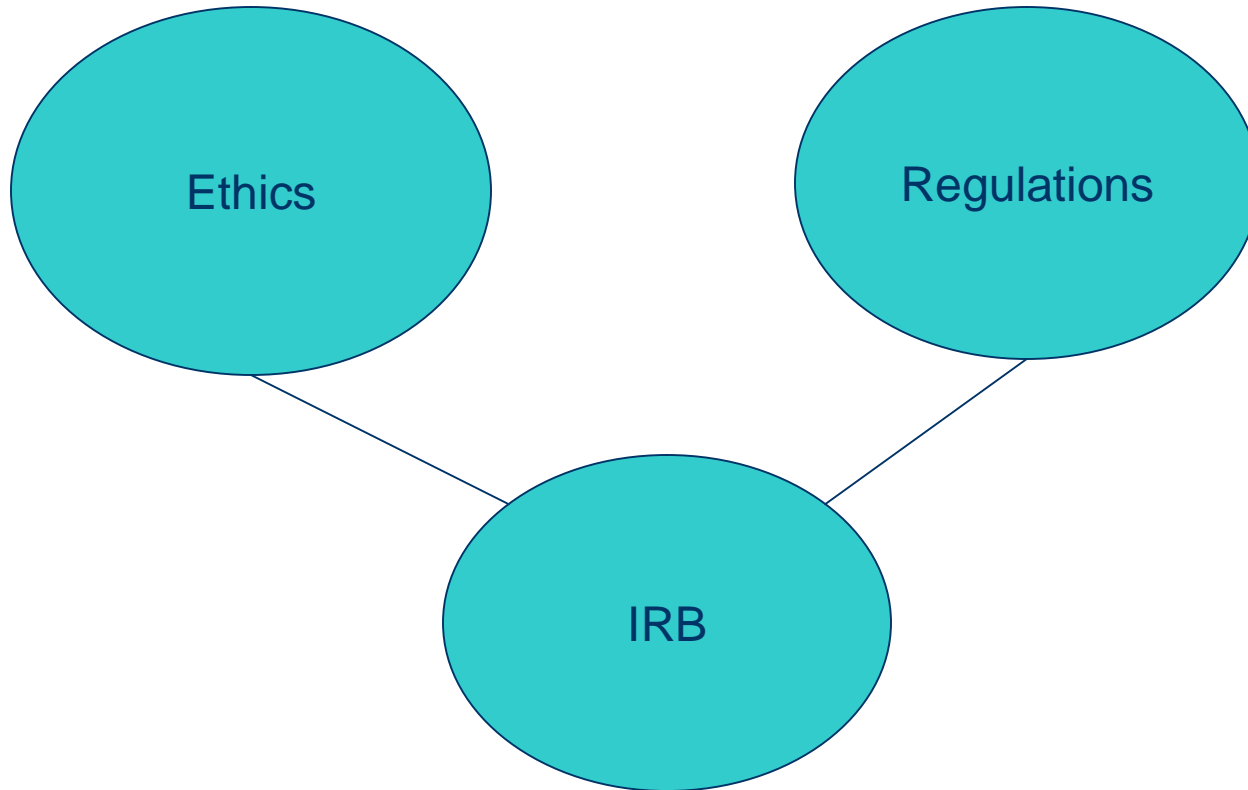


# ***Ethics & QI Research***

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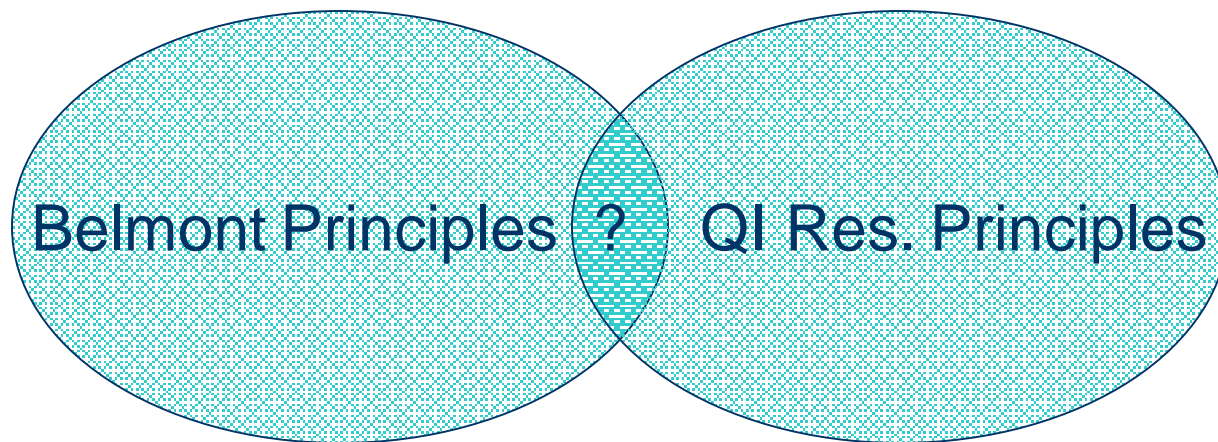
# Overview



# Ethics

- | Ethical principles governing human subjects research: “Belmont Report”
  - Respect for Persons
    - | Individual autonomy
    - | Protection of individuals with reduced autonomy
  - Beneficence
    - | Maximize benefits and minimize harms
  - Justice
    - | Equitable distribution of research burdens and benefits

# Ethics



# Regulations

- I Regulatory definition of human subjects research
  - Research - a systematic investigation designed to develop or contribute to **generalizable knowledge**
  - Human Subject - a living individual **about whom** an investigator conducting research obtains 1) data through intervention or interaction with the individual, or 2) identifiable private information

# IRB Review Issues

- I IRB expertise and models (clinical trials)
  - Need better framework which explains QI research
  - Educate IRBs/Join IRBs (Tierney)
- I Is QI research biomedical research or social science research?
  - Affects IRB review: biomedical IRBs don't do social science well

# IRB Review Issues

*The Common Rule provides sufficient flexibility for IRBs to effectively and efficiently review non-biomedical research*

- Definition of Research
- Exempt Research
- Expedited Review
- Waiver of Consent and/or Documentation of Consent

# Example

- I Patient consent for data collection
  - Eligible for a waiver of consent
    - o Minimal risk
    - o Does not adversely affect the rights and welfare of subjects
    - o Research could not practicably be done without the waiver
    - o Where appropriate, subjects will be debriefed

# Conclusion

- I IRB review of QI research does not have to be a problem if IRBs:
  - Have sufficient knowledge & expertise
  - Understand ethical issues in QI research
  - Utilize the flexibility in regulations
- I QI researchers have to
  - Develop clear research framework and ethical standards
  - Educate and serve on IRBs