UNIVERSITÄT
BERN

Guidelines on the selection of test subjects for research projects in clinical research

The University Board of Directors,

on the basis of Art. 2 para. 2, Art. 10 para. 3 and Art. 39 para. 1 item a of the law governing the University of 5 September 1996 (UniG),

resolves:

I PRINCIPLE

Art. 1 [1] The purpose of clinical research is to provide scientific foundations and findings that contribute to the continuous development of medical care, the prevention and treatment of diseases, the promotion of health and the improvement of the quality of life of human beings.

[2] In order for research findings to be used to enhance the well-being of as many sections of the population as possible, when planning the conduct and evaluation of any clinical trials careful checks must be carried out to ensure that participants are taken from all age groups, both males and females, and as far as possible and appropriate are of different ethnic origin.[1]

II DEFINITIONS

Art. 2 Clinical research is deemed here to mean:

a patient-oriented research involving the study of the mechanisms of human diseases, therapeutic interventions, diagnostic interventions and the development of new technologies (experimental studies);

b epidemiological studies (observational studies).

[1] Subject to the ban on discrimination in accordance with Art. 8 para. 2 of the Swiss Federal Constitution. The new Swiss law on research on human beings (human research law, HFG) is expected to come into effect in 2010. Art. 4 of the draft version should be used mutatis mutandis as a basis for the purposes of this document.

III PLANNING CLINICAL RESEARCH PROJECTS

1. Categories of test subjects

Art. 3 As far as possible and appropriate, it should be firmly established when devising clinical research projects that

a both genders are reasonably and proportionately represented;

b members of different age groups, especially children, young people and the elderly, are included as test subjects;

c members of ethnic minority groups are included as test subjects.

2. Composition of the test population

Art. 4 [1] The research plan should describe the composition of the proposed test population according to gender, age and ethnic origin, and give reasons for the selection. There should be a description of how the subgroups are recruited.

[2] If children and young people participate in the studies, the risk associated with such studies must be as low as possible. Even where the risk is only slightly increased, the benefit must be significant and the risk involved justified.

[3] The number of test subjects should be appropriate to enable a valid and meaningful evaluation.

3. Non-inclusion of test subjects

Art. 5 [1] The non-inclusion of members of different demographic groups in accordance with Article 3 in a research project must be justified. In this case it should be specified why their inclusion is inappropriate.

[2] Clear and compelling grounds justifying the non-inclusion of demographic groups are deemed to be in particular:

a legislation;

b the specified research objective;

c ethical grounds;

d absence of consent from potential test subjects, or their legal representatives (in the case of children, the consent of their parents),

e possible health risks or potential damage to the health of the groups concerned;

f the possibility that findings could be obtained in another way;

g scientific evidence that the variables to be researched do not show any significant differences in respect of their effects on gender, age or members of ethnic minority groups.

[3] The non-inclusion of members of specific demographic subgroups may not be based on economic considerations, unless the data required are already available elsewhere and can be obtained from the corresponding data source.

4. Requirements for the planning, conduct and assessment of clinical trials

Art. 6 [1] It must be probable that the research results will lead to generally valid findings relating to the disease or health condition under study.

[2] A research plan should be checked to determine whether there are indications that over the course of the studies clinically relevant differences may be expected with regard to gender, age and ethnic identity.

[3] Such indications may be established, for example, in data from previous animal testing, clinical observations, metabolism studies, genetic studies, pharmacological studies, epidemiological studies and randomised clinical studies.

Art. 7 [1] The project managers should carry out a preliminary examination to assess the theoretical bases and the scientific evidence for any association between gender, age and ethnic origin and the object of the studies in the research project. On the basis of their evaluation, they will, in liaison with the proposing institution, establish the study procedure and study criteria.

[2] The project managers will have access to the necessary information regarding the inclusion of both genders, age groups, ethnic minorities and other demographic subgroups in the research project, and the reasons for any exceptions.

[3] A relationship of trust should be established between the project managers and their employees, on the one hand, and the persons selected for the research projects, as well as other groups with an interest in the research concerned (e.g. patient organisations), on the other hand, so that all persons participating in the project are able to derive some benefit from it.

[4] Project managers should take ethical issues into consideration where these are intended to minimise the possibility of pressure being exerted on test subjects.

[5] Care must also be taken to ensure that no improper influence can be exerted through incentives or offers of compensation in the recruiting or retaining of test subjects.

[6] This also applies mutatis mutandis to other persons who participate in the study within the scope of the research project.

Art. 8 The Ethics Committee will check the ethical standards and the appropriateness of the participation of test subjects and test groups, and will verify that if children and young people are included, it is guaranteed that the permission of the persons responsible in law and the consent of the children and young people themselves is obtained.

Art. 9 The trials will be conducted in such a way that they provide information to clarify the question of whether the object of the studies affects women, different age groups or members of minority groups differently from other test subjects.

Art. 10 [1] In the case of research projects funded by the US National Institute of Health (NIH), a report must be submitted annually giving information about the inclusion of individuals, separated according to gender, ethnic origin and any other demographic subgroups according to the research project accepted by the third-party financer. The report must include details of data collected in the analyses relating to differences in the specified test groups and about the progress of the project.

[2] If there are no concluding analyses of findings with regard to gender, ethnic origin or other subgroups, if any, for the final report or the application to continue with a project, reasons must be given for this, and it must be demonstrated how the submission of a final analysis will be guaranteed.

[3] It is expressly recommended to include the results of analyses relating to gender, ethnic origin and demographic subgroups in publications. If it is evident from the analyses that no differences can be established, then a reference to this finding will be sufficient.

[4] The guidelines of the NIH must also be observed for NIH-funded research.[2]

IV Effective date

These guidelines are effective from 1 February 2008.

Bern, 29 January 2008

On behalf of the
University Board of Directors:

sig.
Prof. Dr. U. Würgler, Rector

[2] http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part5.htm#_Requirements_for_Inclusiveness