**INTRODUCTION**

Research is done for the wellbeing of human being. So research on man for the interest of science and society should never take precedence over the considerations related to the wellbeing of the subjects.

**Historical aspect:** Concerns about the ethics of the practice of medicine have a long history, but until the middle of this century, they were mostly centered round the practice of therapeutic medicine, not research medicine. In 1946, 23 Nazi physicians went on trial at Nuremberg for crimes committed against prisoners of war. These crimes included exposure of humans to extremes of temperature, performance of mutilating surgery, and deliberate infection with a variety of lethal pathogens. During the trial, fundamental ethical standards for the conduct of research involving humans were codified into the Nuremberg Code, which set forth ten conditions that must be met to justify research involving human subjects. The two most important conditions were the need for voluntary informed consent of subjects and a scientifically-valid research design that could produce fruitful results for the good of the society.

**Table I**

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<td>National Commission for the Protection of Human Subjects of Biomedical Research</td>
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<td>Guidelines for Good Clinical Practice for Trial on Pharmaceutical Products</td>
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Basics of bioethics.

The Belmont Report—Ethical Principles and Guidelines for the Protection of Human Subjects, which was published in 1979, provides the philosophical underpinnings for the current laws governing human subjects research. Although other important principles sometimes apply to research, three basic principles provide a comprehensive framework for ethical decision-making in research involving human subjects, these are: Respect for persons, beneficence, and justice.

1. The principle of Respect for Persons acknowledges the dignity and autonomy of individuals, and requires that people with diminished autonomy be provided special protection. This principle requires that subjects give informed consent to participation in research. Because of their potential vulnerability,
certain subject populations are provided with additional protections. These include live human fetuses, children, prisoners, the mentally disabled, and people with severe illness.

2. The principle of beneficence requires to protect individuals by maximizing anticipated benefits and minimizing possible harms. Therefore, it is necessary to examine carefully the design of the study and its risks and benefits including, in some cases, identifying alternative ways of obtaining the benefits sought from the research. Research risks must always be justified by the expected benefits of research.

3. The principle of Justice requires that we treat subjects fairly. For example, subjects should be carefully and equitably chosen to insure that certain individuals or classes of individuals - such as prisoners, elderly people, or financially impoverished people - are not systematically selected or excluded, unless there are scientifically or ethically valid reasons for doing so. Also, unless there is careful justification for an exception, research should not involve persons from groups that are unlikely to benefit from subsequent applications of the research.

ELEMENTS OF A RESEARCH PROTOCOL

Investigators conducting or collaborating research involving human subjects must receive approval by an Institutional Review Board (IRB) before they begin their study. Generally, an investigator provides the IRB with a research protocol, which is a written description of, and scientific rationale for, the proposed research activity. It includes a discussion of the human subject protection issues that are relevant to the study and addresses, at a minimum: the risks to subjects; all procedures which are experimental; the anticipated benefits to subjects, if any; the anticipated number of subjects; the proposed consent document and consent process to be used, and appropriate additional safeguards if potentially vulnerable subjects are to be enrolled. Potentially vulnerable subjects may include the elderly, prisoners, children, cognitively impaired individuals, or people who are economically or educationally disadvantaged.

The seven requirements make research with human being ethical. They are
1. Social or scientific value
2. Scientific validity
3. Fair subject selection
4. Favorable risk-benefit ratio
5. Independent review
6. Informed consent
7. Respect for potential and enrolled subjects

CONCLUSION

Research investigator should be honest and responsible enough to safeguard the rights and welfare of the people participating in their research activities. On the other hand, society should have a law to protect human research subject and researcher as well and to promote ethically sound research.

REFERENCES
2. Lecture notes of Professor Harun-Ar-Rashid, Director, Bangladesh Medical Research Council, Bangladesh.
3. Regulation and Ethical Guidelines Nuremberg code
5. Regulation and Ethical Guidelines Belmont Report
6. Council for International Organizations of Medical Sciences (CIOMS) cited in Lecture notes of Professor Harun-Ar-Rashid, Director, Bangladesh Medical Research Council, Bangladesh.