INFORMATION INTEGRITY SOLUTIONS

Trust me I'm a Doctor!

Why this isn't working and how to fix it

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International Society for Biological & Environmental Repositories 2013 Annual Meeting

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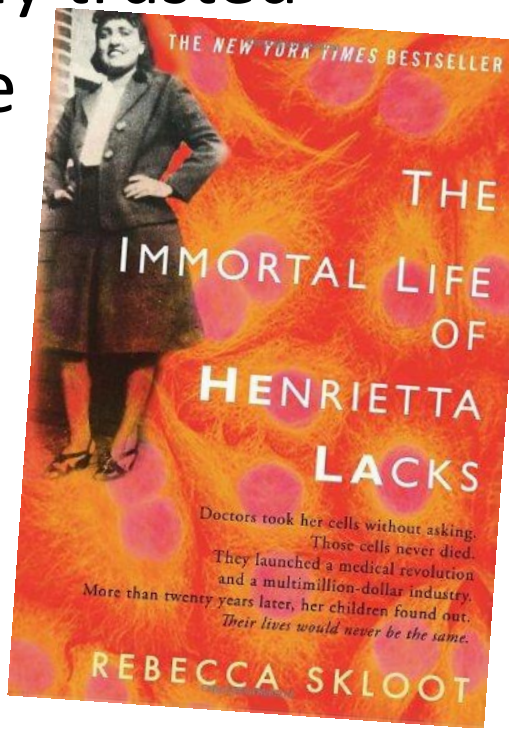
INFORMATION INTEGRITY SOLUTIONS

‘What’s the Problem?’

- Biobanks & medical research are highly valued
- Biobanks & medical research are highly trusted
- Medical information is highly sensitive
- My grandfather was a Patient
  - BUT I am a Health Consumer
- And underlying fears:
  - Internet & Re-identification
  - Surveillance Society
  - Brave New World α-β-γ-δ
  - What’s done can’t be undone
  - Even if it could, who will do it?



Building trust and innovative privacy solutions

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Building trust and inno… …key solutions

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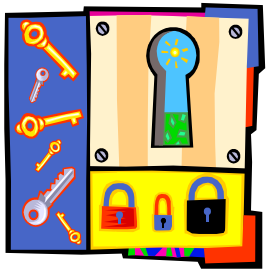
The Solution's Obvious

- More Legislation
  - Researchers and biobankers follow the laws
    - *BUT laws are broken by bad people with malicious intent*
    - *And even the good guys make mistakes*

- More Guidelines
  - Provide guidance about what is the right thing to do
    - *YET constantly evolving as technology and society evolves*
    - *And even the good guys make mistakes*



- More Infrastructure
  - Locks on filing cabinets, passwords, encryption
    - *BUT any system can be broken into with enough determination*
    - *And even the good guys make mistakes*

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‘There has to be a better way’

- But we have to structure the problem properly
- First, winners and losers:

	Research Value	Privacy, Safety etc
Public Interest	☑	?
Private Interest	?	☑

  - Implication: the economics of externalities

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‘There has to be a better way’

- Second, risk management has 3 components:
  - Prevention – Detection – Response
  - Response has 3 components:
    - Learn – Restore – Punish
- Third, there’s a big difference between reversible adverse events & those that aren’t
- Fourth, all systems degrade, even governance
  - 2nd Law of Thermodynamics

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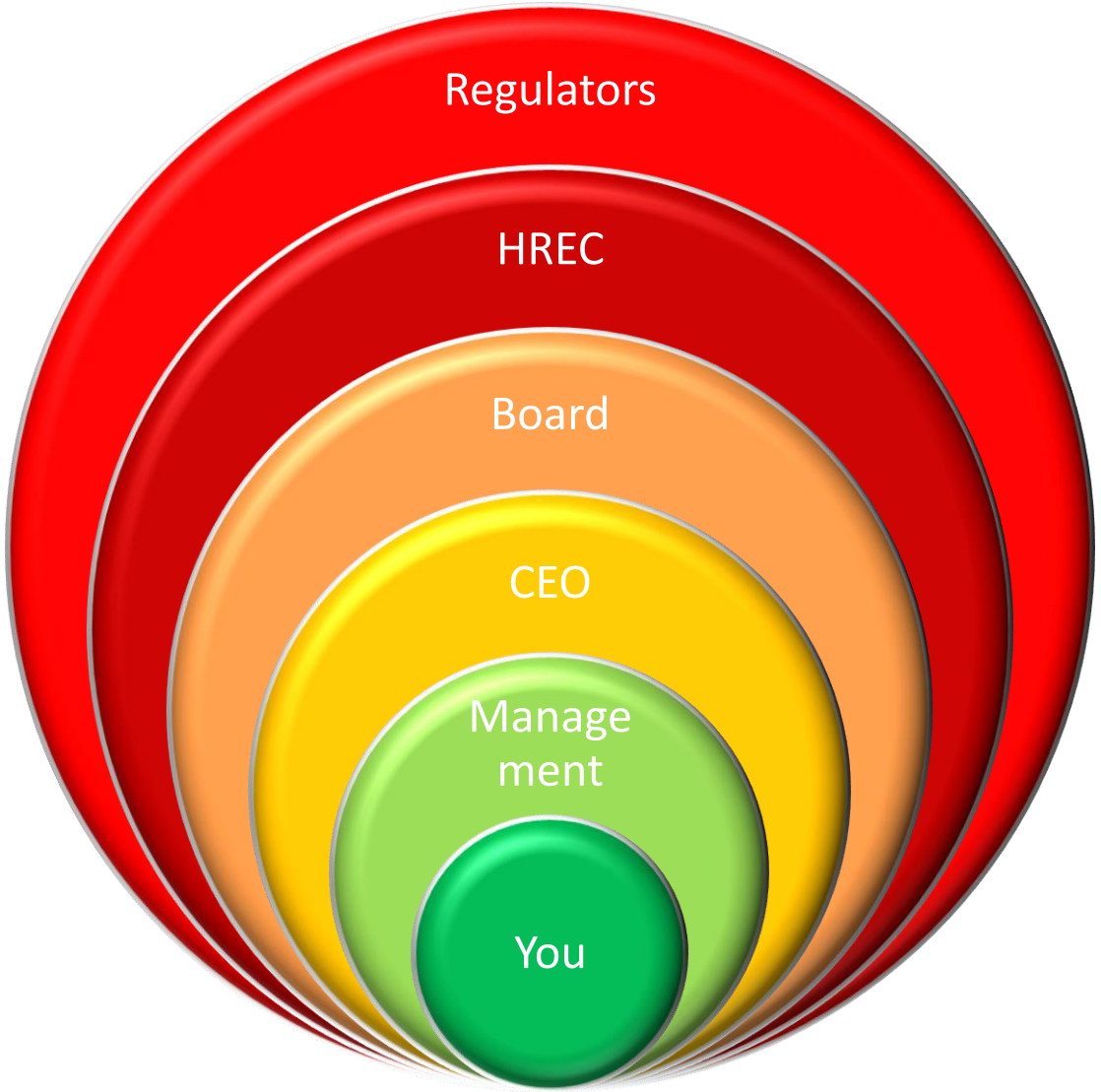
So, what is the better way?

- Governance!
  - Ethical, Effective, Efficient
  - Fit for purpose
- Start with what works
- Improve it or add to it

Remember governance is like an onion

- Eg:



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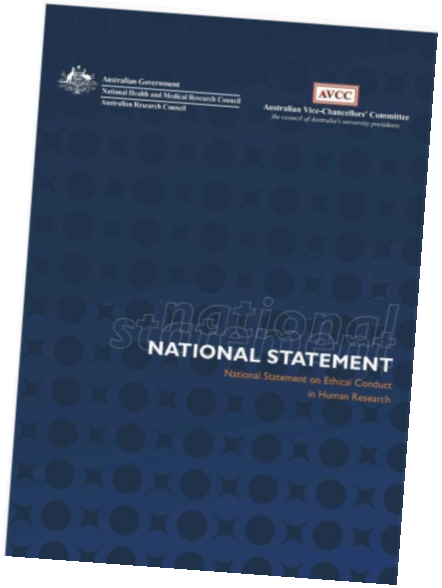
Now let's apply all this to Prevention

- Where would you like the balance to lie?
  - With you!
- Where is the balance now?
  - Too far towards the outer circles?
- So how to re-balance?
  - National Statement, HRECs etc enough?
- **Change Idea No 1:**
  - Strengthen: education, guidance, leadership
  - Evaluate, publish, share, community input



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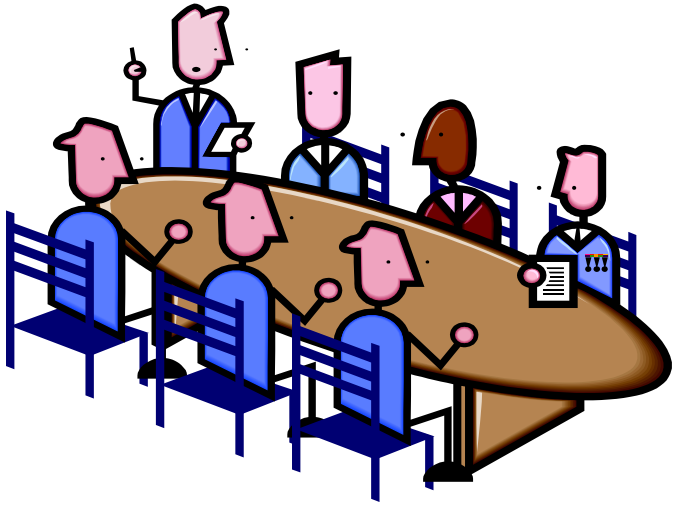
But also!

- The externality problem
  - Real or perceived
- Hence Ethics Committees
  - Research merit
  - AND stand in the shoes of research subject
  - Challenge is process and efficiency



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supporting research and ethics

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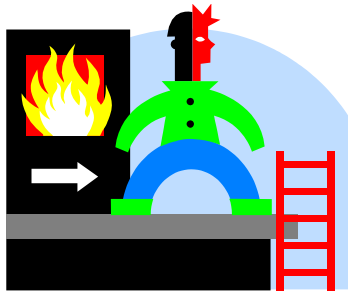
But one more thing … Response when it all goes wrong

- Not if, WHEN
  - Plan and Practice!
  - Fire drill; data back up; …



- Research equivalent?
  - For researcher AND for research subjects?
- **Change Idea No 2**
  - Detection & Response plans MUST
    - Maximise learning
    - Ensure recovery
    - Minimise need for punishment
    - Provide public assurance!

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Yes, the patient perspective

- First, it will depend on whether the adverse event is reversible or irreversible
- Some events genuinely irreversible
  - If you are dead, you are dead
  - Others less so, even reputation and discrimination with effort
- **Change Idea No 3**
  - For the reversible, the better the recovery the greater the acceptable levels of risk
  - What's your plan? How to spread the risk? Insurance?

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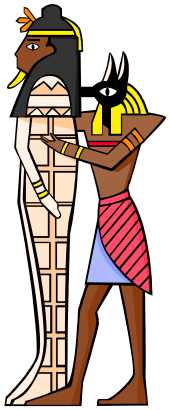
The 2nd Law of Thermodynamics

- So your prevention and recovery strategies address patient risk
- There's still the 2nd Law…
  - Laziness/negligence/malfeasance
  - Times change
    - People move on and get old
    - Corners cut
    - New people come in
    - New technologies & practice



- **Change idea No 4**
  - Plan for this too – Review or be reviewed!
  - Publish, engage, be up front, be honest

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Yes, change is needed

- **Change Idea No 1:**
  - Strengthen with education, guidance, leadership
  - Evaluate, publish, share, seek external views & input
- **Change Idea No 2**
  - Focus your Detection & Response plans to
    - Maximise learning
    - Ensure recovery
    - Minimise need for punishment

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Yes, change is good

- **Change Idea No 3**
  - For the reversible, the better the recovery the greater the acceptable levels of risk
  - What's your plan? How to spread the risk? Insurance?
- **Change idea No 4**
  - Plan for decay – Review or be reviewed!
  - Publish, engage, be up front, be honest

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