



Policy Supporting Document:	E-3.2.4
Policy Holder:	President

RESEARCH GUIDELINES: INCLUSION IN RESEARCH

IN SUPPORT OF POLICY E-3.2 *ETHICAL CONDUCT FOR RESEARCH INVOLVING HUMAN SUBJECTS*

Please Note: This document forms part of the set of research related policies at Camosun College. Its function is to serve as explanation and elaboration only. Should there be a discrepancy between this guideline and any Camosun policy, the policy will supersede.

A. BACKGROUND

An important aspect of the principle of justice is the fair distribution of benefits and burdens. Historically, concern for justice in research involving human subjects has focused on whether research subjects were treated fairly: were they overburdened relative to the direct benefits they received from their participation in research? Contemporary concerns with justice in research have broadened: are the overall benefits and burdens of research distributed fairly, and have disadvantaged individuals and groups received a fair share of the benefits of research?

1. Principle of Distributive Justice

The above two concerns form the basis of the principle of distributive justice: members of society should neither bear an unfair share of the direct burdens of participating in research, nor should they be unfairly excluded from the potential benefits of research participation. The concerns raised by this principle reflect broader obligations to respect human dignity and diversity. They should, therefore, receive the formal attention of researchers, the Research Ethics Board (REB), research institutions, and sponsors.

2. Misuse of Research Subjects

Unfortunately, the history of research involving human subjects contains chapters on the misuse or serious abuse of research subjects. Continuing concerns about such abuses have sharpened ethical focus on the relative levels of benefits and harms that research would impose on prospective subjects. The important concerns about exploiting vulnerable populations and visiting harms on research subjects are also relevant to the guidelines for free and informed consent (see *E-3.2.2 Research Guidelines: Free and Informed Consent*) and privacy and confidentiality (see *E-3.2.3 Research Guidelines: Research Guidelines: Privacy and Confidentiality*), and to the REB. Accordingly, this guideline focuses on the fair distribution of the direct and indirect benefits of research.

3. Exclusions From Research

A number of sources of unfair distribution of the benefits of research can be identified. Sometimes the harms have resulted from intentional exclusion, such as that inspired by concerns about the misuse or abuse of research subjects. Thus, some have argued that

the principle of free and informed consent means that only competent individuals should be permitted to participate in research that would likely be harmful or be of no benefit to them. Strict application of such a principle would deny incompetent individuals many of the benefits of research participation, either directly or indirectly. In a sense, such beneficence-based reasoning and practices intentionally exclude certain groups from research. In attempting to avoid the moral problem of exploiting vulnerable research subjects, such practices may incur the moral problem that individuals in need of the benefits of research may be denied them.

Exclusion from research has also arisen indirectly. For example, concerns about legal liability associated with particular populations have prompted the exclusion of women of child-bearing age from drug trials because of possible harms to potential offspring. Further exclusions have been based

1. on concerns about factors such as the effects of the female hormone cycle on drug trials;
2. on the choice of criteria for inclusion or exclusion, such as those based on age that had the effect of including most male heart attack victims but excluding most females suffering from the same disease; and
3. on financial and other impediments to changing the direction of established research programs.

As another example, age has been used unfairly to exclude individuals from participation in research. The result of such exclusion is that insufficient research has been done on the young and on the elderly. As the Canadian population ages, the necessity for research on the aging process and on the conditions that disproportionately affect the elderly grow concomitantly. Participation of elderly individuals poses significant questions for researchers, one of the most important being how to establish and maintain a balance between respect for the dignity and welfare of the individual and the provision of necessary protection for those who are, or who may become, incompetent (see *E-3.2.2 Research Guidelines: Free and Informed Consent*). Research ethics impose a duty to guard against the exclusion of elderly research subjects on the basis of biases that they may be unable to comply with the researcher's directions.

Whether intentional or inadvertent, the exclusion of some from the benefits of research violates the commitment to societal justice. A commitment to distributive justice in research imposes obligations on activities by researchers, institutions and REBs. All have important roles to play in ensuring a fairer distribution of the benefits and burdens of research. As the following sections make clear, distributive justice imposes on researchers and the REB a duty not to act in a discriminatory fashion. Sometimes it may impose positive duties to include disadvantaged groups in research involving human subjects.

B. EXPLANATION AND ELABORATION

1. Where research is designed to survey a number of living research subjects because of their involvement in generic activities (e.g., in many areas of health research, or in some social science research such as studies of child poverty or of access to legal clinics) that are not specific to particular identifiable groups, researchers shall not exclude prospective or actual research subjects on the basis of such attributes as culture, religion, race, mental or physical disability, sexual orientation, ethnicity, sex or age, unless there is a valid reason for doing so.

2. This statement is not intended to preclude research focused on a single living individual (such as in a biography) or on a group of individuals who share a specific characteristic (as in a study of an identifiable group of painters who happen to be all of one sex, colour or religion, or of a religious order that is restricted to one sex).
3. Women shall not automatically be excluded from research solely on the basis of sex or reproductive capacity.
4. Those who are not competent to consent for themselves shall not be automatically excluded from research that is potentially beneficial to them as individuals, or to the group that they represent.

The principle of distributive justice inspires the statements above. It imposes a duty on researchers not to discriminate against disadvantaged groups. Groups that have been disadvantaged in the context of research include women, people of colour or of different ethnicity, the elderly, children and restricted or dependent people. The intention of this section is not to discourage research that focuses on a particular group, particularly research in the social sciences and the humanities. Rather, the intention is to achieve a more just distribution of the benefits of research across all groups.

C. RESEARCH INVOLVING WOMEN

As indicated, women have historically been excluded from participating in some research, largely because of concerns about:

1. damaging either the foetus or the woman's reproductive capacity; harming the newborn through breast-feeding;
2. the influence of hormonal cycles; or,
3. failing to recognize that diseases and conditions might affect men and women differently.

Such exclusions retard the advance of knowledge, deny potential benefits to women, and may expose women to heightened risk.

Example:

The exclusion of women as research subjects raises serious concerns regarding the generalizability and reliability of some research data. Research data on drug dosages, the effects of devices, treatments, cultural norms, moral development and social behaviour obtained from male-only studies likely will not be generalizable to women. As a result, data for women are lacking and often must be inferred, despite important differences that may render such inferences inaccurate, and treatments or interventions based thereon more harmful. The inclusion of women in research is essential if men and women are equally to benefit from research. It advances both the commitment to justice and to rigorous scholarly or scientific analysis.

The statements presented above impose obligations of equitable treatment of potential subjects on the REB and researchers. While some research is properly focused on particular populations that do not include women or include very few women, in most studies, women should be represented.

The statements above are also clear about presumptive or automatic exclusion from research on the basis of sex or reproductive capacity. If in the past many women have been automatically excluded from research on such grounds. This guideline rejects such an approach as a discriminating and unethical use of inclusion or exclusion criteria. Rather, in

considering research on pregnant women, researchers and the REB must take into account potential harms and benefits for the pregnant woman and her embryo, foetus or infant. The ethical duty to assess the harms and benefits of research thus extends to the special case of research involving pregnant or breast-feeding women.

D. RESEARCH INVOLVING THOSE INCOMPETENT TO CONSENT FOR THEMSELVES

Although ethical duties to vulnerable populations preclude the exploitation of those who are incompetent to consent for themselves for research purposes, there is, nonetheless, an obligation to conduct research involving such people because it is unjust to exclude them from the benefits that can be expected from research (see *Research Guideline: Free and Informed Consent*).

There is a need to recognize that research involving those who, though not competent to consent for themselves, are unique individuals who command all the respect, justice and inclusiveness accorded to competent individuals. The behaviour, psychology, biology and diseases of infants and children who are incompetent because of immaturity often differ markedly from those of adults; also, incompetence is often caused by disease, which cannot be studied only in those without the disease. However, the ethical imperative for research must be interpreted in the context of the safeguards expressed in the *E-3.2.2 Research Guidelines: Free and Informed Consent*.