


Institutional Review Board
Human Subjects Protection
Informed Consent

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Human Subjects Protection

- Why is the IRB Needed?
 - Nazi War Crimes
 - Tuskegee Institute (1932-1972)
 - Vietnam War (1950s) – Effects of LSD
 - Ohio State Prison (1960s) - Live cancer cells
 - Laud Humphreys Team Room Trade Study (1970)
- Nuremberg Code (1947)
- Belmont Report (1979) – respect, beneficence, justice
- 45CFR46 (1991) – Protection of Human Subjects
- 45CFR165 (1996) – HIPAA
- 21CFR (1980) – FDA regulations

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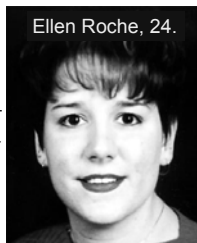
Jesse Gelsinger, 18.

GENE THERAPY – Sept 1999. Ph I trial at Penn – 18 w/ enzyme disorders. Within hrs of 1st injection, Jesse fell sick. Organ system failure, next day coma. 3 d later life support removed. FDA findings → JG ineligible for protocol based on eligibility criteria. FDA troubled by failure to report AEs seen in others. Conflicts of interest.

Time Magazine 4/22/02

ASTHMA - July 2001. Effects of hexamethonium to understand asthma at JHU Asthma/Allergy Ctr – 3 healthy volunteers. 2 days after inhaling chemical, Ellen, resp tech, developed cough, fever & muscle pain. ARDs & died w/in a month. Chemical more toxic than realized. PubMed databases (from 1960), missed earlier studies. IRB & investigator flaws shut down JHU

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Ellen Roche, 24.

HSP Certification

- 12.28.2007, all UMDNJ personnel → human research.
- Collaborative IRB Training Initiative (CITI).
 - 2000 – U Miami, Fred Hutchinson Cancer Ctr.
 - 830 participating institutions.
 - 25 sections – ethics, regulations, behavioral research, genetics, records-based, vulnerable pops, minors, FDA regulated research, HIPAA, conflicts of interest.
 - Commit > 2.0 hrs.
- Required - CITI Refresher Course every 3 yrs.
- Find CITI url at UMDNJ Research website.
- Recertification for old HSP certification.

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Institutional Review Boards

- Objective:
 - Protection of human subjects
 - Medical therapy for injury
 - HIPAA.
- IRBs - Newark, NB/Piscataway, Stratford/Camden.
 - Separate and mutual reviews.
 - Common application.
 - Each campus IRB office – administrative review.
- WIRB – Industry-sponsored, funded, created.

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Institutional Review Boards

- Research: Systematic investigation, incl development, testing/eval, designed to add to generalized knowledge.
- Human Subjects: Living individual about whom an investigator conducting research obtains data through intervention w/ individual or identifiable data.
- IRB Review Criteria:
 - Minimal Risk: Probability/magnitude of harm/discomfort anticipated in the research not greater than those encountered in daily life during performance of routine physical or psych exams or tests.
 - Risk: Everything beyond minimal.
- Harm = physical, psychological, social or economic

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Retrospective Studies

- Research using records collected in the PAST.
 - Medical records
 - Employee records
 - Databases
 - PHI identifiers & no re-contact
- Information must exist prior to approval.
- Often considered under expedited or exempt review due to minor risk status.

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Institutional Review Boards

- Review Types:
 - Full Board = > Minimal risk
 - Expedited = Minimal risk, retrospective studies
 - Exempt = Minimal, retro studies w/ no identifiers
 - See Appendices F & G on website for qualifiers
- Meetings → 1-4 mtgs/mo depending on campus
 - 2 weeks from submission deadline to review
- Written comments w/in 2-4 wks of review
 - Tabled
 - Approval
 - Conditional Approval
 - Disapproval

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IRB Application

- Visit campus website for application download.
- Latest version!
- Complete carefully & fully, or risk return.
 - Participating staff, Conflicts, Sites, Specimens, Privacy/Confidentiality, PHI, Security, Protocol, Subject profile (diminished capacity), Recruitment methods, and consenting procedures.
- Offices will review application.
- Save electronic version of submission for renewals

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IRB Application

- Signed by Dept Chair, co-investigators & other significant research team.
- Require:
 - Copies of CITI certificates
 - Signed Financial Disclosure forms
 - Copies of Protocol
 - Copies of Instruments/Questionnaires
 - GAFA?
- Checklist
- Renewal at least annually.

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Informed Consent Document

- Objective: Person's voluntary agreement based upon adequate knowledge & understanding of relevant information, to participate in research or to undergo a diagnostic, therapeutic, or preventive procedure.
- In receiving informed consent, subjects may not waive or appear to waive any of their legal rights.
- Assent (minors)
- Language issues.
- Waiver of Consent

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Informed Consent Document

- Available UMDNJ template
 - 9th grade reading level
 - Elements: Research, purpose, duration, # of subjects, procedures, exclusions, risks/benefits, alternatives, new information, confidentiality, costs, therapy if injured, right to refuse/withdraw, & contact information.
- Follow closely, match application and protocol.

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Summary

- CITI Education certification
- Minimal risk
- Full Board, Expedited or Exempt Review
- Retrospective Studies
- IRB Application
 - Complete, consistent and precise, otherwise tabled
 - Consent forms – match application & protocol
- Seek advice from IRB offices.

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