

# Ethics, Standards of Prevention, and HIV Prevention Trials

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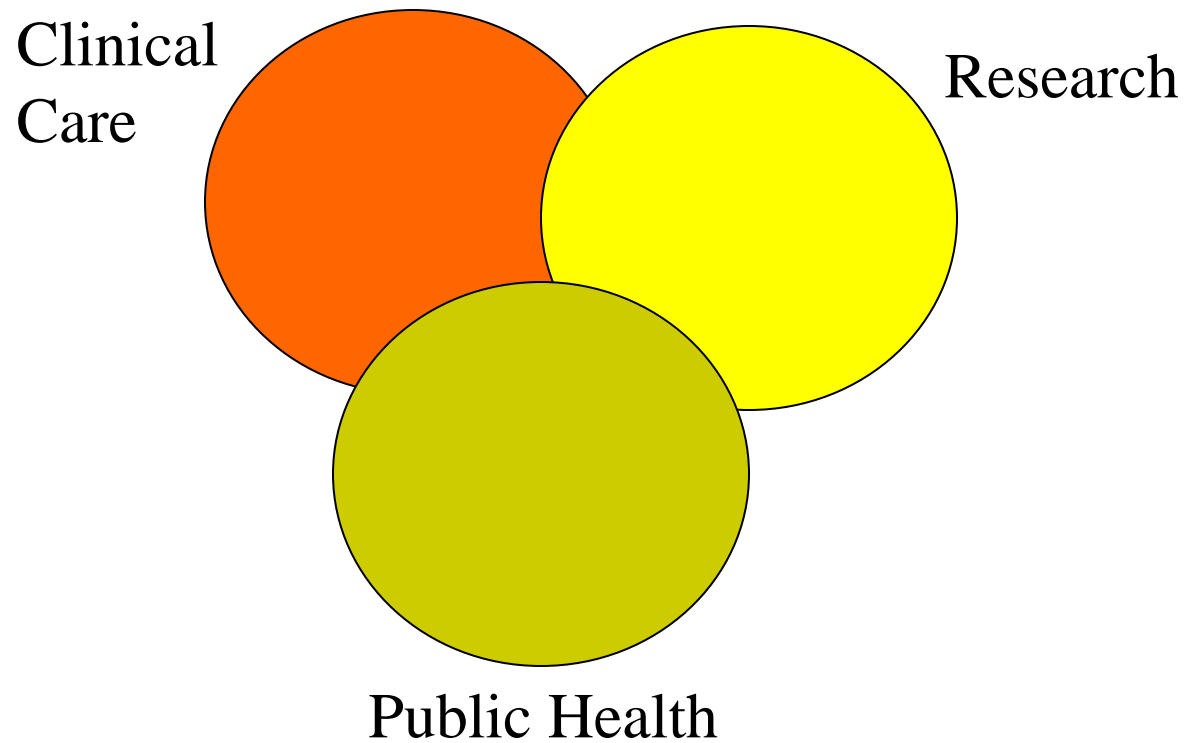
# Central Questions

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- Why is there so much confusion?
- What ethical framework(s) might be employed to enhance understanding and optimize the chances of doing good science that protects the rights and interests of those enrolled?

# HIV Prevention Science

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# Ethical Principles for Research

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- Respect for persons
  - Individual subjects
- Beneficence
  - Maximize benefits of research (knowledge to be gained) while minimizing risks to subjects
- Justice
  - Libertarian



# Ethical Principles for Clinical Care

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- Respect for autonomy
  - Individual decision-making
- Beneficence
  - Promote the health of patients
- Non-maleficence
  - Not harming individuals
- Justice
  - Egalitarian



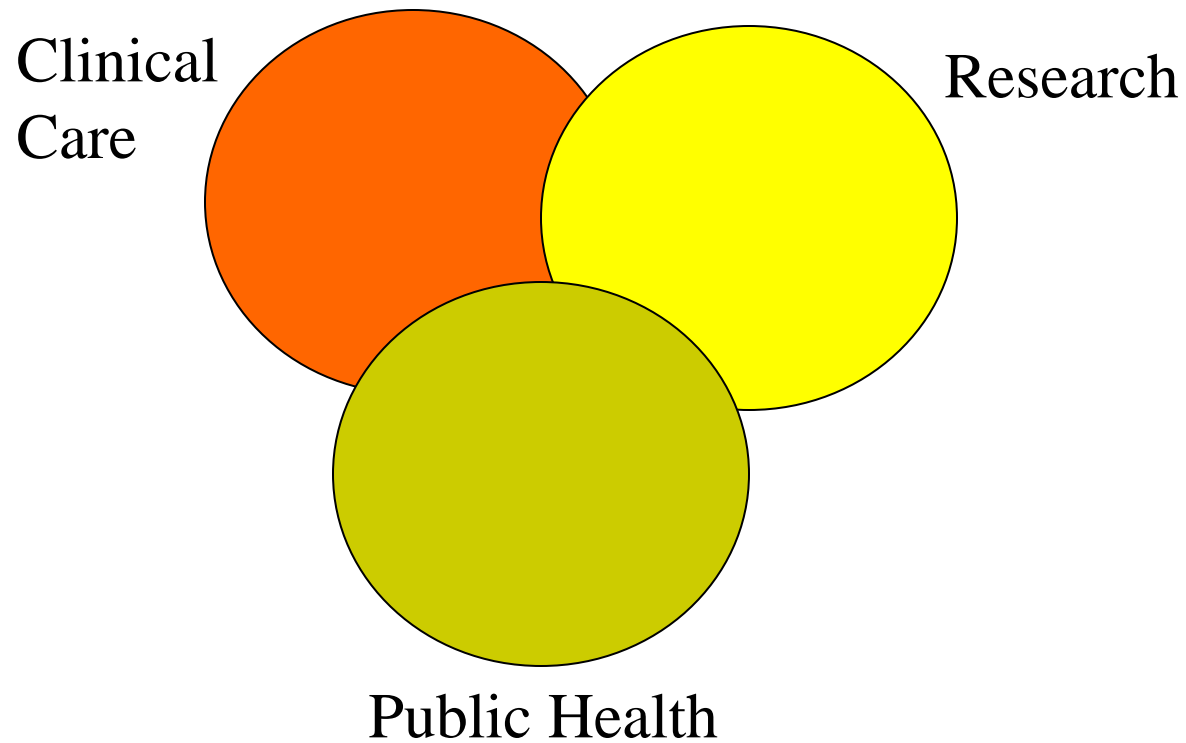
# Ethical Principles in Public Health

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- Respect for autonomy
  - Least restrictive alternative
- Beneficence
  - Enhance the health of communities
- Social justice
  - Utilitarian (risks/benefits; precautionary)

# Ethics in HIV Prevention Science

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# HPTN Ethics Guidance (2003)

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- General considerations
- Meeting local needs and priorities
- Care and prevention
- Informed consent



[http://www.hptn.org/ResearchEthics/HPTN\\_Ethics\\_Guidance.htm](http://www.hptn.org/ResearchEthics/HPTN_Ethics_Guidance.htm)



# HPTN Ethics Guidance (2009)

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- Revision in process
- Guidance across the research continuum





# Standard of Prevention

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**Guidance Point 9:** In partnership with key stakeholders, HPTN should establish a package of effective, comprehensive and locally sustainable prevention services to be offered to participants in each HPTN study.

- Ethical obligation: Provision of prevention package
- Ethical aspiration: Content of the prevention package

Draft Language: Not for quotation or citation.



# Reality Strikes

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- Prevention paradox
- Evidence
  - Efficacy and safety
  - Context
- Appropriateness
  - Cultural/religious
  - Legal
  - Equity
- Resource constraints
  - Primary goals
  - Stewardship



# Necessary Conditions

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- Effective
- Practically achievable
- Reasonably accessible

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# Preventive Ethics

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- Sensitivity to the normative aspects of practice across and within particular domains
- Policies and systems
- Informed consent
- Community engagement