Caribbean Public Health Agency

Preventing disease
Promoting and protecting health
Standards for Ethical Review: Fair Selection of Research Participants

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Preventing disease, promoting and protecting health
Preamble

• 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.
Presentation Outline

• Goals of Fair Selection
• Fair Selection in the context of Justice
• Issues of benefits and burdens
• Criteria (7) to consider for fair selection
• Decision point for the fair selection of research subjects
Goals

Selection, Recruitment, and Retention should:

1. Distribute burdens and benefits fairly
2. Ensure social value of research
3. Enhance scientific validity
4. Minimize risks to subjects
5. Enhance benefits to subjects
6. Protect the vulnerable
Fair Selection of Research Participants

Addresses one of the guiding ethical principles for the protection of human subjects as research participants - Justice.
JUSTICE

- Implies fair, equitable and appropriate treatment and consideration in light of what is due or owed to persons.

- The selection of subjects for participation in research should be fair, and persons should be protected from bearing a disproportionate share of the burdens or risk of research.
JUSTICE

• Operationalised by the fair selection of subjects.

• Requires that the benefits and burdens of research be distributed fairly i.e. that subjects be fairly selected.
Fair selection of research participants must:
• be the result of fair selection procedures and
• result in fair selection of outcomes (risks and benefits)
Fair selection of research participants

“Fairness” must relate to both:
○ Subject as an individual
    as well as
○ Subject as a member of social, racial, religious, sexual, age range or ethnic groups

Unjust social practices or undercurrent racial, sexual or cultural biases affect the ethical validity of the research process.
Fair selection of research participants

Status as individuals:
• Should not be favoured nor held in contempt (undesirables in risky research)

Status as group member:
• Social justice dictates an order/hierarchy of preference in the selection of classes of subjects for research. e.g. adults > children, competent > incompetent individuals, non-institutionalised > institutionalised, institutionalised persons only with conditionalities.
Fair selection of research participants

- **Distributive justice/equitable selection of participants ensures that the benefits and burdens of research are fairly distributed.**

- Important in avoiding institutionalised biases in society – racial, sexual, economic, cultural etc.

- Also has implications for the generalizability of the research results.
Fair selection of research participants

- Captive, easy to manipulate (due to illness or socio-economic condition) and institutionalised persons should not be unduly represented as research participants/subjects – guiding ethical principle of non-maleficence.
Fair selection of research participants

- Both the risks/burdens and the potential benefits of research should be spread fairly among potential individual research participants and groups of individuals participating in research

- Study design and selection of participants should avoid bias for or against particular groups (social, racial, sexual or ethnic)
Sharing research risks

• Any risks of the research should fall upon the groups that might benefit from the research

• Fair sampling of groups likely to benefit rather than burden groups already burdened

• Competent, non-institutionalised groups before vulnerable populations
Sharing research benefits

- Individuals or groups who may benefit should share in some of the risks

- Those who bear the risks and burdens of research should be in a position to enjoy its benefits

- Necessary to ensure generalizability of research results/outcomes to all social, racial, sexual and ethnic groups
Criteria to consider for ‘Fair selection’

1. Purpose of the Research
2. Setting in which research will be conducted
3. Inclusion and exclusion criteria
4. Payments or mechanisms for coercion or undue influence for participation
5. Participant recruitment and enrolment procedures
6. Fair/equitable distribution of risks/burdens and benefits
7. Characteristics of study/subject population
Purpose of the Research

• The nature of the research should dictate the subject population.

• Benefits from the research should be distributed fairly. Groups likely to benefit should be considered for inclusion.

• Burdens from the research should be distributed fairly. If the proposed subject population is already burdened, it may be unfair for them to accept an extra burden.
Setting where research will be conducted

- Institutions e.g. Prisons, Hospitals, Clinics, Schools/Universities
- Urban vs Rural
Inclusion and exclusion criteria

- Should not result in participants included or excluded for non-scientific reasons e.g. cost, language etc.
- Persons more susceptible to the risks presented by the study must be identified by stated procedures to ensure their exclusion.
Recruitment and enrolment procedures

These procedures/methods must lead to equitable selection. e.g. there should be mechanisms in place to reduce the pressure or minimise the impact for persons susceptible to pressures.
Payments or mechanisms for coercion etc.

Are there payments or other mechanisms by which the participants will be coerced or unduly influenced to take part in the study/research?

The amount of payment/benefit, its timing or method of disbursement should not present undue influence or coercion.
Fair/equitable burdens and benefits

Does the study impose fair/equitable burdens and benefits so that 1 group does not disproportionately receive the benefits compared to another group assuming only the risks?
Characteristics of study/subject population

- Age
- Sex
- Diversity
- Vulnerability
Decision Re: Fair selection

Balancing of risks and benefits for individuals & groups appropriate to the scientific goals/objectives of the study and not the easy availability of/access to subjects or their reduced autonomy. i.e. Ensure subjects/participants are recruited for reasons of science, not compromised position. (Belmont Report)

The scientific goals of the study should be the 1° consideration in assessing study participants.
Conclusion

- Subject selection, recruitment and retention are central to the ethics of clinical research.

- The principle of Justice holds that particular individuals, groups or communities 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.
THANK YOU