



### Asian and Pacific Rim Research Integrity (APRI)

Network Meeting 2017 20-22 February

**Plenary 4** 

High level institutional mechanisms to promote RI and the effectiveness of RI education



Chair: Tony Mayer
Nanyang Technological
University Singapore

#### **Plenary 4**







**Panel Members** 

Dr John Carfora, Loyola Marymount University, USA





Professor Danny Chan, University of Hong Kong, HK (SAE)





Professor Lam Khin Yong, Nanyang Technological University, Singapore





Professor El-Nasir M A Lalani, Aga Khan University, Pakistan





Professor Prasit Palittapongarnpim, Mahidol University, Thailand



#### **Plenary 4**



#### High level institutional mechanisms to promote RI and the effectiveness of RI education

#### **Singapore Statement on Research Integrity**





#### Montreal Statement on Research Integrity in Cross-Boundary Research Collaborations

**Global Research Council Statement of Principles** 



Local funding agencies' requirements

#### **Grant Conditions Prevailing in Singapore**

- Each Investigator shall use his/her best endeavours to......carry out.......consistent with internationally recognised good research practices and ethical standards. Each Institution shall ensure that the Research Personnel.....undertake and properly discharge the foregoing obligations.
- The Host Institution should be responsible for ensuring that the Investigators adopt the highest achievable standards, exhibit impeccable integrity and follow all prevailing guidelines on good research practices in Singapore (or internationally established guidelines, where applicable) in the conduct of the Research;
- ensuring, where applicable, that local IRB, research ethics committee and multi-centre research ethics committee approvals are granted for the research and that no research requiring such approval is initiated before it has been granted

#### **Plenary 4**



#### High level institutional mechanisms to promote RI and the effectiveness of RI education

#### **Conditions for Good Research Practice – Research Integrity**

- Leadership from the top in promoting RI
- Those in authority positions must demonstrate commitment RI (Deans, Chairs, Directors)
- Educational programmes should be mandatory for all engage faculty
- Embedding good practice so it becomes 'second nature' not an 'overhead'
- Sound policy and procedures linked to 'zero tolerance'
- Mentoring the mentors
- Need for proper infrastructure ELNs, data management planning, data archives etc

Thoughts and Experiences on Introducing and Implementing Research Integrity and RCR Training and Education at Institutions of Higher Learning: *Engaging Senior Leadership* 

Asian and Pacific Rim Research Integrity (APRI)
Network Meeting
University of Hong Kong
February 20-22, 2017

#### Today's Theme

- What strategies can we help introduce and enhance to assure that our colleges and universities have adequate systems in-place for managing, monitoring and overseeing research and scholarly integrity, the Responsible Conduct of Research <u>and</u> the Responsible Conduct of Scholarly Activity, along with larger compliance-related themes?
- How might we better educate and align our efforts with a range of college/university constituents and senior academic leaders in particular about organizational ethics, research integrity, RCR and compliance-related issues?
- Finally, how do we now if the system(s) we have developed are actually effective?

#### Opening Questions

- Who and what would be included in a meaningful ethics, integrity, RCR, and/or a research compliance program? Are they different?
- Who should be involved in establishing it, or maintaining its vitality?
- How does the institution get started?
- How does the institution monitor the effectiveness of a meaningful ethics, integrity, RCR, and/or a research compliance program?
- How does the government judge the effectiveness of a meaningful ethics, integrity, RCR, and/or a research compliance program? How might they differ?

#### Session Objectives

O I want to share my thinking and experiences with you today – and invite you to also share with us your thoughts on ideas and strategies – as we all have a meaningful interest in organizational ethics, research and scholarly integrity and RCR.

#### Presenter

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#### Disclaimer

- Opinions expressed in this presentation are those of the presenter, and as such do not necessarily represent the position(s) of other professionals, or any institution(s).
- O Thank you.

#### Context: Early Experiences

My Background and an Early Influential Article of Note:

Creating Effective Research Compliance Programs in Academic Institutions

By Geoffrey Grant, Odell Guyton, & Robert Forrester. Academic Medicine, 74(9), September 1999.

My experience: established a research compliance committee at Dartmouth College, was Director of Sponsored Research at Boston College, and currently serve as Associate Provost for Research Advancement and Compliance at Loyola Marymount University.

I have presented on the subject of ethics, integrity, RCR and compliance throughout the USA and abroad.

#### My Research

- For over 20-years I have been interviewing college and university leaders particularly presidents, provosts, and deans around the following themes:
  - Interdisciplinary
  - Clife-Long Learning
  - O Globalization
  - International Collaboration(s)
  - On-Line Learning
  - Ethics, Compliance, and Integrity (Research / Scholarly)

#### Ethics, Integrity and Compliance

I hesitate to offer definitions of ethics, integrity compliance or research compliance, preferring to direct you to just two of many excellent resources that discuss these themes in-depth:

- 1. Regulations and Compliance: A Compendium of Regulations and Certifications Applicable to Sponsored Programs (2014 Edition). By Jane A. Youngers. Published by the National Council of University Research Administrators (NCURA).
- 2. Defining Compliance and Ethics. By David Gebler, JD. The Complete Compliance and Ethics Manual (2<sup>nd</sup> Edition). SCCE, 2011, pp. 1.1-1.6.



#### Integrity, Ethics, and Compliance

I like to take a values-based approach toward ethics, integrity, compliance or research compliance offered by Professor Lynne Sharp Paine in her article *Managing for Organizational Integrity* (Harvard Business Review, March-April, 1994, p. 106), as cited in David Gebler's article, previously noted (*Defining Compliance and Ethics*. By David Gebler, JD. *The Complete Compliance and Ethics Manual* (2<sup>nd</sup> Edition). SCCE, 2011, p. 1.3). According to Professor Paine:

"A firm using a compliance-based program focuses its efforts on deterrence through threat of detection and punishment for violations of the law or the code of conduct. A firm using an integrity-based approach, on the other hand, focuses its efforts on establishing legitimacy with employees through internally developed organizational values and self-governance" (p. 1.3 in Gebler).

# Institutional Frames of Reference That Attract the Attention of Academic Leaders: Elements of an Integrity and Compliance Program

- For those of you familiar with SCCE's or HCCA's Basic Compliance & Ethics Academies, the "Seven Essential Elements of a Compliance Plan" include:
- 1. Standards and Procedures
  - Code of Conduct/Code of Ethics
  - Clearly Articulated Standards and Procedures
- 2. Compliance Oversight
  - Compliance Officer, Compliance/Oversight Committee, Campus Leadership, the Board.
- 3. Education and Training
  - Internal (highly recommended), for Faculty, Staff, Research Administrators
  - External (SCCE, HCCA, NCURA, SRA, etc)
- 4. Monitoring and Auditing
  - Critical elements to success

### Core Elements of a Integrity and Compliance Program

- 5. Reporting and Investigation
  - Clear Policies/Procedures on Reporting
  - Clear Policies/Procedures on Investigation
  - Institution Trust is Important
- 6. Enforcement and Discipline
  - Clear Policies/Procedures on or non-compliant behavior
  - Incentives (such as Performance Reviews, etc)
- 7. Response and Prevention
  - Timely and Thoughtful Response
  - Assess What Was at the Root of the Problem
  - Education and Awareness

#### Quick Case Study

I recently received the following email:

Dear Dr. Carfora, I am a research administrator at a small college, and I heard from a colleague that organizations like mine have different requirements for meeting federal ethics, integrity and compliance standards.

Can you please direct me toward an answer and can you advise?

An excellent question, and not the first time we have head it. Shall we discuss it?

#### Management & Oversight of Programs Related to Integrity, RCR and Research Compliance

I think one of the best places to manage and oversee research integrity, RCR, research compliance in general actually begins with an institutions "routing form," which is the form that moves a pre-award proposal through a system of review (budgetary and compliance) by an Office of Research and Sponsored Projects (ORSP), Post-Award Accounting and Administration, departmental chairs, deans and the institutions chief research officer (VPR/VCR or ARP/ACR). Flag for Training

#### Routing Form Basics - 1

- A well-conceived Routing Form asks:
  - If an applicant or key personnel might have a conflict of interest (financial, administrative/managerial, commitment, etc). *Flag for Training*.
  - If the proposed project will involve human research participants. If "yes," has an IRB application been submitted (add link to IRB website). *Flag for Training*.
  - If the proposed project will involve animals? If "yes," has an IACUC application been submitted (add link to IACUC). *Flag for Training*.

#### Routing Form Basics - 2

- O If the proposed project will use hazardous materials. If "yes," provide a link to the EHS website and ask that such materials be listed on the routing form.
- O If the proposed project will involve:
  - An agreement/collaboration with a foreign entity?
  - O Shipment of equipment materials or data outside the USA?
  - Proprietary/confidential information/materials from the sponsor or a third-party?
  - O International travel?
  - All of the above are flags for training.

## Management & Oversight of Research Compliance: Some Concluding Thoughts

O If you have not done so already, connect with fellow institutional stakeholders – such as Director of Risk Management, Director of Internal Audit, and with the respective heads of the IRB, IACUC, EHS and the RIO – and discuss integrity and compliance related risks and how collaborations across institutional divisions/offices can minimize compliance-related risks.

- Review institutional standards (Code of Conduct/Code of Ethics) and ask how they are shared across your institution and viewed and received across your campus. Are your integrity, ethics and compliance related standards clear?
- If you don't have a Research Integrity Officer (RIO), and/or a compliance officer, discuss with your institutional leadership and with fellow stakeholders the importance of having a RIO, compliance officer and/or a Compliance Oversight Committee.

- O I find that a research compliance report in which I cover such areas as the IRB, IACUC, EHS, RCR, Misconduct in Science, patents and intellectual property policies, conflicts-of-interest, and export controls to be most valuable in identifying compliance-related "gaps" and for making the case for additional resources and training and education programs.
- Review policies for monitoring and auditing compliance. If such processes are not in place, I urge you to develop them.

- O Do you have clear policies in place for Training, Reporting and Investigation. Please don't wait for an adverse event BEFORE policies are in place.
- O Work to develop "institutional trust" along with a "culture of integrity" and a "culture of compliance."
- O Do you have clear enforcement and discipline policies in place? Once again, Please don't wait for an adverse event to happen BEFORE such policies are in place.

- O Do you have clear Response and Prevention enforcement policies in place? Once again, Please don't wait for an adverse event to happen BEFORE such policies are in place. Old Quote: *People Respect What We Inspect.*
- O Education and Training is the core element for me, for it allows us to work with faculty, staff, students and administrators on what integrity, ethics and compliance mean at our campus. It helps us promote and extend a values-based culture of integrity and ethics across the organization/campus.

- Advancement and Compliance, I encourage colleagues from ORSP, IACUC, IRB, PAAA, EHS, etc to attend training and education programs offered by professional organizations (NCURA, SRA, NORDP, COGR, FDP, etc), and come back to campus willing and ready to share what they learned.
- O I further encourage staff to attend Basic Compliance Academies offered by SCCE and HCCA. Both very good.
- O Start and maintain an ethics and compliance library/archive.

- Institution-wide education and training should be regularly offered for the entire campus community. This is an effective way to monitor ethics, integrity and compliance activity across your campus and a great way to keep campus stakeholders abreast of compliance-related matters.
- Make sure to brief senior leaders Board members, President/Chancellor, Provost/Vice Chancellor, and Deans/Associate Deans on ethics, integrity, RCR and compliance-related matters.

- Who and what would be included in a meaningful ethics, integrity, RCR, and/or a research compliance program? Are they different?
- Who should be involved in establishing it, or maintaining its vitality?
- How does the institution get started?
- How does the institution monitor effectiveness?
- How does the government judge the effectiveness of a meaningful ethics, integrity RCR, and/or a research compliance program? How might they differ?

#### The End

O Thanks for your time and Questions...

John M. Carfora, Ed.D., CCEP, RIO

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The University of Hong Kong

Mechanism promoting research integrity



### Integrity

Our 3+1 Is:

nternationalisation nnovation nterdisciplinarity

#### **L**MPACT



#### INTERNATIONALISATION

To promote global citizenship and competitiveness, we plan to provide all students with at least one mainland China and one overseas learning opportunity by 2022.



#### **INNOVATION**

Is there life out there? Are we alone? We wish to continue encouraging critical questioning and thinking to innovate for change and social good.



#### INTERDISCIPLINARITY

By bringing together different and divergent minds, we aim to drive and catalyse new ways of thinking, new ideas and concepts and new ways of doing things.

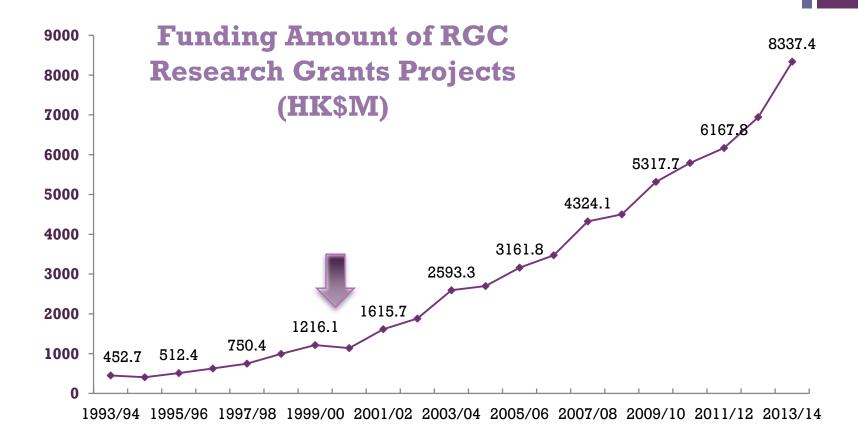


#### IMPACT

From contributing to finding cures for the world's greatest diseases, promoting oral hygiene in developing countries, to rebuilding homes in China, our aim is to embed impact into all of our academic and educational outcomes.

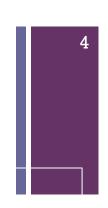


#### Research development



<sup>(1)</sup> Based on data obtained from the RGC website in May 2015. The sources of funding include UGC Block Grant, Other UGC Grants, RGC Direct Allocation, Other RGC Grants and Other Sources.





#### **HKU Research Output**





#### Research Integrity @ HKU

- Research integrity as the central and guiding principle for all the University's scholarly activities
- "Office" of Education and Development for Research Integrity (since 2011)
- Liaison Person(s) on RI Matters at Faculty level
  - Communication between Central and Faculties



#### The People

Peter Mathieson





Paul Tam

Andy Hor





Mai Har Sham

Frederick Leung





Danny Chan





### The University of Hong Kong



### Research Services

Support and information for HKU researchers





About Us

Research Funding

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### Research Integrity

Responsible Conduct of Research

Research Data and Records Management

Research Ethics Compliance

Safety Approval & Insurance

Honours & Awards

RAE 2014 & Resources

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### Research Integrity

As a world-class comprehensive university with research activities spanning all major disciplines, HKU always realises the vital importance of research integrity, and all members of the University must observe the highest standards of professional conduct in pursuing their research activities. The institutional policy and arrangements for safeguarding research integrity, as approved by the Council on January 29, 2013 and adopted with immediate effect, are set out in the following documents:

- Policy on Research Integrity
- Procedures for Dealing with Alleged Staff Misconduct in Research
- ▶ Regulations Governing Students' Academic Conduct Concerning Assessment

### Responsible Conduct of Research

HKU promotes and fosters the highest standards of conduct in the research activities of all of its members, and the University has introduced a range of initiatives including courses, seminars and a funding scheme.

▶ Responsible Conduct of Research

### Research Data and Records Management

Effective research data and records management supports both high quality research and academic integrity. HKU's *Policy on the Management of Research Data and Records* was approved by the Senate on May 5, 2015. A Task Force will oversee the planning for the implementation.

▶ Policy on the Management of Research Data and Records



# Promoting Responsible Conduct of Research

- 1. University wide seminars on RCR
- 2. Research integrity funding schemes for promotion of RCR
- 3. Online RCR materials for self education
- 4. Education and promotion of RCR practices for research students



# Typical HKU RCR seminar program

Time	Programme	Presented by
8:45 a.m.	Registration (Welcome coffee/tea)	
9:00 a.m.	Welcome Speech	Professor Peter Mathieson
9:10 a.m.	Introduction	Professor Frederick Leung
9:15 a.m.	Conflict of Interest (a) Mentor/Trainee Responsibilities (b) Peer review and Other Power Relationships (c) Loyalty and Different Institutions Q & A	Professor David Hill
9:55 a.m.	Group Discussion:	
	Group A Cheung Kung Hai Lecture Theatre 4 Group B Cheung Kung Hai Lecture Theatre 3 Group C Cheung Kung Hai Lecture Theatre 2	Facilitator Professor Paul Tam Professor John Bacon-Shone Dr. Roger Chan
11:05 a.m.	Coffee/ fea break with refreshment	
11:20 a.m.	Questionable Research Practices  (a) Plagiarism  (b) Falsification/Fabrication  (c) Authorship/Co-authorship  Q & A	Professor Terry Au
12:00 noon	Introduction to the Web-based CITI Programme Q & A	Dr. Roger Chan
12:15 p.m.	Parallel Session:  For Clinical Faculties (Cheung Kung Hai Lecture Theatre 3):  Protecting the Rights of Human Research Subjects: Role of IRB Q&A	Dr. James Ho
	For Non-Clinical Faculties (Cheung Kung Hai Lecture Theatre 4):  Regulations regarding Human Subjects and Ethical Approval Q & A	Professor John Bacon-Shone
12:55 p.m.	Wrap-up Session	Professor Paul Tam
1:10 p.m.	Lunch at Faculty of Medicine Building Restaurant, 7/F.,	William MW Mong Block



(September 20, 2014)





# Example of the course at Faculty of Medicine

- Introduction session (1h)
- What Constitute Research Misconduct, Falsification, Fabrication and Plagiarization? (2h)
- Ownership and the Legal Aspects of your Research Data (2h)
- Animal Research Ethics: Laboratory Animal Welfare Compliance (2h)
- Contribution and Justification of Authorship (2h)
- Clinical Research Ethics: The Rights of the Human Research Subjects (2h)
- Conflict of Interest: Declare and Beware! (2h)
- Wrap up session (1h)

### +

# A typical research student workshop

- Class size ~120 students
- 20-30 min introduction by 1-2 facilitators
- 60 min small group case discussions, each with a faculty moderator (lunch)
- 30 min reporting by students
- Interactive discussions

Guest speakers in specific topics





# RCR activities in 2016

■ Mandatory for existing staff to attend an RCR seminar by June 30, 2017

Faculty Groups	Date of Seminar
Engineering and Science	May 5, 2016
Architecture, Arts, Business and Economics, Education, Law and Social Sciences	May 6, 2016
Dentistry and Medicine	June 4, 2016

Sabine Kleinert



Tony Mayer





# Joined RCR activities in 2016/2017

- Faculty of Medicine
- Faculty of Architecture
- Faculty of Dentistry

### Michael Kalichman



Promoting ethics in research "Training the trainers"

Feb 2017

### Rebecca Davis



Safeguarding sound science with Good Research Practices

Nov 2016

Zoe Hammatt



Nov 2017



# Research Integrity @ HKU



- Institutional and individual levels of responsibility and commitments promoting trustworthiness of research
- Practices fostering Research Integrity
- Research is produced by individuals who engage in RCR, in an institution that is committed to RCR

+



Effectiveness?

Outcome measures?

Rubrics measurement of RI?

# HIGH LEVEL INSTITUTIONAL MECHANISM TO PROMOTE RESEARCH INTEGRITY, AND THE EFFECTIVENESS OF RESEARCH INTEGRITY EDUCATION

Prof. El-Nasir Lalani BSc(Hons) MBChB MRCPath FRCPath PhD FHEA

Director Aga Khan Centre for Regenerative Medicine Professor of Molecular &Cellular Pathology Aga Khan University

# A. IRB

- Assuring Independence of IRB and supporting Chair & Members
  - Pressure from senior faculty, "bullying"
- Formation of a Research Integrity Unit
  - Audit, education, training function
  - Small and large group town hall dialogue meetings
- University Research Council (Council carries forward and supports the research mission of AKU):
  - Annual reporting by the IRBs debate, discussion and dissemination
  - Reporting to the Senate (academic Council) and Board Of Trustees

### B. IRB

- Joint Commission International Accreditation (AKUH 2006)
  - Chapter on Research and RI
  - Independent review of all Human Subject Research
  - Setting up of a joint hospital-university RI unit (in pipeline)
- Office of Sponsored Research and IRB
  - Closing the loop Grant submitted externally is the same as that submitted to IRB
- Independent Internal Audit Committee
  - Reviews a selection of projects (IRB, financials, data collection etc). Reports to the President/Provost and Board of Trustee
- Institutional Data Repository

# Aga Khan University Research Related Policies

- 01 Authorship Policy (Approved July 2014)
- 02 Policy on Research Misconduct (Approved July 2013)
- 03 IPR Policy (Approved July 2014)
- 04 Publications Policy (Approved July 2014)
- 05 Policy Mechanism for Change of PI (Approved May 2016)
- 06 Code of Good Research Practice (Approved Sep 2013)