

## **FREQUENTLY ASKED QUESTIONS**

The questions below are referenced to the appropriate sections/questions on the Ethics Form

### **RESEARCH & PARTICIPANT**

**Q. What is a gatekeeper?**

A. The role of a gatekeeper is to protect the interests of the participants and to ensure that they are not under any pressure to participate. They act as a neutral buffer between the researcher and the participant. For example if a lecturer wanted to give a questionnaire to their students, the students might feel pressurised to take part. Therefore a third party (the gatekeeper) should distribute the questionnaires, thus removing the direct link between the researcher and the participant, thereby eliminating the pressure to participate.

**Q. I am conducting a study that involves distribution of questionnaires for anonymous return. Do I need to obtain informed consent?**

A. As long as the circumstances guarantee anonymity, return of the questionnaire itself implies consent and no separate form needs to be used.

**Q. What circumstances might endanger anonymity of questionnaires and therefore require informed consent to be sought?**

A. If the population surveyed and/or the nature of questions asked may be such that certain respondents can be identified by their responses. For instance, in surveys of practitioners which identify the employing institution, a particular institution may employ only 1-2 practitioners. It is important that questionnaires are designed in a way that avoids this sort of problem.

**Q. I intend to distribute a questionnaire to students in TCD. Are there specific guidelines about how to distribute and collect this questionnaire?**

A. First, you should consider the time that it takes to complete the questionnaire and whether therefore it can be completed immediately it is distributed. Second, you must recognise that completion and return during a scheduled lecture slot is usually impossible because it interferes with the teaching programme. If this seems to be the only way to handle the survey, then you need to consult the lecturer involved well in advance. Finally, anonymity may be perceived to be endangered if completed questionnaires are handed directly to the investigator. It is preferable to provide a lodgement box. If distributing by email the permission of the College Secretary is required.

### **CONSENT, CONFIDENTIALITY (INCLUDING DATA PROTECTION)**

**Q. Can I obtain informed consent by e-mail?**

A. No. The official record of consent must be held in hard copy with an original signature.

**Q. My study involves research on normal subjects less than 18 years of age. If I have obtained consent from their parents or guardians, do I need to obtain consent also from the subjects?**

A. It is accepted by the Irish courts and international guidelines that minors have independent rights. All minors regardless of age should therefore be informed as fully as is practicable about the research and agree to be involved. If they do not wish to do so, then this must take precedence over any consent given by a responsible adult.

**Q. For how long do I need to retain records of the participants and the data collected?**

A. International best practice requires that all research data should be stored for several years subsequent to any publication. To allow for this, we recommend secure retention for 5 years after the study is completed. However, these data must be fully anonymised. Any records that identify particular participants should be retained only for as long as may be needed for cross-reference during the study.

**Q. My experimental data consist of video and audio tapes that allow participants to be identified. What do I do about this?**

A. Wherever possible, data should be transcribed into some format that precludes identification of individuals. We recognize that occasionally this is impossible: in these cases, all that can be done is to guarantee storage under secure conditions and to ensure that access is restricted as much as is consistent with the analytic needs of the project. Where individuals can be identified from stored data, this must be mentioned in the subject information leaflet and the informed consent form, and subjects should be offered the opportunity of removing any self-identifying information before storage. The recordings should not be played in a public forum without specific permission of the subject.

**Q. How do I ensure anonymity of data obtained from known individuals?**

A. Each participant must be anonymised at the commencement of the study by allocation of a code number and this number must be used in all subsequent stored data records. The Committee recommends that if there is an overwhelming reason not to use code numbers then this should be addressed in Section 3.7 of the application form.

**Q. Other investigators in my unit may wish to reanalyse the data from my project for use in other studies in the future, or use it in teaching. Do my participants need to know this?**

A. Informed consent must be given for all use of acquired personal data, regardless of whether it has been anonymised after acquisition. Therefore, under the circumstances outlined above, the informed consent form either must seek agreement for possible use of data in future studies as well as in the current one, OR must specify that additional consent would be sought if the data were to be re-used. This of course has the implication that the key to the anonymisation code may have to be retained for longer than is usual. It also needs to be borne in mind that re-access to stored data itself will require ethics committee approval.

**Q: In an interview-based study, do I need to supply interviewees with a record?**

A: Yes, it is good practice to give each subject a transcript of the interview and, where appropriate, to provide them with the opportunity of deleting any wording that they may perceive as identifying them. Applications should indicate that these procedures will be followed. If transcribed the transcription must be checked with the subject for accuracy before publication.

## **FUNDING & PAYMENT**

**Q. Can I encourage enrolment in my study by offering participants payment?**

A. Since it is a basic tenet of human research that subjects participate on a voluntary basis, it is not acceptable to provide direct payment. It is however appropriate to offer reimbursement of any expenses incurred in participation. It is also acceptable to enrol all participants in a raffle provided that any legislative requirements are complied with. The prize for such a raffle should be reasonable and not excessive in value.