



LEGAL AND ETHICAL
ISSUES IN HUMAN
SUBJECT RESEARCH

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THERAPY VS RESEARCH

- EXPERIMENTAL THERAPY
 - NONTHERAPEUTIC RESEARCH
 - CLINICAL TRIALS
 - CHALLENGE STUDY
 - THERAPEUTIC RESEARCH
 - NEW VS. EXISTING THERAPY
 - NO THERAPEUTIC ALTERNATIVE
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ETHICAL REQUIREMENTS

- NUREMBERG CODE
 - HELSINKI DECLARATION
 - BELMONT REPORT
 - THE COMMON RULE
 - FUNDAMENTAL RIGHT TO BE TREATED WITH ESSENTIAL HUMAN DIGNITY
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EXPERIMENT MUST BE ETHICALLY DESIGNED

- VALID
 - PRECLINICAL UNDERSTANDING OF UNIVERSE OF HARM
 - VALUABLE
 - RISKS MINIMIZED AND OUTWEIGHED BY BENEFITS
 - THERAPEUTIC: CLINICAL EQUIPOISE
 - NONTHERAPEUTIC: SHOMEIR P'TAYIM
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PRINCIPAL INVESTIGATOR

- SCIENTIFICALLY QUALIFIED
 - SUPERVISION BY CLINICALLY QUALIFIED MEDICAL PERSONNEL
 - NO CONFLICTED INTERESTS
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INFORMED CONSENT

- PURPOSE
 - PROCEDURE
 - RISKS
 - BENEFITS
 - SELECTION
 - ALTERNATIVES
 - FINANCIAL INTERESTS
-

UNINFORMED CONSENT: MYTH OF INFORMED CONSENT

- NOT THERAPEUTIC CONSENT
 - EXPERIMENT
 - THERAPEUTIC MISCONCEPTION
 - PARENTS AND THEIR CHILDREN
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RESPONSIBLE PROTECTORS OF HUMAN SUBJECTS

- IRB MEMBERS: EXPERIENCED,
AVAILABLE, INFORMED
 - SUBJECT ADVOCATES
 - RAC
 - OHRP
 - FDA
 - ALL OF US
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