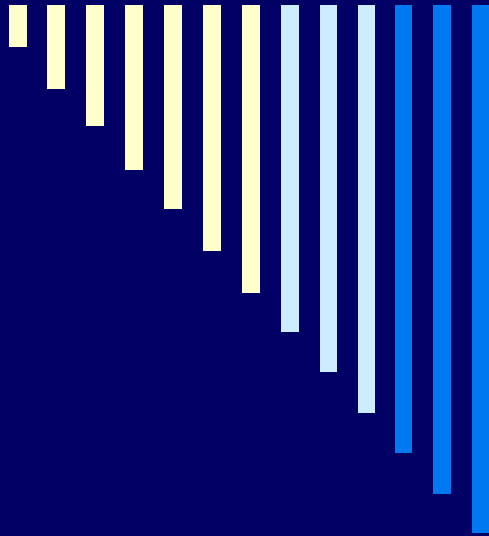


**Great Lakes Centers for
Occupational and Environmental Safety and Health
University of Illinois School of Public Health**



Ethical Issues in Human Research

Sofia, Bulgaria

June 3, 2003

PRISONERS



Peter Orris, MD, MPH

Professor and Chair

Institutional Review Board


Cook County Bureau of Health Services



THE NUREMBERG CODE

Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10. Nuremberg, October 1946–April 1949. Washington, D.C

1. The voluntary consent of the human subject is absolutely essential.



“This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other **ulterior form of constraint or coercion.**”

Ethical Issues in Human Research

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INSTITUTIONAL REVIEW BOARD

Review Principals

RESPECT FOR PERSONS

Recognition of the personal dignity and autonomy of individuals

BENEFICENCE

Protection of persons from harm by maximizing benefits and minimizing risks

JUSTICE

Provision that the benefits and burdens of research are distributed fairly



Ethical Issues in Human Research

Sofia, Bulgaria

June 3, 2003



May 19, 2000

TO:

OPRR Staff

FROM:

Director of Regulatory Affairs, OPRR
Director, Division of Human Subject Protections

SUBJECT:

OPRR GUIDANCE ON APPROVING RESEARCH INVOLVING PRISONERS

Ethical Issues in Human Research

Sofia, Bulgaria

June 3, 2003

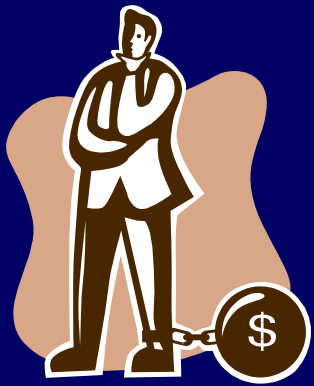


Ethical Issues in Human Research

Sofia, Bulgaria

June 3, 2003

- A majority of the Board (exclusive of prisoner members) shall have no association with the prison(s) involved, apart from their membership on the Board.
- (b) At least one member of the Board shall be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity,



Ethical Issues in Human Research

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Cook County Bureau of Health Services

Cook County Hospital

464 Bed Tertiary Care Hospital

Provident Hospital

260 Bed Community Hospital

Oak Forest Hospital

600+ Bed Rehabilitation and Extended
Care Hospital

Core Center

Outpatient Treatment of AIDS & Related Diseases

Community Clinics

Network of 33 Primary Care Clinics

Cermak Health Services

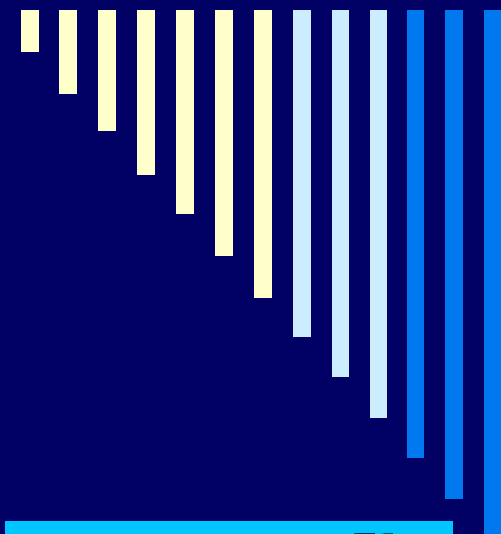
Cook County Jail Health Services

Cook County Bureau of Public Health

Preventive and Surveillance Services

Public Private Partnerships

Health Service Programs

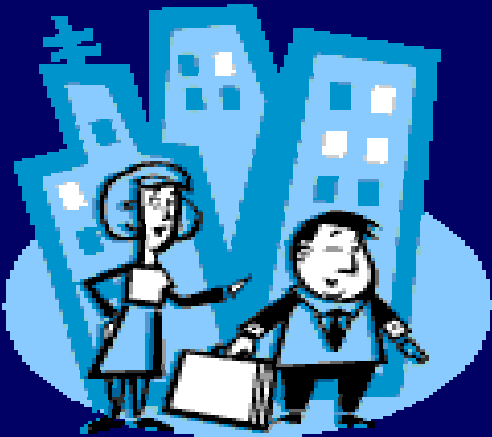


Cook County Bureau of Health Services

Serving primarily an:

indigent
immigrant
minority

Patient Population



PRISONERS

Categories Of Permissible Research:

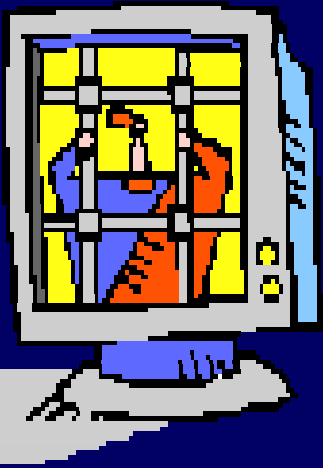
Minimal risk studies of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;



PRISONERS

Categories Of Permissible Research:

Minimal risk studies of prisons as
institutional structures or of
prisoners as incarcerated persons



Ethical Issues in Human Research

Sofia, Bulgaria

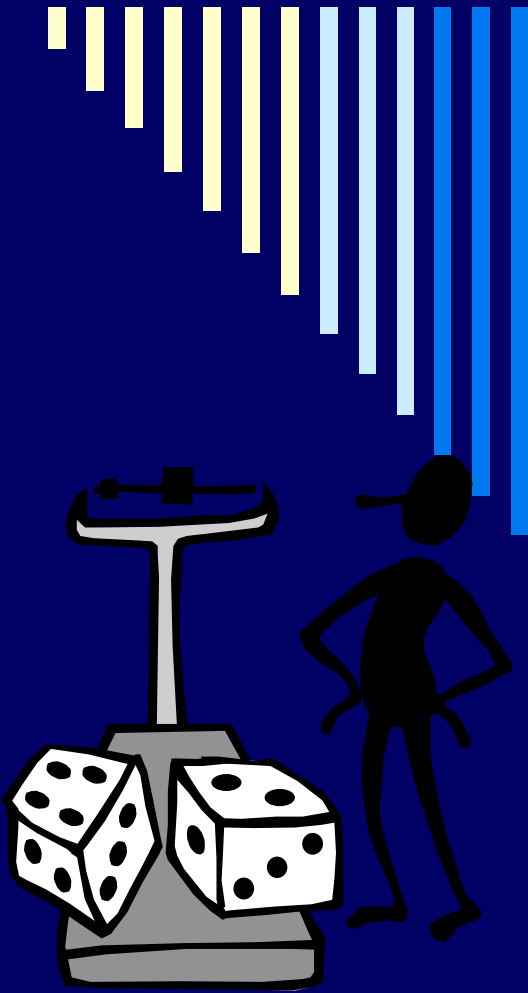
June 3, 2003

Prisoners:

Minimal risk is the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.

Patients:

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.



PRISONERS

Categories Of Permissible Research:

Research on conditions particularly affecting prisoners as a class

For example,

vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere

or

research on social and psychological problems such as alcoholism, drug addition, and sexual assaults



(provided that the study may proceed only after the Secretary has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice, in the **Federal Register**, of his intent to approve such research)

PRISONERS

Categories Of Permissible Research:

research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject.

Or

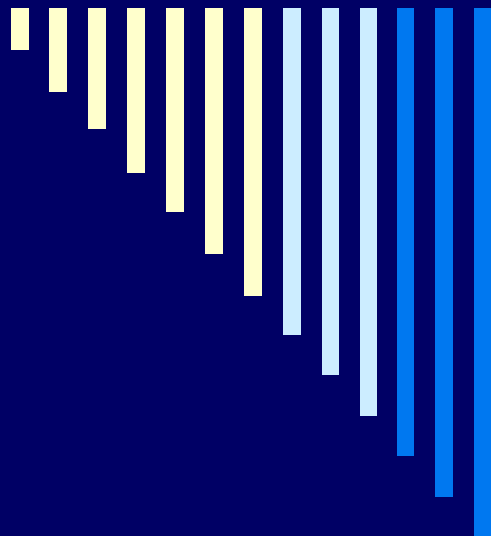
in which the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research



IRB REVIEW MUST ASSESS:

1. Any possible advantages accruing to the prisoner through his or her participation in the research, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired;

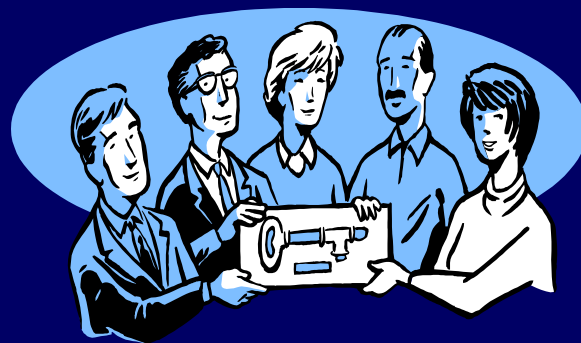




IRB REVIEW MUST ASSESS:

- (3) the risks involved in the research are commensurate with risks that would be accepted by nonprisoner volunteers

- (4) procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners.



IRB REVIEW MUST ASSESS:

(6) adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole; and



PRISONERS

Example:

Study of the Prevalence of Anti Social Personalities amongst prisoners at the Cook County Jail.

Utilize psychological interviews at the time of Intake into the jail by jail psychologists to identify subjects And Controls.

