

Application for  
Concentration in International Research Ethics  
Master of Arts in Philosophy  
Department of Philosophy  
School of Liberal Arts  
IUPUI

Approved by the Faculty of the IUPUI Department of Philosophy: March 2009  
Approved by the SLA Graduate Curriculum Committee: April 2009

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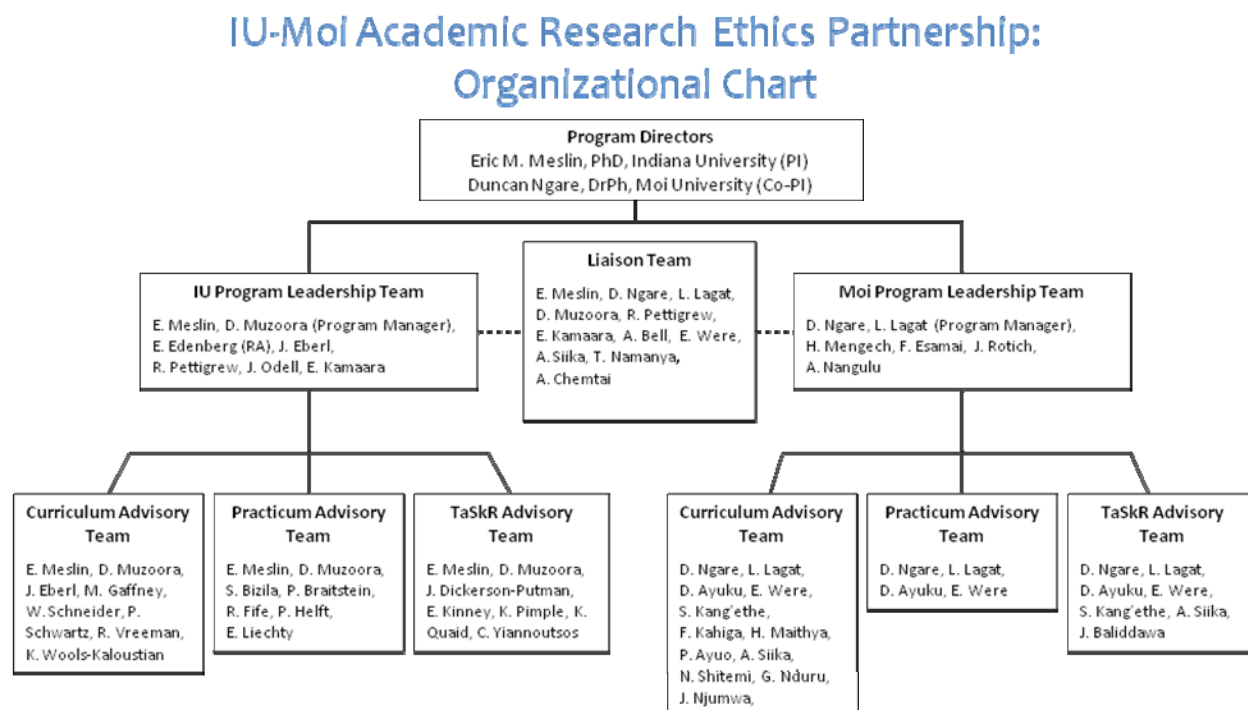
Title of Concentration  
International Research Ethics

Proposing Department  
Department of Philosophy, School of Liberal Arts, IUPUI.

### Statement of Purpose and Rationale

This is a proposal to establish a new Concentration in International Research Ethics within the existing MA Program in Philosophy. This new Concentration is a key component of the Indiana University-Moi University Academic Research Ethics Partnership (IU-Moi AREP) established between Indiana University and Moi University in Eldoret, Kenya through an R25 grant from Fogarty International Center at the National Institutes of Health (PI: Eric M. Meslin, PhD, Professor of Philosophy in the IU School of Liberal Arts, Director of the IU Center for Bioethics, and Associate Dean for Bioethics in the IU School of Medicine).<sup>1</sup> The new Concentration is one component of this partnership, which includes development of a parallel Master's degree at Moi, and teaching workshops at both institutions. The partnership is established and the organizational structure is in place for each of these components, including the "curriculum advisory team" -- a multidisciplinary group of dedicated IUPUI faculty from the Schools of Liberal Arts, Medicine, and Law -- that is responsible for the development of this proposal. (See Figure 1)

Figure 1:



<sup>1</sup> The rationale and other accompanying materials are adapted directly from the funded grant application awarded to Professor Meslin.

Preparing researchers to engage in the responsible conduct of research has its own challenges, but they are often magnified when experienced by educators, institutions, investigators and students in low and middle income countries. Like all health research, studies conducted in economically developing countries must be both scientifically valid and ethically sound. This means that, at a minimum, research must be designed and conducted by competent individuals within a system that respects the rights and welfare of human subjects and is sensitive to the appropriate cultural, ethnic and social considerations of the host country.

Similarly, preparing teachers and mentors to acquire the skills necessary to teach about the ethical issues that arise in the international environment is necessary to prepare learners to function in this environment. Currently, many ethical issues are emerging that have international relevance for investigators, trainees and students, irrespective of whether the research is conducted in economically developed or developing countries. For example, before the promise of genetic science is fully realized for clinical medicine, many ethical and policy issues must be addressed that extend beyond the design and conduct of research. These include the use of human biological materials, the “ownership” of DNA, the lack of harmonization in both domestic and international rules for the protection of human subjects, conflicts of interest between academic and private sector partners, and the impact on research from the rise of philanthropic support. Indeed, a recent authoritative volume of case studies on international research ethics notes that while much of the debate about international research over the past decade has focused on the standard of care issue, “the ethics of international research goes well beyond this important issue.”<sup>2</sup>

The proposed Concentration will offer a comprehensive graduate-level education in international research ethics that is responsive to the needs of faculty, trainees, researchers, and ethics review committee members in Indianapolis and at collaborating institutions in East Africa. A parallel Master of Science degree program is under development at Moi University under the direction of Professor Duncan Ngare, DrPh, Associate Professor of International Health and Head of the Department of Mental Health and Behavioral Sciences at Moi University.

## Target Audience

There are a number of target audiences of the proposed Concentration:

- Philosophy undergraduate students with specific interest in Master’s-level training in international research ethics;
- Professionals working in the life sciences community (including those working at the hospitals located on the IUPUI campus) who want to enhance their expertise in international research ethics and their professional credentials;
- Graduate students, trainees, postdoctoral fellows in the life sciences working toward a PhD, who intend to work in an international research environment;

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<sup>2</sup> Lavery JV. Ethical issues in international biomedical research : a casebook. New York: Oxford University Press; 2007. 3

- Established researchers working in the pharmaceutical and biotechnology industries; officials in policy or regulatory agencies who have responsibility for the protection of human subjects;
- Students interested in the ethics of international health research who are enrolled in health-related and other professional schools at IUPUI with which combined-degrees programs have been (MD/MA, JD/MA) or may be developed.

## Evidence of Need and Compatibility with Campus Mission

In his inauguration speech, President Michael McRobbie described the essence of Indiana University's "international imperative" when he observed:

"Looking beyond Indiana's physical borders, in a flat world, a more uncertain world, and a more competitive world, the best programs in most professions and disciplines will increasingly require a period of study abroad. In turn, students will demand this as part of a world-class education."

By establishing this new Concentration, which includes a study-abroad component, we are contributing to the President's vision and the university's mission. By locating the Concentration within the new IU-Moi Academic Research Ethics Partnership, we are assuring that students will be able to take advantage of the world class strengths of the IU Center for Bioethics and the IU-Kenya Partnership. And by building the new Concentration in an already successful graduate program in the IUPUI Philosophy Department, we are assuring that these benefits will be sustainable.

Teaching about research ethics and responsible conduct of research has a long history in North American universities, but this has not translated across the globe. For example, despite a provision of the U.S. Federal Policy for the Protection of Human Subjects (the "Common Rule") that permits the U.S. government to determine that another country's guidelines provide protections that are "substantially equivalent" to those found in the U.S. Federal Policy [45 CFR46 111(h)], this provision has not been systematically implemented.<sup>3</sup> These inconsistencies make teaching about issues in international collaborative research even more difficult than teaching about domestic issues. Teaching research ethics in an international setting is especially challenging; the curriculum must address the topical issues arising in research generally (such as informed consent, risk/benefit assessment, and confidentiality), while respecting specific needs, values, customs and mores that may vary according to the country in which the research is conducted. At the same time it must account for diverse learning styles and pedagogical approaches. **There is no other program of its kind on any of the Indiana University campuses.**

## Relation to Existing Programs

The proposed Concentration will run concurrently with the Bioethics Concentration of the MA program that is already being offered by the Philosophy Department. It will share its resources and its faculty, augmented with specialized faculty from other departments at IUPUI, as listed

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<sup>3</sup> Shapiro HT and Meslin, EM. Ethical Issues in the Design and Conduct of Clinical Trials in Developing Countries. *New England Journal of Medicine* 2001; 345:139-141; Lavery, JV, McDonald M, Meslin EM. Research Ethics Across the 49<sup>th</sup> Parallel: The potential value of Pilot Testing "equivalent protections" in Canadian Research Institutions, *Health Law Review* 2005; 13: 85-96.

below, and with mentors from our partners at Moi University. The current Bioethics Concentration has been exceptionally successful. As noted in a recent external review of the Philosophy Department,

“The MA program in bioethics makes excellent use of local resources, has dynamic leadership and has achieved a level of stability and growth that suggests it could become a major center for bioethics. In a very short period of time, the program has grown considerably, and graduates are already serving the community. The program has achieved stability in the numbers of students and faculty.”

Students in the Bioethics Concentration may also take advantage of combined-degrees programs with Law (JD/MA) or Medicine (MD/MA), and similar arrangements will be made for students in the new Concentration. Therefore the relationship between the two Concentrations will be complimentary, rather than competitive. Admission criteria will utilize a similar approach.

### Existing Resources

IUPUI is well-placed to play a leading role in academic training in international research ethics. IUPUI is home to one of the nation’s largest health-profession complexes, one that boasts not only the nation’s second largest school of medicine and its largest multi-purpose school of nursing, but also has sizable programs in dentistry and allied health sciences. In addition, the IU School of Liberal Arts and IU School of Law-Indianapolis boast faculty with active research programs in health-related social sciences, bioethics, health law, and public policy. Some of these key programs include:

#### **Indiana University-Kenya Partnership**

The IU-Moi AREP is a component of the IU-Kenya Partnership, a nearly twenty year-long teaching, service, and research collaboration that has become a model for international clinical exchange, education, and research. The IU-Kenya Partnership depends on counterpart relationships to exchange ideas and manpower, not the transfer of money or technology, and now provides the umbrella for two other closely connected groups: the America/Sub-Saharan Africa Network for Training and Education in Medicine (ASANTE Consortium), and the Academic Model for Providing Access To Health care (AMPATH). The new Concentration, seeks to expand the research ethics capabilities of the IU-Kenya Partnership.

#### **Indiana University Center for Bioethics (IUCB)**

The IUCB was established in 2001 to provide leadership in advancing academic and public understanding of bioethics and to inform the development of social and public policy in health, research, and related fields. The Center’s faculty and affiliates have nationally and internationally recognized expertise in ethical and regulatory issues relevant to research involving human subjects, generating nearly \$2 million in external funding since 2001 and over 100 publications on studies involving informed consent, international research, conflict of interest, biobanking, and bioethics education. Of relevance to this proposal, the IUCB has ongoing research collaborations with colleagues in Kenya to undertake research in international issues.<sup>4</sup> Professor Meslin plays a leading role in various programs involving international

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<sup>4</sup> Shaffer DN, Greene JY, Kimaiyo S, Sidle J, Ballidawa J, Meslin EM, Yebey V, Tierney WM. Equitable treatment for HIV/AIDS clinical trial participants: A focus group study of patients, researchers, and health administrators in western Kenya. *Journal of Medical Ethics* 2006; 32: 55-60; Sidle JE, Were E, Wools-Kaloustian K, Chuani C,

research on the IUPUI campus including, regularly teaching the only course in this subject at Indiana University (PHIL-P 555), co-directing the Bioethics Core of the ASANTE Consortium, as well as participating actively in East Africa's International Epidemiologic Databases to Evaluate AIDS (IeDEA) and AMPATH. Moreover, as the principal investigators on the new Fogarty R25 grant that established the IU-Moi Academic Research Ethics Partnership *and of which this proposed Concentration is a key component*, he is now a part of a network of other Fogarty Center-funded R25 training programs around the world.<sup>5</sup> Lastly, the IUCB Reference Center, a non-circulating branch of the IU School of Medicine Ruth Lilly Library, is a key resource for this new Concentration. The Reference Center has piloted several web-based information portals—including the free, publicly accessible Bioethics Digital Library (BEDL). As with the existing Bioethics Concentration, we expect the IUCB Reference Center to be a valuable resource for Masters Students in this new Concentration.

### **Indiana University School of Liberal Arts (SLA)**

Several SLA faculty members will be involved in the new Concentration, including faculty from the Departments of History, Sociology, Anthropology, and Philosophy. Two other SLA-based programs—the Medical Humanities and Health Studies Program (directed by William Schneider) and the Social Science Research Network (directed by Jeanette Dickerson-Putman)—will contribute expertise to the IU-Moi AREP in general, and to the new Concentration in particular. Professors Dickerson-Putman and Schneider are active members of the IU-Moi AREP advisory teams.

### **IUPUI Signature Center Consortium on Health Policy, Law and Bioethics**

The Consortium was established in 2007 involving three constituent research/education centers on the IUPUI campus: the Indiana University Center for Bioethics, the Hall Center for Law and Health and the SPEA Center for Health Policy. The directors of these three centers (Meslin, Eleanor Kinney and Eric Wright respectively) are the co-directors of the Consortium. Its founding vision has been to create an innovative and dynamic environment to facilitate research, education, and public policy service on issues in health care, health and science policy, and the life sciences. In addition to Meslin's expertise, Professor Kinney brings a reputation of scholarship in international research, particularly the emphasis on international human rights.

### **Medical Humanities and Health Studies Program (MHHS)**

The MHHS Program studies the state of health care and concepts of health and illness from an interdisciplinary perspective. Participating faculty represent a diversity of expertise from across the campus, including the Schools of Law, Liberal Arts, Medicine, Nursing, and Public and Environmental Affairs. They teach courses and conduct research covering a wide range of topics, such as biomedical/health care ethics, literature and medicine, history of medicine and public health, health economics and policy, medical sociology and anthropology, and health communication. The program offers an undergraduate minor and is developing graduate courses for an eventual certificate. The program conducts interdisciplinary research, offers a monthly seminar series, and hosts periodic symposia on health and humanities topics with national and international participants.

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Salmon K, Tierney WM, Meslin EM. A Needs Assessment to Build International Research Ethics Capacity. *Journal of Empirical Research in Human Research Ethics* 2006; 1: 23-38.

<sup>5</sup> [http://www.fic.nih.gov/programs/training\\_grants/bioethics/index.htm](http://www.fic.nih.gov/programs/training_grants/bioethics/index.htm)

Professor William Schneider, the MHHS director, also holds the Baker-Ort Chair in International Healthcare Philanthropy which brings additional resources relevant for the new Concentration. Also, specifically pertinent to the new Concentration, Professor Schneider is developing a new History graduate course focused on Global Health History (H546); additionally, the MHHS program will sponsor the development of a new 1 cr. graduate course to orient students in the new Concentration to East African culture and health issues.

### **IUPUI-Moi University Steering Committee**

The mission of the IUPUI-Moi University Steering Committee (led by Dr. Ian McIntosh) is to coordinate IUPUI relationships with Moi University (beyond those already in place with the IU School of Medicine), encourage the development of the IUPUI-Moi University relationship as an IUPUI Strategic or ‘Core’ Partnership, provide advice to faculty and units considering new projects, share ideas and information, and seek cross-campus synergies in working with colleagues at Moi University.

### **Moi University**

A key component of the new Concentration will be a “practicum” requirement that will be undertaken at both IUPUI and Moi University. Practicum opportunities will be available at two institutions: the Moi Teaching and Referral Hospital (MTRH) and the AMPATH Training Institute (ATI). The MTRH is the second referral hospital in Kenya after Kenyatta National Hospital in Nairobi. The Hospital was established in the 1920s and accommodates 500 inpatient beds and a large Out-Patient Department (OPD). The ATI, which is run by the Moi School of Medicine, is responsive to the demands of a rapidly expanding AMPATH Clinical Care Program. ATI was also established at the request of the National AIDS and STI Control Program (NASCOP), a Government of Kenya Institution that is responsible for provision of anti-retroviral medicines. The MTRH and ATI are ideal locations to provide students with diverse experiences in international research ethics, such as ethics review committees, research administration, and design of clinical trials. Practicum opportunities and logistics will be provided by IU and Moi faculty (see Figure 1 above).

### **New Resources Required**

No new resources are required at this time. Existing courses at IUPUI will populate the new Concentration’s curriculum. Any new courses that need to be developed are being established under existing programs. The budget for Professor Meslin’s grant will provide modest support for a small number of students to travel to Kenya for their practicum requirement, though additional support may be needed if the number of eligible students exceeds the budget.<sup>6</sup> The new Concentration is, however, linked to the R25 grant, which runs from 2008-2012. A renewal application will be sought by Professor Meslin, but long term sustainability of the new Concentration will be no more precarious than that of the current Bioethics Concentration.

### **Proposed Date of Initiation**

Fall 2009

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<sup>6</sup> It should be noted that there are some additional costs for student travel to Kenya that will not be covered by the grant, including visa application, immunizations and related costs. These will have to be borne by students.

## Program Directors

Eric M. Meslin, PhD, Professor of Philosophy in the IU School of Liberal Arts, Director of the IU Center for Bioethics, and Associate Dean for Bioethics in the IU School of Medicine.

Jason T. Eberl, PhD, Associate Professor, Department of Philosophy, Director of the Bioethics Concentration of the department's existing MA program. Prof. Eberl will serve as the Director of the International Research Ethics Concentration.

Daphne Kyomuhendo Muzoora, MA, MS, MBChB, Faculty Investigator at the IU Center for Bioethics, Adjunct Faculty, Department of Philosophy.

## Initial Concentration Program Faculty

The uniqueness of the proposed Concentration will require ongoing advice and mentoring for all students. Therefore, each student admitted will have a formal Advisory Committee chaired by the primary mentor and consisting of 2-3 additional faculty members relevant to the student's research interests and career development. This Advisory Committee meets regularly, verifies completion of the requirements for the MA, and advises the trainee on research and career development. IUPUI faculty members who have been identified as either course instructors or faculty mentors for students in the new Concentration are identified in Figure 2:

Figure 2: Advisory and Teaching Faculty	
IUPUI (Indianapolis)	Department (expertise)
Eric M. Meslin, Ph.D. (Program Director) **	Center for Bioethics
Shelley Bizila, MS, CIP ++	Research and Sponsored Programs
Paula Braitstein, Ph.D.** ++	Medicine, IU-Kenya Program
Cornelis de Waal, Ph.D.	Philosophy, Institute for American Thought
Jeneatte Dickerson-Putman, Ph.D	Anthropology
Jennifer Drobac, J.D., J.S.D.	Law
Jason Eberl, Ph.D. **	Philosophy
Rose Fife, M.D.,	Medicine, Women's Health
William Gronfein, Ph.D.	Sociology
Richard Gunderman, M.D., Ph.D.	Philosophy, Philanthropy, Radiology
Eleanor Kinney, J.D., M.P.H.	Law
Kurt Kroenke M.D.	Medicine, Clinical Research
Edward Liechty, M.D.,	Pediatrics
Timothy Lyons, Ph.D.	Philosophy
David Orentlicher, M.D., J.D.	Law
Scott Pegg, Ph.D.	Political Science, International Studies
Kenneth Pimple Ph.D	Poynter Center, Education, Ethics
Kimberly A. Quaid Ph.D.	Center for Bioethics, Medical and Molecular Genetics
Greg Sachs, M.D.	Internal Medicine, Research Ethics
William Schneider, Ph.D.**	Medical Humanities
Peter H. Schwartz, M.D., Ph.D.	Center for Bioethics, Medicine, Philosophy
John Sidle, M.D.** ++	Medicine, IU Kenya Program
William Tierney M.D**	Medicine, Regenstrief Institute
John Tilley, Ph.D.	Philosophy
Richard Ward, Ph.D.	Anthropology
Kara Wools-Kaloustian, M.D.** ++	Medicine, IU Kenya Program
Constantin Yiannoutsos Ph.D.	Biostatistics, IU Kenya Program, IeDEA
Moi University (Eldoret)	Department
Duncan Ngare, DrPH (Program Director)**	Mental Health and Behavioral Sciences
Abraham Siika, M.Med **	School of Medicine; AMPATH Training Institute



Eunice Kamaara, Ph.D **	Philosophy & Religious studies
Gilbert Nduru, Ph.D	Geography
Harrison Maithya, Ph.D **	Anthropology
Simon Kang'ethe, Ph.D **	Medical Education
Naomi Shitemi, Ph.D	Linguistics
Haroun Mengech, Ph.D **	Director, Moi Teaching and Referral Hospital
Alfred Mutema, Ph.D **	Medical Education
Edwin Were, M.Med **	Reproductive Health
Rose Ay Ayikukwei, MPH	AMPATH
Alex Chemtai, Ph.D	Immunology
Fabian Esamai, Ph.D **	Paediatrics
Paul Ayuo, M.Med	Medicine
David Ayuku, Ph.D	Behavioural Sciences
Joyce Ballidawa, MA	Behavioural Sciences
** Member of the Program Advisory Committee	
++ Member of the Practicum in International Research Ethics Advisory Team	

## Recruitment Plans

The strongest indicator of interested and qualified applicants is the success of the current MA in Philosophy's Concentration in Bioethics. IUPUI has admitted 27 students since the program was established in 2003, an average of more than 6 students each of the past 4 years. Furthermore, there have already been several inquiries about this program following the press announcement of the R25 funding award. We have used a variety of methods to publicize the current MA in Philosophy which we will use and supplement to ensure widespread awareness of prospective applicants. For example, we will:

- Create a Web site to publish a program description, application forms, contact information, and links with other relevant Web sites;
- Develop a brochure for mail distribution to campus leaders at our partner schools and at schools across the country, as well as for distribution at professional meetings, such as the American Society for Bioethics and Humanities;
- Include information about the Concentration in the recruitment programs of new residents and fellows, incoming medical students (those considering a joint MD/MA) and incoming law students (those considering a joint JD/MA);
- Conduct stakeholder meetings with key individuals (e.g., school deans, department chairs, division/section heads, and program directors).
- Circulate program materials to all current Fogarty Center R25 directors (N=15), international research ethics-based organizations, such as PRIM&R, the Global Forum for Health Research and others.

Initial selection criteria have been established by the Philosophy Department for admitting students to the MA program; however, we have also developed a recruitment and selection process that will attract the best candidates specifically for this Concentration and will consider a number of criteria, including: research potential, mentorship, diversity, innovation, and collaboration. For example, we expect that candidates will:

- Have an interest in international health and research generally, and the ethical issues associated with these issues in particular;
- Demonstrate a strong likelihood that they will be able to provide leadership in an area of International Research Ethics in their home academic department or institution;

- Identify areas that are most consistent with their academic interests or professional role, so that their course work and training experiences can be targeted to the needs and interests of the trainee and to his or her position;
- Have a satisfactory application portfolio, including prior transcripts, writing sample, GRE scores, and letters of recommendation, as determined by the Admissions Committee.

### Projected Steady-State Enrollment

We have conservatively projected enrollment in the new Concentration at a minimum of 3 students per year during the initial period of the R25 grant. Assuming we meet our admission goal of enrolling our first students in Fall 2009, this translates into 9 students (3 per year for the remaining three years of the grant). We have, however, the capacity to admit more students. It is reasonable to expect that we will admit approximately 3-6 students per year to the International Research Ethics Concentration, the same number currently admitted to the Bioethics Concentration.

### Student Financial Support Available

For the first three years of the program, students will receive some support for travel through the NIH R25 grant described above. Continued external support from the NIH or other agencies will be sought after the initial grant expires. The funds available to support students for their practicum experience in Kenya may limit the number of students we will initially be able to support in this program. Students also may be eligible for research assistantships in the IU Center for Bioethics.

### Employment Possibilities

Students who pursue this Concentration will have a number of employment opportunities. Some may choose to continue on to a PhD program in philosophy or bioethics, after which they can be expected to compete for research or faculty positions. Others may choose to complete the MA in concert with a professional degree in medicine, science, nursing, health sciences, or law. Professionals already employed in health-related fields can expect that the MA will enhance their professional credentials. A master's degree with a Concentration in International Research Ethics will be useful to those responsible for international policy analysis and development, as well as those responsible for compliance at institutions engaged in international research activities. Given the emphasis that the supporting grant places on building international research ethics capacity, it is expected that students trained in this Concentration will compete for professional positions in the U.S. or other countries and in international organizations. We expect that our students will compete for ethics teaching, research, and administrative positions in colleges/universities, national research organizations, international organizations, and NGOs. This Concentration will also be useful to professionals working in legislative or other policy positions with an international focus.

### Admissions Requirements

The basic admissions requirements for the new Concentration are the same as those for the current Bioethics Concentration. Applicants are expected to have a bachelor's degree from an accredited university or its equivalent, with a grade point average of at least 3.0 overall (on a scale of 4.0) and at least 3.0 in the student's major. There is no specific major requirement, but

applicants must show a record of coursework (or equivalent experience) demonstrating that they are sufficiently prepared to do graduate work in philosophy. Acceptable coursework includes an undergraduate degree in philosophy; a degree in international relations with good performance in upper level undergraduate philosophy classes also might be considered. Professional training or experience relevant to this Concentration could be accepted in lieu of coursework. Applicants must also show an appropriate level of achievement on the Graduate Record Examination (GRE) or an equivalent test (e.g., LSAT or MCAT), unless the applicant already holds an advanced degree. For their application, students are required to submit in addition to their application form and statement of purpose: official transcripts, 3 letters of recommendation, GRE or equivalent test scores, and a writing sample or professional resume. Foreign applicants are required to take the Test of English as a Foreign Language (TOEFL). They must also take the IUPUI English (ESL) examination prior to their first semester of coursework and may be required to take additional classes in English as a second language.

### Completion Requirements

To complete the MA degree students should take thirty (30) credit hours, at least fifteen (15) of which must be taken at IUPUI and at least eighteen (18) of which must be in philosophy. All courses must be at the 500-level or higher (with the exception of E445 Medical Anthropology) and be completed with a grade B or higher. Students are required to take Foundations of Bioethics (P547), Contemporary Ethical Theories (P540), and Ethical and Policy Issues in International Research (P555), all of which are currently offered every academic year, as well as a newly developed course focused on African culture and health issues; these required courses total ten (10) credit hours. In addition, students will take twelve (12) credit hours in Concentration specific electives. The remaining credit hours will be comprised of a six (6) credit practicum in which students will develop and implement a capstone research project, and a two (2) credit capstone workshop in which they will work closely with their faculty mentors to complete the final write-up of their project.

### Curriculum Structure

All courses listed below are already being offered at IUPUI with two exceptions: (1) PHIL P5xx Practicum in International Research Ethics will be a newly developed course designed specifically for students in this Concentration, but it will be structurally based upon, as well as have overlapping content and share faculty resources with, the current PHIL P548 Clinical Ethics Practicum for students in the Bioethics Concentration; (2) two new 1 credit graduate courses will be offered to provide the requisite orientation for studying research ethics in Kenya, and for undertaking the practicum. The former (tailored specifically to students in this program) will focus on key issues in African culture and health and will be developed within the School of Liberal Arts' Medical Humanities and Health Studies Program; the latter will focus on those issues that arise in the context of research ethics at Moi University. All courses, with the exception of the Moi component of the practicum, are offered at the IUPUI campus and none are offered in a distance-learning format. All of the credits will be through IUPUI; none will be awarded through Moi.

*Module 1: Core Courses (10 cr. required)*

PHIL P540 Contemporary Ethical Theories (3 cr.)  
PHIL P547 Foundations of Bioethics (3 cr.)  
PHIL P555 Ethical and Policy Issues in International Research (3 cr.)  
MHHS M5xx African Culture and Health Issues (1 cr.)

*Module 2: Concentration specific electives (12 cr. required)*

ANTH E445 Medical Anthropology (3 cr.)  
HIST H546 History of Medicine: Global Health and History (3 cr.)  
†LAW DN696 AIDS: Ethical, Legal, and Policy Issues (2 cr.)  
†LAW DN761 Law and Public Health (2 cr.)  
†LAW DN813 International Human Rights (2 cr.)  
LAW DN838 Bioethics and Law (2 cr.)  
MHHS M504 Introduction to Research Ethics (3 cr.)  
PHIL P549 Bioethics and Pragmatism (3 cr.)  
PHIL P553 Philosophy of Science (3 cr.)  
PHIL P600 Topics in Philosophy: Philosophy of Medicine (3 cr.)  
PHIL P696 Topics in Biomedical Ethics (3 cr.)  
SOC R515 Sociology of Health and Illness (3 cr.)

*Module 3: Practicum/Research Project in International Research Ethics (8 cr. required)*

PHIL P5xx Practicum Orientation (1 cr.)  
PHIL P5xx Practicum in International Research Ethics (5 cr.)  
PHIL G901 Advanced Research: IU-Moi AREP Capstone (2 cr.)

† Pre-requisite: DN838

Sample Curriculum

<b>Semester 1 (Indianapolis)</b>  ❖PHIL P547 Foundations of Bioethics ❖PHIL P540 Contemporary Ethical Theories ❖PHIL P555 Ethical and Policy Issues International Research ❖MHHS M5xx African Culture and Health Issues	<b>Semester 2 (Indianapolis)</b>  ❖PHIL P5xx Practicum Orientation ❖Elective ❖Elective ❖Elective
<b>Semester 3 (Indianapolis/Eldoret)</b>  ❖PHIL P5xx Practicum in International Research Ethics	<b>Semester 4 (Indianapolis)</b>  ❖PHIL G901 Advanced Research: IU-Moi AREP Capstone  ❖Elective

## Program Governance

The day-to-day management of the overall R25 grant is conducted by Professors Eric Meslin, Program Director and PI of the NIH R25 grant; Daphne Kyomuhendo Muzoora, Program Manager of the NIH R25 grant; and Jason T. Eberl, Co-Director of Graduate Studies in Philosophy. The governance of the new Concentration in International Research Ethics will be overseen on a day-to-day-basis by Professors Eberl and Meslin, aided by the Curriculum Advisory Team (see Figure 1). In addition, to ensure seamless coordination with colleagues at Moi University—especially for coordinating the Practicum course—a “Liaison Team” has been established (see Figure 1).

## Procedures for Program Evaluation

Evaluation will consist of two components, Student Evaluation and Program Evaluation.

### Student Evaluation

- (1) The primary mentor will meet with students on a regular basis to review research progress, address goals and concerns, and provide feedback.
- (2) A formal Advisory Committee consisting of the primary mentor and 2-3 other faculty members will meet a minimum of 5 times during the student’s participation in the program. This is particularly important to ensure close coordination with the Practicum in International Research Ethics.
- (3) Following each Advisory Committee meeting, the primary mentor prepares an Advisory Committee Report that is forwarded to the Program Director. The Program Director reviews the report initially to identify any issues that need immediate attention, and also keeps a copy on file for review at an annual meeting.
- (4) Monthly meetings of the Program Advisory Committee (a committee distinct from the specific committee for each student) will discuss student progress and other curricular and administrative issues.
- (5) The Program Directors will meet individually with each student for semi-annual Progress Report meetings (July-August and January-February). At this meeting, the director reviews their files—which includes the student’s advisory committee reports, course grades, and other items. Issues will be discussed in 3 major areas: coursework, research progress/mentorship, and career development. A summary of each meeting will be dictated and maintained in the student’s file.

### Program Evaluation

- (1) Students will complete a course evaluation form for each course, providing an overall rating as well as specific comments on what would further improve the course. The results will be tabulated, reviewed by the Program Director, and provided to the course director.
- (2) Students will complete an Annual Program Evaluation Form providing summative feedback for quality improvement in courses, mentorship, and other aspects of the program.
- (3) Both the student’s Advisory Committee meetings and the semi-annual Progress Report meetings with the Program Director are conducted in a bi-directional fashion: trainees are encouraged to offer feedback both on what they feel is working well and areas for improvement.

*We will track:*

- (4) The number of students graduated;

- (5) The number of student papers published in peer-reviewed journals;
- (6) The number of presentations and posters at national/international meetings.

## Assessment of Student Learning

### *Statement of Learning Goals and Objectives*

The proposed Concentration is designed to produce graduates who will make contributions in different ways, in different environments, and to different groups of stakeholders. Within these parameters, assessment of learning will occur using the following approach. First, given that the general purpose of the Concentration is to provide a thorough foundation in international research ethics, students will be expected to have a working knowledge of the main themes that characterize bioethical inquiry and a general knowledge of pertinent issues in the field. They will demonstrate this through the mandatory courses P540 and P547. Second, students will be expected to have a more in-depth knowledge of issues or areas of inquiry within the ethics of international research. They will demonstrate this through the mandatory course, P555, and through a comprehensive set of electives. All those who complete the proposed Concentration are further expected to be able to conduct independent research in international research ethics.

### *Assessment of Outcomes*

Outcomes will be assessed largely through the avenues of exams and term papers that are required for the courses students take. Students are required to write papers for most courses that qualify for the proposed Concentration, and they typically receive coaching from the professor and do rewritings of their papers before submitting a final version. The professor evaluates each paper according to a high standard: the paper should be of sufficient quality to be either publishable or presentable at a professional conference. In some courses, each student is also required to give a presentation based on his or her paper, or actually to teach a class session or a part thereof. The professor evaluates both the content and the delivery of this in-class presentation, and gives feedback to the student. The program will involve frequent one-on-one advising to assess each student's progress and to ensure the quality of the student's performance. The final outcome of each student's progress will be the capstone research project, which will be designed in close consultation with each student's Advisory Committee, implemented during the course of each student's practicum experience at both IU and Moi University, and completed in the student's final semester as part of a two (2) credit capstone workshop in which the student will not only continue to work closely with his or her own Advisory Committee, but will also be able to receive and offer critical feedback to other students in the same cohort.