Introduction to Research Ethics.

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LEHIGH VALLEY
HOSPITAL
AND HEALTH NETWORK

INTRODUCTION TO RESEARCH ETHICS

Scott J. Lipkin, DPM
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Historical Overview

- The Nuremberg Code
- The Declaration of Helsinki
- The Belmont Report
- The Common Rule

Nuremberg Code

- End of WWII
- Prosecution of Nazi Physicians and Scientists
- The Tribunal drafted a set of 10 ethical principles for inclusion of humans in research
- Basic Tenant: Participation as a research subject in any medical experiment must be voluntary

Declaration of Helsinki

- Drafted by the World Medical Association (1964, last updated in 2000)
- Next step toward creation of standard ethical guidelines
- Has become the basis for Good Clinical Practices (GCPs) that are used today

Research Abuses in the US

- Radiation Experiments (1940-1960s)
- Willowbrook Hepatitis Study (1963-1966)
- Public Health Services Syphilis Study (1932-1972)

Responses to Research Abuses

- Congress enacted the National Research Act in 1974 as a result of the publicity from the Tuskegee syphilis study

National Research Act

- Created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research
- Goal of the Commission: Conduct a comprehensive investigation to identify the basic ethical principles that should underlie the conduct of research involving human subjects

National Commission Reports

- Research on the fetus (1975)
- Research involving prisoners (1976)
- Research involving children (1977)
- Institutional Review Boards (1978)
- Delivery of Health Services (1978)
- Research involving mentally infirm (1978)
- The Belmont Report (1979)

Belmont Report

- Cornerstone for the principles and regulations governing the ethical conduct of research in the US involving human subjects
- Written in 1979 by the National Commission for the Protection of Human Research Subjects

Belmont Report

Three basic principles:

- Respect
- Beneficence
- Justice

Belmont Report

- Respect
  - Respect for individuals as autonomous agents
  - Requires additional protections for those with diminished autonomy
- Clinical Applications
  - Informed Consent must include
    - Disclosure of information about the research
    - Tailoring the information to an individual's ability to comprehend
    - Assuring that the consent process occurs in an environment free of coercion and undue influence

Belmont Report

- Beneficence
  - Research subjects should not be harmed
  - Research should maximize benefits and minimize harms
- Clinical Applications
  - Research should begin only after the expected benefits outweigh the anticipated harms

Belmont Report

- Justice
  - Benefits and risks should be distributed fairly
- Clinical Applications
  - Equitable selection of subjects

Protection of Human Research Subjects

- 1974: Regulations protecting human research subjects became effective in the United States
- 1981: Significant revisions of the regulations by both the DHHS and FDA
- 1991: Revision involved adoption of the Federal Policy for the Protection of Human Subjects (the Common Rule: 45 CFR 46)

FDA Regulations

- 1980: The FDA adopted many of the provisions of the common rule (21 CFR 50 and 56)
- 1991: Final revision to 21 CFR 50 and 56

Additional Protections

- 45 CFR 46, Subpart A (vulnerable subjects in general)
- 45 CFR 46, Subpart B (pregnant women, fetuses)
- 45 CFR 46, Subpart C (prisoners)
- 45 CFR 46, Subpart D (children)
- 21 CFR 50, Subpart D (children)

Institutional Review Boards

- "Investigators should not have the sole responsibility for determining whether research involving human subjects fulfills ethical standards. Others who are independent of the research must share the responsibility."

National Commission Report on IRBs, 1978

Responsibilities of the IRB

- Approve, disapprove, or require modifications of research
- Conduct continuing review of IRB approved research
- Observe/monitor/audit on-going research
- Suspend or terminate approval of research

45 CFR 109

21 CFR 56.109

Authority of the IRB

- 45 CFR 46
- 21 CFR 50 and 56
- 21 CFR 312
- 21 CFR 812
- Institutional Policies
- Federal Wide Assurance

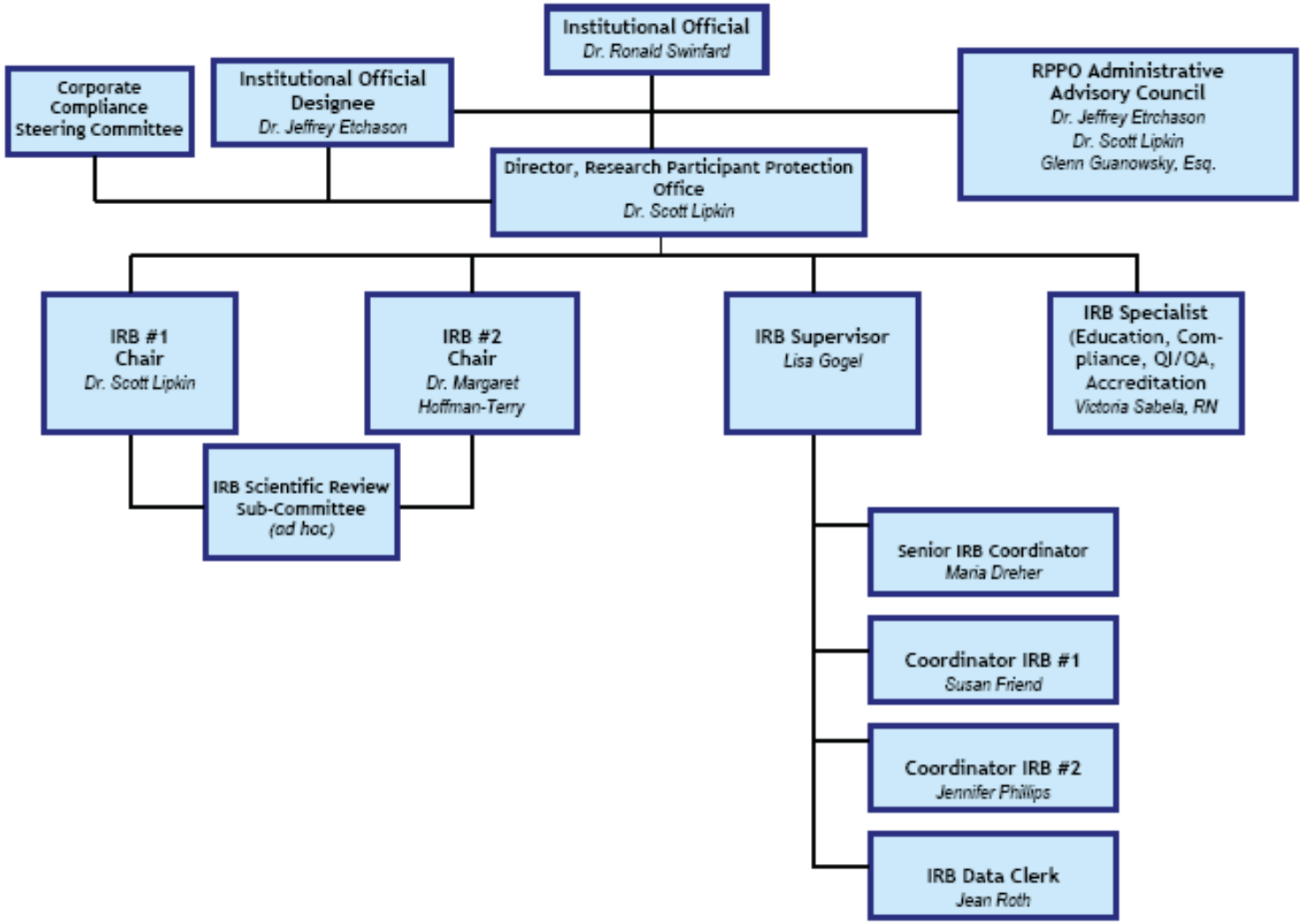
IRB Criteria to Approve Research

- Risks to subjects are minimized (B)
- Risks to subjects are reasonable in relation to the anticipated benefits (B)
- Selection of subjects is equitable (J)
- Safety monitoring is in place (B)
- Privacy and confidentiality are maintained (B)
- The informed consent process is appropriate (R)
- Informed consent is appropriately documented (R)
- Additional protections for vulnerable subjects are in place (R,B)

Research Protection at LVH

- Comprehensive HRPP
- Support from the “Institution”
- Research Participant Protection Program
- Two Institutional Review Boards

Organizational Chart— LVH Human Research Protection Program

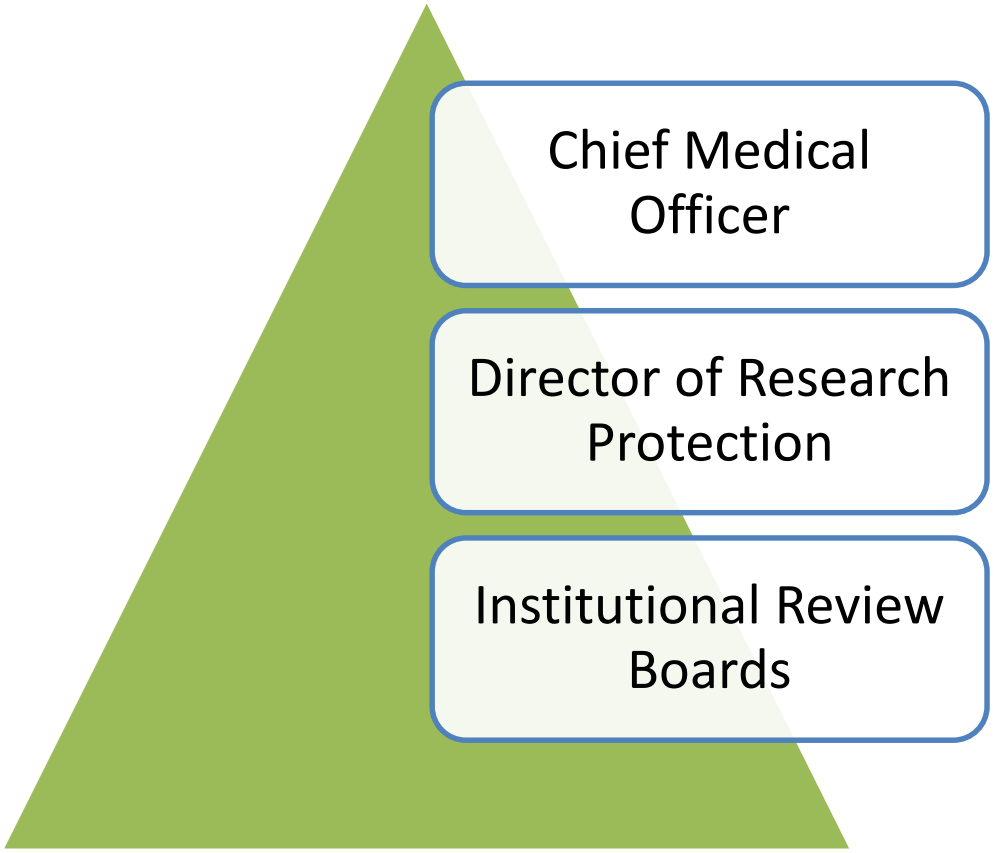


Lehigh Valley Hospital and Health Network

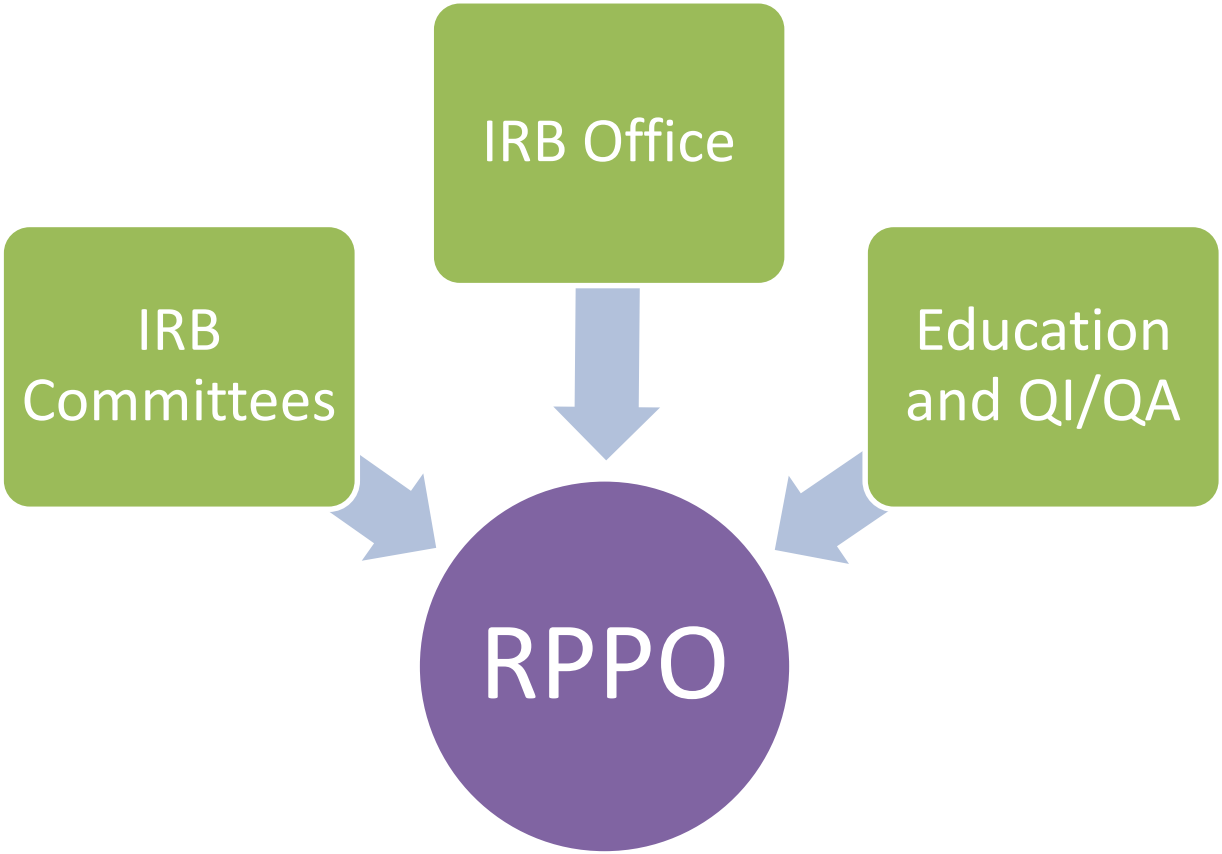
Overview of the Human Research Protection Program

- The **HRPP** is the institution's (LVHHN's) program to protect our research participants
- The supporting entity of the HRPP is the Research Participant Protection Office (**RPPO**)
- The **IRB** Office is a component of the RPPO

Overview of the HRPP



The Human Research Protection Program of LVHHN



LVH IRBs

- Two committees
- Each committee meets monthly
- Each IRB reviews all types of research