

Annex H

ETHICS GUIDELINES - RESEARCH WITH HUMAN SUBJECTS

While recognizing the vital importance of research to human progress, the Council affirms that the welfare and integrity of the individual or particular collective must prevail over the advancement of knowledge and the researcher's use of human subjects for that purpose. The Council is not itself vested with any authority to decide when an individual's rights may be superseded by the need for research but, as a trustee of public funds, the Council has a responsibility to ensure that the activities it supports respect the rights of the public it serves.

The guidelines are offered to assist the researcher and the institutional ethics review committee in avoiding any adverse effects of research involving human subjects.

Institutional Ethics Review Committees

1. Research projects involving human subjects must be approved by the ethics review committee of the institution employing the principal investigator before being submitted to Council, or shortly thereafter.
2. The review committee should include representatives from inside and outside the department and discipline in question, and the institution should keep the Council informed of disciplinary affiliation of the members. The Council may sometimes require names.
3. If the review committee makes an exception to these guidelines, an explanation must be provided.
4. Any dissent within a review committee must be made known to the Council.
5. The Council is concerned that monitoring procedures be established by review committees; it leaves them to propose their own approaches and to inform the Council. But special attention must be paid to research on children or captive and dependent populations, and to projects involving deception or an element of risk. With regard to children, review committees should seek expert advice, whenever necessary, on potential short- or long-term risks. Unforeseen damage must be remedied without delay or the research terminated.
6. Institutional review committee approval should not be advertised as an inducement to potential subjects; the researcher has, however, the right to inform them of such approval.

Definition of "Human Subject"

7. The term "subject" signifies any person who is a source of raw or unformulated data and who is not acting as, or assisting, the principal investigator.

Rights of the Individual

8. Certain individual or collective "rights" must be maintained. These include: the right to know the precise nature and purpose of the research, so that consent may be given or withheld advisedly; the right to know of the risks and benefits; the right to assurance that privacy will not be invaded and that information disclosed will remain confidential; the right of cultural groups to accurate and respectful description of their heritage and customs and to the discreet use of information on their lives and aspirations.

Informed Consent

Information given to subjects should respect their levels of comprehension. A description should be provided of purpose; usefulness; expected benefits; methods; effects; risks (including risks to physical and psychological well-being and jeopardy to social position) and possible alternative procedures. Subjects should always be told of factors which might lead them to refuse to participate. In exceptional circumstances, the guidelines on deception should be applied.

9. Participants should be apprised of the rights to inquire about the research and have recourse to a resource person outside the research group.
10. There should be no coercion, constraint or undue inducement (see special guidelines for captive and dependent populations).
11. Participants should understand that they may withdraw at any time, just as investigators may terminate their research in the interest of the subjects, the project or themselves.
12. Informed consent of parents or guardian and, where practical, of children should be obtained in research involving children (see special guidelines concerning research on children).
13. Participants should be informed of the degree of confidentiality that will be maintained in the study.
14. Informed consent should be obtained in writing. Where this is not practical, the procedures used in obtaining consent should be on record.
15. Written consent should set out:
 - a) purpose of the research;
 - b) benefits envisaged;
 - c) any inconveniences;
 - d) tasks to be performed;
 - e) rights of the subject, e.g. the right to withdraw at any time without penalty the right to confidentiality of personal information;

f) risks involved;

g) the name(s) of the person(s), group(s) or institution(s) eliciting or receiving the consent.

16. The wording of the consent form should be as similar as possible to the oral description given to the subject. The form should provide for hearing any subsequent complaint.

Deception

Deception is a situation in which subjects have essential information withheld and/or are intentionally misled about procedures and purposes.

17. Deception should never be permitted when there is risk of harm to the subject or when it is not possible to advise subjects subsequently as to the reasons why the deception was necessary.

18. The researcher must satisfy the review committee that: a) significant scientific advance could result; and that b) no other methodology would suffice.

19. Nothing must be withheld which might have caused subjects to refuse to participate.

Risk and Benefit

Greater consideration must be given to the risks to physical, psychological, humane, proprietary and cultural values than to the potential contribution of the research to knowledge. The more incalculable the risk, the more cautious should be the researcher and the review committee in proceeding.

20. Where procedures involve risk, the researcher should have previously carried them out successfully, at least under supervision, without detriment to the subjects. For a new procedure, the investigator must convince the review committee that adequate precautions will be taken, and monitor preliminary work to ensure appropriateness. The results should be available to the committee.

21. Except where there is clear foreseeable benefit to the participant, such as in therapeutic research, the researcher has no right to attempt to make long-term changes in a person's behaviour or attitudes. Where the researcher plans to induce short-term behavioural changes, permission to proceed should depend upon reversibility.

22. The researchers must guard against risks to non-participants (third-party risks).

23. The onus is on the researcher to avoid or minimize risks to subjects, both in carrying out the research and in publication of results.

Privacy

The right to privacy extends to all information on a person's physical and mental condition, personal circumstances and social relationships which is not in the public

domain. It gives to the individual or collective the freedom to decide when, where, in what circumstances and to what extent their personal attitudes, opinions, habits, eccentricities, doubts and fears are to be published.

24. If there is to be a probing of private personality or private affairs the intention should be explicit. Where there is an implication of protection of privacy, the protection should be more generous than the promise.
25. Informed consent should be obtained from those to be observed or studied in private settings.
26. Since concepts of privacy vary from culture to culture, the question of invasion of privacy should be looked at from the point of view of those being studied.

Confidentiality and Anonymity

27. If confidentiality or anonymity cannot be guaranteed, participants should be made aware of possible consequences.
28. There should be a clear understanding between investigator and subjects as to what extent information they divulge will be kept confidential in the original use of data and their deposit for future use.
29. Unless there is an explicit statement by the researcher to the contrary, to which the subject agrees, personal information given by the subject will be confidential and the researcher will explain steps to be taken to ensure confidentiality and anonymity.
30. Steps should be taken to guard against indirect or unwitting disclosure of identity of subjects by association or by combination of information.
31. The researcher has an obligation to third parties.
32. Obtaining access to institutional record should respect the individual's rights to confidentiality and anonymity.

Research on Captive and Dependent Populations

"Captive and dependent populations" are individuals or groups in a relationship where a power differential could operate to their disadvantage as subjects: for example, students, minors, prisoners, employees, military personnel, minority groups, incapacitated people and the socially deprived. Review committees should be especially alert to ensure that consent obtained is not obtained by subtle pressures on the captive subject. Such pressures may invalidate the consent.

33. In addition to consent of the subjects themselves, informed consent of the authorities should be obtained.
34. Where consent of the subjects themselves cannot be obtained, it must be sought from someone in authority, together with written consent from a person who may act as an independent advocate.
35. Captive subjects should always have the right and power to veto others' consent.

Research on Children

36. Informed consent of parents or guardians should be obtained before using minors. In school, camp, or other group settings, consent of the principal, director or other appropriate authority must also be obtained. Where a child is a ward of the state or of an agency, such as the Children's Aid Society, informed consent of the agency director, as well as of the person having custody, must be obtained.
37. Children should be given individually the opportunity to refuse to participate or to withdraw.

Research in the Humanities

38. Research ethics are involved wherever an investigator intervenes in the lives of others. Historical and/or biographical investigation may pose problems of confidentiality or invasion of privacy if living persons are likely to be affected by the publication of private materials.
39. Researchers should be careful, in purchasing and taking out of the country original manuscripts, that they are not depriving another country of what may be a national treasure.
40. Those writing history, biography or artistic criticism should be aware that private papers, photographs or artistic productions are protected by copyright, regardless of whether such material resides in an archive, gallery or museum. One cannot legally consult, cite, reproduce, publish, refer to or distribute such documents or articles without permission, either from the author or heirs or from the person or institution given copyright ownership.

Acquisition and Use of Cultural Properties

41. Acquisitions should be for the purpose of scholarship and not for personal gain, private collection or sale.
42. Legal requirements of the country of origin must be observed.
43. Where there is doubt as to legal ownership, the researcher acquires an object at risk and must immediately inform the authorities of the country concerned. If the acquisition is not approved, the researcher should return the object to those authorities.
44. The researcher should not accept or otherwise acquire objects unless proper storage, protection and preservation of the objects can be provided.
45. Materials should be catalogued, with a description of their provenance, and this catalogue made part of the public record.
46. After a reasonable time, objects or documents should be made accessible to other scholars with legitimate research interests.
47. If objects or documents are to be de-accessioned or discarded, they should be offered to public authorities or educational institutions in the country or district of origin. If the offer is refused or cannot be made, they should be offered to educational institutions in Canada where they could be put to proper use or preserved. Such objects or documents should never be traded or sold to individuals or to dealers, but always remain in the public domain.

48. All copies or reproductions of documents and objects, whether collected for exhibition or distribution, should be clearly marked.
49. Material should not be publicly exhibited, discussed or published in a way which causes embarrassment to individuals, groups or countries associated with it.
50. Objects or documents should not be exhibited in ways likely to damage them.

Research on Other Cultures, Countries and Ethnic Groups

Research on cultures, countries and ethnic groups different from one's own requires a different ethic. Researchers in the field have to give an account of themselves acceptable to the people among whom they are working and in accord with the role the subjects will observe. To gain the subjects' trust and cooperation, researchers may tell them that they have come to learn about their way of life, languages, customs and beliefs. But the problems of communicating what uses will be made of the information may be insurmountable.

This communication gap may make informed consent impossible, especially as the people under study may be unable to estimate the risks to their well-being and reputations, and potential damage to their descendants. To add to the problem in fieldwork, individual consent may not be feasible, and there may not be any person with authority to give collective consent. Absence of informed consent places additional responsibility and restrictions on researchers. Researchers must satisfy the review committee concerning the safeguards in the methodology.

51. Subjects may be paid for their time and this remuneration may take into consideration the inconvenience of participation. In anthropological field work, reciprocity is normal in some regions for certain persons, in the form of gifts, loans, transportation and other services.
52. If dangers can be foreseen but not forestalled it is questionable whether research should be undertaken. Intentions and risks must not be concealed to obtain cooperation.
53. In some societies, privacy and confidentiality may apply to unexpected kinds of activity. Certain ceremonies may be the privilege of a particular class or group: men may not view ceremonies of women, or youths may not be a party to deliberations of elders. Concepts of privacy must be viewed from the perspective of the research subject or the subject's culture.
54. When researchers outside their own culture are operating from a position of advantage, they have particular responsibility to subjects as regards publication. Margaret Mead sums these up: "There is first of all the responsibility to individuals who, if identified, must not thereby be exposed to legal sanctions, to ridicule or to danger. Second there is the responsibility to the group as a whole. Where customs are portrayed that contrast with the ethical standards of those who govern them or with the missionized or educated members of their own society, these must be represented in such a way that full justice is done to the cultural framework within which a given practice, however apparently abhorrent, occurs. Finally, there is the responsibility of the anthropologist for the way in which his findings are interpreted and articulated into the ongoing understanding of human behaviour in the human sciences of his day.