



Stony Brook University

# FAR BEYOND

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IRB Meeting - Discussion

# Research with Human Subjects

## Review Criteria

Each IRB member should participate in the criteria for IRB approval of research

- **Selection of subjects is equitable.** In making this assessment the IRB should take into account the **purpose** of the research and the **setting** in which the research will be conducted.

Study: Inhaler use and compliance among under-privileged youth (setting is an adult prison)

# Research with Human Subjects

The IRB should make sure that criteria for selecting certain groups of individuals to participate in a study are scientifically related to the goals of the research and not based merely on convenience

Bankert and Amdur, 2006

# Research with Human Subjects

Research findings should be generalizable to individuals outside the study population and IRBs should not overprotect vulnerable populations. Routine exclusion of individuals can result in a disparity of information about treatment options for the excluded group.

Bankert and Amdur, 2006

# Research with Human Subjects

The IRB should review a description of the study population. Every study should provide a thorough description of the study population. Ask the following:

- Is the study limited to certain groups? (studies that plan to include men and women from multiple races and ethnic backgrounds, but recruit in hospitals where the majority of the patients are white)
- In this case, the IRB would be justified in questioning the recruitment methodology as inadequate to meet the goal of the study

# Research with Human Subjects

- Review the inclusion/exclusion criteria for the study population and see if any group that could be affected by the research is excluded. If so, is there justification for the exclusion (usually based on risks, benefits and the purpose of the research).
  - Study of risk factors for breast cancer could justifiably exclude men, but not minority women

# Research with Human Subjects

## Review Criteria

The IRB approves only those studies where this requirement is satisfied. If the criteria is not satisfied, the study must be deferred