Research and Institutional Review Committee Research Subjects

A. Purpose

The purpose of this procedure is to outline the aspects of involving subjects in research.

B. Equitable sample of research subjects

The selection of research subjects needs to be scrutinized in order to determine whether some classes (e.g. racial or ethnic minorities, the poor, the homeless, the terminally ill or persons confined to institutions) are being systematically selected simply because of their easy availability, their compromised position or their manipulability, rather than for reasons directly related to the problem being studied. The ethical principle of justice requires fairness in distribution. Therefore, justice demands that research not provide advantages to only those who can afford them and that research should not unduly involve persons from groups unlikely to be among the beneficiaries of subsequent applications of research. The principle of justice requires fair procedures and outcomes in the selection of subjects. The equitable requirements for age, gender and ethnicity/race shall not apply to a project of research if the inclusion:

1. is inappropriate with respect to the health/disease of the subjects;
2. is inappropriate with respect to the purpose of the research; or
3. is inappropriate due to other relevant circumstances.

(The above requirements are in part from the NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research as published in the Federal Register of March 9, 1994 [59 FR11146-11151])

C. Subject recruitment

1. Approaching subjects to participate
   Protocols submitted to the RIRC for review and approval must specify how subjects will be identified and recruited. Patients expect that information on their medical condition will be kept confidential, although an investigator may access this information in the conduct of a RIRC approved research project (see Expedited Review – Chart Review Studies). Patients would consider it a serious breach of confidentiality and of medical ethics to be contacted by someone not involved in their care who has obtained this information. For this reason, permission to recruit a patient as a subject in a research study should be obtained from the patient's primary (attending) physician before the patient is contacted.

2. Advertisements

All forms of advertising or dissemination of information for the purpose of recruitment of subjects into a research protocol, including newspaper advertisements, The Queen's Medical Center postings on bulletin boards, posters, fliers, videos, TV announcements, letters to fellow physicians (both within and outside the institution) or newspaper articles which include recruitment information must be approved by the RIRC. The information should not be misleading to subjects, especially when a study involves vulnerable populations. If appropriately worded, the following may be included:[1]

a. The name and address of the clinical investigator and/or research facility;
b. The condition under study and or the purpose of the study;
c. In summary form, the criteria that will be used to determine eligibility for the study;
d. A brief description of benefits to the subject if any;
e. The time or other commitment required of the subjects;
f. The RA number of the protocol and the expiration date;
g. The name and number of whom to contact for further information;
h. The location of the research; and
i. Simple language (6^{th} to 8^{th} grade reading level).

Nothing in the text should serve as an undue inducement to potential subjects to enter the study. Such inducements might include claims (explicit or implicit) about safety or efficacy of an investigational drug or device, equivalence or superiority to existing treatments, closer monitoring of the patients condition. The availability of compensation (monetary or other) for time and effort related to participation can be included without mention of any specific amounts.[2] There should be no claim made as to the superiority, safety, or effectiveness of drugs or devices used in research.

D. Subject Compensation

Subjects many be compensated in a variety of ways for taking part in research activities. Forms of compensation may include: financial remuneration, merchandise (gifts, toys, or vouchers), provision of services (parking fees, free meals, medical treatment) and educational credit. The method of compensation must be described in the consent form. Compensation is meant to reimburse subjects for time and inconvenience, not for risk. The amount of compensation offered should not be such that it would be the sole motivation for a subject to participate in the research.

Compensation should be pro-rated for subjects unable to complete the study. A description of the payment plan must be included in the consent form.

Since payments to research subjects are tax reportable as income, the subject's name, mailing address and social security number must be record. Because the use of names and social security numbers increases the risk of loss of confidentiality and may be a cause for concern for some subjects, both the protocol and the consent form should address this issue in writing.

E. Subject compensation for adverse events

Both FDA (Title 21 CFR 50.25) and DHHS (Title 46 CFR 46.116) require an additional element of consent regarding treatment and compensation for injury resulting from participation in research (see SOP on informed consent)

F. The Queen's Medical Center Employees as Subjects

Investigators proposing to recruit QMC staff as research subjects should justify in the protocol the necessity for the inclusion of the dependent subject. Staff as potential subjects should not feel coerced into participating in research, nor must they fear the loss of some benefit to which they are otherwise entitled if they choose not to participate. A person in authority, such as a physician, manager or teacher, should take special precautions to ensure that a potential subject's decision to participate in research is not based on subtle pressure as fear of retaliation, loss of benefits or impact on grade for a class.