

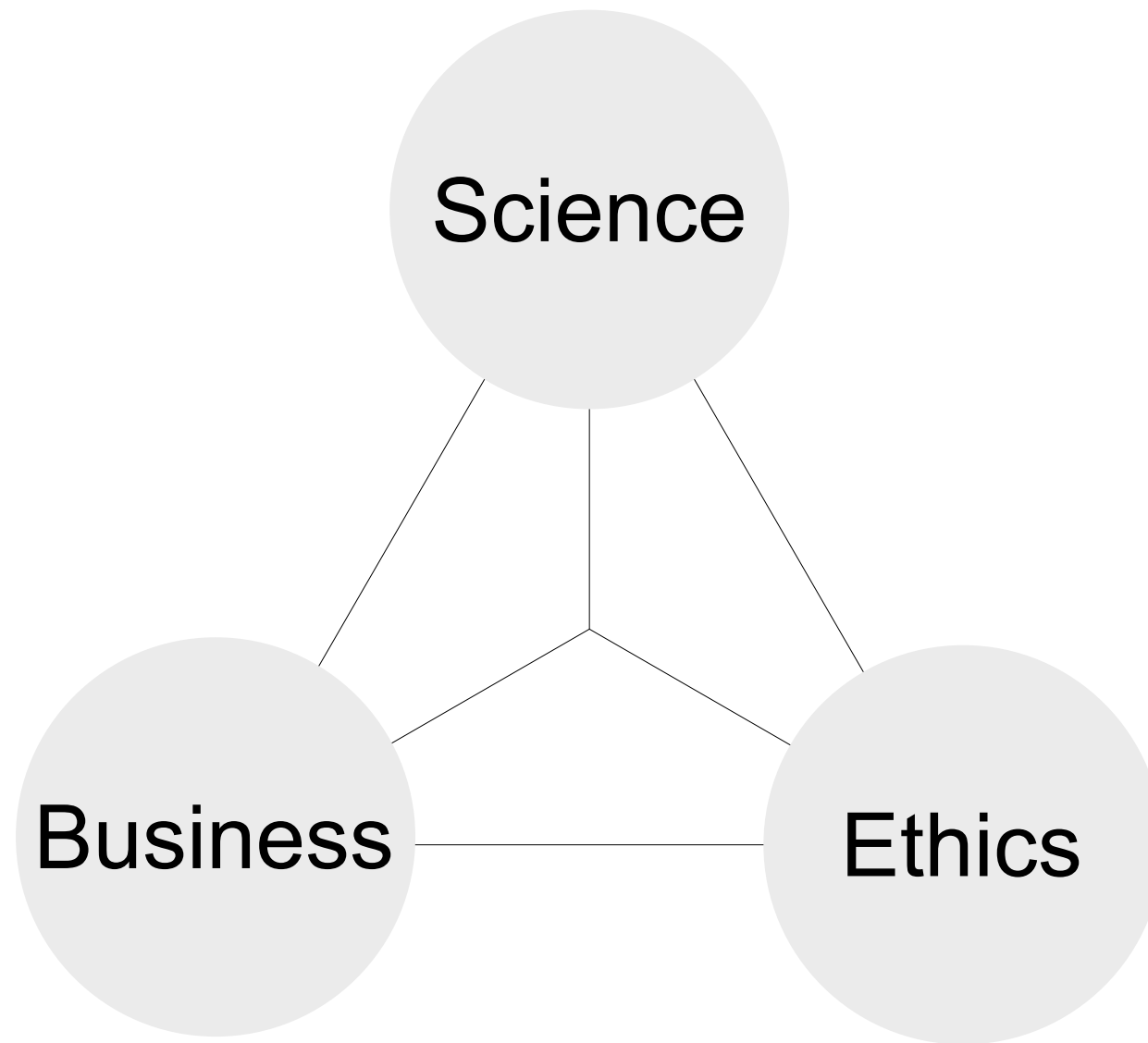
The case for a nonprofit independent IRB – improving the ethical review of research

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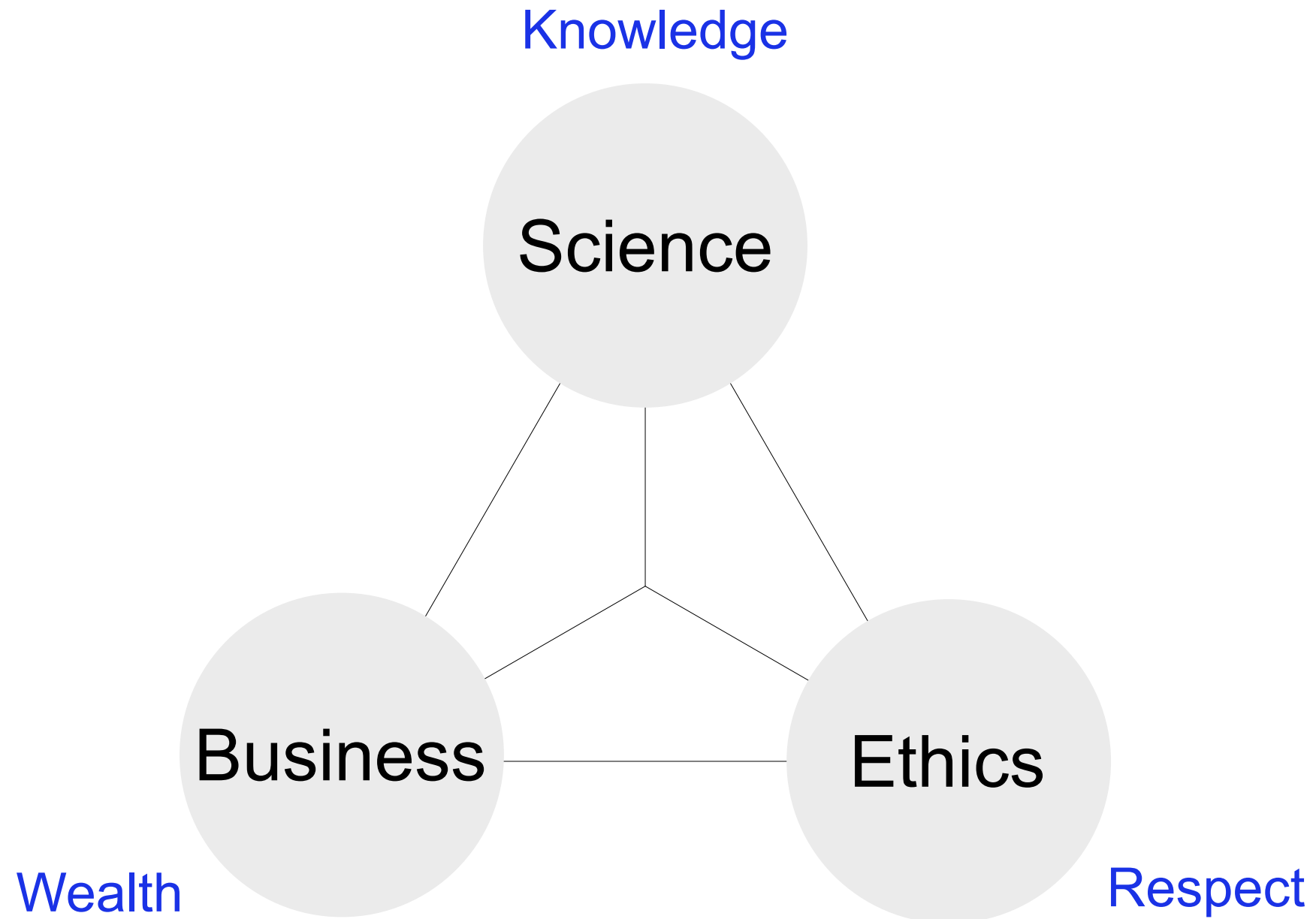
About me

- Internal medicine/hematology
- Clinical researcher at NIH
- CIO of the NIH clinical center
- CIO of MaineHealth
- CEO of Western IRB
- Executive Board Chair of Quorum IRB
- PRIM&R and AAHRP Boards
- SACHRP Chair

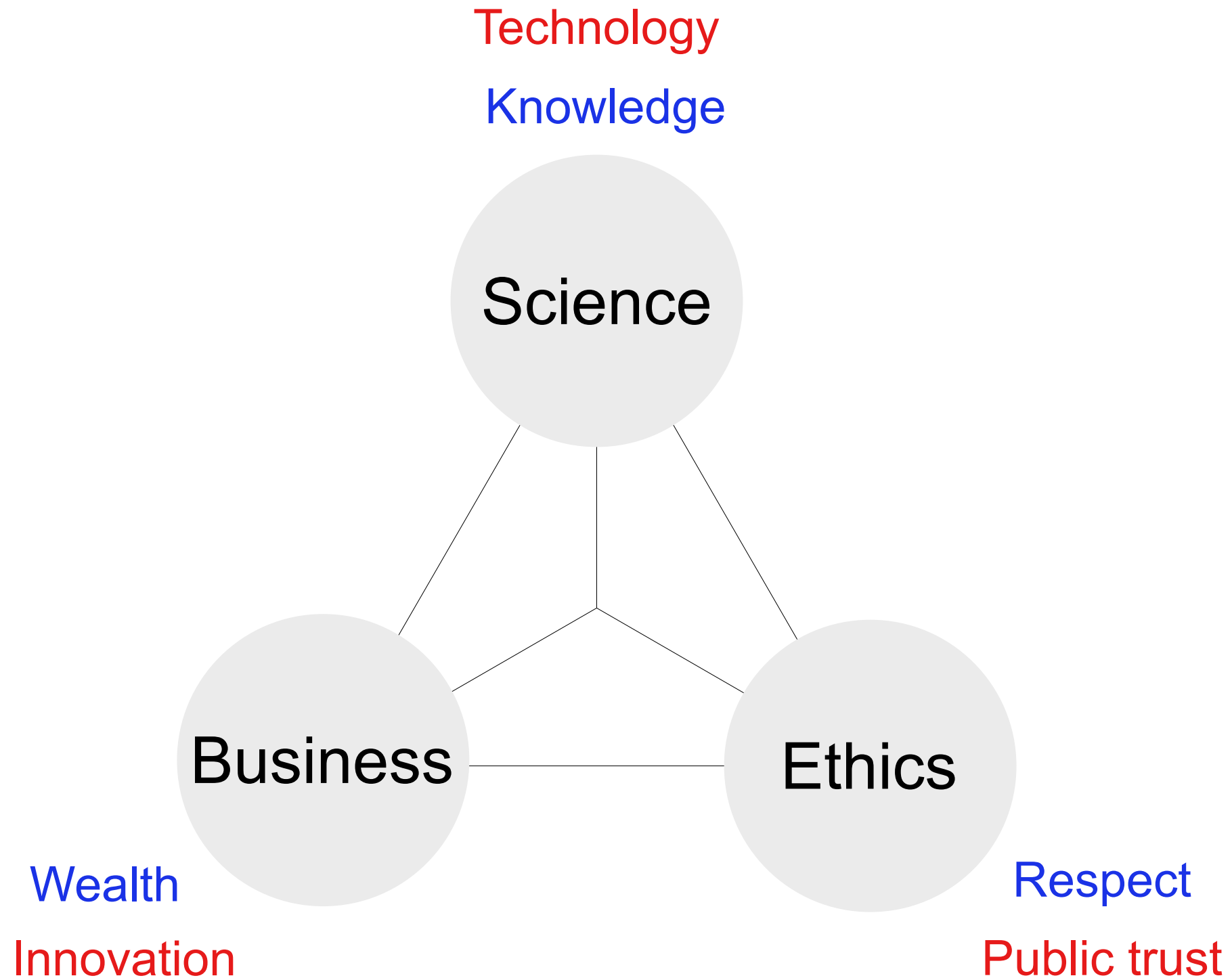
Importance of IRBs



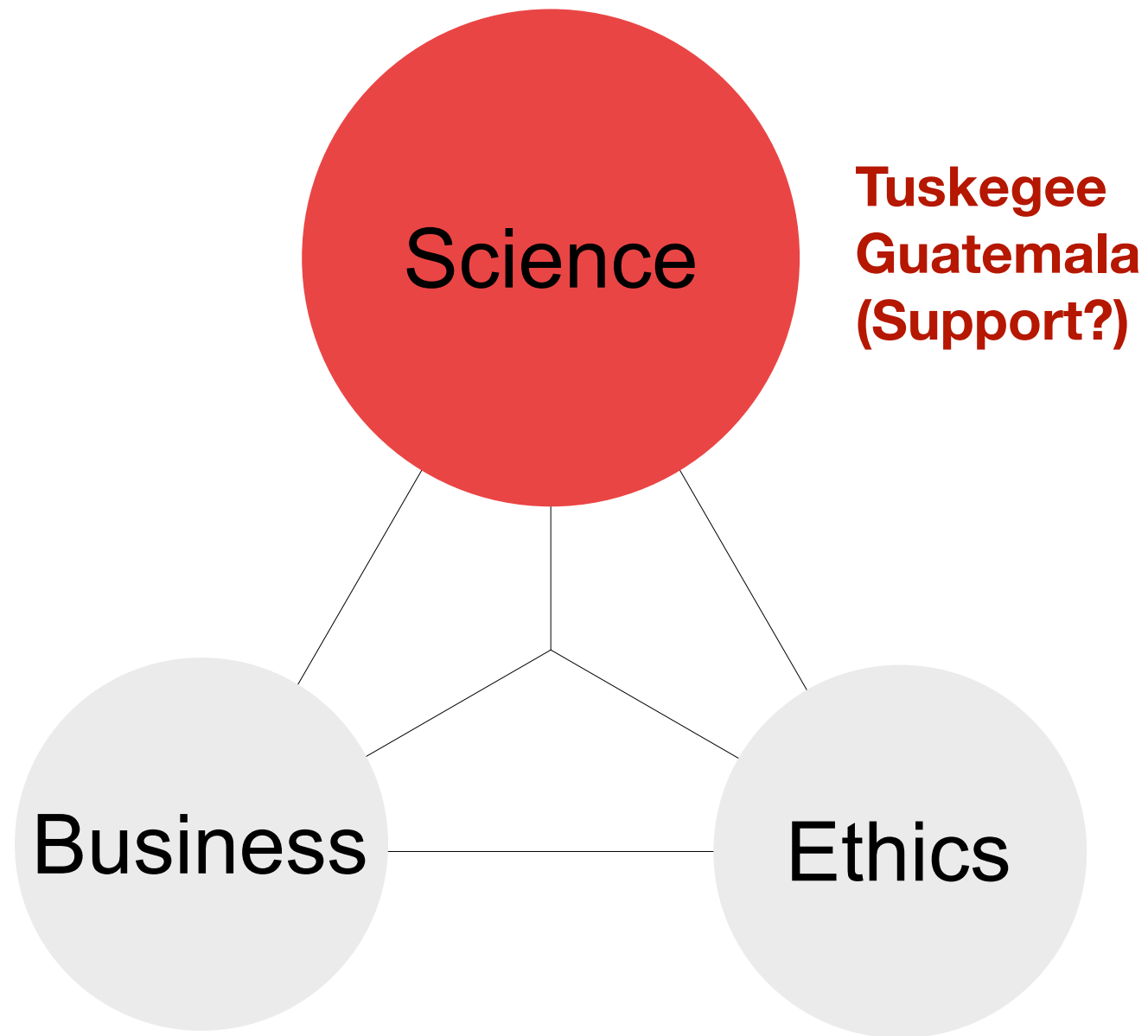
Importance of IRBs



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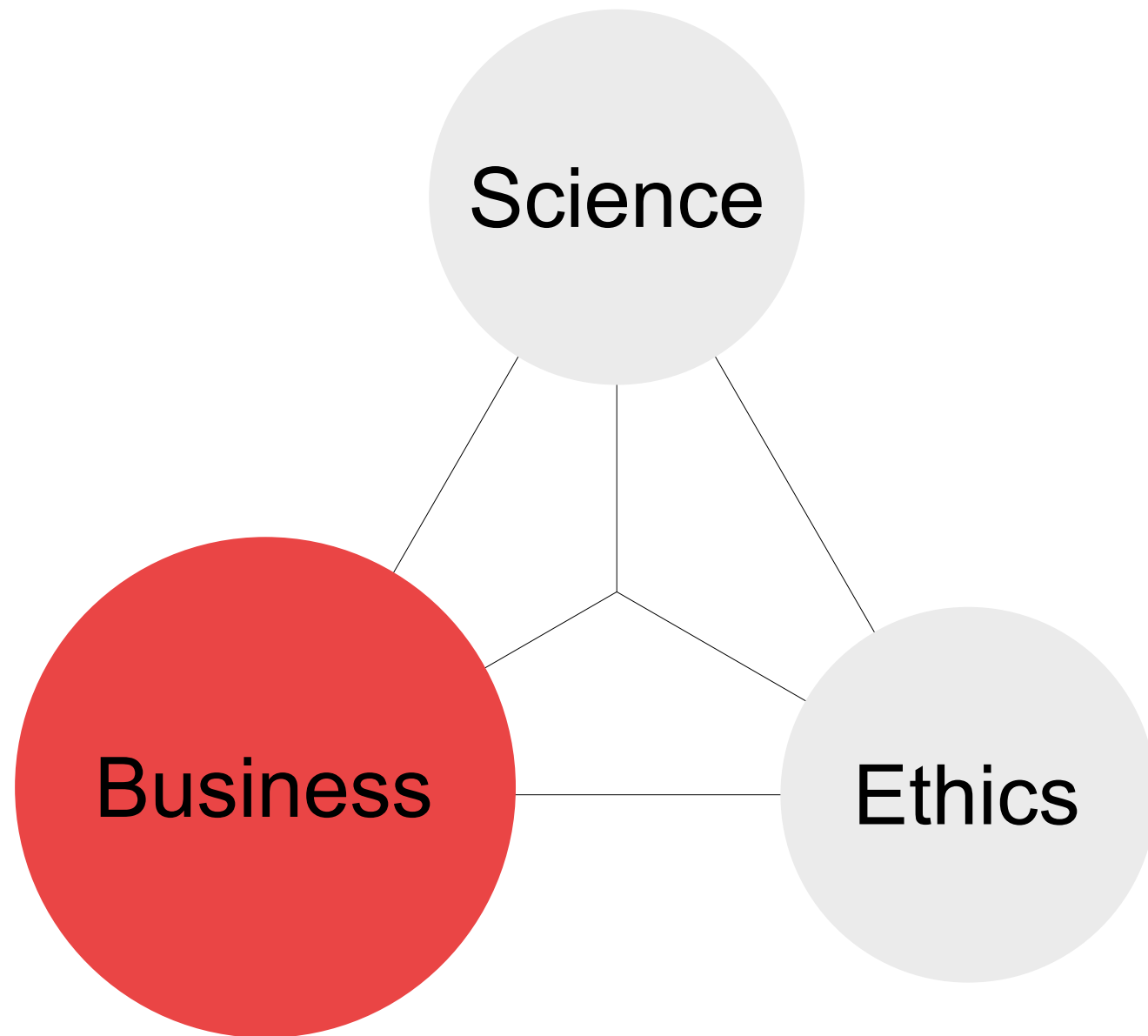


Importance of IRBs

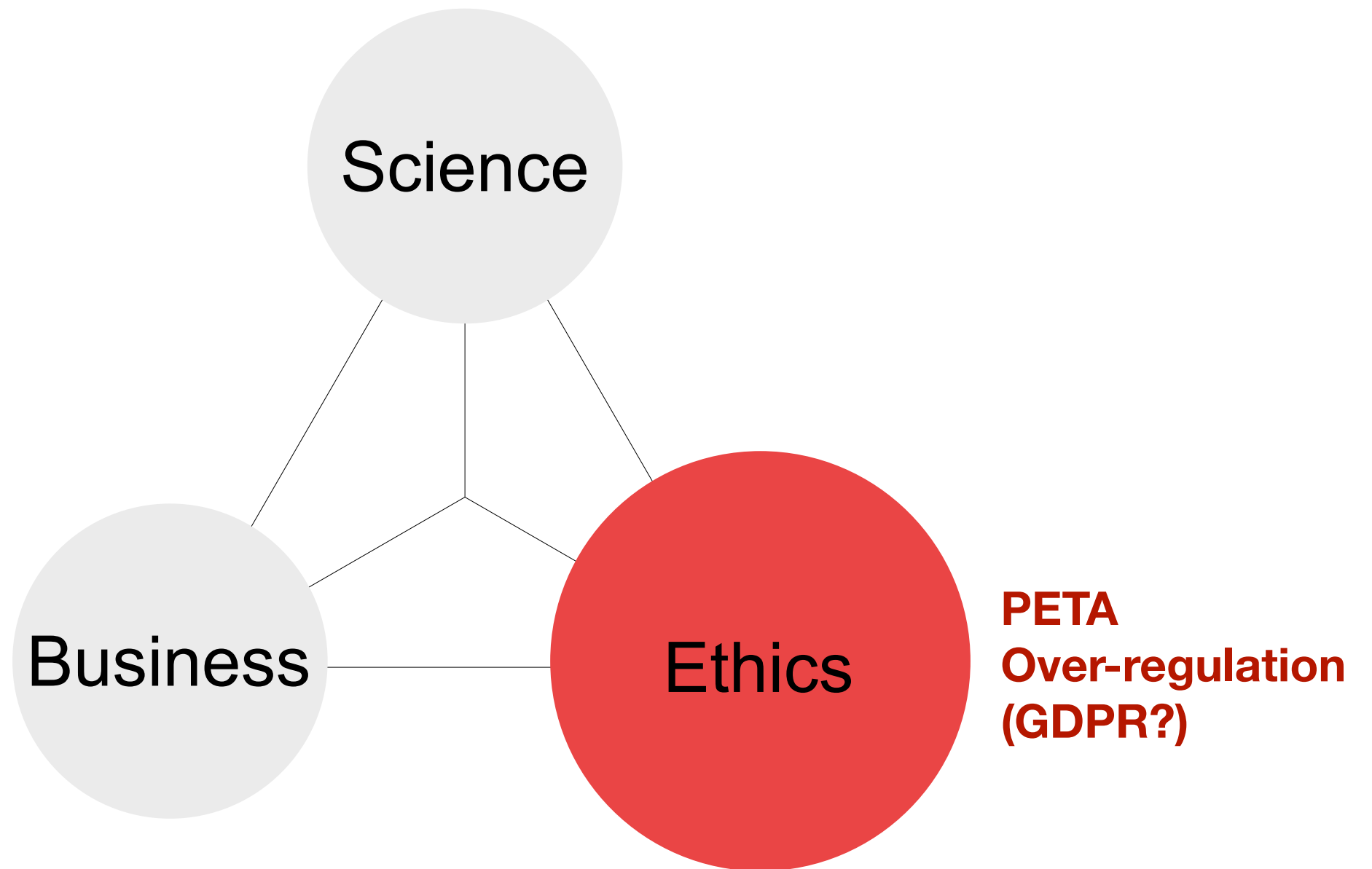


Importance of IRBs

**Vioxx
Stem Cell Clinics
(Boeing 737 Max?)**



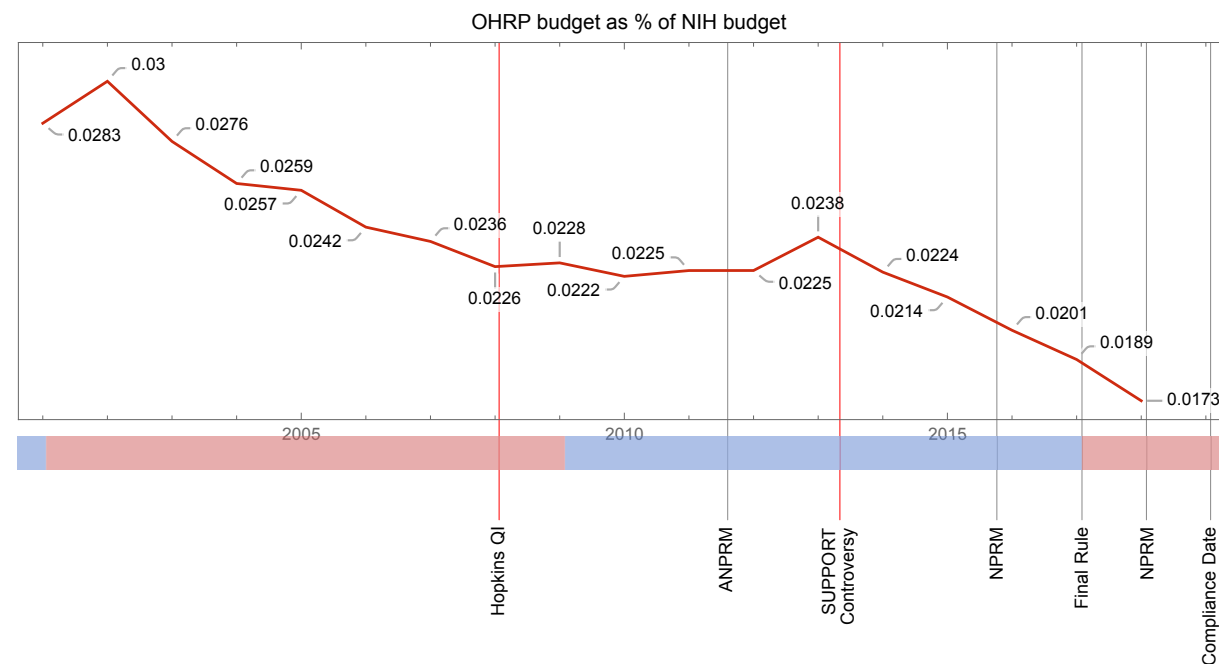
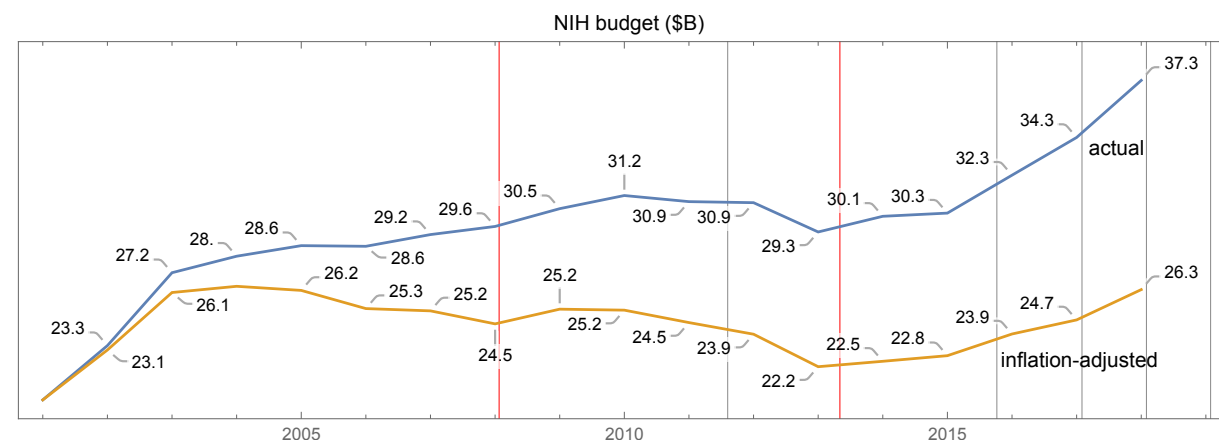
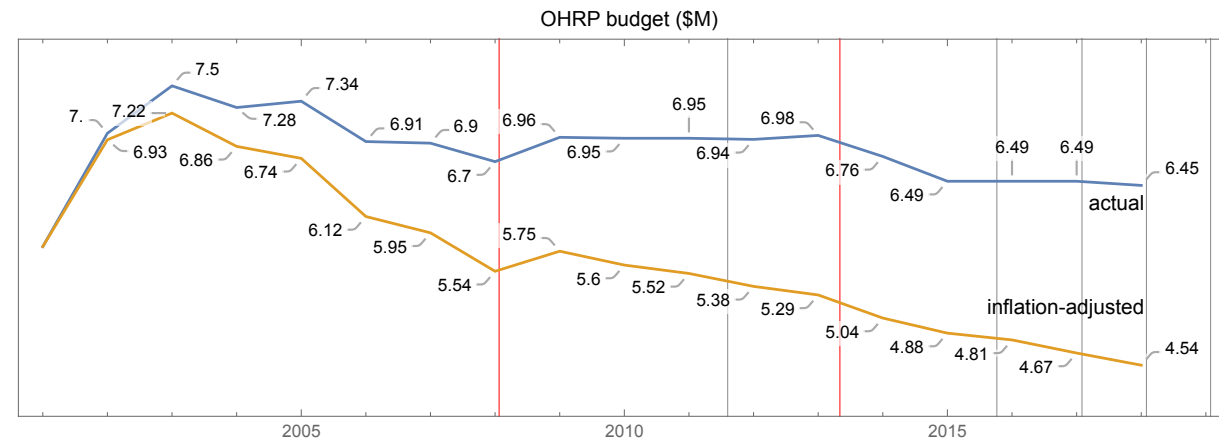
Importance of IRBs



State-of-the-IRB

- Not a learning system
- Opaque
- Quality v. process metrics
- Emphasis on compliance rather than ethics (loss of mission-focus), but...

Recent developments



Recent developments

- **Regulations**
 - Single IRB mandates
 - Impact on institutional IRBs/HRPPPs
 - Difficulty changing institutional staffing, budgets, processes
 - Leadership - change is not seen as mission-driven

Recent developments

- **Research**

- Genomics
- “Big data”
- Wearables and Apps
- Citizen science
- Decedents...
- And no more “box”

“**Human subject** means a living individual about whom an investigator (whether professional or student) conducting research: (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.”

Recent developments

- **Independent IRBs**
 - Investor-ownership
 - Competing fiduciary obligations
 - Consolidation and lack of competition
 - Focus on cost-cutting
 - Little reason to innovate
 - *Business Roundtable...*

Proposal: nonprofit independent IRB

- Flexibility of a small business (**independent**)
- Fiduciary obligation to research subjects (**nonprofit**)
- Platform for innovation in quality, process, precedent, transparency, inclusion of the participant perspective (**“learning IRB”**)
- and... financially self-sustaining