

CHILDREN'S HOSPITAL AND REGIONAL MEDICAL CENTER  
Seattle, Washington

OPERATING POLICIES / PROCEDURES

DEPARTMENT: Office of Vice President for Research  
POLICY NUMBER: OVPR-25  
REPLACES: NA  
EFFECTIVE DATE: October 1, 2005  
REVISION DATE: \_\_\_\_\_

POLICY TITLE: Translation Costs for Consent Documents

POLICY:

The Federal Regulations require equitable selection of subjects [45 CFR 46.111(a)(3)]. In assessing equitable selection of research subjects, the IRB must take into account the purpose of the research and the setting in which the research will be conducted. The inclusion of minorities in research is important, both to ensure that they receive an equal share of the benefits of research and to ensure that they do not bear a disproportionate burden. The choice of geographic area and/or physical location bears directly on the problem of inclusion of minorities. Recruiting subjects from a single geographic area or location (e.g., private doctor's office versus public hospital) may contribute to the homogeneity of a study population. The use of multi-site trials provides a mechanism for ensuring appropriate representation.

To ensure open and effective communication between the researcher and prospective subject, consent documents must be written in a language easily understandable to subjects. When documents in foreign languages are deemed necessary by the IRB, the cost of translation will be born by the IRB budget in accordance with this policy.

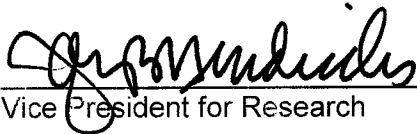
PROCEDURE:

- 25.1. Non-english speaking subjects may not be excluded from therapeutic studies on the basis of language use if there is a possibility that they might benefit from participating.
- 25.2. For pharmaceutical sponsored clinical research, the cost of translation shall be the responsibility of the sponsor. Investigators shall be responsible for budgeting these costs at the time of application.

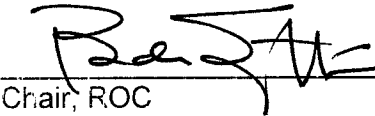
- 25.3. For NIH sponsored clinical research, the cost of translation should be budgeted as a direct expense to the grant. Investigators shall be responsible for budgeting accordingly.
- 25.4. Under special circumstances, investigators may apply to the Office of the Vice President for Research (OVPR) for funding of translations. Applications shall consist of a letter of request documenting special circumstances and the funding source. Under no circumstances will translations associated with industry sponsored research be approved. Funding for translations will be provided only after the English version of study documents have been approved by the IRB. The investigator shall be responsible for obtaining a qualified translation in accordance with IRB policies.

Submitting Office: Vice President for Research

Approved by:

  
Vice President for Research

10/25/05  
Date

  
Chair, ROC

10/25/05  
Date