



EQUITABLE SELECTION OF PARTICIPANTS

Description

The concept of justice is one of the basic ethical principles in the Belmont Report. Justice is described as the concept that “equals ought to be treated equally,” and further qualified by explaining that “equality” is based on numerous factors. The concept of justice is relevant to research involving human participants in part because of a long history of hardship and burdens placed on vulnerable populations, such as those that occurred during the Tuskegee syphilis study.

In the federal regulations governing research involving human participants, justice is applied in the directive that the IRB must determine that the selection of participants is equitable.

Investigators are required provide the following information to allow the IRB to determine whether the selection of participants is equitable:

1. The purpose of the research and the setting in which the research would be conducted.
2. Whether prospective participants would be vulnerable to coercion or undue influence.
3. The selection (inclusion/exclusion) criteria.
4. Participant recruitment and enrollment procedures.
5. The amount and timing of payments to participants.

IRB members are directed to determine that selection of participants is equitable as part of the overall criteria for approval. In determining whether selection of participants is equitable, consideration should be given to the following points:

1. The purpose of the research and the setting in which the research would be conducted.

- Equitable selection of participants requires that researchers attempt to recruit potential participants who are appropriate to answer the scientific question. The nature of the research should require inclusion of the proposed subject population.
- Benefits resulting from the research should be distributed fairly. Other groups of potential participants should be considered for inclusion if they have a greater need to receive any of the anticipated benefits.
- Burdens resulting from the research should be distributed fairly. If the proposed subject population is already burdened, it may be unfair to ask them to accept an extra burden.

2. Whether prospective participants would be vulnerable to coercion or undue influence and what measures are being proposed to minimize coercion or undue influence to these vulnerable participants.

- The researcher must justify the involvement of participants who may either be susceptible to pressure or who are already burdened (i.e. vulnerable populations).
- The selection process should not *overprotect* potential participants who are considered vulnerable so that they are denied opportunities to participate in research.

3. The selection (inclusion/exclusion) criteria.

- Evaluate the selection criteria (inclusion and exclusion criteria) to determine that participants are not excluded for non-scientific reasons. For example, if recruitment of minorities into a research study would be more expensive, this fact does not count as a reason why minorities should be excluded from participation in research.

Please contact the IRB Office at (801) 581-3655 or irb@hsc.utah.edu for additional guidance.



- If there are any groups of people who might be more susceptible to the risks presented by the study and therefore ought to be excluded from the research, the procedures for identifying such individuals should be adequate.

4. Participant recruitment and enrollment procedures.

- A research study may have fair selection criteria but use recruitment methods that lead to inequitable selection. If the participants are susceptible to pressures, there should be mechanisms in place that may reduce the pressures or minimize their impact. For more information and the guidelines provided to investigators, refer to the Investigator Guidance Series: Recruitment Methods and the Investigator Guidance Series: Advertisements.

5. The amount and timing of payments to participants.

- The amount of payment to participants, the proposed method of payments and/or the timing of disbursement of payments should not present undue influence or coercion. For more information and the guidelines provided to investigators, refer to the Investigator Guidance Series: Compensation.

Federal Regulations

45 CFR 46.111(a)(3): Criteria for IRB approval of research. “In order to approve research covered by this policy the IRB shall determine that... (3) Selection of participants is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.”

21 CFR 56.111(a)(3): Criteria for IRB approval of research. “In order to approve research covered by these regulations the IRB shall determine that... (3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, handicapped, or mentally disabled persons, or economically or educationally disadvantaged persons.”

Points to Address

Reviewer Checklist: Criteria for Approval

- 1. Equitable Selection of Subjects:** The reviewer checklist will document whether the reviewer feels that the selection of participants is equitable. Board members must answer the question, “Is the selection of participants equitable?”
- 2. Vulnerable Populations:** Board members must consider whether vulnerable participants will be involved and if so, whether safeguards are in place to prevent coercion or undue influence. Board members must select one of the following:
 - None of the participants are likely to be vulnerable to coercion or undue influence.
 - Additional safeguards been included in the study to protect the rights and welfare of participants likely to be vulnerable to coercion or undue influence.
 If a vulnerable population is involved, an additional checklist may be required.

Reviewer Checklist: Additional Considerations

- 1. Compensation:** Board members must evaluate compensation to determine that it is not coercive or present undue influence. Board members must answer the question, “Is compensation offered to the participants appropriate?” If no compensation is provided, board members may select “N/A”.

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2. **Recruitment:** Board members must evaluate the recruitment methods and advertisements. Board members must answer the question, “Do the recruitment methods, including advertisements, support an equitable selection of participants?” If there are no advertisements or recruitment methods, board members may select “N/A”.

References & Links

Investigator Guidance Series: Recruitment Methods <http://irb.utah.edu/guidelines/investigator.php>

Investigator Guidance Series: Advertisements <http://irb.utah.edu/guidelines/investigator.php>

Investigator Guidance Series: Compensation <http://irb.utah.edu/guidelines/investigator.php>

Tuskegee Syphilis Study <http://www.cdc.gov/tuskegee/timeline.htm>

Belmont Report <http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html>

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