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
Sydney, 6 May 2013
‘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?

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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
‘There has to be a better way’

But we have to structure the problem properly

First, winners and losers:

<table>
<thead>
<tr>
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<th>Research Value</th>
<th>Privacy, Safety etc</th>
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<tbody>
<tr>
<td>Public Interest</td>
<td>✅</td>
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<tr>
<td>Private Interest</td>
<td>?</td>
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- Implication: the economics of externalities
‘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
- 2\textsuperscript{nd} Law of Thermodynamics
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:
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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The externality problem
- Real or perceived

Hence Ethics Committees
- Research merit
- AND stand in the shoes of research subject
- Challenge is process and efficiency
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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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?
The 2\textsuperscript{nd} Law of Thermodynamics

- So your prevention and recovery strategies address patient risk

- There’s still the 2\textsuperscript{nd} 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
Yes, change is good

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Change idea No 4
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