

HANDOUT ON INTERNATIONAL REVIEW BOARD GUIDELINES

PROTECTING HUMAN SUBJECTS

Take the Hippocratic Oath seriously: “Do no harm.”

The Belmont Report and three (3) basic ethical principles

1. **Respect** – treat subjects as autonomous agents;
Self-determination (implement this via the “**informed consent**” form).
2. **Beneficence** – “Do no harm”;
Researcher has to know what is harmful;
Researcher is obligated to help both subjects and society;
Researcher has to assess risks and benefits;
Researcher has to know what they are and to keep monitoring them.
3. **Justice** – Who should receive the benefits of the research?
Who should suffer the risks?
Give the subject a chance to withdraw.

Criteria for IRB Protocol Review Approval (but not necessarily unconditional approval):

1. Risks to subject(s) must be kept to a minimum;
2. Risks in general must be kept to a minimum;
3. There must be an equitable selection of subjects (i.e., populations);
4. This is **KEY**: there must be **informed consent**;
5. There must be safeguards for insuring privacy and confidentiality;
6. There must be continuous monitoring of the data.

Two important questions:

1. Can the answer be gotten any other way?
2. Is it necessary and important enough?