval reaches them. This creates delays in the R&D approval as it is often the first time that the R&D officers have heard of the study. **It is therefore essential to contact the R&D office early on in the process, at pre-proposal stage, if possible.**

### ***Conducting a research study involving human participants***

Researchers are advised to consult documents, on which this section is based, from professional societies (such as the Social Research Association) for detailed information on research involving human participants in their discipline. Links to these can be found in **Error! Reference source not found..**

### **Informed consent and right to withdraw**

Participants in research studies should have confidence in the investigators. The quality of the data collected will, in many cases, be dependent upon mutual respect and confidence between the research team and the study participants. It is, therefore, essential from the onset of the research project that participants take part in a voluntary way, free of coercion. Researchers must inform subjects of their right to refuse to participate or to withdraw from the study at any stage and for whatever reason.

The investigators should inform all participants of the objectives of the study as well as all aspects of the research which may have an influence on their willingness to participate. Study participants should also receive details on methodologies to be used and the impact of using these for the subjects. All information given to participants must be clearly written in lay terms so that all participants can understand it. Informed consent should not be regarded solely as an administrative process. It is an essential part of research studies and is a matter of good practice. Informed consent forms must go through the ethical review process to ensure their suitability. Researchers should submit the rationale for gaining consent and explain how “informed” their subjects can be considered to be.

One extreme would be to overwhelm participants with overly technical or incomprehensible information about the origin, content and methods of the study. At the other extreme, however, it is inappropriate to withhold relevant information from study participants or to mislead subjects about matters related to the investigation.

In cases of multi-disciplinary or international research work, the definition of informed consent should be carefully evaluated. It will depend on diverse methodologies and cultural backgrounds.

In observational research projects, the privacy and well-being of individuals must be respected and retrospective consent should be sought wherever practical. The US Office for Protection from Research Risks accepts observational research to be exempt from consent unless:

Information is recorded in a way which allows identification of the subjects, directly or indirectly

Disclosure or publication of the participants' responses may place them at risk of criminal/civil liability or be damaging to their reputation.

The Social Research Association recommends that covert observation and any forms of research which use deception are used only when there is no other ethically sound way of collecting accurate and appropriate data. In studies where individuals are aware of their participation, the investigator should provide the participants with any necessary information to complete their understanding of the nature of the research, by providing a debriefing at the end of the study. After participants have taken part in a study or after debriefing (for instance, in observational studies), participants have the right to withdraw retrospectively any consent given and to request that data relating to them is destroyed. Long-term studies or research which involves repeat visits may require informed consent to be obtained on several occasions.

### **Protection of participants and avoidance of harm**

Research involving human subjects is based on the principle that it should be conducted in such a way that minimises harm or risk. Researchers have the primary responsibility to protect participants from lasting and prolonged harm. Researchers should be aware of the intrusive potential of their work. The advancement of knowledge is not a sufficient justification for overriding social and cultural values. Great care must be taken in planning the research so that the participants' well being, dignity, privacy, beliefs and cultural values are respected.

Normally, the risk of harm should not be greater than that expected in everyday life. There may be exceptional circumstances, in some research disciplines when, with the informed consent of the participants, some short-term and minimal degree of harm or discomfort may be acceptable. Special provisions, such as obtaining the disinterested approval of independent advisors, should be applied. Participants must be assured that they will suffer no lasting effects or prolonged personal discomfort.

Researchers should also strive to avoid harm not only to an immediate population of subjects but also to their wider family, kin and community. This also applies to the respondents' organisations or businesses which should not suffer detrimental consequences due to participation in research studies. While it is often difficult to get

the right balance between potential risks and effects, researchers are required to attempt to anticipate the likely effects of their research and to explain these to the research participants.

For research involving vulnerable groups such as children, great caution should be exercised at all stages of the research study

### **Anonymity and confidentiality**

Anonymity and confidentiality of data pertaining to human participants are requirements of the current legislation including the Data Protection Act. Information obtained about a participant during a research study is confidential and should remain confidential, unless participants have consented to their disclosure. Participants have the right to expect that information they provide will be treated as such and, if published, will not be identifiable as theirs. Systems must also be in place for storage and access to the data.

Researchers are advised to have plans and systems in place in the eventuality that they are made privy to information of criminal or illegal nature. The risk of being made aware of such information should be considered during the design of questionnaire and interview process. Confidentiality issues (and level of disclosure) must also be considered if third party involvement is sought, for example if researchers are using the services of translators, readers or sign language specialists.

### **Vulnerable participants**

A major limitation upon gaining informed consent lies with “vulnerable” populations. In cases where the research involves vulnerable groups such as children, older persons or adults with learning difficulties, every effort should be made to secure their informed consent. It may not always be possible to do so because they are not considered competent to give legal consent directly and obtaining consent may have to be done through “proxies”. However, persons with dementia or learning disabilities, for example, keep a capacity for decision-making (better thought as making choices) after the legal “threshold” has been crossed and demonstrate wide ranging variations in capacity which can be extremely situational and temporal. In addition, they keep and even build on sensory and experientially-based capacity as well as communicate through behaviours, verbal and other non-verbal means their preferences and choice-making. This does not mean that vulnerable group should not be included in research studies since research in these areas aims at improving

the life of those individuals. However, special provisions will need to be applied and the potential risk to the subjects must be regarded of the utmost importance.

For moral reasons, persons living with dementia and learning disabilities need to be included and enabled to participate in consent (and subsequent research) even when they “lack” legal capacity. Including those individuals in the process of consent is consistent with the core principles of the capacity legislation. Informed consent needs to be considered at all stage of a research project for those living with progressive or advancing loss of capacity to consent and more creative/dementia-sensitive ways of enabling inclusion to happen must be devised.

#### The Capacity legislation – principles and safeguards

<i>Principles</i>	<i>Safeguards regarding research</i>
Assumption that capacity to consent exists	Consultation with others
Support for making decisions	Honouring signs of unwillingness to participate
Respecting values and beliefs underpinning decisions	Honouring advance directives and known statements
Best interests	Approved documentation
Least restriction on human rights and freedom	Direct benefit and no harm or distress
	Taking into account loss of capacity during existing research

Researchers are required to familiarise themselves with the Adults with Incapacity (Scotland) Act 2000 and comply to the legal requirements set out in the document [\[Link to Adults with Incapacity \(Scotland\) Act 2000\]](#).

Similarly, the justification of research involving prisoners is based on the fact that results yielded cannot be obtained by research in the community; benefit for prisoners is highly probable and the risks are low; and access of prisoner patients would benefit Phase III trials and prisoner participants.

Proxies may include, for example, parents, carers, social workers or medical professionals. If research involves children, the issue of informed consent should be done through a dialogue with both the children and their parents (or carer). Researchers should not devolve to the proxies their responsibility to protect the participants from harm. It is also important to respect the relationship between the participant and the person giving informed consent on their behalf.

If research participants are identified through a third party, for example for individuals in prison facilities, authorisation to carry out the study must not be considered as a substitute for informed consent. This must be sought from potential participants. Useful and authoritative information can be found on the website of the Prison Health Research Network [\[Link to Prison Health Research Network\]](#), in particular in the Researcher’s handbook (see Annex 2).

Vulnerable groups, may be defined as those who are in a dependent relationship to the researcher or funding body, for example students, junior researchers or detained individuals (in prisons or psychiatric institutions) may find it difficult to refuse participation in research study as it may be perceived as a potential threat to their studies, employment or well-being. This relationship must not be allowed to pressurise the participants to take part or remain in a study.

## **Incentives**

Incentives can be provided to compensate research subjects for their time and inconvenience. However, financial rewards should not be used to induce participants to risk harm beyond what they would normally expect during the course of their day-to-day life. Incentives in the form of access to social or medical services, in particular in deprived areas, should be avoided.

An agreement to participate in research constitutes a valid consent only if voluntarily given. This element of informed consent requires conditions free of coercion and undue influence. This may be compromised when incentives offered to research participants are in excess of the level of compensation expected. Indeed, excessive monetary incentives may induce a “corruption of judgment”. Grant and Sugarman, (2004) *“have argued that incentives become problematic when conjoined with the following factors, singly or in combination with one another. Where the subject is in a dependency relationship with the researcher, where the risks are particularly high, where the research is degrading, where the participant will only consent if the incentive is relatively large because the participant’s aversion to the study is strong, and where the aversion is a principled one—when these conditions are present, the use of incentives is highly questionable.”*

[\[Link to publication\]](#)

### *Incentives in research with children as participants*

Incentives to participate in a research project must be fair and must not unduly exceed the range of incentives that the child normally experiences. *“Whatever incentives are used, the investigator should always keep in mind that the greater the possible effects of the investigation on the child, the greater is the obligation to protect the child's welfare and freedom”*, From the Society for Research in Child Development [\[Link to SRCD\]](#).

### *Incentives in research conducted abroad*

For research taking place in geographical areas of with a relative low level of income or healthcare provision, financial compensation is important as there are often no

sick leave or unemployment benefits. However, it can be difficult to determine what is reasonable not to induce participants in taking part in the study. In some cases, participation in the trial itself can be considered an inducement since basic medical/social care may be very limited. Additionally, researchers must take care not to undermine what is available locally, in particular if they are testing a new medication or a new service which is claimed to be more “better” than what is currently used.