Research Integrity in the Fogarty Collaborative Research Ethics Education Program with Costa Rica (CREE) – Costa Rica

Vanderbilt University Medical Center
Nashville, TN  USA

Hospital Nacional de Niños
San José, Costa Rica, CA
Financial Disclosure – Elizabeth Heitman, PhD

This work is supported by grant # R25 TW007697 from the Fogarty International Center (Bioethics). Additional work was supported by NSF grant #0551837 (Ethics & Values in Science).

My work receives no financial support from any proprietary organization.

My husband is president and majority owner of the privately held Anesthetic Gas Reclamation, LLC, which has no relation to my work or the current presentation.

I will NOT include discussion of investigational or off-label use of any product in my presentation.
Entering the Orosi Valley, Costa Rica
Program Highlights

- Costa Rica’s size, geography, and integrated national health system supported extensive research and permitted a centralized infrastructure- and capacity-building effort.

- The Hospital Nacional de Niños has had an active research ethics committee since 1975.

- 2005 federal regulation required RECs at CCSS institutions.

- Clinical microbiology fellows prepared to meet identified need for leadership in research and research ethics.

- Plan for capacity building in research ethics and integrity that includes biomedical and life science educators permitted positive response to shutdown of clinical trials in 2010.
Some Lessons From CREE-Costa Rica

1. Collaboration requires willing partners and common goals and good communication.

2. True collaboration recognizes that both (all) partners have something to offer the other(s). Capacity building addresses the partners’ respective goals, strengths, and needs.

3. Researchers care about research: research integrity education has to be about the research.

4. Establishing collaboration takes longer than you expect, even when you expect it to take longer than you expect.

5. People, programs, institutions, funding, and law change; adapting to change can produce learning.
Elizabeth Heitman, Ph.D., and Ellen Wright Clayton, M.D., recently returned from the first International Symposium in Bioethics in San José, Costa Rica.

The event was held in celebration of the 30th anniversary of the country's first Bioethics and Research Committee, or institutional review board (IRB). Heitman and Clayton were invited speakers on ethics in research, with Clayton speaking specifically on research with children and direct-to-consumer advertising of pharmaceuticals and genetic testing, and Heitman speaking on ethical issues in epidemiologic research and the ethics of community-based research.
Requests for Applications

International Research Ethics Education And Curriculum Development Award (R25) (RFA-TW-06-003)

John E. Fogarty International Center
National Human Genome Research Institute
National Institute of Dental and Craniofacial Research
National Institute of Environmental Health Sciences
National Institute of Neurological Disorders and Stroke

Application Receipt Date(s): January 13, 2006
REGLAMENTO PARA LA INVESTIGACIÓN BIOMEDICA EN LOS SERVICIOS ASISTENCIALES DE LA CAJA COSTARRICENSE DE SEGURO SOCIAL

(Aprobado en el artículo 9º de la sesión número 8009, celebrada el 17 de noviembre del año 2005).
CREE-Costa Rica Program Team

**Program Director**
Elizabeth Heitman, PhD

**Advisory Committee**
Mayra Achío, MS
Carlos de Céspedes, PhD
Dafna Feinholz, PhD, MA
Gabriel Macaya, PhD
Sten Vermund, MD, PhD

**Faculty**
Ruth Ellen Bulger, PhD
Abdón Castro, MD
Ellen Wright Clayton, MD, JD
Mark Denison, MD
Rafael Jiménez, MD
Mario Rojas, MD
Margaret Rush, MD
Evaluation

- 4 day visit to San José (February 2007)

Collaborative Practicum in research ethics & 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

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
Costa Rican Regulatory Structure for Human Subjects Research (Pre-2010)

Ministry of Health

National Council for Health Research (CONIS)

Research Ethics Committees (CEC)
  - 5 Public Institutions (incl. universities)
  - 2 Private Institutions

Caja Costarricense de Seguro Social
Centro de Desarrollo Estratégico e Información en Salud y Seguridad Social (CENDEISSS)
Institutional Committee for Bioethics in Research (COIBI-CCSS)

Local Committee for Bioethics in Research (CLOBI)
  - National Hospitals
  - Specialty Hospitals
  - Regional Hospitals
  - Major Clinics
  - Health Districts
Costa Rican Practicum Participants

Isabel Castro, MD, MS, INISA, Universidad de Costa Rica

Yéssika Gamboa, MD, Hospital Nacional de Niños

Rafael Jiménez, MD, MQC, Hospital Nacional de Niños

Roxana Reyes, MA, Instituto Tecnológico de Costa Rica

Heileen Sánchez, MD, Hospital Tony Facio

Carlos Trabado, MQC, INCIENSA

Carlos Valerio, Lic., National Ombudsman’s Office / UCIMED
Clinical Research Ethics Fellows
(2007-2010)

José Pablo Mora, MQC, MSCI
Effect of extracorporeal photophoresis (ECP) on T cell phenotype in patients with chronic Graft versus Host Disease (cGVHD)

Natalia Jiménez, MQC, MSCI
Molecular epidemiology of strains of methicillin-resistant Staphylococcus aureus (MRSA) in the Hospital Nacional de Ninos between March and December 2008

Carolina Loría, MQC, MSCI
Epidemiology of Viral Respiratory Illnesses in Pediatric HSCT Recipients in the First 100 days Post-Transplantation
# MSCI Requirements

MSCI Requirements: 31 hours of Didactic Work; Mentored Research Apprenticeship; Career Path Development; Master's Thesis

## Required Courses

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<tr>
<td>Biostatistics I with SPSS</td>
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<td>Biostatistics II with SPSS</td>
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<tr>
<td>Case Studies in Clinical Investigation I</td>
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<td>Case Studies in Clinical Investigation II</td>
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<td>Clinical Trials</td>
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<td>Drug &amp; Device Development</td>
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<td>Epidemiology I</td>
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<td>Grant Writing I</td>
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<td>Research Ethics and Scientific Integrity</td>
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<td>Molecular Medicine</td>
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<td>Medical Writing for Clinical Investigators</td>
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## Elective Courses

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<td>Data Management</td>
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<td>Epidemiology II</td>
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<td>Human Genetics</td>
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<td>Measuring Pharmacological and Physiological Responses</td>
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<td>Research Skills</td>
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<td>Pharmacokinetics</td>
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<td>Proteomics</td>
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## Advanced Topics

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<tr>
<td>Advanced Topics in Research Ethics and Scientific Integrity</td>
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Symposium in Research Ethics and Administration (March 2008)
Workshops led by Costa Rican partners (March 2008)
Sala IV prohíbe nuevas investigaciones clínicas en humanos

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 ex diputado 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
  - 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
“Administrative Supplement” Grant (2010-2011)

Short Course in Ethical Study Design and Research Methods at Vanderbilt (“Cursillo”)

- 10 mid-career investigators and research administrators
- Focus on study design, biostatistics, data management, and informatics, medical writing, research ethics
- VUMC MSCI faculty and Costa Rican MSCI graduates as instructors/facilitators
- CCSS educator put on a 5-day version of the program in June 2011
Future Activities (2012 - )

Clinical research at a standstill with no regulation

Collaboration with Pan American Bioethics Initiative (PABI) and the University of Miami’s CITI Program

- CENDEISSS educational development: authorship and publication; Ethics in epidemiology
- Costa Rica beyond CCSS?
- Costa Rica as base for Central American activities (Honduras, Panama, Guatemala, El Salvador)
- College of Nursing seeking research and research ethics education, partnership with Vanderbilt SON