Human Research Ethics Committee

Some Background on Human Research Ethics

HREC Document No: 2

Approved by the UCD Research Ethics Committee on February 28th 2008
Research Involving Human Subjects

Research is defined as a systematic inquiry which may include testing, evaluation and research development, and is designed to develop or contribute to generalisable knowledge.

A human subject is a living person about whom a researcher gains information via intervention or interaction with individuals or through the use of identifiable personal information. In general, human subject research refers to any research that involves people, human tissue, surveys of human subjects, or human subjects' records.

While cadavers are not conventionally defined as human subjects, their use in research comes within the remit of the Human Research Ethics Sub-Committee. Information derived from cadavers may result in the researcher obtaining information about the cadaver’s living relatives, as in genetic research. Investigations, such as genetic research, in which an investigator collects private, identifiable information about third parties would be defined as human subjects research.

Thus, a systematic investigation designed to develop or contribute to generalisable knowledge, and which involves interventions and/or interactions with living people and/or identifiable private information about living persons qualifies as human subjects research.
Historical Context

The modern codes of ethical principles pertaining to humans evolved from the response to unethical practices in the 20th century, particularly those occurring during World War II. In particular, the judgment of the Nuremberg military tribunal on war crimes established principles and standards regarding medical experiments and significantly influenced contemporary codes of ethics pertaining to responsibility and accountability. The Nuremberg Code, established in 1947 and adopted internationally in 1949, provides the basic principles of respect for the voluntary nature of human participation in research, true informed consent, and ethical responsibilities of the researcher to ensure human welfare. The first provision of the Nuremberg Code, states that “The voluntary consent of the human subject is absolutely essential”. The implications of voluntary consent are delineated, including the legal capacity to consent, freedom from constraint or coercion and adequate knowledge and comprehension of the research and its risks and benefits in order to make an enlightened decision. The Code stipulates that research should involve minimal risk and harm, that the benefits should outweigh the risks, that only researchers who are scientifically qualified should conduct research, and that subjects should be free to withdraw from the research at any time. Subsequent codes have incorporated these principles.

The World Medical Association’s 1964 Declaration of Helsinki made recommendations similar to those in the Nuremberg Code and established the International Code of Medical Ethics. The Declaration of Helsinki emphasizes that the needs of research are secondary to the care and well-being of participants, and distinguishes between therapeutic and non-therapeutic research. In the post World War II human rights era, other international documents related to rights in general (human, social, cultural, civil, economic, political) and rights of specific groups (children, mentally disabled, physically disabled, etc.) were adopted. The contemporary international trend is to make ethical
standards pertaining to human research more explicit. In regard to research involving 
humans, it is important to maintain an ongoing review of standards for and systems of 
research.

More recently, these ethical principles have been reiterated in the Convention for 
the Protection of Human Rights and Dignity of the Human Being with regard to the 
Application of biology and Medicine: Convention on Human Rights and Biomedicine. The 
Convention states that the dignity and identity of all persons must be protected and that 
respect for the integrity, rights and fundamental freedoms of all people must be 
guaranteed, without discrimination. In addition, the interest of science or society is 
secondary to the interests and welfare of human beings and equitable access to 
appropriate healthcare must be made available to all people. All health interventions, 
including research, must be conducted in accordance to professional obligations and 
standards and may only be conducted where the individual has voluntarily provided 
informed consent.

Informed consent means that the individual has been given a detailed description of the 
purpose, nature, consequences and risks of the intervention and told that he or she has 
the right to withdraw his or her consent at any time. Protections are in place for persons 
who are not able to consent. Research involving persons who are not able to consent 
may only be conducted if the individual will benefit directly from the study. Informed 
consent must be obtained from a guardian or legal representative if the individual does 
not have the legal capacity to consent, as in the case of children under the age or 18 or 
the mental capacity to consent, for example, due to a mental disability or disease.

Persons with severe mental disorders may be subjected to an intervention aimed at 
treating his or her mental disorder, without his/her consent, only where serious harm to 
his or her health may occur without such treatment. In emergency situations in which 
appropriate consent cannot be obtained, medically necessary intervention may be
carried out for the benefit of the individual’s health. The previously expressed preferences of an individual will be taken into consideration in situations where a person is not able to state an opinion at the time of an intervention but has previously expressed his or her wishes. Individuals have a right to know any information collected about him or her but the wishes of those who do not want to be informed about his information should also be respected.

In regard to scientific research, the Convention states that research should be conducted freely, subject to the Convention and other legal provisions to ensure the protection of human participants. Research involving humans may only be conducted where the following conditions are met: a comparable, effective alternative does not exist; the risks of the research do not outweigh the benefits; a competent body has approved the scientific merit and ethical acceptability of the research; the research participants have been informed of their rights and legal safeguards for their protection; and voluntary, informed consent has been obtained and documented and the participant has been informed that he or she may withdraw his or her consent at any time.

The Convention states that research involving persons not able to provide consent to the research may be conducted if the research results have the potential to produce real and direct benefits to the individual’s health; it is not possible to conduct comparable, effective research on individuals who are able to provide consent; specific, authorized informed consent has been obtained from a legal representative in writing; and the individual concerned does not object. In exceptional circumstances, under protective legal conditions, where the research results will not directly benefit to the participant’s health, a study may be authorized if the research involves only minimal risk and burden to the participants’ and aims to benefit the participants’ or others in the same age group and/or affected by the same condition, disease or disorder by significantly improving the scientific understanding of a particular condition.
Other documents, that are relevant to researchers while not directly addressing research ethics, include the UN Convention on the Rights of the Child (1989). This *Convention* was ratified by the Irish Government in 1992. Many aspects of this document will be pertinent to researchers, however of particular importance is the right of the child to be consulted on issues that are relevant to their lives (Article 12). Many researchers in the area of childhood see this as placing an onus on researchers to support children’s participation in research. The recent UN Convention on the Rights of Persons with Disabilities (2006) may have additional implications for researchers.

**Basic Ethical Principles**

The essential prerequisite for ethical research is the integrity of the researcher. Integrity can be defined as being truthful and living up to professional standards, in practice it means that research is conducted according to established rules, regulations, guidelines, or professional codes, as in the *UCD Code of Good Practice in Research*. The researcher must only pursue research questions that are designed to contribute to knowledge, be committed to the pursuit and protection of truth, and rely only on research methods which are appropriate to the discipline and to the training and experience of the researcher.

The basic ethical principles of respect for persons, beneficence and justice, are clearly defined in *The Belmont Report*, published in the United States in April 1979, by the National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research.

*Respect for Persons*: Respect for persons means that individuals should be treated as autonomous agents and persons with diminished autonomy must be protected. Ethics require that decisions are respected and persons are protected from harm. Human dignity and individual rights must be treated with respect, and people should not be
used merely as a means to an end. In practice, respect for individuals is ensured by the informed consent process in which a discussion of the research project occurs between the researcher and potential participants. Subjects are provided with full and comprehensible information about the research and are given clear assurance that participation is voluntary. Agreement to participate is indicated by a signature on a consent form.

**Beneficence and Non-maleficence:** Beneficence and non-maleficence are concern for the protection and well-being of subjects, the researcher is obliged to ensure that the possible benefits to the participants will be maximized and possible harm minimized. Harm includes physical discomfort, psychological or emotional distress, and social and economic disadvantages. Researchers must assess the potential for risks and the possibility of benefits to the participants and be sensitive to their rights and interests. In addition, researchers should reflect on the social and cultural implications of their research. In the end, the benefits to the individual and the importance of the knowledge gained should outweigh the risks.

**Justice:** Researchers must examine the questions of justice and right, in terms of fairness in distribution of the research benefits and burdens. The selection process must be scrutinized to determine whether participants are selected in a fair and equitable manner, and for reasons directly related to the problem being investigated and not for reasons such as availability or manipulability. Particular concern must be exercised in regard to vulnerable or dependent subjects.

Researchers must only pursue research questions that are designed to contribute to knowledge, be committed to the pursuit and protection of truth, and rely only on research methods that are appropriate to the discipline.
**Competence:** Researchers must strive to ensure and maintain the highest standards of competence in their work. They should recognise the boundaries of their particular competence and the limitations of their expertise. In so doing, researchers should engage in only those research practices and techniques for which they are qualified by education, training or experience. Researchers must show ethical awareness, recognise the risk to subjects of exceeding the boundaries of their competence, and seek to terminate research activity when it is clear the activity is harmful. There is a duty on the researcher to maintain and develop competence by remaining up to date on relevant knowledge, research methods and techniques.

**Legal considerations**

Researchers should be aware that human rights are protected by the European Convention on Human Rights which has been bolstered in Irish domestic law by the European Convention on Human Rights Act, 2003.

Furthermore, under the Control of Clinical Trials Acts, 1987/90 certain types of clinical trials e.g. invasive or administering drugs or substances to human beings must be conducted in accordance with a statutory permission to undertake such a clinical trial. EU Directive 2001/20/EC deals with principles of good clinical practice and directs certain permissions should be obtained in relation to clinical trials involving medicinal products.

It is the sole responsibility of the researcher to apply and obtain any necessary permission for clinical trials. The researcher should note that application to the UCD Ethics Committee is an internal matter within the University and will not satisfy the Irish or European legislation should statutory consents also be necessary.
Neither the University, the Committee nor individual members of the Committee accept legal liability for any advice or assistance offered to the applicant or to any third party in the processing of the application or for the subsequent supervision or conduct of the research.