Fogarty Bioethics Program Network Meeting

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Gaps and Opportunities in Research Ethics Capacity in the Latin American Region: Research Ethics and Research Integrity

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Challenges for research ethics education in Latin America

- Research ethics ("bioética") perceived as limited to protection of human subjects in clinical trials
- Some attention to fraud & misconduct (plagiarism)
- Limited sense of scope of research integrity/ RCR
- Developing more than aspirational standards
- US and national understanding funding and oversight procedures in the region
- Enhancing trust between institutions
- Capacity building: grass roots and certificate/degree
- Overcoming ideological bias

Aggravating factors in Latin America

- Diverse definitions of research misconduct
- Lack of formal policies for handling allegations of research misconduct
- Lack of independent bodies with authority to investigate allegations of research misconduct
- Risk-benefit ratio favourable to misconduct
- General corruption makes research misconduct appear trivial

Little is known about the integrity of research conduct in Latin America

- Fabrication, falsification, and plagiarism
  - Manipulation of data or images
- Publication of humans and animal studies where data were obtained without oversight
- Breaches of privacy and confidentiality
- Conflicts of interests
- Data management and statistical analysis
- Ghostwriting/ PhRMA promotion
- Accountability in authorship

Collaborative Research Ethics Education with Costa Rica

(CREE – Costa Rica)

Vanderbilt University Medical Center
Nashville, TN USA

Hospital Nacional de Niños
San José, Costa Rica, CA

Key features of CREE-Costa Rica

- In 2005-06, Costa Rica had extensive clinical research, and its size, geography, and national health system permitted centralized capacity-building in research ethics and RCR.
- The Hospital Nacional de Niños, our primary partner, has had an active REC since 1975.
- New regulations in 2005 required RECs across the CCSS.
- National strength in microbiology provided fellows prepared to meet need for leadership in research and research ethics.
- Clinical research regulations found unconstitutional in 2010.
- Plan for capacity building in RCR among biomedical and life science educators permitted positive response to shutdown.

Format and Schedule

Evaluation

- 4 day visit to San José (February 2007)

Collaborative Practicum in research ethics, RCR, & administration

- Five-weeks at Vanderbilt (May – June 2007)
- 7 IRB directors/members

Postdoctoral fellowship in clinical research & research ethics

- Two-year MSCI program at Vanderbilt (August 2007 – June 2010)
- 3 fellows studying clinical research, research ethics, & RCR

Symposium in research ethics and administration

- 200 IRB members, researchers, educators, journalists (March 2008)
- Four-day meeting in San José (March 2008)

Educators' course in research ethics and RCR

- Three-day symposium in Costa Rica (May > August 2010)
- 40 biomedical & general science educators

Constitutional Court prohibits new clinical trials

- January 26, 2010

LA NACIÓN /el país

Sala IV prohíbe nuevas investigaciones clínicas en humanos

LUIS EDO. DÍAZ luisdiaz@nacion.com **4:15 P.M.** 17/05/2010

San José (Redacción). La Sala IV envió hoy la aclaración del fallo que suspendió las investigaciones clínicas en seres humanos y determinó que hasta que se promulgue una ley que regule la actividad, las autoridades de salud podrán autorizar nuevos estudios.

La Sala también explicó que "las experimentaciones clínicas iniciadas con posterioridad al 27 de mayo del 2003, no tienen por qué suspenderse si se determina medicamente -mediante documento idóneo que conste dentro del expediente, con la firma responsable de un médico- que ello resulta más beneficioso para la preservación del derecho a la vida".

Por el contrario, los magistrados consideraron que "sólo deben suspenderse aquellas experimentaciones que no cuenten con dicha certeza médica".

A inicios de abril la ministra de Salud, María Luisa Ávila, informó de que en ese entonces todas las investigaciones clínicas seguían en pie porque no habían sido notificados por la Sala sobre el fallo.

Fue en enero anterior cuando la Sala Constitucional suspendió las investigaciones tras resolver un recurso de amparo del exdiputado José Miguel Corrales, quien alegaba que los estudios eran regidos por reglamentos, cuando en realidad tenían que ser regidos por ley.

Educators' course in research integrity and research ethics education (August 2010)

- Pre-course publicity focused on health and life science *educators*, a previously untargeted group
- Held at the UCR School of Microbiology
- Goal to teach RCR content and develop knowledge and enthusiasm for incorporating RCR into undergraduate health and life sciences education.
- 140 registrants over 3 days (Original plan for 40)
  - Of 68 who completed pre-course survey, 80% were educators, rest were REC members or researchers
  - High interest in topics, less experience or reported expertise

Pre-symposium survey found high interest in learning more about RCR topics (N=68 as %)

	No answer	Not at all Interested	Not Interested	Interested	Very Interested
Study Design		1	12	17	62
Data Mgt			13	22	54
COI		1		32	66
Misconduct		2		30	68
IP		9		36	34
Mentoring		3	12	32	53
Publication		3	6	32	59
Peer Review	1	3	12	42	37
Animals		4	16	46	34
Humans			3	15	82
Biosafety/Env	3		5	38	58

Pre-symposium survey found variable experience with RCR topics (N=68 as %)

	No answer	Little to none	Basic	Moderate	Expert
Study Design		24	32	37	7
Data Mgt	1	19	30	40	10
COI	1	28	30	34	7
Misconduct	1	43	21	21	4
IP		55	30	15	
Mentoring		30	28	30	12
Publication	6	28	32	28	12
Peer Review	3	45	33	15	6
Animals		61	25	9	4
Humans		23	27	30	20
Biosafety	3	44	21	23	12

"Administrative Supplement" Grant (2010-2011)

Short Course in Ethical Study Design and Research Methods at Vanderbilt ("Cursillo"), February 2011

- 10 mid-career investigators and research administrators
- Focus on study design, research integrity, biostatistics, data management, informatics, medical writing & public speaking
- VUMC MSCI faculty and Costa Rican MSCI graduates as instructors/facilitators
- ***Participant from CCSS Bioethics Office put on a 5-day version of the program in June 2011***

Still no research legislation in Costa Rica…

26 January 2012 to May 29, 2012

- Bill drafted in May 2010 by group from MOH with CREE-CR participants
- Stalled in legislative processes since Summer 2010
- Active anti-research, anti-vaccine lobbying; public critique of private physicians in research
- MOH's new priorities (financial, political, ethical)