BEYOND RESISTANCE: INSTITUTIONALIZING RESEARCH ETHICS IN A MEGA-UNIVERSITY

• Setting the Scene
• Background and context
• Challenges
• Solution
• Approach
• Lessons learnt
• Recommendations
University expels scientist behind 'illegal' gene-editing of babies

Mimi Leung 22 January 2019

The Chinese scientist behind the gene-edited babies scandal that caused a storm of condemnation from around the world on ethical grounds has been expelled from his university as the results of a preliminary official investigation into the case were made public this week.

He Jiankui, a scientist from the Southern University of Science and Technology (SUSTech) in Shenzhen in Southern Guangdong province, revealed in November that he had created the world’s first gene-edited twins using the gene-editing technology CRISPR, shocking the scientific community around the world.
Research ethics now a strategic priority for doctoral schools

Brendan O’Malley  18 January 2019

Research ethics and integrity has become one of the top strategic priorities in doctoral education in Europe, according to a landscape report published by the European University Association’s Council for Doctoral Education (EUA-CDE), commissioned to examine progress in the reform or professionalisation of doctoral education and the strategic priorities ahead for the sector.

The report of the survey says this is one aspect that points to the increasing relevance of doctoral education for the implementation of research policies within universities.
The challenge of harmonising research ethics standards

Grace Karram Stephenson and Emmanuelle Fick  04 May 2018

At universities in Canada, as in many other countries, professors must have their research plan approved by the research ethics board or REB at their institution before they can launch their study. This process ensures that participants are not exposed to physical or psychological harm.

Interviews, surveys, focus groups or medical interventions, all methods that involve human participants, must receive REB approval, and for good reason. We have distanced ourselves from the days of recruiting vulnerable members of society and testing new discoveries on them.
Culling Wildlife for the Sake of Research

A case in which the University of Florida killed birds to protect crop research raises questions on the ethics of field studies’ potential side effects.

Aug 27, 2018
ANNA AZVOLINSKY

A news article in the Gainesville Sun last week revealed that researchers at the University of Florida had shot more than 150 wild birds that were eating and damaging crops grown on test plots over the course of 10 years. The culled animals included 105 ring-billed gulls and 47 sandhill cranes, a bird whose population has declined such that the state designated it a threatened species.

In 2016, after reviewing the records of the bird culling, the new director of the University of Florida’s Plant Science Research and Education Unit, Jim Boyer, changed the policy so that only nonlethal means could be used against the cranes. Instead of guns, his group brandished scarecrows and reflective tape.

Environmental groups praised the move. “We at Audubon don’t have a lot of sympathy for folks that are eager to take lethal action against wildlife when that wildlife is seen as an inconvenience,” says Julie Wraithmell, executive director of the Florida Audubon Society. “The important thing is that IFIS [the Institute of Food and Agricultural Sciences] did the right thing. They revisited their policy and changed it.”
Johns Hopkins Sued for Guatemala Experiments

The university is among defendants listed on a lawsuit filed this week by participants in controversial experiments conducted in Guatemala in the 1940s.

April 2, 2015
TRACY VENCE

Johns Hopkins University and other institutions are facing an up-to-$1 billion lawsuit brought by nearly 800 research participants and their families regarding experiments conducted in Guatemala during the 1940s that involved some participants getting sexually transmitted diseases (STDs) like gonorrhea, The Baltimore Sun reported yesterday (April 1). In August 2011, a US federal bioethics commission released a report detailing its probe of the experiments, finding ethical misconduct. A year earlier, President Barack Obama apologized to the participants and their families.

This latest suit, filed in Baltimore Circuit Court, also names the Rockefeller Foundation and Bristol-Myers Squibb (BMS) as defendants, The Sun reported. Officials at both Johns Hopkins and Rockefeller told the newspaper they found the experiments “deplorable . . . unconscionable,” and “morally repugnant,” respectively, while BMS officials declined to comment.
Paolo Macchiarini: A surgeon’s downfall

By William Kremer
BBC World Service

10 September 2016

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Nissan boss to step down amid pay scandal
1 hour ago

Features

ETHICS
MACCHIARINI SCANDAL: OVERSTEPPING THE RESEARCH ETHICS MARK

29 September, 2016
SABINE LOUËT
3 COMMENTS

Lessons from the story of a superstar scientists over-stating his progress at a complacent research institute

It has taken several deaths for Paolo Macchiarini to be found guilty of scientific fraud and medical misconduct. He was the ultimate star surgeon, delivering the promises of regenerative medicine. He focused on building artificial trachea seeded with the stem cells of his patients.
Stellenbosch race row continues after coloured women study

Stellenbosch University has come under fire from academics following a controversial study on the cognitive function of coloured women.

Stellenbosch University apologises 'for trauma caused by research article'

Stellenbosch University has apologised "unconditionally" for trauma caused by a research article which has come under fire from academics, political parties and the public.

Cape Town - Stellenbosch University on Tuesday apologised "unconditionally" for trauma caused by a research article which has come under fire from academics, political parties and the public.
WHERE TO START?

• WHY? - Moral + Legislative + Reputation

• HOW? - Governance of research ethics

• WHAT? - Resistance

* Start with Why: How Great Leaders Inspire Everyone to Take Action Paperback (2011) by Simon Sinek
WHAT DO WE WANT TO ACHIEVE?

• **Session aim**
  • Case study about formulation and implementation of a research ethics strategy (RES)

• **Session objectives**
  1. Using AI to formulate and implement RES
  2. Lessons Learnt
  3. Recommendations
BACKGROUND

• Mega University

  • Large distance education universities with +100,000 students

  • Online programs + Physical campuses

  • Students are mainly working adults

https://www.igi-global.com/dictionary/ten-scalability-factors-distance-education/18251
BACKGROUND

• Research Ethics
  • Started as system to protect the wellbeing of research participants/subjects
  • Response to human dignity violations in biomedical / behavioural research (1900s) and experimentation on animals (1950s)
  • Moral obligations by researchers
    • Researchers agree with moral imperatives, but resist governing systems and procedures
CONTEXT – About the South African Higher Education System

• 25 Publicly Funded Universities
• Legislation - Higher Education Act
• 1 million students / 58 million population
CONTEXT - About UNISA

• Largest open distance learning institution in Africa
• Longest standing dedicated distance education university in the world (founded in 1873)
• Comprehensive University
  • Academic + Vocational programs
  • 1st year to PhD
• 1/3 of all South African students
CONTEXT - About UNISA

- Undergraduate teaching university until 2011
- New portfolio created to advance research
- No regulatory environment for research ethics
  - Structures, policies, procedures, systems
- 8 Colleges / Faculties
- 350k students / 20k M&D
- 1,600 permanent faculty
- No health faculty / medical school
CONTEXT - Research Ethics @ UNISA

• Prior to 2007
  • Self governance
• 2007 to 2011
  • Policy on Research Ethics and Guidelines for review
• 2011 to 2014
  • Centralized research ethics review structure
• 2014 to present
  • Formal decentralized research ethics review ecosystem
CHALLENGES - Research Ethics @ UNISA (2014)

• **Challenges**
  • Active & passive resistance
  • Insufficient strategic alignment of RE governance structures, systems and procedures
  • No formal RE strategy

• **Solution**
  • Research Integrity Office (RIO) established
  • Full-time Research Integrity Manager (RIM) appointed
SOLUTION

“The ageless essence of leadership is to create an alignment in ways that make a system’s weaknesses irrelevant” – Peter Drucker

Appreciative Inquiry (AI)

Research Ethics Strategy (RES)
APPROACH

• Drawing inspiration from AI theory and professional experience of its application

• Aim is to institutionalize research ethics through the design and implementation of strategy (RES)
APPROACH – AI intervention

• Appreciative Inquiry (AI) – a transformational organizational change process that emerged during the late 1990s

• Constructive inquiry process that searches for everything that ‘gives life’ to organizations

• Celebrates human potential, strengths and collective ‘life giving’ stories as vehicles for change and cooperation

APPROACH - AI as strategic planning tool

- Strength-based vs. deficit-based
- Wholeness principle
- Provides broad directions vs. narrow objectives
- Data plays a key role
PHASE 1 - Define AFFIRMATIVE topic choice

PHASE 2 - Discovery (what gives life”)

PHASE 3 - Dream (what might be)

PHASE 4 - Design (what should be)

PHASE 5 - Destiny (Inspired action and improvisation)

2 day workshop
**APPROACH - Application of AI**

**PHASE 0**
Introduce AI

1. Select core team
2. Select facilitator(s)
3. Select Affirmative Topic

**PHASE 1**
Plan AI intervention

1. Confirm AT
2. Apply AI approach
   2.1 Discover (7 S)
   2.2 Dream (3 S)
   2.3 Design – step 1

**PHASE 2-3**
Step 1 AI workshop

**PHASE 3**
Step 2: Write RES

1. Design – Step 2
   - Who?
   - How?
   - Buy-in and support

**PHASE 5**
Implement RES

Continuous review

July 2015
PHASE 1 – Plan AI

• Step 1 - Introduce AI to key stakeholders

• Step 2 - Select the facilitator(s)
  • *External + RIM (internal)*

• Step 3 - Select the core team
  • *Research Ethics Committee members*
  • *Faculty Representatives*
  • *Faculty RMAs*
PHASE 1 – Plan AI

• Step 4 - Select the Affirmative Topic (AT)
  • Set the stage for applying AI

Exceptional strategic engagement of RECs

• Criteria
  • Positive, desirable, stimulate learning and conversations

• Topic selection + affirmed
  • Facilitators + Core team
PHASE 2 - Discover / “What gives life” (Workshop)

- Step 1 - Appreciative interviews in pairs

1. Tell me about a person that you admire for her/his ability to truly engage with others in a transformative way?

2. What do you value most about this person?

3. Based on these stories, what do you believe are core personal factors of engagement?
PHASE 2 - Discover / “What gives life”

• Step 2
  • Share highlights of the stories in 2 smaller groups
• Step 3
  • List major themes
• Step 4
  • Identify 3 – 5 themes which you believe as a group are most important for exceptional engagement
• Step 5
  Share themes in big group
• Step 6
  • Prioritizing themes (nominal group technique)
Results from Step 6

1. Passion
2. Peer recognition/respect
3. Being appreciated
4. Dedication/strong sense of commitment
5. Knowledge enrichment
PHASE 2 - Discover / “What gives life”

• Step 7
  • Moving from the personal to the institutional
  • Celebrate “What is”
  • In two smaller groups, discuss:

1. What are our greatest achievements as a REC?
2. What are our greatest strengths?
Results from Step 7

Q1 – Greatest Achievements:
1. Getting things done
2. Timeous approval process & communication
3. External certification of committees
4. Disciplinary diversity
5. Improved guidance to student supervisors

Q2 – Greatest Strengths:
1. Knowledge of RE
2. Willingness to promote sound research practices
3. Objective review of RE applications
4. Dedication of time & resources
5. Diverse disciplines & decentralized system
PHASE 3 – Dream / “What might be”

• Envision the future of “exceptionally engaged RECs” based on the learnings from the discovery phase (phase 2)

• Step 1
  • Opportunity mapping – small group activity

What are our best opportunities for becoming exceptionally engaged?
Results of Step 1

Institutionalizing RE within UNISA by:

1. Building RE capabilities
   • REC members, student supervisors & students
2. Knowledge sharing
3. Utilize technology
4. Standardize processes
5. Mentoring
PHASE 3 - Dream / “What might be”

• Step 2
  • Share aspirations – small group activity

1. Considering our greatest achievements and strengths, what do we value most?
2. Who should we become (our most compelling aspiration)?
Results from step 2

Q1: What do we value most? (informs value proposition and vision)

1. Integrity
2. Accountability & responsibility
3. Credible research
4. Fairness
5. Transparency
6. Respect
7. Efficiency
8. Dignity
Results from step 2

• Q2: Who should we become? (Informs mission)

1. Become leaders at the forefront of ethical, high quality research in line with our vision as ‘the African University shaping futures in the Service of Humanity’

2. Integration and awareness of RE into all aspects of research

3. Obtain the buy-in of all university stakeholders to create awareness, build capacity and enhance visibility

4. Take collective action to inspire ethical research
PHASE 4 - Design / “What should be”

• “Giving form to values and ideals”
  *(Whitney & Trosten-Bloom, 2010)*

• Step 1
  • Designing the strategic initiatives guided by the information from the discovery and dream phases

• Key decisions:
  1. What are the design agenda and target?
  2. Who should champion the outcomes?
## Results from step 1

<table>
<thead>
<tr>
<th>Design Agenda</th>
<th>Design Target</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research ethics strategy (RES)</td>
<td>Write: 2016 – 2020 UNISA RES</td>
</tr>
</tbody>
</table>
Results from step 1 (Design Target 1)

Create an enabling environment for research ethics to flourish and inspire quality research exemplified in Unisa’s vision to be

*The African University shaping futures in the service of humanity*

Values:

*Integrity*

*Accountability*

*Human dignity (fairness, transparency and respect)*

*Excellence*
Results from step 1 (*Design Target 2*)

**Mission**

- Become leaders at the forefront of ethical, high quality research in line with our vision to be “*The African University shaping futures in the service of humanity*”;  
- Enhance our research ethics profile as a leading ODeL, comprehensive university by responding to the diverse needs of all our stakeholders;  
- Take collective action to inspire ethical research practices guided by integrity, quality, rigor, agile research ethics systems and collaborative relationships.
## Results from step 1 *(Design Target 3)*

<table>
<thead>
<tr>
<th>Objectives</th>
<th>Measurable Results</th>
</tr>
</thead>
</table>
| 1. **Grow research ethics capabilities of Unisa employees through training programmes** | 1.1 Train 1000 UNISA employees over the next 5 years (200/annum)  
1.2 Implement a literature awareness campaign for UREC members  
1.3 Promote certified, online training |
| 2. **Create an enabling environment for research ethics to flourish**       | 2.1 Increase legislative compliance by registering 4 HRECs by 2018  
2.1 Increase compliance with UNISA policies (develop SOPs)  
2.2 Promote institution-wide implementation of the SOP on RE risk assessment (4 Colleges/annum) |
| 3. **Harness ICTs to provide a quality RE review system through RIMS**      | 3.1 Implement the RIMS RE compliance module by 2020 |
PHASE 4 - Design / “What should be”

• Step 2
  • Write the RES
  • Who will be responsible?
  • Incorporate the data generated during the workshop with relevant institutional strategic documents
    • UNISA Strategy 2030 + R&I Strategic Plan
  • Consult – core group & key stakeholders
PHASE 5 - Destiny / “Inspired action and improvisation”

• Inspire continued action to achieve results
• Involve champions and create continued cross-institutional engagement
• Get buy-in from key stakeholders and structures
• Key strategic deliverables incorporated in Faculty R&I plans
### Sample of Actions – Strategic target 1

**Grow research ethics capabilities through training programmes**

<table>
<thead>
<tr>
<th>Results</th>
<th>Actions</th>
<th>Successes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.Train 200 UNISA employees /annum</td>
<td>1.1 Develop and implement a formal RE training plan/program (RIO) – awareness raising and training</td>
<td># employees trained</td>
</tr>
<tr>
<td></td>
<td>1.2 Appoint an administrator to coordinate the training program</td>
<td>2016 – 325</td>
</tr>
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<td></td>
<td>1.3 Issue attendance certificates</td>
<td>2017 – 369</td>
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<tr>
<td></td>
<td>1.4 Initiate an integrated reporting system (Quarterly reporting)</td>
<td>2018 – 548</td>
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<tr>
<td></td>
<td>1.5 Develop an institutional research ethics training register</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td># external stakeholders trained</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2016 – 35</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2017 – 105</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2018 – 102</td>
</tr>
</tbody>
</table>
Additional evidence of success

- Increased compliance with National legislation (NHREC)
  - Number of Registered RECs increased
    - 2015 - 1
    - 2018 - 4
  - Design and implementation of Registered RECs required SOPs
    - 2015 – 1 (SOP on Research Ethics Risk Assessment)
    - 2018 – 19

- Increased compliance with Institutional Policy and Procedures
  - Institution-wide uptake of standardized application forms
  - Adoption by Faculties of the SOP on Risk Assessment
  - Improved reporting mechanisms
LESSONS LEARNT

• Different manifestations of passive resistance
• The role of “Early Converts”
• Push and Pull approach / “Carrot and stick”
  • Internal audit of faculties (leadership)
  • Prerequisite for Research Support (faculty)
  • Prerequisite for graduation (students)
• Paradox of change
  • Fear / Danger / Benefit
• Make people accountable
  • Leadership + RMA + Researchers
LESSONS LEARNED

- AI provides a valuable framework to design a RES
  - Clarity of vision, mission and strategic objectives
- Tangible successes
- Create a sense of ownership that improve strategic engagement at all levels (buy-in)
- Whole system engagement critical for institution-wide implementation and institutionalization
RECOMMENDATIONS

• Start with “Why?” (Simon Sinek)
• Research Ethics Champion to drive initiative
• Identify role players and what would motivate them
  • Leadership – Accountable for consequences
  • RMAs – Job descriptions + Performance agreements
  • Researchers – Support + Incentives
RECOMMENDATIONS

• Clear destination but flexible path to get there (AI)
  • Understand the AI methodology and application
• Expect and prepare for resistance (not personal)
• Reflect and learn to improve the process continuously
• AI RES is a living document - annual strategic review to refine the strategy
Questions?

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References

