Human Research Ethics Committee

Further Exploration of the Process of Seeking Ethics Approval for Research

HREC Document No: 7

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

1. Criteria for Applying for Ethical Approval

All research involving human subjects requires ethical approval from the UCD HREC.

Although the UCD Human Research Ethics Sub Committees provides full ethical reviews of research protocols that involve human subjects, some categories of research must first be reviewed and approved by the appropriate local REC. For example, research involving recruitment of patients from a hospital must first be approved by the local hospital REC. Where such approval has been granted, UCD HREC approval may be obtained without the need for further full review (see point 1 *Applying for Ethical Approval* and point 2 *Criteria for Exemption from Ethical Review by UCD HREC*).

Subject to meeting certain criteria, other research protocols may obtain ethical approval from the UCD HREC without undergoing full review by the HREC.

1.1 Applying for Ethical Approval

Approval can be obtained either via

(a) Successful review of full research protocol by UCD Human Research Ethics Committee. This requires completion and submission of the *Human Subjects Ethical Approval Application Form* (HREC Doc 9).

(b) Grant of approval with exemption from full review by UCD HREC.
Ethical approval with exemption from review of full protocol may be granted where (1) all aspects of the protocol have received ethical approval from an approved body (e.g. Hospital REC) or (2) the research protocol meets the criteria for exemption from review as detailed below in 7.2.

In order to obtain a grant of approval with exemption from full review by UCD HREC, researchers must complete and submit the *Human Subjects Ethical Approval Exemption from Review Form.*

2. Criteria for Exemption from Ethical Review by UCD HREC

A research protocol is exempt from the need for full review by UCD HREC if all aspects of the research protocol have been reviewed and approved by a recognised REC. Where a study has been approved elsewhere, UCD HREC approval, with exemption from ethical review, will only be granted for those aspects of the study over which the REC granting the approval has full jurisdiction. If the reviewing REC(s) does not, or do not, have full jurisdiction over all aspects of the research, approval must be obtained from the relevant REC(s) for all other aspects of the protocol. This includes, but is not limited to, full review by UCD HREC for recruitment of UCD students.

There are six other categories of research in which a full review is **generally not** required by the HREC:

These six categories are: *standard educational practices*, *standard educational tests, anonymous surveys or interviews*, *public observations*, *research involving persons elected to or candidates for public office* and *research which uses only existing data which is publicly available*.

However, not all research in these categories is exempt from review; please refer to the relevant section below for further details. In general, a study that involves vulnerable groups, sensitive topics, or would expose participants to risk or harm to a degree that is greater than they would normally be exposed to is not exempt.

Standard Educational Practices:

Research conducted in established educational settings that involve normal educational practices (those occurring within an educational setting independent of the research), for example, studies of educational instructional strategies, the effectiveness of or comparison of instructional techniques, curriculum, or classroom management methods. However, research involving educational practices is **not exempt from review** if it involves:

a) the introduction of a new instructional technique, curriculum or classroom management method that is not currently in place in the educational setting.
b) school records in which students are identifiable or interviews of instructors about specific students.
c) Specific assessment of students to evaluate the educational practices for the purpose of the research project and which would not otherwise be carried out.

Standard Educational Tests:

The use of educational tests (cognitive, diagnostic, aptitude, or achievement), which occur within the educational setting independent of the research, if the

a) information is recorded in a way that subjects cannot be identified, directly or through identifiers linked to the subjects

b) information, if disclosed, could not reasonably put the participant at risk of liability (criminal or civil) or be damaging to his/her reputation, employability or financial standing.

It should be noted that research involving educational tests research is **not exempt from review** if it involves the introduction of an educational assessment that is not currently in place in the educational setting.

Anonymous Surveys or Interviews:

The use of surveys or interview procedures with adults, if

a) responses are recorded anonymously, in a way in which participants cannot be identified directly or through identifiers linked to the subject

b) information, if disclosed, could not reasonably put the participant at risk of liability (criminal or civil) or be damaging to his/her reputation, employability or financial standing.

However, research involving surveys or interview is **not exempt from review** if it involves:

a) sensitive aspects of the subject's own behaviour, such as drug or alcohol use, illegal conduct or sexual behaviour.

b) children or other vulnerable populations.

Public Observations:

Research involving the observation of public behaviour* when data is recorded in a way that people can not be identified:

a) if responses are recorded anonymously, in a way in which participants cannot be identified directly or through identifiers linked to the subject

b) where information, if disclosed, could not reasonably put the participant at risk of liability (criminal or civil) or be damaging to his/her reputation, employability or financial standing

c) where research involves children, the researcher is not participating in the activities being observed.

***Please note:** workplace meetings, workplace activities, classroom activities are not public behaviour.

Research Involving Persons Elected To or Candidates for Public Office: Research involving the use of observations, surveys, and/or interviews when the respondents are elected or candidates for public office, provided that the research is related to aspects of public office or policy.

Research Which Uses Only Existing Data Which Is Publicly Available:
Research involving the collection or study of existing data, documents, records, pathological or diagnostic specimens, if

a) these sources are publicly available or
b) the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

In determining whether ethical review of the protocol by UCD HREC is needed, it is important to consider the following questions:

Does this research involve any vulnerable groups?
Vulnerable groups refer to categories of people who are not legally able to provide informed consent due to age or incompetence, or who are in an unequal relationship with the researcher. Children, students, people who have a language difficulty, persons who have an intellectual or mental impairment, certain groups of elderly people, persons who are incarcerated or residents in institutions and people in dependent or unequal relationships (teacher-student, therapist-client, employees as participants) are viewed as vulnerable groups.

Does the research involve sensitive topics?

'Sensitive topics' refers to questions about sensitive topics or sensitive aspects of the subject's own behaviour, such as drug or alcohol use, illegal conduct or sexual behaviour; participant involvement in sensitive areas that may make some participants feel uncomfortable, i.e. sexual behaviour, illegal activities, racial biases.

Does the research involve drugs, invasive procedures, physical or psychological stress/distress or discomfort?

Does the research involve deception or withholding of information from participants?

Does the research involve access to data by persons or organizations other than the researcher?

Does the research involve conflict of interest issues or ethical dilemmas?

If the answer to any of these questions is yes, formal review of the protocol by the UCD HREC is required (See the *Human Subjects Ethical Approval Application Form*), unless all aspects of the protocol have been approved appropriately by another REC or RECs.

If the answer to all of these questions is no, your research *may* be exempt from review but will require the completion and submission of a *Human Subjects Ethical Approval Exemption from Form*. However, if the Committee determines that the study is not exempt, full review of the research protocol will be required.

In all cases where students conduct research as part of a course, the protection of participants is the responsibility of the research supervisor.

3 Ethical Approval Applications: Process and Outcomes

In the process of ethical review, the Human Research Ethics Sub Committee examines the ethical approval application, the research proposal and supporting documentation to ensure that the investigator has addressed the risks and benefits which potential research participants may be exposed to or experience, that the proposed selection of participants is equitable, and that the informed consent process will provide sufficient information to potential participants so that they can make informed decisions about participating in the research. If any issues or concerns are identified by the Sub Committee during the review process, these will be conveyed to the investigator after the review is completed. These issues or concerns should not be viewed as negative comments about the content of the research.

The outcome categories of ethical approval applications include *approval* (approved, as is, with no conditions attached), *contingent approval* (approved, subject to implementation of recommended changes), *re-tabled* (requires that the principal investigator address questions posed by the Committee and that the responses of the principal investigator have been discussed by the Committee at the next regularly convened meeting) and *rejected* (the Committee will provide written reasons for the decision, and the application may be submitted for reconsideration when reasons for rejection have been addressed by the principal investigator).

4 Revocation and suspension of approvals

All approvals are subject to the University at any time and for any reason revoking, suspending, modifying, altering or reconsidering the approval decision. Any such action by the University to suspend, revoke, alter, modify or to reconsider shall have immediate effect. The matter may be placed back on the Committee agenda for the purpose of further consideration.

5 Adherence to the approval decision

It is the sole responsibility of the researcher to adhere fully to the approval decision and to any conditions or contingencies laid out within the same. Furthermore, the researcher should ensure that he does not extend the research, modify or alter it in a material way without reverting to the Committee for the purpose of obtaining approval to any proposed extensions, modifications or, alterations or other changes of design.

6 Duration of approval

All decisions must be implemented within any time laid out in the decision notice. If no time is laid out, then the decision must be implemented within a period of one year. Otherwise, the researcher must apply to have the decision renewed and on such an application, the whole matter may be reviewed in its entirety by the Committee who may consider the matter afresh and reach a different decision.

7 Insurance criteria

Any research conducted on a UCD campus must be covered by insurance and the researcher will be automatically obliged to comply with the terms of any insurance policy applicable to that research. If a researcher is in any doubt in relation to insurance or the terms/conditions applying to it clarification can be sought by consulting with the *Guidelines for Insurance/Indemnity* or by contacting the Corporate and Legal Affairs Secretary's Office on extn 1458 or by email to: corporate.legal@ucd.ie.

The decisions of the Human Research Ethics Sub Committees can be appealed by writing to the UCD Research Ethics Committee (see *Guidelines for Appealing Decisions of Reviewed Applications*).