BOARD OF REGENTS

SUMMARY OF ITEM FOR ACTION,
INFORMATION OR DISCUSSION

TOPIC: University of Maryland, Baltimore: Post-Baccalaureate Certificate in Research Ethics

COMMITTEE: Education Policy and Student Life

DATE OF COMMITTEE MEETING: June 5, 2013

SUMMARY: The proposed certificate program will provide students with an understanding of human subjects research regulations and their historical foundations, an in-depth understanding of ethical principles that govern research, and the skills needed to analyze ethical issues that arise in the conduct of research. The program will be targeted to enrolled master's and doctoral students at UMB who conduct human subjects research and to in-state and out-of-state adult members of the workforce who are involved in the different aspects of the research enterprise, including those who serve on institutional review boards. Through the use of distance learning technologies, the program will meet the needs of the working professionals who have few opportunities to enroll in an on-site program.

This certificate program fosters a new inter-professional education program bringing together students from the specialties of medicine, nursing, law, dentistry, pharmacy, and social work that mirrors the current model of research that relies on the interdisciplinary interactions of the many different actors in the research enterprise. Furthermore, inclusion of those attending other institutions and the workforce at the UMMS hospitals and in the private sector contributes to the inter-professional education model.

ALTERNATIVE(S): The Regents may not approve the program or may request further information.

FISCAL IMPACT: No additional funding is necessary. The program will be supported through tuition.

CHANCELLOR'S RECOMMENDATION: That the Committee on Education Policy and Student Life recommend that the Board of Regents approve the proposal from the University of Maryland, Baltimore to offer the Post-Baccalaureate Certificate in Research Ethics.

COMMITTEE RECOMMENDATION:	DATE:
BOARD ACTION:	DATE:

SUBMITTED BY: Joann Boughman 301-445-1992 jboughman@usmd.edu

PROPOSAL FOR A STAND-ALONE CERTIFICATE PROGRAM

IN RESEARCH ETHICS

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A. Centrality to Institutional mission statement and planning priorities

1. Provide a description of the program, including each area of concentration (if applicable), and how it relates to the institution's approved mission.

The University of Maryland, Baltimore (UMB) Certificate in Research Ethics will be a post-baccalaureate program consisting of 6 courses (12 credits) and will be delivered predominantly by distance-learning technologies. The courses have been taught at UMB in other programs and hence, the goal of this Certificate Program is to establish a coherent program in research ethics consisting of these courses. Within this program, students will acquire an understanding of human subjects research regulations and their historical foundations, gain an in-depth understanding of the ethical principles that govern research, explore current topics in research ethics, and acquire the skills needed to analyze ethical issues that arise in the conduct of research. The Certificate Program is intended to meet the needs of individuals who are involved in all aspects of the research enterprise: the conduct, the ethical review, and the monitoring and regulation of research. As such, the Certificate Program will target a) enrolled master's and doctoral students at UMB who conduct human subjects research and b) the in-state and out-of-state adult workforce who are involved in the different aspects of the research enterprise, including those who serve on Institutional Review Boards (IRBs). UMB's proximity to Washington D.C. also entails that the Certificate Program will be responsive to the needs of those who are involved in the regulatory aspects of research (e.g., FDA and OHRP). The use of distance learning technologies will meet the needs of working professionals who have few opportunities to enroll in an on-site program. Finally, the Certificate Program will interrelate with the funded Fogarty/National Institutes of Health training program that is focused on enhancing research ethics capacity for individuals from the Middle East (www.mereti.net). The inclusion of these targeted audiences will ensure an interprofessional and global experience for all enrolled students.

The Certificate Program is aligned with several items in the UMB's mission statement (see complete Mission Statement in *Appendix 1*). Specifically, the Certificate Program will help UMB a) to excel in "professional and graduate education [and] research"; b) to "educate leaders in health care delivery, biomedical science, [and] global health"; and c) to "emphasize interdisciplinary education and research in an atmosphere that explicitly values civility, diversity, collaboration, teamwork and accountability". In regards to the latter, our survey data will show that the interest in the Certificate Program extends across the different professional schools at UMB and across the different employment positions in the research ethics workforce, thus ensuring an interdisciplinary enrollment. Finally, the Certificate Program will be responsive to UMB's mission to conduct "internationally recognized research to cure disease and to improve the health…and just treatment of the people we serve", as research ethics is fundamental to the conduct of research.

2. Explain how the proposed program supports the institution's strategic goals and provide evidence that affirms it is an institutional priority.

The goals of the Certificate Program are consistent and supportive of UMB's 2011 - 2016 Strategic Plan, which includes the following themes:

Achieve Pre-Eminence as an Innovator

The Certificate Program will advance the goal of achieving pre-eminence as an innovator. Essentially, many areas of science depend on the use of human volunteers as research subjects. The involvement of human participants is confined to biomedical science, and also extends to many areas of social sciences and humanities. Research on humans fulfills many functions – the creation

of new knowledge, the formation of new social and economic policy, and the development of innovative new products and processes for human health, education and social development. The research enterprise is viewed by many in the public and private sectors as a driver of economic and social development, innovation, and national prosperity. A sub-sector of this research enterprise, research with humans, depends on the willingness of individuals, organizations, collectivities and communities to become engaged in research in the social, behavioral, natural, and medical and health sciences. It is therefore essential that the public trust on which the participation of volunteer subjects depends be maintained and increased. The Certificate Program in Research Ethics is central towards enhancing and maintaining the public's trust in the research enterprise.

Excel at Interdisciplinary Research and Inter-professional Education, Clinical Care and Practice, and Public Service

The focus of the Certificate Program in Research Ethics cuts across professional lines and hence, will be responsive to the needs of students across the different schools at UMB. By bringing together students from the different schools, it will enhance collaborative and interprofessional learning and interdisciplinary efforts at enhancing ethically appropriate research. Essentially, this Certificate Program fosters a new interprofessional education program that will serve as a model for future degree programs. Essentially, the interprofessional focus of this degree program (bringing together students from the specialties of medicine, nursing, law, dentistry, pharmacy, and social work) mirrors current models of research that rely on the interdisciplinary interactions of the many different actors in the research enterprise.

Furthermore, the centrality of the Certificate Program on distance learning technology enhances the goal of interprofessional education, as its courses will be more accessible by those attending not only the schools on the UMB campus, but by those attending the other USM institutions, the workforce at the University of Maryland Medical System hospitals, and the workforce in the private sector. Essentially, the Certificate Program aims to leverage technology to enhance access to learning and facilitate collaborative projects to catalyze new discoveries.

Develop Local and Global Initiatives that Address Critical Issues

One of the goals of this theme is to strengthen the University's capacity to improve the health and the economic, political, and social well being of its community partners locally and globally. Essentially, global engagement is important to students and faculty. Surveys conducted as part of the strategic plan indicate a strong desire of students and faculty in all University professional schools for robust global education, research, and service. There are existing University programs, such as the Institute for Human Virology and the Center for Vaccine Development, that have already attained global significance. During the six years between 2009 and 2014 the United States is expected to spend $63 billion on global health initiatives, providing significant commercial and business opportunities in developing education, health care, and research capacity in emerging economies. Aligned with the goal of improving the health of global communities would be a focus on enhancing research ethics capacity of individuals involved in international collaborative investigations to ensure quality research and research that addresses the specific needs of our global partners.

The above demonstrates how the Certificate Program in Research Ethics will be integral with achieving several of the institution's strategic goals, and hence, its development, effectiveness, and success represent an institutional priority for program development. **[SEE LETTER OF SUPPORT THAT AFFIRMS ITS PRIORITY**]

B. Adequacy of curriculum design and delivery to related learning outcomes consistent with Regulation .10 of this chapter

Rationale and Significance of the Proposed Certificate Program in Research Ethics

Among the various changes recommended in enhancing the ethics of research, there is broad agreement that educational programs be available to all parties involved in research. Several governmental commissions and committees have expounded on the value and importance of such educational efforts (1, 2). The National Bioethics Advisory Commission (NBAC) listed "educational programs aimed at the responsibilities of all parties" as "the foundation of the oversight system and is essential to protecting research participants." (3) The focus on education stems from the concern that without adequate training of its members, even the best intentioned IRBs may act with little knowledge of or attention to the regulations or may miss or ignore important ethical issues. Education is also essential for investigators and their research staff, because they need to know the ethical implications of their research endeavors, that their projects are subject to regulations, and that their responsibilities go beyond securing and maintaining IRB approval.

In the past few years, several educational programs in research ethics have been developed within several of the U.S. institutions. These have consisted largely of workshops (4-7), short courses (8), and self-paced on-line tutorials (9, 10). These opportunities lack the necessary rigor and scope of learning desired by those desiring advanced degrees and they fail to reach a broad audience. To close the current gap in educational opportunities in research ethics, our overall aim is to make available a certificate program in research ethics that embraces the necessary rigor in its content and achieves relevance to a multidisciplinary group of professionals who are involved in all aspects of the research endeavor. Our proposed use of distance learning technologies will be able to reach out to a broad audience, embrace active learning concepts, and promote collaboration between interprofessional groups of individuals.

Organization Structure of the Program

The organizational structure of the Certificate Program is show in *Appendix 2.*

Program Director: Dr. Silverman will have overall academic, administrative and budgetary responsibility for all aspects of the Certificate program. In association with the teaching faculty on this proposal, he will continue to develop, refine, and implement the aspects of the curriculum and ensure the monitoring and evaluation of the progress of the students, as well as the program.

Program Management Specialist: This person will be charged with administering all aspects of the program and coordinating between the different committees. This person will serve as the liaison between the Program Director, the faculty and the students. This person will be responsible for addressing student issues and ensure there are mentors matched for each student in the program.

Curriculum Committee

The purpose of the Curriculum Committee consists of developing and renewing the curriculum and assessing its quality and effectiveness to the highest of professional standards. The charge to the curriculum committee will be to ensure that the all aspects of the Certificate Program are meeting the stated program and learning objectives, monitor content and workload of courses, monitor and propose changes in teaching methodology, and evaluate courses and curriculum. Membership of this committee will consist of the program director, the course masters, an instructional designer, two student representatives and the Associate Dean Graduate School. This committee will meet on a quarterly basis. Specific responsibilities will include the following:

- Review current syllabi of all of the courses and ensure that the objectives, activities, and assessment strategies continue to be in alignment.
- Review proposed changes in courses and ensure that such changes are aligned with program objectives.
- Review evaluation reports of the students and faculty
- Review satisfaction reports from the students and faculty
- Review the long-range outcomes of the students (e.g., academic achievement, job placement, etc.)

Distance Learning Committee (DLC)

The purpose of the DLC is to support the development of distance learning that meets the needs of our students and faculty in a manner. In so doing, distance learning at UMB will employ the best pedagogical practices based on the existing research literature. The charge to the DLC is to: 1) establish the technical training necessary for instructors who want to teach distance learning courses; 2) establish the diagnostic standards that will ensure the success of distance learning courses; and 3) establish adequate resources for the students to ensure their success in learning by distance learning. Membership of this committee will consist of the program director, the instructional designers, one faculty member, and a student representative. This committee will meet on a quarterly basis. Specific responsibilities will include the following:

- Ensure that learning outcomes remain appropriate to the rigor and breadth of the degree program.
- Ensure that the degree program delivered by distance education shall be coherent and complete.
- Assess appropriate use of real-time or delayed interaction between faculty and students.
- Ensure that the objectives, learning activities, assessment and evaluation methods remain aligned.
- Assess effectiveness of course design and delivery.
- Review faculty and student satisfaction as it relates to their online experience.

Admissions Committee

The purpose of the Admissions Committee is to review all applications to the program, assure compliance with graduate admissions policies and practices, conduct periodic review of admissions policies and practices, adopt necessary revisions and recommend admissions to the Graduate School. This committee will continually review the admission criteria to ensure that it promotes equitable access to individuals applying from the different private and public sectors and ensure that there is equity in representation of gender and minorities. Membership of this committee will consist of the program director, several members of the teaching faculty, and the Associate Dean of the Graduate School. This committee will meet weekly to discuss and rank the applicants during the early spring of each academic year and then semi-annually to review its operations.

The specific admission criteria will be as follows: Applicants must complete the following:

- On-line application information
- 3 letters of recommendation
- One (1) set of official transcripts or marks sheets from all prior colleges/universities – Including GPA
- Official standardized score reports (GRE, TOEFL, IELTS, etc.)
- Statement of Academic Goals and Research Interests
- Application for In-State Status Classification (Maryland residents only)
- Certificate of Finances Form (international applicants only)

1. Provide a list of courses with title, semester credit hours and course descriptions, along with a description of program requirements.

Each of the courses in the Certificate Program will be taught during a yearly academic cycle. The accompanying table shows the order in which the courses will be taught, which is based on a logical content sequence. Students, however, can enter at any point in the cycle based on their backgrounds and prior experiences. A more complete description of the courses, which are all approved by the Graduate School, can be found in *Appendix 3*.

Course #/ Credit Hours	**Semester Taught**	**Course Titles**	**Descriptions and Objectives**
PREV 640 (1 credit)	Summer I	Ethics of Globalization	This course is designed to introduce students to the identification and evaluation of moral dilemmas in the context of changes and development in an increasingly globalized world with attention to both its theoretical and practical dimensions, including global health. Upon completion of this course, the student will be able to: • Explain the forces associated with globalization • Evaluate the impact of globalization on social justice issues • Evaluate the moral theories underlying a just globalization • Explain the moral dilemmas posed by an increasing globalization world
PREV 637 (3 credits)	Summer I	Introduction to Research Ethics	This course will examine the ethical and philosophical issues raised by research involving human subjects. The course will acquaint the student with basic concepts in research ethics Upon completion of this course, the student will be able to: • List the controversies involved with research abuses. • Analyze research protocols involving vulnerable populations, e.g., children, mentally ill. • Apply concepts of vulnerability • Explain concepts of minimal risk and therapeutic misconception.
PREV 629 (2 credits)	Fall I	Introduction to Ethical Theory	The course introduces students to the prominent theories in ethics and political philosophy that inform our ethical arguments and the articulation of our values. Upon completion of this course, the student

			will be able to: • Articulate ethical problems, understanding how they are different from problems that can be addressed by empirical investigations or scientific discoveries. • Explain the difference between various schools of thoughts in ethics. • Analyze ethical claims in terms of their theoretical assumptions and commitments.
PREV 639 (2 credits)	Fall I	Institutional Review Boards	This course will cover the application of legal and regulatory topics critical to performing clinical research, including submitting protocols to the institutional review boards, understanding investigational new drug (IND) applications, financial disclosure and conflict of interest. Upon completion of this course, students will be able to: • Describe examples of research misconduct. • Discuss methods of dealing with misconduct. • Discuss the relationship between authorship and accountability. • Discuss the ethical and legal foundations of intellectual property. • Discuss controversies related to patents on biological materials. • Describe how conflicts of interest can corrupt scientific objectivity. • Analyze methods of managing conflict of interest. • Discuss issues related to international collaborations
PREV 638 (3 credits)	Spring I	Issues in International Research Ethics	This course will examine the ethical and philosophical issues raised by research involving human subjects that is conducted in international settings. Upon completion of this course, the student will be able to: • Construct and support valid arguments in the analysis of exploitative research. • Analyze ethical questions regarding international collaborations in research. • Evaluate the ethical issues involved in international research. • List methods to achieve a culturally

			valid informed consent. • Describe the issues involved with tissue sample research performed between international partners. • Perform an ethical review an international protocol
PREV 665 (1 credit)	Spring I	Responsible Conduct of Research in International Affairs	This course will examine the ethical responsibilities of conducting research with special emphasis on collaborative international research that involve scientific integrity, determination of authorship, peer review, conflicts of interest, ownership of data and intellectual property across borders with differing laws. At the end of this course, students will be able to: • Describe examples of research misconduct. • Discuss methods of dealing with misconduct. • Discuss the relationship between authorship and accountability. • Discuss the ethical and legal foundations of intellectual property. • Discuss controversies related to patents on biological materials. • Describe how conflicts of interest can corrupt scientific objectivity. • Analyze methods of managing conflict of interest. • Discuss issues related to international collaborations

The following are the requirements of the Certificate Program in Research Ethics:

- Maintenance of a B average in all courses
- Completion of all required evaluation forms
- Compliance with codes of academic conduct in relations with other students and faculty
- Compliance with Policy and Procedures on Plagiarism

2. Describe the educational objectives and intended student learning outcomes.

Program Goal: The overall goal of the Certificate Program in Research Ethics is to enhance research participant protection by promoting the training of individuals who are involved in research in the conduct, review, approval, monitoring, and regulation of research.

Program Objectives: The Certificate in Research Ethics is designed to graduate students with competencies that they can draw on throughout their careers, whether they design and conduct research studies, review and monitor research, develop policies and standards, or administer or oversee large research programs. The Certificate Program will also prepare students for continued collaborative, interprofessional learning and to lead successful and productive careers in academia,

government, and industry. Accordingly, our alumni are expected to:

1. Apply knowledge, critical thinking skills, and problem solving skills situated in growing careers related to the conduct, review, monitoring, and regulatory aspects of human subjects research.
2. Become effective collaborators within interprofessional groups.
3. Lead or participate in efforts to address global, social, technical, and business challenges in the domain of research ethics.
4. Engage in life-long learning and professional development through self-study and continuing education.

Intended student learning outcomes: Upon graduation, students will be able to:

a. Explain the importance of past research ethics abuses on current concepts of research ethics.
b. Apply knowledge of different research ethics guidelines and current concepts of research ethics to emerging issues in research.
c. Describe the ethical requirements for review of research.
d. Evaluate the different equivalent protections for vulnerable populations.
e. Describe the impact of globalization on research practices.
f. Explain the relevance of current notions of research ethics in a global and societal context.
g. Integrate the leading ethical theories into the analysis of research ethics issues.
h. Evaluate the ethical issues involved in international research.
i. Construct and support valid arguments in the analysis of exploitative research.
j. Analyze ethical questions regarding international collaborations in research.
k. Analyze the issues promoting misconduct in research.
l. Describe the regulatory aspects of clinical trials.
m. Analyze research protocols from an ethical point of view.
n. Collaborate in groups in the review of protocols.
o. Demonstrate the ability to function within interprofessional teams.
p. Demonstrate the recognition of the need for engaging in life-long learning.

Appendix 4 shows the mapping of the individual courses, learning outcomes, program objectives, and aspects of the mission statement of UMB.

3. Discuss how general education requirements will be met, if applicable.
Not applicable

4. Identify any specialized accreditation or graduate certification requirements for this program and its students.
There are no specialized accreditation or graduate certification requirements.

C. Critical and Compelling Regional or Statewide Need as Identified in the State Plan

The State of Maryland has identified the bioscience industry a strategic priority as a growth driver for its economy. The recent report "BioMaryland 2020: A Strategic plan for the Life Sciences in Maryland" (11) recognizes that the biosciences represents a large and fast-growing sector including a wide range of job-producing manufacturing, service, and research activities. This report details Maryland's strategic plan to promote life sciences research, promote collaboration and coordination among Maryland's research and higher education institutions, and coordinate state

and federal life sciences resources to attract private sector investment and job creation in Maryland. According to latest Bureau of labor Statistics data over the 10-year period ending in 2010, the bioscience industry is averaging annual job growth of 2.9 percent, nearly double the overall national employment growth projection of 1.6 percent annually. Specifically, overall bioscience industry employment in Maryland is growing robustly, rising 14.5 percent from 2001 to 2006, adding 3,200 jobs, to reach more than 25,000 jobs. Not surprisingly, a significant portion of federal medical research dollars are spent within the state at institutions such as the National Institutes of Health and the Food and Drug Administration. Furthermore, the report indicates that Maryland is home to one of the nation's and the world's largest bioscience research complexes, notable for its federal intramural research activities and major universities, as well as significant industry research activities. Some of the biggest companies in the area include Merck, Pfizer, Cel-Sci, Intrexon Corporation, Health Diagnostic Labs, Human Genome Sciences, Martek Biosciences Corporation, MedImmune and Qiagen. Taken together, Maryland's bioscience research complex is conservatively estimated to represent nearly $8 billion in research and development expenditures annually and is third in total size only to California and New Jersey. Finally, University bioscience research grew substantially: from 2002 to 2007, Maryland's life science research base grew 44.2 percent from $877,598,000 to $1.3 billion.

Maryland's Bioscience Strategic Plan also documents the State's interest in assuming global leadership in the life science. Maryland is the home to major universities who perform international research. At the University of Maryland, there are currently almost 60 grants and contracts that are global in reach, and total funding received from the federal President's Emergency Plan for AIDS Relief (PEPFAR) exceeds $400 million to date. This activity mirrors what is occurring nationally, as during the six years between 2009 and 2014, the United States is expected to spend $63 billion on global health initiatives, providing significant commercial and business opportunities in developing education, health care, and research capacity in emerging economies. Specifically, the last twenty years has witnessed an enormous growth of international research consisting of a) international collaborative research between investigators from the developing and developed world and b) pharmaceutical sponsored research in the developing world.

However, commentators (12-14) have expressed many ethical issues associated with such international research including issues involving a) standard of care, b) informed consent, c) functionality of research ethics committees, d) exploitation of vulnerable populations, and e) obligations of sponsors to the host communities. Presently, there are no other programs in Maryland that addresses issues in international research ethics. There is a need to ensure that the IRBs of the Maryland Universities to understand the issues involved with their investigators performing research in the international arena. The University of Maryland is home to an NIH-sponsored training grant that aims to enhance institutional and individual capacity in research ethics. Having a formal and externally reviewed certificate program in research ethics would ensure that the aims of this training program are realized.

There is compelling State wide need for the Certificate Program in terms of meeting present and future job market requirements and in terms of being consistent with the Maryland State Plan for Postsecondary Education. Specifically, as the Certificate Program will be distance education program, it will address the educational needs of adult learners, particularly unable to travel and spend considerable amount of travel time. In FY 2010, enrollment of adult learners in the State of Maryland increased by 2.5%. Increasing adult education services within a seamless adult learning system is vital to future workforce creation in Maryland. Finally, the use of distance learning

technologies will result in expanding access of low-income adult learners and out-of-school youth to learning opportunities, thus addressing inequities in access to higher educational programs.

D. Quantifiable & reliable evidence and documentation of market supply & demand in the region and State

1. Present data and analysis projecting market demand and the availability of openings in a job market to be served by the new program.

Several lines of data provide evidence of the availability of openings in the job market to be served by the new program. First, a job search on several career websites demonstrate the large availability of openings in research related areas that would be served by the Certificate Program in Research Ethics. The below table shows a typical search on www.simplyhired.com (performed on November 6, 2012) showing the availability of different types of jobs to which graduates of the Certificate Program would make application. Also, individuals who are graduates of the Certificate Program would have enhanced marketability when they apply for these types of jobs

Number of jobs available for different keywords on www.simplyhired.com

Keyword Search	Number of jobs available in Maryland
Research coordinator	142
Research associate	265
Research nurse	108
IRB	223
Research	16,689

Finally, *Appendix 5* shows a screen shot of the types of jobs obtained when using "IRB" as the searchable word. Graduates of our Certificate Program would be interested in and be well qualified for these types of positions.

2. *Discuss and provide evidence of market surveys that clearly provide quantifiable and reliable data on the educational and training needs and the anticipated number of vacancies expected over the next 5 years.*

3. *Data showing the current and projected supply of prospective graduates.*

We expect that the projected supply of new graduates would come from the following sources: 1) enrolled students at the different professional schools at UMB who would be interested in supplementing their primary degree program with a certificate degree in research ethics; 2) the workforce at area academic hospitals (e.g. the University of Maryland Medical System), particularly those individuals who currently hold research related positions; and 3) the Research Ethics Workforce (i.e., individuals currently employed in research related positions who would enroll in the Certificate Program to advance their skills and future employment opportunities).

To assess the potential interest in the Certificate Program in Research Ethics from these three different types of audiences, we surveyed the following groups: 1) UMB students, 2) the hospital workforce at the University of Maryland Medical System (UMMS), and individuals currently the Research Ethics Workforce, i.e., individuals employed in research related positions, e.g., individuals

at a) at the University of Maryland IRB, b) at a private IRB in Columbia, Maryland, c) Phase I Biotechnology Company at the Biotechnology Park at University of Maryland; d) a Research Coordinator List Serve, and e) members of a national research ethics organization (Public Responsibility in Medicine & Research - PRIM&R; www.primr.org).

We developed a web-based survey and emailed to these audiences a web link to complete the survey via www.surveymonkey.com. The survey explained the goals and objectives of the Certificate Program and described the list of courses. Respondents were asked to use a 5-point Likert scale to rate their level of interest in enrolling in a Certificate Program in Research Ethics and to rate their interest in taking the Certificate Program either via face-to-face, distance learning, or a blended approach (mixture of face-to-face and distance).

Total responses were obtained as follows:

UMB students (n=344)
UMMS Workforce (n=159)
Research Ethics Workforce (n=131)

Appendix 6 (figures 1-7) shows school affiliation and job positions of the respondents, their interest in a Certificate Program in Research Ethics and their preference for type of program delivery.

Figure 1 shows the UMB student data: more than 60% of the students were from the graduate school, followed by the Nursing School (24%), School of Medicine (24%), Social Work (22%), and the School of Law (18%). Figure 2 shows the UMB interest in a Certificate Program in Research Ethics: 14.2% of the UMB student body would be "very interested" and 30.0% would be "somewhat interested".

Regarding the UMMS workforce, figure 3 shows that the predominant groups responding to the survey consisted of nurses (50.6%), physicians (30.5%), and advance practice nurses (18.5%). Regarding preferences, figure 4 shows that 17.3% would be "very interested" in such a program and 23.1% would be "somewhat interested".

Regarding the Research Ethics Workforce, figure 5 shows that the predominant groups responding to the survey consisted of Research Coordinators (38.5%), IRB analysts (19.2%), IRB members (18.3%), Investigators (16.3%), physicians (9.6%), and nurses (5.8%). Figure 6 shows that 55.8% would be "very interested in such a program while 23.5% would be "somewhat interested".

Figure 7 shows preferences for the type of course delivery for the curriculum among the three different target groups. UMB students were more interested in face-to-face courses (68%) compared with the UMMS workforce (36%) and the Research Ethics Workforce (39%). The Research Ethics Workforce were more interested in a completely distance learning format (79%) compared with the UMB students (49%) and the UMMS workforce (54%). Finally, more than 70% of the respondents from all of the groups demonstrated a preference for a blended approach.

We separately analyzed the PRIM&R data (n=36) that represents the out-of-state research ethics workforce. Of these respondents, 78% was "very interested" in a Certificate Program in Research Ethics and another 8% was "somewhat interested" in such a program. Regarding preferences for type of course delivery, 82.4% (28/36) favored distance learning and 18.8% (6/36) favored a blended approach.

The above data shows a strong interest in our Certificate Program in Research Ethics from the different types of audiences that we surveyed. Specifically, approximately 25% of UMB students and 25% of the UMMS workforce showed strong interest in the Certificate Program and approximately 50% of the current Research Ethics Workforce showed strong interest. Such interest represents the educational and training needs of these individuals.

Although it is difficult to predict actual enrollment numbers, we conservatively estimate that 10, 14, 16, 20, and 24 students will enroll in Years 1, 2, 3, 4, and 5, respectively, in which the Certificate Program will be offered. These projected numbers are based on our survey data and also based on the increased market demand of job positions (i.e., number of vacancies) that will be present in Maryland in the research and biotechnology fields; as explained earlier, the State of Maryland has identified the bioscience industry a strategic priority as a growth driver for its economy (see page 7).

E. Reasonableness of program duplication

Accessing the MHEC website (http://www.mhec.state.md.us/higherEd/HEPrograms.asp), we performed a web-based search of the academic programs at the other major institutions in the State of Maryland using the following keywords: research, ethics, research ethics, institutional review boards. We found that not even a remotely similar course of study existed at any of the other institutions in the State of Maryland. We also went to the website of several of the major universities. This latter search also included the Historically Black Colleges: Bowie State University, Coppin State University, Morgan State University, University of Maryland, Eastern Shore, and Sojourner-Douglas College.

F. Relevance to Historically Black Institutions (HBIs)

We did a specific search of all of the degree programs and mission statements at each of the Historically Black Institutions and discovered no programs that were similar in scope or content to the Certificate Program in Research Ethics. Accordingly, we can confidently conclude that our proposed program will neither have an impact on the implementation or maintenance of high-demand programs at HBIs nor will it have an impact on the uniqueness and institutional identities and missions of HBIs.

G. Delivery of Certificate Program via Distance Learning (Principles of Good Practice)

Introduction: The courses in the Certificate Program will be offered predominantly by using distance learning technologies (both asynchronous and synchronous). We say "predominantly", because for those students in the area who are able to attend and travel to the UMB campus, we will hold face-to-face meetings for orientation and for end-of-course presentations. The proportion of distance learning and face-to-face will be approximately 85% and 15%, respectively. The motivation for this blended approach is based on our survey data showing a strong interest in a blended approach among all of our targeted groups. For those students who cannot attend the face-to-face sessions, they will be able to access and participate in these sessions by the use of the "live" web conferencing program that is available on the Blackboard Learning Management System.

The use of distance learning technologies is motivated by our goal to meet the needs of the following targeted audiences: a) adult learners living in Maryland and out-of-state who are unable due to logistical reasons to enroll in a traditional face-to-face class room instruction and b) international trainees who are accepted in our Fogarty Training Grant, for whom student visas for

travel are proving increasingly difficult to obtain and for whom the cost of travel and living expenses are becoming prohibitive.

Distance learning program is consistent with the institution's mission

As the State's public health, law and human services university, the mission of UMB is to excel at professional and graduate education, research, patient care, and public service, and to educate leaders in health care delivery, biomedical science, global health, social work and the law. Also, UMB emphasizes interdisciplinary education and research in an atmosphere that explicitly values civility, diversity, collaboration, teamwork and accountability. If UMB expects to achieve its mission in education excellence and to be competitive, it must design and offer online degree programs that respond to the following changes occurring in higher education (15).

- **Education pipeline**
  - Inputs at every level
  - Lifelong (18-80)
  - Highly diverse
  - Oriented to part-time, non-residential, working adults
  - Results must become outcomes-based
- **Changing demographics**: Data indicate a shift from the traditional student (the 18-22 year old, full-time resident) to older students studying part-time.
- **Technology shift**: Online delivery is far outpacing traditional forms of delivery. From 2002 to 2008, online enrollments grew at an annual compound rate of 19% vs. 1.5% for all of Higher Education. By the fall of 2008, 25% (4.6 million) of all students took at least one online course. There is a growing acceptance that online education as being as good as or better than traditional face-to-face delivery models. It is estimated that by 2020, half of all learning may be online.
- **Growth of Mobile Technologies**: Mobile technologies and miniaturization are changing the computing environment and the educational delivery paradigm. Technologies like netbooks, e-Readers, iPhones and iPads have the potential to revolutionize the delivery space and to provide anywhere, anytime learning.
- **Web 2.0 Revolution**: Other technologies that are already figuring widely into the future of education are part of the Web 2.0 revolution. The use of a variety of technologies is disaggregating the educational experience into 'the cloud'. Many of the technologies for the future, like blogs, wikis, podcasts, video, social networking and social media, virtual worlds, mobile learning, and Personal Learning environments, will have profound effects on the future learning landscape

Essentially, online education represents a strategy that can address the restriction of offering college courses to the privileged few. Not everyone can pause in their life for what is rapidly becoming an insular and confining structure that may be well suited for a high school graduate, but is considered irrelevant to groups of adult learners. Essentially, online learning seeks to expand knowledge beyond the walls of the campus. Online programs also have the ability to respond to individual student learning needs and styles in ways that cannot be duplicated in the face-to-face classroom. Major determinants of successful online programs include 1) course design that incorporates best practices, 2) quality faculty who can engage students in the material, and 3) responsible academic oversight. All three of these determinants are present in this proposal.

Effectiveness of distance learning compared with traditional classes: Critics of online learning claim that students are exposed to an inferior education when compared to traditional in-class instruction, but a recent report, "Interactive Learning Online at Public Universities: Evidence from Randomized Trials," showed that students who utilize interactive online learning produce

equivalent, or better, results than students participating in face-to-face education, although the results were not significantly different) (15). Several other studies, including one by the U.S. Department of Education, suggest that students are able to retain more and perform slightly better in an online setting than in a traditional one.

Time Commitment between traditional (face-to-face) and online learning: Course content and workload are equivalent for traditional (face-to-face) and online courses. The "rule of thumb" often used in academe is that for every course credit hour, a student should expect to spend 2 – 3 hours/credit hour per week engaged in "class work" for that course. For a 3-credit course, using this formula, a student should expect to spend six to nine (6 - 9) hours per week in a typical 15-week course. Courses delivered asynchronously incorporate the traditional weekly readings and required assignments, and students "attend" class through a variety of interactive activities that promote three types of interactions: learner-to-content, learner-to-instructor, and learner-to-learner(s) [see below]. These include discussion forums, chat messages, blog, wikis, and glossary. Studies have showed that asynchronous threaded discussions provide a reasonably similar experience in terms of time spent participating in classroom activity. A benefit to online learning is that the outside hours tend to be more flexible, and individuals can commonly work according to their availability.

Distance Learning Pedagogy

Types of distance learning have existed for several generations and the features and pedagogical principles of each generation of distance learning are technology driven, with their features to emerge directly from the type of the technology used (16, 17). For example, correspondence learning (the first type of distance learning) consisted of printed materials and customized textbooks. There are no pedagogic principles that technology serves; rather technology drives the pedagogic principles that are exploited in the distance learning systems. The technology used in the current distance learning environment seeks to achieve interaction and collaboration representing a shift from "instructor-led" to "learner-centered approach and student-student interaction". The web is used as a tool to foster constructivist student-centered learning environments that are characterized by engaged cooperating and collaborating students with teachers assuming the role of facilitators (18).

Three types of interaction can be promoted in distance learning systems. The first is learner-content interaction, where the students work with a web-based instructional program with the system adapting to their inputs. The second type of interaction is the learner-instructor interaction that may be more versatile in web-based environments via synchronous and asynchronous communication. This second type of interaction occurs via print, electronic dialog, e-mail, computer conferencing or electronic online classroom discussions. The last type is learner-learner interaction, e.g., such interaction occurs when learners engage in online discussions whether moderated by the instructor or not. At the same time, learners' groups may be given responsibility to act autonomously for conducting group projects, or other forms of group-lead activities. Learner-learner interaction provides for the opportunity for the social negotiation of knowledge and construction of meaning. Also, interaction might take place more actively in distance learning environments than in traditional classrooms, as interaction is limited in traditional instruction when conducted in large classrooms. These types of interaction in web-based environments support collaborative construction of knowledge through social negotiation, which is a key feature of constructivist learning environments.

Also, distance learning technologies serve many learning styles by the varied activities that are incorporated in distance learning. Hence, learning can be optimal for all students. Visual learners

need pictures, videos, and slides; auditory learner needs Podcasts so that they can hear and read at the same time; and kinesthetic learners need to be able to take reading materials and highlight what is important to them.

Also, during the last decade, online courses have incorporated a combination of synchronous and asynchronous communication tools. The goal is to maintain the positive aspects of a traditional classroom in an effort to avoid the social isolation problems learners encounter in virtual and remote environments. We intend to use both synchronous and asynchronous communication tools in the Certificate Program.

To summarize, the several benefits offered by the use of online technology include (19):

- On-line classes exhibit a high degree of interactivity.
- Classmates have the opportunity to see and compare their work and ideas.
- Asynchronous conferencing provides ample time for students to reflect and compose responses.
- Computer conferencing reduces impact of discrimination due to physical characteristics.
- On-line courses are much more student centered than teacher controlled.
- On-line courses engender a much higher "social context " than traditional classrooms

Pedagogical Methods To Be Used In The Proposed Certificate Program: The Certificate Program will use a combination of asynchronous (delayed interaction) and synchronous (real time) activities.

Asynchronous Learning: Learning in which interaction between instructors and students occurs intermittently with a time delay. As opposed to traditional instructor-led training or even distance learning that centers on teleconferencing and online presentations, asynchronous eLearning occurs in an environment where a single learner interacts directly with content, fellow students, and faculty via a technology system, maximizing flexibility in timing and access for the learner by allowing learner control of pace, schedule, and location.

Synchronous Learning: A real-time, instructor-led online learning event in which all participants are logged on at the same time and communicate directly with each other. In this virtual classroom setting the instructor maintains control of the class, with the ability to "call on" participants. In most platforms, students and teachers can use a whiteboard to see work in progress and share knowledge. Interaction may also occur via audio or chat. Learners and teachers experience synchronous eLearning as a more social activity, as it includes discussion in real time. Synchronous sessions help learners feel like participants rather than isolates. These real time activities will be taped and archived for either repeat or first time viewing by learners who were unable to attend the live sessions.

Types of Asynchronous Interactions

The predominant types of learning activities we will use to foster a) learner-content interaction; b) learner-learner interaction; and c) learner-faculty interaction are shown below (more examples are shown in *Appendix 7*).

Learner to content Interaction	***Learner to Instructor Interaction***	***Learner to Learner(s) Interaction***
▪ RSS feeds ▪ YouTube video	▪ Lesson ▪ Quiz (Test)	▪ Chat ▪ Discussion Forum

▪ Glossary ▪ FAQ	▪ Written Assignments ▪ Quick email ▪ Discussion Forum	▪ Blog ▪ Wiki ▪ Glossary ▪ Group Projects

The Discussion Forum will be used predominantly to foster learner-to-instructor and learner-to-learner interactions. We have developed a rubric to grade the posts entered in the Discussion Forum. Please see *Appendix 8*.

Distance Learning Best Practices

Based on several sources, we have developed a checklist that details the best practices for distance education; see *Appendix 9* (20, 21). This document will help faculty and instructional designers develop the courses; assess the readiness of the course, and ensure that the online courses are instructionally and pedagogically sound. The best practices are a synthesis of strategies, activities, design techniques, and organizational items that have been successful in higher education. The specific domains of this checklist are as follows and are detailed in Appendix 9:

- Course overview and introduction to the students
- Course organization and design
- Learning Objectives (competencies)
- Instructional Materials
- Learner Communication, Interaction and Collaboration
- Assessment and Evaluation (measurement)
- Course Technology
- Learner Support

Distance Learning Technology to be used in the Certificate Program

Learning Management Platform: UMB utilizes and provides IT support for the Blackboard Learning Management System for online course delivery. Within Blackboard, is the Collaborate conferencing software that we will use for our synchronous live activities, i.e., orientation and presentation face-to-face class sessions and recurring webinars.

Audio/Visual Equipment: The Distance Learning Team has available to them the use of a video cam recorder to tape lectures, webcams, and an interactive smart board. We also use the Camtasia software for screen lecture capture.

[See letter documenting approval of the technology to be used to deliver the distance education program has been reviewed and approved and will meet the program's objectives.]

Distance Learning Team:

Henry Silverman, MD, MA: Dr. Silverman will provide the oversight for the distance learning education. He has been involved with distance learning with his Fogarty International Center /NIH sponsored training grant in research ethics: Middle East Research Ethics Training Initiative (MERETI). This training program consists of face to face and distance education instruction for the past several years. Recently, Dr. Silverman was awarded a supplement grant to determine best practices in eLearning across all of the Fogarty training programs that offer distance learning. Dr. Silverman will provide appropriate oversight of the program.

Zelalem Hailu: Instructional Designer. Mr. Hailu has over 10 years of experiences in the development and delivery of interactive online course. He has helped with the design of online courses for Dr. Silverman's Fogarty-sponsored research ethics training grant.
Yogesh L. Nahar: Instructional Technologist. Mr. Nahar has over 3 years of experience in setting up, customizing and developing SCORM-compliant courses and modules for e-learning environments. Mr. Nahar will provide advice on technology upgrades to the faculty.
Samuel Gurmu: Audio Visual Support. Mr. Gurmu will assist the faculty with the taping of the lectures for archiving and with uploading videos and audio files. He will ensure that the audio and video files are appropriate for streaming on the LMS and be responsible for implementing the Collaborate video conferencing in the courses.

Training and Support of Faculty in Distance Learning Techniques

For over a decade, the distance learning field has recognized that institutional support is critical to the level of faculty participation in distance learning (22, 23). Schifter's study of factors that motivate and inhibit faculty participation in Asynchronous Learning Networks (ALNs) suggests that the lack of "institutional support for faculty, technical infrastructure and course development needs" are the top three factors that inhibit faculty participation in ALNs (24). The distance learning team will provide the following services to ensure that best pedagogical practices are used to support the most of effective presentation of their course content.

Training:

- Written instructions accompanied by training videos will be developed to teach the faculty how to use the learning management system.
- A manual for the faculty regarding principles of good practice and the pedagogy of distance education.

Support:

- Provide timely support to the faculty in the use of the technology and troubleshoot any problems that might arise during the course of instruction.
- Work with faculty to design and develop courses, monitor the delivery of the course, and assess and revise the course for future offerings.

Support of Students in Distance Learning

We realize that the key to the success of an online program is dependent on a) students knowing upfront the assumptions, requirements and responsibilities of taking an online course, 2) the ability of students to have the background, knowledge, and technical skills to undertake an online program; and 3) their having access to academic and technical support services to support their online activities. Accordingly, we will provide the following services to support the students in accessing distance learning technology:

- Communicate to students the nature of online learning, including their requirements, roles and responsibilities, and access to support services. We have also prepared a short questionnaire for students that will help them decide whether online learning is right for them (See *Appendix 10*, "Is online learning right for you?"). All of our advertising, recruiting, and admissions materials shall clearly and accurately represent the program and the services available.
- Ensure that enrolled students shall have reasonable and adequate access to the range of student services to support their learning.
- Ensure that accepted students will have the background, knowledge, and technical skills needed to undertake the program.

- Make available the HS/HS Library Services to students so that they can have access to research databases, online catalog of books and media, chat with or e-mail a librarian, electronic interlibrary loan, and more.

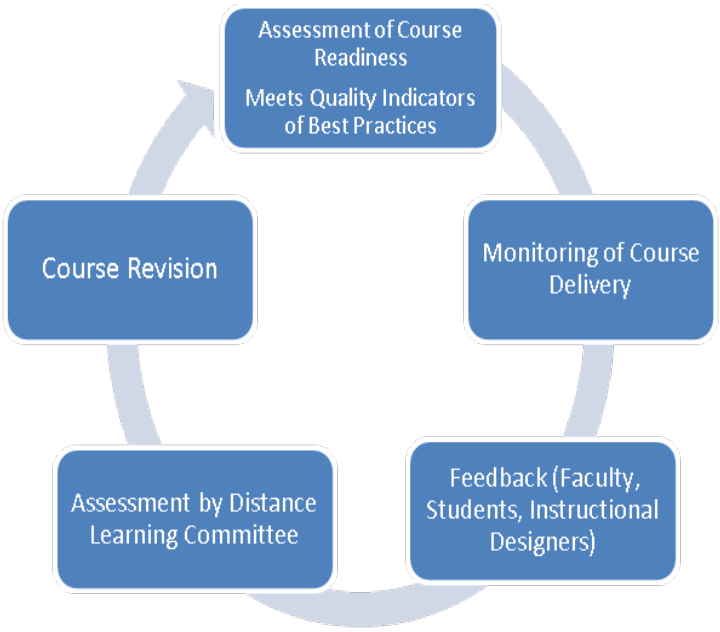
Mentoring of Students

The PI in conjunction with the other faculty will assign each student a mentor (faculty) throughout their tenure in the program. Students will meet with their mentors upon entering the program to discuss their goals and needs and during the program to discuss their progress, any difficulties they might be having with the curriculum and their developing plans after graduation

Evaluation and Assessment of Online Courses

We will adhere to a quality improvement model for assuring the continuous quality of the online courses as indicated in the accompany figure. The process will involve the following steps:

- Assessment of course readiness as measured by our quality indicators of best practices (including assessment of faculty readiness).
- Monitoring of course delivery as assessed by the instructional designers with use of our "course evaluation' rubric (see *Appendix 11*).
- Obtainment of feedback from the faculty and students and instructional designers.
- Analysis of feedback as performed by the Distance Learning Committee.
- Institute course revisions based on comments by the Distance Learning Committee.



We provide more details regarding our evaluative and assessment methods on pages 19-20 of this proposal. .

UMB Commitment to Support.

To ensure the sustainability of the distance learning program, the Office of Academic Affairs affirms the following:

- UMB Policies for faculty evaluation includes appropriate consideration of teaching and scholarly activities related to programs offered through distance learning.
- Commitment to ongoing support, both financial and technical, and to a continuation of the program for a period sufficient to enable students to complete a degree/certificate. [**SEE LETTER OF SUPPORT**]

H. Adequacy of Faculty Resources

I. Provide a brief narrative demonstrating the quality of program faculty. Include a summary list of faculty with appointment type, terminal degree title and field, academic title/rank, status (full-time, adjunct) and the course(s) each faculty member will teach. ***Please see CVs in Appendix 13.***

Program Director: Henry J. Silverman, MD, MA.

Dr. Silverman is Professor of Medicine. He received a Master's Degree in Philosophy from Georgetown University and is chair of the Clinical Ethics Committee at the University of Maryland. Dr. Silverman teaches several graduates courses in ethics in the Master of Public Health Program. Since 2005, he has directed an NIH-sponsored international training program in research ethics focused on developing individual capacity in research ethics for individuals from the Middle East. From his experience in this training program, he has demonstrated the skills necessary to accept

overall responsibility, to organize, administer, monitor, and evaluate a training program. His mentoring activities have guided the career development of the trainees of this training program, which include teaching activities, publications, and abstract presentations at national and international conferences.

Robert Wachbroit, PhD (Philosophy)

Dr. Wachbroit is part-time Adjunct Faculty (Assistant Professor). He is former Research Scholar at the Institute for Philosophy and Public Policy at the University of Maryland, College Park. Dr. Wachbroit has written articles in the philosophy of science and medical ethics, including articles on the challenges of genetic testing, ethical issues in cloning and stem cell research, and the problems inherent in risk characterization and risk communication.

Adil Shamoo, PhD

Dr. Shamoo is Professor of Medicine at UMB School of Medicine. He is the Editor-in-Chief (since 1988) of the journal, Accountability in Research. He currently teaches a graduate course, "Responsible Conduct of Research." Dr. Shamoo co-authored a textbook in 2003: Responsible Conduct of Research.

Clement A Adebamowo D.Sc., MD, FWACS, FACS

Dr. Adebamowo has worked as a professor of surgery and director of Institute of Advanced Medical Research and Training at the University of Ibadan, Nigeria where he conducted cancer and genomics research before coming to Baltimore. He is also Director of the West African Bioethics Training Program and is Chairman of the Nigerian National Health Research Ethics Committee.

Faculty	Appointment Type	Terminal degree and field	Academic Rank/ Status	Courses *(course master)
Henry Silverman	Full Time	MD MA Philosophy	Professor Full Time	• Ethics of Globalization* • Introduction to Research Ethics* • Issues in International Research Ethics* • Institutional Review Boards*
Robert Wachbroit	Part Time	PhD Philosophy	Asst Prof. Part Time	• Introduction to Ethical Theory* • Introduction to Research Ethics • Issues in International Research Ethics
Adil Shamoo	Full Time	PhD Biochemistry	Professor Full Time	• Responsible Conduct in International Research*
Clement Adebamowo	Full Time	MD, MSc Bioethics	Professor Full Time	• Ethics of Globalization • Issues in International Research Ethics

I. Adequacy of library resources

Describe the library resources available and/or the measures to be taken t o ensure resources are adequate to support the proposed program. If the program is to be implemented within existing institutional resources, include a supportive statement by the President for library resources to meet the program's needs.

The Health Sciences and Human Services Library (HS/HSL) provides collections and services for faculty, staff, and students of the University of Maryland, Baltimore as well as for the University of Maryland Medical Center (UMMC). The Library also serves as the Regional Medical Library for the Southeastern/Atlantic Region in the National Library of Medicine's National Network of Libraries of Medicine. The Library is the second largest medical school library on the East Coast. The current facility, which opened in 1998, provides over 900 seats, 45 group study rooms, 130 individual study-carrels, 50 public-access computers, 1500 data connections for laptops and 3 microcomputer classrooms. The 190,000 square foot building also houses the HS/HSL coffee lounge. The Library provides access to 386,787 print volumes, 19,594 e-journals, 275 print-only journal subscriptions and 82 databases. The HS/HSL Faculty, Staff and Student web site provides access to a full range of information and services including e-resources (e-books and e-journals), course reserves, subject-specific web collections, digital reference, and interlibrary loan. The Library maintains web sites for Consumers, Corporate Members, Friends and Alumni and Parish Nursing. The site is also available by mobile device. The Library offers an array of services including traditional reference, interlibrary loan, and photocopying as well as consultations and database searching by faculty librarians, educational programs covering database and information management topics, and planning support for integrating information skills into curricula. We will work with the Library management team to ensure that resources are adequate to support the proposed program.

J. Adequacy of physical facilities, infrastructure and instructional equipment

UMB's 61-acre research and technology complex encompasses 62 buildings in west Baltimore near the Inner Harbor. Faculty has offices provided within their respective departments. UMB has adequate facilities, infrastructure, and equipment to support the distance learning needs of the Certificate Program. See pg.13 for a description of the infrastructure and equipment for distance learning.

Although the Certificate Program will be largely taught by distance learning, we mentioned previously that there will be opportunities for face-to-face encounters for those students who live near the UMB campus. These face-to-face sessions will occur in existing classrooms on campus (we anticipate that there will be two face-to-face sessions per academic semester. The institution provides a safe, accessible, functional and appropriately maintained facilities for the faculty and the students. Based on surveys undertaken as part of the strategic planning process, the campus is perceived by faculty, staff, and students as a safe place to work and study during the day.

Students will have full access to computing facilities at UMB. Students will be provided with UMB e-mail and library accounts and will have complete journal searching ability via PubMed. UMB possess computing facilities that includes a networked computing environment for support of broad range of information technology functions, including basic research, clinical research, patient information, and general office management.

[See Letter documenting support for adequate equipment and facilities to meet the program's needs.]

K. Adequacy of financial resources with documentation
The resources and expenditures are shown in Tables 1 and 2, respectively (*Appendix 12*).

The narrative for each of the resource categories in Table 1 is as follows:
1. Reallocated Funds: None

2. Tuition and Fee Revenue: We are budgeting for an enrollment of 10 in Year 1, with steady increases for Years 2-5 (14, 16, 20, and 24, respectively). We anticipate 60% in-state enrollment 40% out-of-state enrollment. These figures are based on the results obtained from our market interest survey that demonstrated considerable interest in the proposed Certificate Program. To summarize, approximately 25% of UMB students and 25% of the UMMS workforce showed strong interest in the Certificate Program and approximately 50% of the Research Ethics Workforce showed strong interest. Our out-of-state projections are based on the PRIM&R data that involved out-of-state respondents. Approximately 80% of the respondents expressed strong interest in the Certificate Program and more that 80% favored a distance learning only approach. Although it is difficult to predict actual enrollment numbers, our anticipated enrollment figures for the first three years represent conservative estimates.

3. Grants and Contracts: None

4. Other Sources: Dr. Henry Silverman is presently the program director of a Fogarty/NIH sponsored training program in research ethics that aims to provide master's level training to individuals from the Middle East (Grant #RTW007090B), Appendix IV). He is currently in Year 2 of a 5-year non-competitive renewal award. Trainees supported by this grant will participate in the courses in the proposed Certificate Program. Accordingly, we have allocated funding for Years 1, 2, and 3 from this grant that will go towards the support of the distance learning staff ($15,000/year).

The narrative for each of the expenditures in Table 2 is as follows:

1. Faculty (salaries calculated with 4% merit and COLA increases for Years 2-5)

Henry Silverman, M.D. (15% teaching and 5% administrative Year 1) Dr. Silverman will be the program directors and will be the course master for 4 of the 6 courses (9 credits). He will be responsible for the educational and financial aspects of the program. He will play an active role in all three committees (Admissions, Curriculum, and Distance Learning Committees) and ensure that the faculty and students are adequately supported by the Distance Learning Team. For Year I, he will receive 15% salary support for his teaching efforts and 5% for his administrative efforts, with appropriate increases as the program grows in the succeeding years.

Robert Wachbroit, PhD (10.0% salary support Year 1): Dr. Wachbroit will be the course master for the 2-credit Introduction to Ethical Theory course and will participate in the teaching for three other courses (see Table on page 28 of the proposal). He will also participate in the mentoring activities. For his efforts, he will receive 10.0% salary support for Year 1 with appropriate increases for the succeeding years.

Adil Shamoo, PhD: (5% salary support Year 1)**.** Dr. Shamoo will be the course master for the 1-credit Responsible Conduct of Research in International Issues and will participate in the teaching of the Introduction to Research Ethics course. He will also participate in the mentoring activities. For his efforts, he will receive 5% salary support for Year I with appropriate increases for the succeeding years.

Clement Adabomowo, MD (3% salary support Year 1). Dr. Adabomowo will participate in the teaching of several of the courses in the Certificate Program. He will also participate in the mentoring activities. For his efforts, he will receive 3% salary support for Year I with appropriate increases for the succeeding years.

2. Administrative Staff:
Instructional Technologist: This in-house person will provide support for instructional design, web support, and online course delivery. As the program develops and as the resources increase, it is our intention to transition from hiring distance learning staff who work on a contract basis to establishing in-house expertise for online course design, delivery, and technical support.

3. Support Staff:
Program Management Specialist (25% salary support for Year 1 and 2, 35% for year 3, 40% for Year, and 50% for Year 5). This position will coordinate admissions processing, student progression and other related administrative support tasks for the program and related committees. All salaries are calculated with 4% merit and COLA increases for Years 2 – 5.

4. Equipment:
Equipment will include IT hardware for online course management and delivery (servers, network, and A/V equipment). We are allocating $2,500 in years 1-4 and $5,000 in year 5.

5. Library Services: none

6. New or Renovated Space: None

7. Other Expenses:
Distance Learning Staff ($20,000 for Year 1, $15,000 for Year 2, and $10,000 for Years 3-5)
The following distance learning staff will be employed on a contract basis: Zelalem Hailu: Instructional Designer; Yogesh L. Nahar: Instructional Technologist; and Samuel Gurmu: Audio-Visual Technologist.
Other expenses in this category will include software expenses (e.g., Camtasia software), web support, office supplies and communication expenses.

L. Adequacy of provisions for evaluation of program (as outlined in COMAR 13B.02.03.15).
Discuss procedures for evaluating courses, faculty, and student learning outcomes.

We will evaluate the effectiveness of the Certificate Program by instituting evaluative processes for a) the courses, faculty, and student learning outcomes and b) for the overall effectiveness of the program's objectives (please also refer to page 15).

Individual Courses
For each course, we will use the following assessment methods:

- Students will be asked to complete an online survey using SurveyMonkey® to assess their satisfaction with various aspects of the course (e.g., content, format, delivery of the course, satisfaction with the learning activities, and whether the audiovisual and written materials were clear and understandable). We will use Likert-type questions and open-ended questions for assessment. Such feedback surveys will be used at the mid-semester and end of semester time points.
- Instructional Designers will assess adequacy of course delivery and the appropriateness of course content, activities, and assessment activities. They will also assess how students are managing the online delivery methods.

Faculty
We will use the following methods to assess each faculty:

- Students' end-of-course rating forms and written comments. Students will report on the extent to which a teacher appears prepared for class sessions, communicates clearly, stimulates interest, and demonstrates enthusiasm and respect for students; research shows that student responses on these dimensions are valid and reliable.
- Focus-group interviews and exit interviews. Focus-group interviews and "exit interviews" will be used to provide information about faculty members. Such interviews can provide a depth and breadth of information, elicit unanticipated responses, and allow for clarification of student satisfaction and concerns.
- Mid-course and periodic student feedback. We will ask students to provide informal assessments of their teaching effectiveness at mid-semester by the use of student rating forms, especially ones that include open-ended questions. Throughout the term, faculty also may invite students to comment informally -- perhaps by e-mail or by writing short evaluations at the end of a class period.
- Peer Review: Colleagues will also participate in the evaluation of faculty. For example, colleagues evaluation of classroom teaching through classroom visits. We will use a standardized observation form that will yield systematic and comparable data, especially if participating faculty are trained in what and how to observe. Colleagues can evaluate course materials, such as syllabi, textbooks, handouts, assignments, graded exams, graded papers, etc. This latter aspect will be coordinated by the curriculum committee.

Evaluation of Student Learning Outcomes

We will assess student outcomes by the following methods:

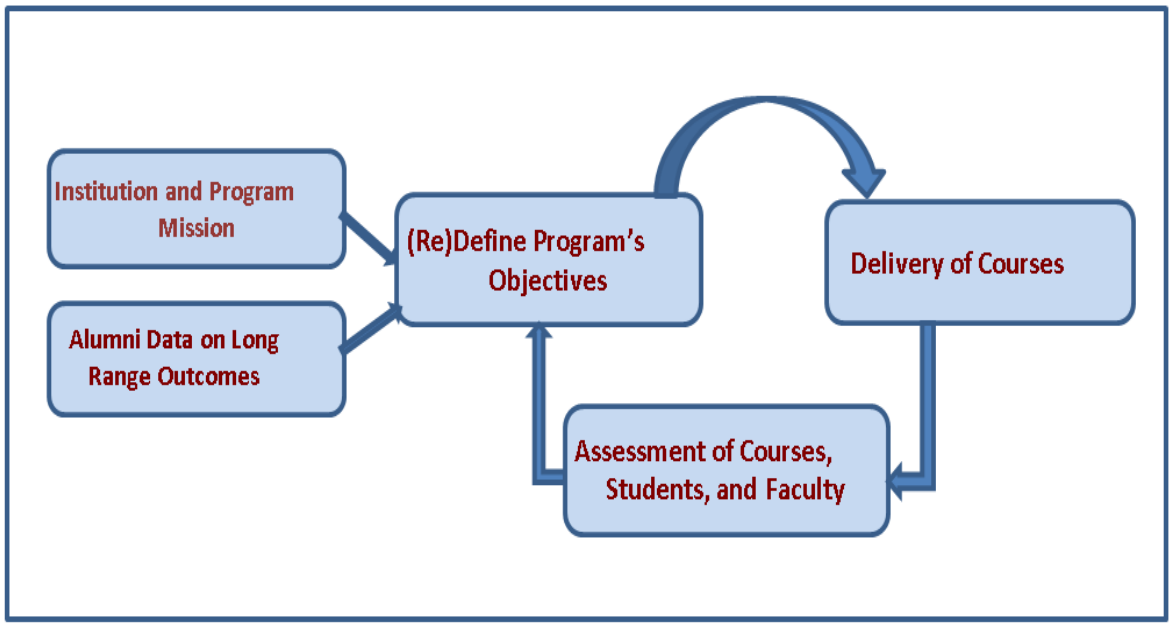
- Course-embedded assessment – Faculty will directly assess the students' attainment of specific course outcomes based on performance in specific evaluative components of a course. These will include online assignments, quizzes, written exams, discussion forum, online journals, and group work activities. Final exams and final papers will also be used to assess accomplishments of the learning outcomes.
- Student Surveys: Students will be asked to self-assess the opportunities to achieve and demonstrate the various student outcomes in a given class.

Processes for Measuring Effectiveness of Program's Objectives (see below figure)

The program objectives were designed to meet the educational needs of the students in a manner consistent with the mission of UMB. Accordingly, the Certificate Program's overall effectiveness in achieving its objectives will be evaluated by a combination of the above assessment methods (of courses, learning outcomes and faculty) and the following additional inputs:

a. Alumni Survey on Long Range Outcomes: Alumni (3-5 years out of program) will self-assess the extent to which they have attained the objectives of the programs. In addition to their comments, we will collect data regarding current career status, scholarly activities (e.g., published papers, presentations, involvement in group activities), leadership roles, etc.
b. Exit interviews will be performed for each student. A member of the Graduate School will meet individually with the students to discuss their satisfaction with the structure and content of the program, discuss their progress toward meeting their goals, and elicit any criticism with any aspect of the program.
c. Student retention rate (number of drop-outs and reasons causing drop-outs)
d. Evaluation of revenues against expenses (yearly budgets).

We will compare these various inputs with UMB's Mission Statement to confirm alignment and hence, assess the necessity of re-defining the program's objectives. See below figure.



M. Consistency with the State's minority student achievement goals

Discuss how the proposed program addresses minority student access & success, and the institution's cultural diversity goals and initiatives.

A key feature of UMB's mission and strategic planning involves respecting, valuing, and achieving "diversity". For example, The Strategic Plan states the following: "diversity" represents a core value, which is defined as being "committed to a culture that is enriched by diversity, in the broadest sense, in its thoughts, actions, and leadership." UMB realizes that it must embrace and celebrate diversity and become culturally competent. In a similar fashion, the State has a goal of expanding educational opportunities for minority and educationally disadvantaged students.

The proposed Certificate Program in Research Ethics aims to address both UMB's and the State's cultural diversity goals. First, the delivery of the Certificate Program by the use of distance learning technology will enhance minority student access, as it expands access and success for learners from diverse communities. Essentially, distance learning is quickly becoming the educational opportunity for those students who may not or would not be able to participate in a traditional college education. The desire to achieve diversity was a common challenge for higher education during the 20th century, when there was an increasing demand for education from populations that had been excluded from pursuing a college degree. Although the social movements and legal mandates such as the GI Bill, Civil Rights, and Affirmative Action in the 20th Century led to increasingly more women and minorities to gain admission to college, many segments of the national population still remain grossly underrepresented, predominantly due to an inherent reluctance of universities to modify systems that sustain traditional academic cultures (25). However, at the beginning of the 21st Century, developments in distance learning technology encouraged institutions to consider new ways of teaching, learning and doing research. The emergence of the so-called "virtual universities" has had more success in attracting diverse populations than traditional colleges. Universities and their missions and Internet-based degree programs embracing core values emphasizing social change and community engagement have been highly attractive to historically underrepresented groups (26). For rural and isolated communities, distance learning can be the vehicle that conquers geography and "space" between teachers and students.

The second manner in which the Certificate Program addresses diversity goals is that distance learning not only achieves "access", but can also help ensure "success", as the technology of distance learning meets the needs of various learners and allows for differentiated instruction. Increasingly, culture, language, and social factors are being recognized as having an impact on learning styles (27). To be sure, to avoid any charge of stereotyping, we recognize that individuals within a particular culture display the traditional traits and cultural markers of that group to varying degrees and hence, while on one hand, all behaviors are found in all cultural groups, some behaviors are demonstrated more so in some cultures than in others. These variations can be due to ethnic group differences within the larger culture, socio-economic status, degree of acculturation to the mainstream society, gender, religion, and myriad other factors. Essentially, with the proper used of its varied technology, distance learning can address the needs of all populations, and especially underrepresented groups that can not only attract, but can help thrive as well. Also, with its varied types of interactions, distance learning embraces a shift from passive to active learning, and from competition to collaboration. Different learning styles and cultures can be accommodated more easily because effective collaborative learning values diversity (28, 29). This contrasts with the traditional university's predominance of a particular and preferred learning environment grounded on outmoded ideas about one-size fits all educational pipelines tends to exclude all the others.

Finally, the proposed Certificate Program will be coordinated with the Fogarty training grant that is focused in enhancing research ethics capacity for individuals from the Middle East. Accordingly, this Certificate Program will bring together the many different cultures within Maryland with those from the Middle East.

N. Relationship to low productivity programs identified by the Commission:

The proposed program is not directly related to an identified low productivity program, and hence, there will not be any need for any redistribution of resources (including faculty, administration, library resources and general operating expenses) to this program.

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University of Maryland, Baltimore
Certificate in Research Ethics Program Proposal

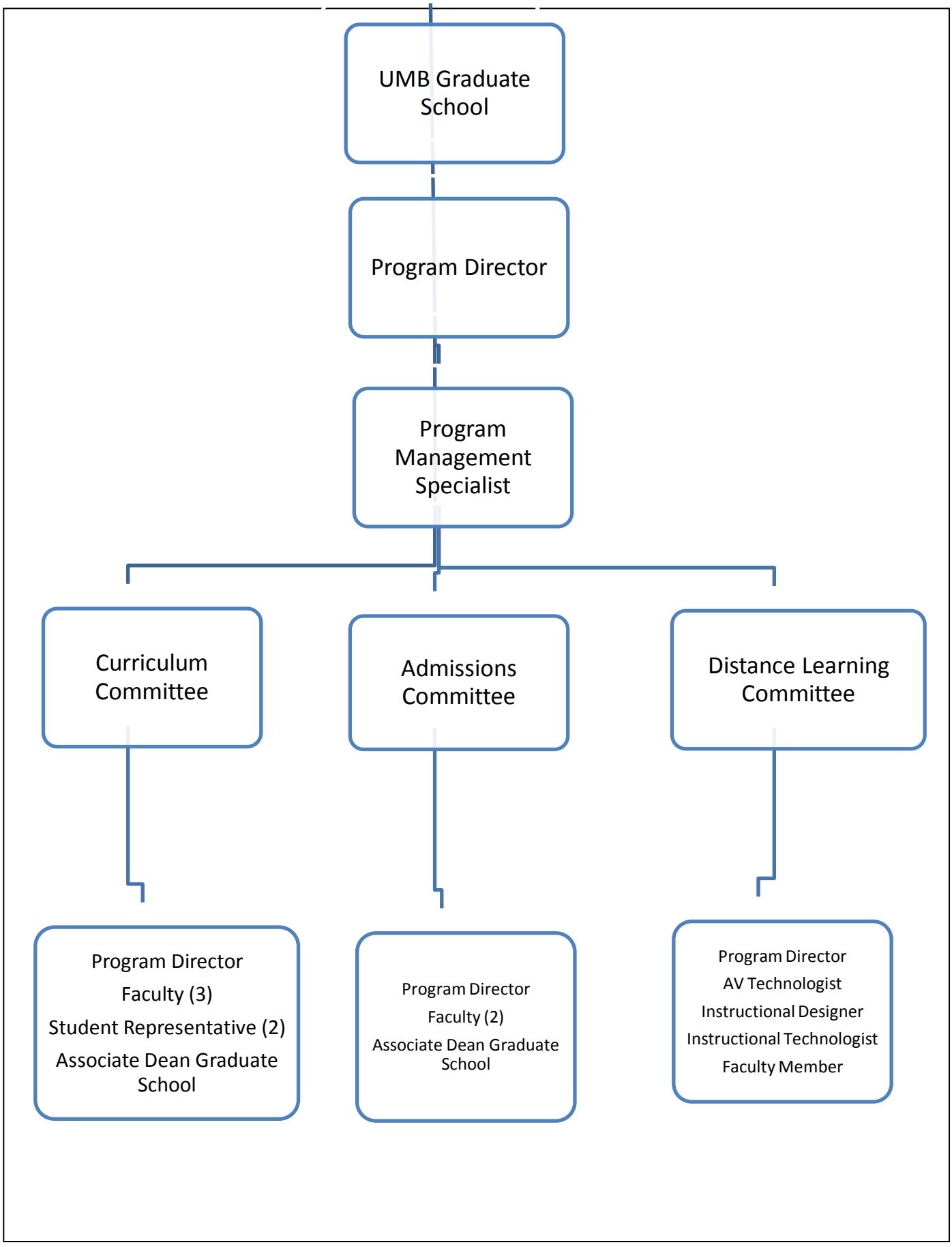
Appendices

APPENDIX 1

The Mission of the University of Maryland, Baltimore

"The University of Maryland, Baltimore (UMB) is the State's public health, law and human services university devoted to excellence in professional and graduate education, research, patient care, and public service. As a diverse community of outstanding faculty, staff and students, and using state-of-the-art technological support, we educate leaders in health care delivery, biomedical science, global health, social work and the law. We emphasize interdisciplinary education and research in an atmosphere that explicitly values civility, diversity, collaboration, teamwork and accountability. By conducting internationally recognized research to cure disease and to improve the health, social functioning and just treatment of the people we serve, we foster economic development in the City, State, and Nation. We are committed to ensuring that the knowledge we generate provides maximum benefit to society and directly enhances our various communities."

Appendix 2. Organizational Structure of the Certificate Program



Appendix 3. DESCRIPTION OF THE COURSES

1. Introduction to Ethical Theory PREV 629 (2 Credits) Instructor: Robert Wachbroit

The course introduces students to the prominent theories in ethics and political philosophy that inform our ethical arguments and the articulation of our values. For the most part, these theories are meant to be comprehensive, general, and prescriptive. Consequently, the course is organized around broad philosophical claims and arguments rather than specific challenging dilemmas. The courses can thus serve as a background or foundation to other courses on more specific topics — e.g., clinical ethics, research ethics, etc.

Course Objectives: Upon completion of this course, the student will be able to:

- Articulate ethical problems, understanding how they are different from problems that can be addressed by empirical investigations or scientific discoveries.
- Explain the difference between various schools of thoughts in ethics.
- Analyze ethical claims in terms of their theoretical assumptions and commitments.

2. Introduction to Research Ethics (3 Credits) Instructors: Henry Silverman and Robert Wachbroit

This course will examine the ethical and philosophical issues raised by research involving human subjects. The course begins with acquaintance with basic concepts in research ethics, e.g., informed consent; risk assessment; vulnerability and the fair selection of research participants. The course will equip students with the skills necessary to analyze human subject research.

Course Objectives: Upon completion of this course, the student will be able to:

- List the controversies involved with research abuses.
- Analyze research protocols involving vulnerable populations, e.g., children, mentally ill.
- Apply concepts of vulnerability
- Explain concepts of minimal risk and therapeutic misconception.
- Explain concept of equipoise

3. Ethics of Globalization PREV 640 (1 credit) Instructors: Henry Silverman and Clement Adebamowo

Although ethical issues are prevalent in global health, the discipline of international ethics has only just begun to come into its own in recent years. Accordingly, this course is designed to introduce students to the identification and evaluation of moral dilemmas in the context of changes and development in an increasingly globalized world with attention to both its theoretical and practical dimensions. This course will examine various and divergent perspectives exploring what we owe each other globally. To frame our course, we will begin with an overview of the major philosophical themes will include human rights theory, utilitarianism, Kant deontological theory, cosmopolitan theory, and the currency of distributive justice.

One fundamental question of the course is this: are there global moral principles that apply to everyone or is morality culturally relative? This question will be critically examined by exploring the conflicting ethical theories of moral universalism and moral relativism. We will also extend our philosophical frameworks to practice-oriented discussions of global inequality and poverty, the nature of global human rights, humanitarian intervention, global research, violence against women and children, and global warming. These are ethical issues on a global scale, and they are being answered, reflectively or accidentally, by individuals, governments, and non-governmental organizations every day.

Course Objectives: Upon completion of this course, the student will be able to:

- Explain the forces associated with globalization
- Evaluate the impact of globalization on issues involving social justice
- Evaluate the moral theories underlying a just globalization
- Explain the moral dilemmas posed by an increasing globalization world

4. Issues in International Research PREV 638 (3 credits) Instructors: Henry Silverman, Robert Wachbroit and Clement Adebamowo

This course will examine the ethical and philosophical issues raised by research involving human subjects that is conducted in international settings. The course assumes that the student has had at least some elementary acquaintance with basic concepts in research ethics, e.g., prior or concurrent study of research ethics or experience in conducting human subject research. The student should contact the Instructor if further clarification is needed.) The course begins with an introduction to the general issues regarding research conducted in international settings followed by a discussion about the broad issues regarding the universality of bioethics and the professional role and obligations of a scientific or biomedical researcher. The course then turns to specific issues; e.g., informed consent; risk assessment; vulnerability and the fair selection of research participants; genetic research; ethics and human rights; what is owed to research participants communities and countries after the research is completed; exploitation and justice; and science and academic integrity – in the context of international research. In sum, the course will present the students with the standard controversies in international research ethics as well as intellectual tools needed to assess these disputes.

Objectives: Upon completion of this course, the student will be able to:

- Construct and support valid arguments in the analysis of exploitative research.
- Analyze ethical questions regarding international collaborations in research.
- Evaluate the ethical issues involved in international research.
- List methods to achieve a culturally valid informed consent.
- Describe the issues involved with tissue sample research performed between international partners.
- Perform an ethical review an international protocol

5. Institutional Review Boards PREV 639 (2 credits) Instructor: Henry Silverman

A one-semester, two-credit course covering application of legal and regulatory topics critical to performing clinical research, including submitting protocols to the institutional review boards, understanding investigational new drug (IND) applications, financial disclosure and conflict of interest, basis of clinical trial design, Good Clinical Practice, recruitment and retention strategies, data safety monitoring plans and quality management and clinical research conduct issues

Course Objectives: Upon completion of this course, the student will be able to:

- Analyze and apply key points of specific legal and regulatory topics critical to performing clinical research
- Demonstrate the ability to apply interdisciplinary resolutions to issues central to clinical research

6. Responsible Conduct in International Research PREV 665 (1 credit) Instructor: Adil E. Shamoo, Ph.D.

Responsible Conduct in International Research (RCIR) is an analysis and discussion of topics in international research to prepare the student for the ethical responsibilities of participating in the complex area of international research. Course content includes concept of scientific integrity as manifested in international arena of collaboration and limited resources. The areas of concentration are: data acquisition and management, multiple authorship, peer review, conflicts of interest and the cultural context, defining/identifying/handling fraud and misconduct, issues in animal, ownership of data and intellectual property across borders with differing laws, genetics, cloning and stem cells, and international research.

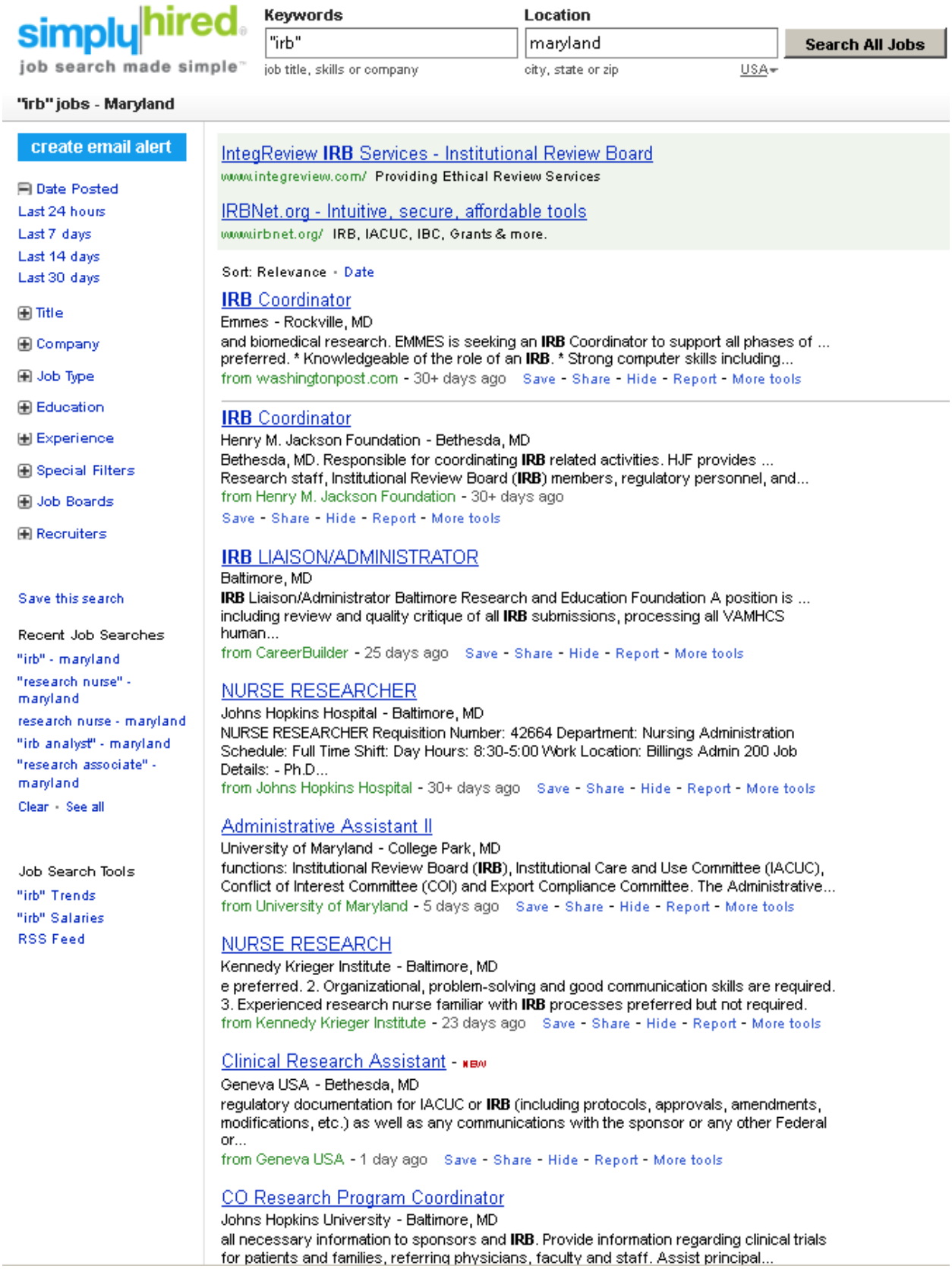
Course Objectives: At the end of this course, students will be able to:

- Describe examples of research misconduct.
- Discuss the relationship between authorship and accountability.
- Discuss the ethical and legal foundations of intellectual property.
- Discuss controversies related to patents on biological materials.
- Describe how conflicts of interest can corrupt scientific objectivity.
- Analyze methods of managing conflict of interest.
- Discuss issues related to international collaborations

Appendix 4: Mapping of Courses, Learning Outcomes, Program Objectives and UMB Mission

UMB Mission	***Program Objectives***	***Learning Outcomes*** *(see page 6 of proposal)*	***Courses***
"excel in professional and graduate education [and] research"	*Apply knowledge, critical thinking skills, and problem solving skills situated in growing careers related to the conduct, review, monitoring, and regulatory aspects of human subjects research.*	*(a), (b), (c), (d), (g), (h), (j), (k), (l)*	*PREV 637* *PREV 638* *PREV 639* *PREV 629*
"emphasize interdisciplinary education and research in an atmosphere that explicitly values civility, diversity, collaboration, teamwork and accountability"	*Become effective collaborators within interprofessional groups.*	*(m), (n), (o)*	*All Courses*
"conduct internationally recognized research to cure disease and to improve the health…and just treatment of the people we serve"	*Lead or participate in efforts to address global, social, technical, and business challenges in the domain of research ethics.*	*(e), (f), (h), (i), (j)*	*PREV 629* *PREV 638* *PREV 640*
"educate leaders in health care delivery, biomedical science, [and] global health"	*Engage in life-long learning and professional development through self-study and continuing education.*	*(p)*	*All Courses*

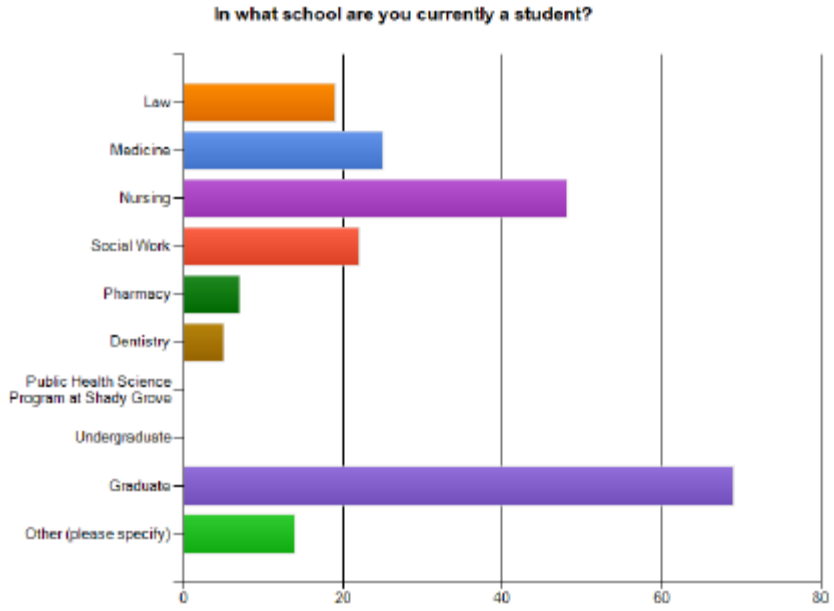
Appendix 5. Types of jobs that resulted from performing a search using the keyword “IRB”.



APPENDIX 6

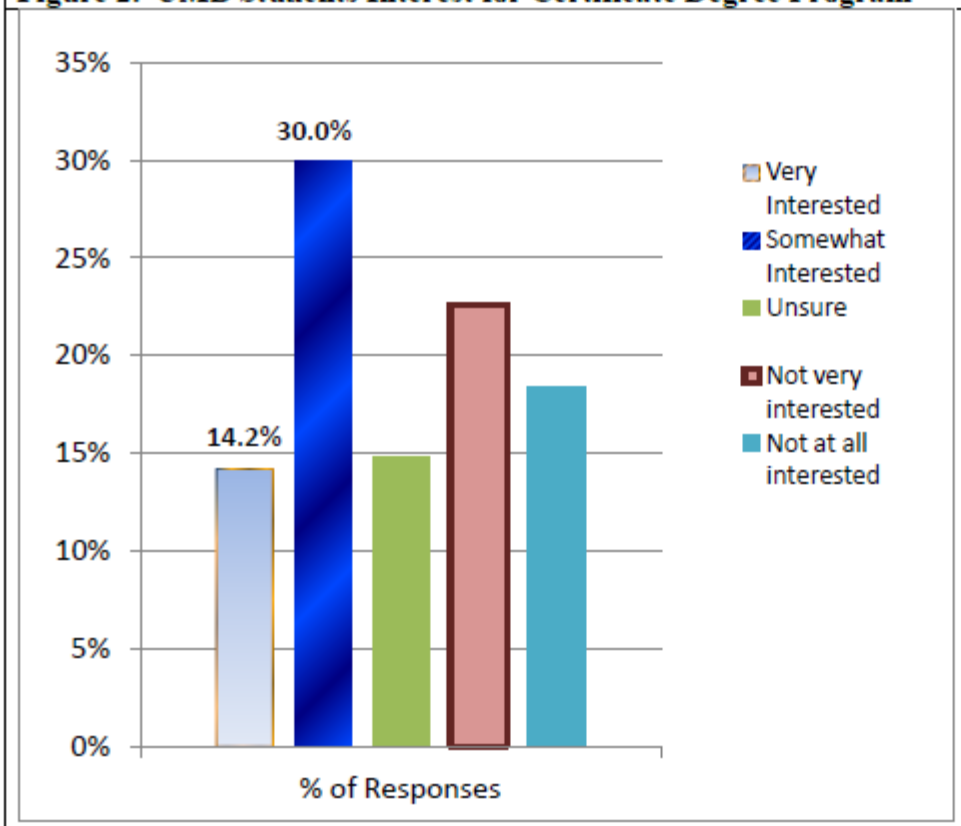
Market Interest Survey Data

Figure 1. UMB Students by Professional Types (n= 344)



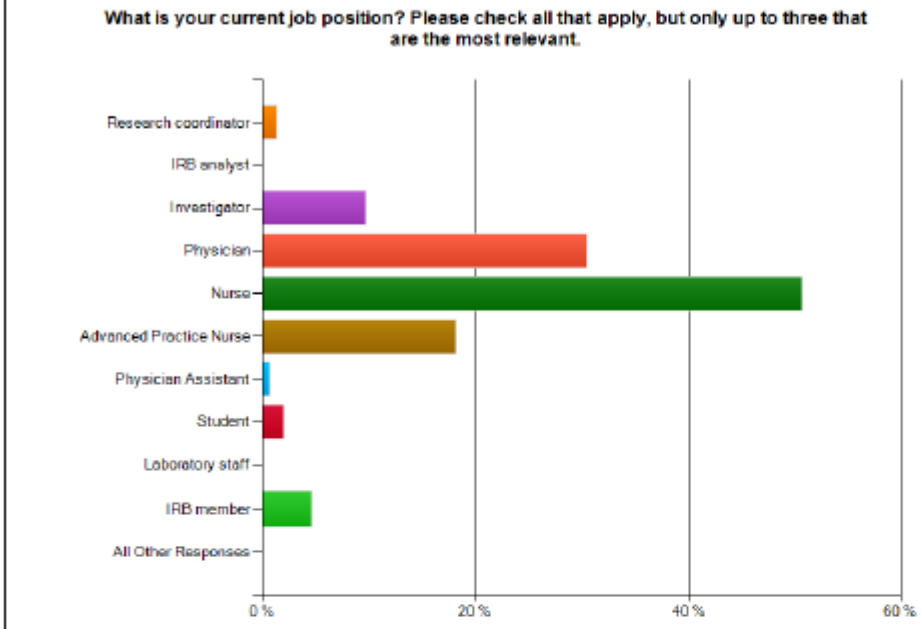
More than 60% of the students represented the Graduate School, followed by the School of Nursing (44%), School of Medicine (24%), Social Work (22%), and the School of Law (18%).

Figure 2. UMB Students Interest for Certificate Degree Program



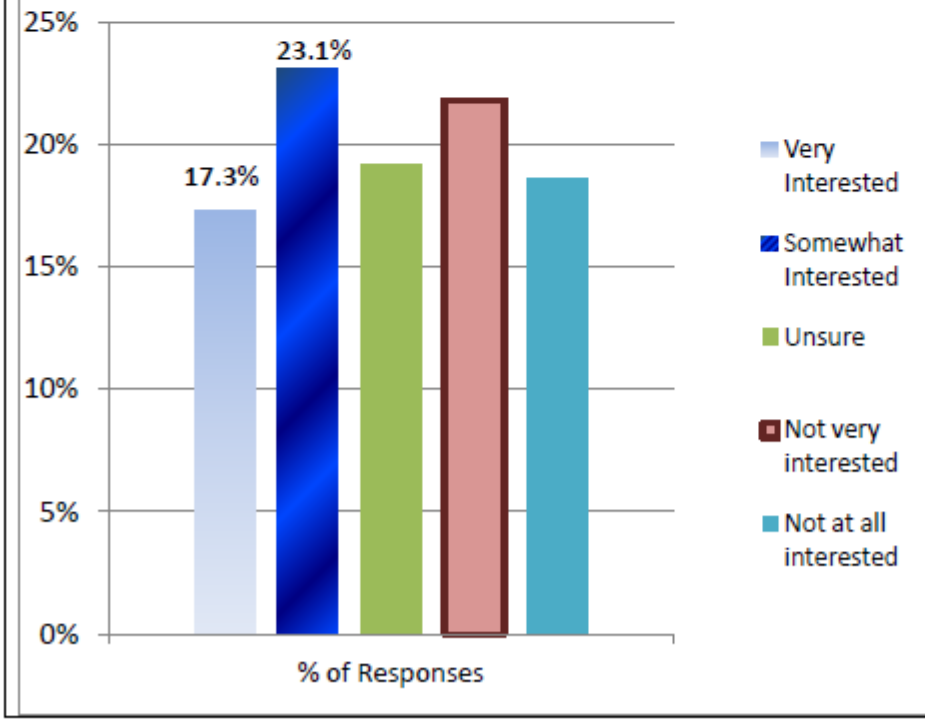
Regarding interest, 14.2% of the UMB student body would be "very interested" in such a program and 30.0% would be "somewhat interested".

Figure 3: UMMS Workforce by Job Position (n=159)



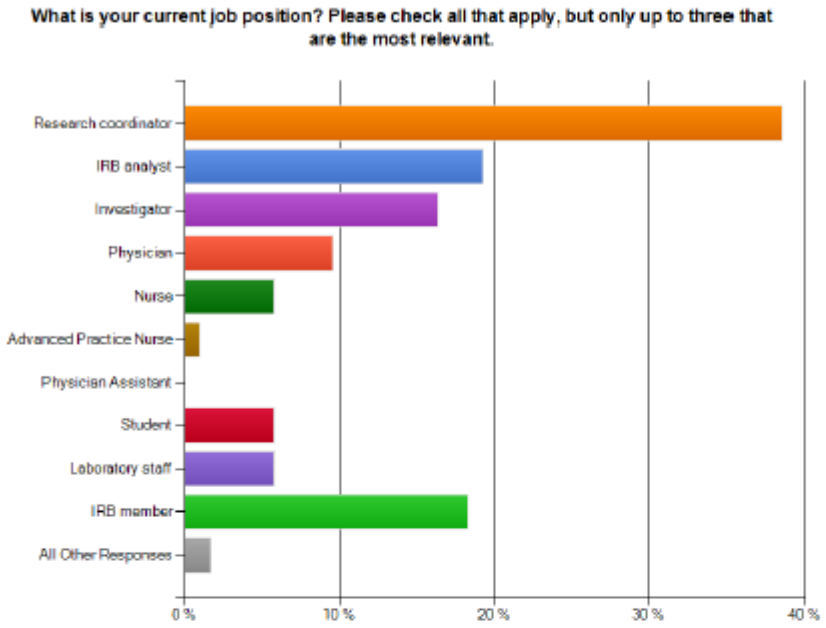
Of the total UMMS workforce responding to the survey, 50.6% were nurses, 30.5% were physicians, and 18.5% were Advanced Practice Nurses.

Figure 4. UMMS Workforce Interest in the Certificate Degree Program



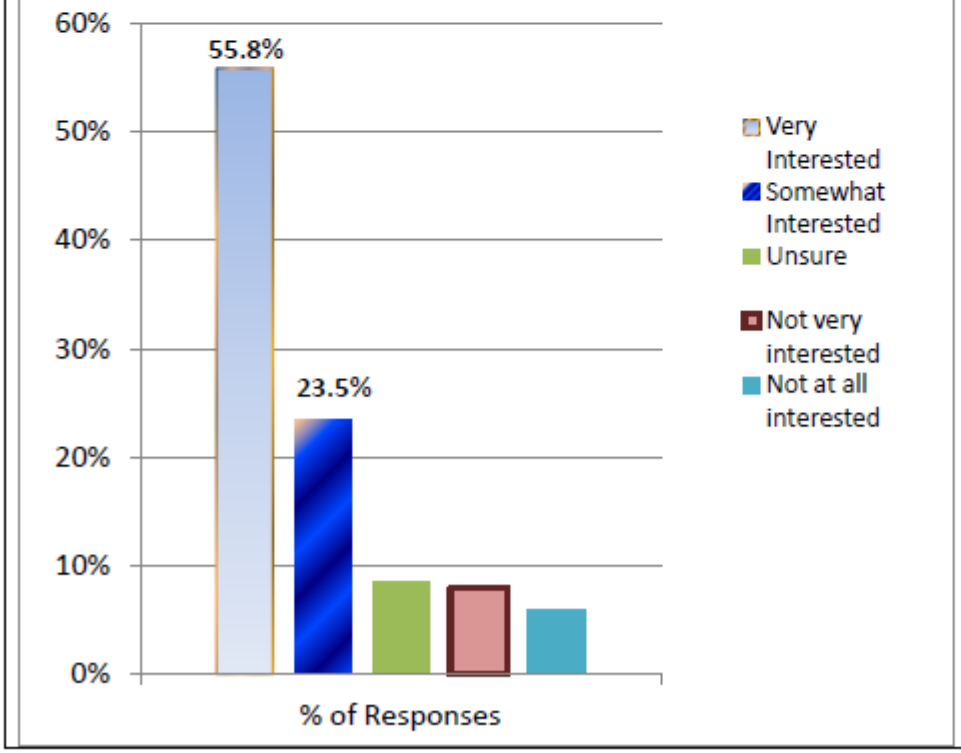
Regarding Interest, 17.3% would be "very interested" in such a program and 23.1% would be "somewhat interested".

Figure 5. Research Ethics Workforce (n=131)



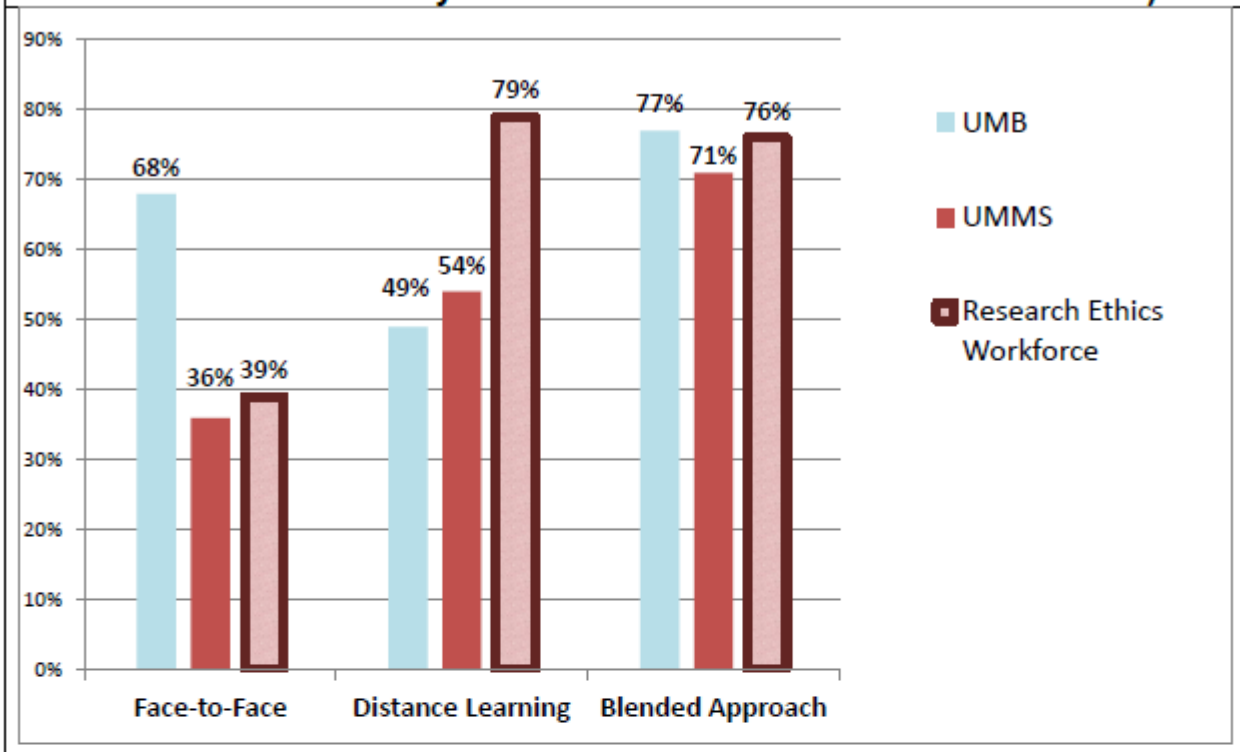
Major position types included Research Coordinators (38.5%), IRB analyst (19.2%), IRB member (18.3%), Investigators (16.3%), physician (9.6%), and nurses (5.8%).

Figure 6. Research Ethics Workforce Interest in the Certificate Program



Regarding interest, 55.8.% would be "very interested" in such a program while 23.5% would be "somewhat interested".

Figure 7. Respondents' Preferences for Learning Type (preferences included "very interested" and "somewhat interested")



- **UMB students favored a 'face-to-face' approach (68%) more than the UMMS workforce (36%) and the Research Ethics Workforce (39%).**
- **The Research Ethics Workforce favored a distance learning approach (79%) more than UMB students (49%) and the UMMS workforce (54%).**
- **All groups showed a large and similar interest in a blended approach (face-to-face and distance learning).**

APPENDIX 6a

Survey Narrative Responses Regarding Interest in Certificate Program in Research Ethics

UMB Narrative Responses

It is important to know how to conduct research in an ethical manner to prevent future issues once the research is underway.

Would expand my ethical training when doing research and/or teaching

Incredibel assest especially working in the field of public health. I am too far into my program to do a whole concenration (which would be fantastic) butwould love to do the certificate as a current student

Obtaining a certification in research ethics would be helpful prior to pursuing my Ph.D

Would have loved this concentration to be available but will totally pursue a certificate!

Complement an academic career that includes clinical research

It would help with my research efforts in the future

Would like to become a research Nurse. The certificate would help with my goals

Important to do good research and abide by all regulations, both mandated and moral. Medical research pushed the boundaries of moral issues and the line between right and wrong is often unclear.

I am a MSW/MPH student and would have enjoyed more conversation about ethics in my MPH course work

A lot of public health anything is based on evidence. it would be beneficial to know about aspects of research and get a good foundation of the ethical framework

I am employed as a clinical research nurse at NIH in Bethesda, MD. I work with volunteer patients who are directly involved in research. I am motivated to pursue advanced learning to help me to better perform my work.

The research supports the lack of adherence/understanding of HSP laws and ethics. More sources of training for researchers and staff are necessary.

Evidence based practice is based in research, additional training will provide a comprehensive base of treatment practice

As a bench scientist, I have always had a personal interest in research ethics from both philosophical and practical points of view. Eventually I expect to pursue career opportunities in science policy and administration, and an understanding of the ethical ussues involved in biomedical research will be essential in this regard.

The certificate program would add another dimension to the research PhD and could make me a more attractive candidate for future industry jobs.

I am in the DPT progarm and I am interested in MPH and ethics. Combination of both will be the best for my future.

I feel that healthcare is a continually evolving field. Research leads this evolution and I have interest in new discoveries relevant to my field of practice. The ethical nature of the research is necessary for its success and validity

Nursing is a field that has a lot to do with ethics so this training will help my in my field

If well-designed, these programs could cover a fascinating range of material. Federal and university-level supervision of research ethics is very interesting and complex terrain. A certificate program might be attractive to nurses at UMMC and other academic medical centers who are interested in becoming more involved in research.

Because research results can so easily be skewed and because I think it's important to be up to date with research to apply to practice.

Research ethics is, like any field, a progressive field. It is imperative that research ethics continue to move forward to protect research participants rights and health.

In Nursing, we are encouraged to use evidence based practice to improve patient care and outcomes. I think it would be important for nurses to understand that they can conduct their own research but they have to understand the ethics behind it.

Strong interest in pursuing public health as a career, so research ethics would play a part in that

It is an increasingly important topic in modern research. Someone who is more knowledgable is more competitive in the career they choose.

I think research ethics is a very important discipline in public health, especially for basic researchers. I am not currently interested in pursuing research ethics at this time, but I think its addition to the university is an important program for students. This program could be especially appealing to MPH students who want additional certifications in their field.

An interesting field with possible job implications

Research ethics is often overlooked by most universities, but I feel that students should learn more about research ethics. In order to create more ethical researchers, courses should be taught about the subject.

Relevant to a career in health/FDA law where clinical trials are a vital part to the medical products industry, and law and ethics are often intertwined in decision-making.

Research ethics is a challenging aspect of healthcare and healthcare law. Both of these are areas I intend to be practicing within.

 I think that if I was an incoming student, I would be very interested in pursuing research ethics training, but I'm at the tail-end of my graduate schooling, and it's not really appropriate for me to add on additional

coursework at this time. I think that adding specialty training at UMB makes sense because it bridges the many disciplines we have on campus and because we have a vested interest not only in conducting research and practicing medicine in the State of Maryland, but also in making the decisions about what research to conduct and how best to use state and federal funds to help people.

I'd like to pursue dnp, and research would enhance the quality of research that can positively contribute to nursing

Due to the recent political and financial climate, more emphasis has been placed on the value and efficiency of research study, which is tied into ethics.

As an advanced practice nurse, it will be important to use ethical research to discover evidence-based practices. In my career, I may have opportunities to conduct pilot studies and participate in nursing research.

I have an interest in research ethics, and would possibly like to pursue a career in the field.

It could be helpful for those pursuing a degree in health law as ethics pervades almost any issue.

Would complement a Science PhD well, for a position in government or industry.

As a student interested in health care law who has a background in research administration, I don't think enough people have a full understanding of all the potential ethical issues that arise in research. I think, especially in this economy, that the ability to specialize in a particular field is invaluable. This field is only going to grow.

Additional training in research ethics would support my research career and could elevate me above other candidates when applying for post doctoral positions. I am particularly interested in the MPH program and think that a program of that caliber would be more useful if transitioning to the research industry than the certificate program.

would desire to focus on international research particularly in the area of HIV/AIDS. I'm currently in the global health track of the MPH program

Medical and research ethics are fascinating to me.

i took a course through Hopkins that was primarily online & asynchronous but included three 1 hour "live talks" with the option to participate online or in person. I participated in the in person live talks & really enjoyed being able to meet the professor & some fellow students, while still having the fexibility offered by the primarily online format.

I hope this happens! Good luck!

I think it is an important academic program to develop at our institution

I hope it happens!

In regards to making either program online vs. traditional class, I would not make it 100% online. I have taken a couple online classes and I feel that the information I "learned" was not actually learned. I think that being able

to listen to a professor lecture about material and actually apply it is very helpful. Finding the motivation to REALLY understand information is also difficult in a self paced online class.

Will some of these courses be made available to other graduate students in other departments?

I think ethics and public health go hand in hand. Research, especially as it relates to aging is important to the future of public health.

The Masters program looks like it doesn't contain but one class dedicated to research ethics. If I were interested in such a major, I would want it to have more in the way of related classes.

I would very much be interested in these programs because the content is related to my work environment.

I would generally applaud the establishment of these programs and the positive impact they would likely have on the furtherance of biomedical research in the service of improving the human condition globally

I really think this programs are good because they give students enlightenment about workplace and how to the ethical when they graduate and join the workforce

More ethics programs are needed at UMB!

I'd be interested in taking classes as part of my PhD course work.

These programs would be a positive addition to the university. These programs could attract many students to the university, especially as a distance learning format where students have more flexibility to complete their coursework.

Fantastic idea and will be greatly utilized by the DC, MD, VA area. The only hesitation I have with an online course is that ethics lends itself to discussion of cases. This is difficult to do online. I have had an ethics class online and one face to face. I definitely prefer the face to face discussions.

The certificate program would be ideal for a law student to pursue in addition to the law school's health law certificate, especially for health lawyers interested in pursuing careers in clinical trials law/regulation or at institutions involved in the clinical trials enterprise.

I hope that this certificate program will be avaliable to students of every applicable school (Nursing, Medicine, Law, Social Work, etc.).

Research ethics is a field of quickly growing interest within law. It would be a good complement to the Health Law program that already exists at the Law School.

UMMS responses

Currently on a KO-8 award and required to take ethics courses. Difficult to access face to face courses.

There are limited programs available in our region regarding biomedical ethics. WHile I would prefer the degree be a doctoral one, I would certainly consider a certificate program to enhance this area of my strong interest.

Research is the cornerstone of providing comprehensive medical care. Whether I am conducting medical research or reading the research of others, it is important to understand the appropriate use of scientific methodology and the ethics of sound biomedical research.

I am currently working in the President's office and as Project Director my focus is on community and health. I believe that this type of degree might be beneficial to my current work.

I would pursue a degree or certificate program because I don't feel I don't have a good grasp of Evidence Based Practice and overall comprehension of research studies and practices.

I think the field of ethics and what goes into decisions is fascinating and a dynamic topic.

I have always been interested in ethics.

I'm currently a PhD student so a certificate in research ethics could be a nice complement

I would be interested in knowing how feasible and flexible the admission process would be for employees of either the University campus or Medical Center. I am also interested in the aspects of tuition reimbursement.

Having taken graduate courses and completing a program almost exclusively online - I found that I did not miss the face to face and still felt connected to peers and the instructor via discussion boards, conference calls, electronic lectures, etc... Just as effective and much, much more convenient!

Great idea and long over due

I personally feel there has been a need for this for many years...

Research Ethics Work Force Narrative Responses

believe that my current MPH and ultimate career goals would be strengthened by being able to take this certificate course, as research ethics was not a focus area of my concentration (health policy & management) and I have a strong desire to work in the field.

The certificate program would be a great opportunity to get additional continuing education experience and a great resume builder!

Research ethics is a very important field within the health care and clinical research industries to ensure protection within the health care/research industries

Fast paced field with not enough certificate, professional development opportunities Orshy recognition of expertise or of the profession and I have a bioethics degree, continous study is important. Please make it available to Canadians.

The coursework I have completed in ethics through my MPH training was interesting and insightful. It opened me up to thinking about research in a way that was less scientific and maintained a humanity to research that is often overlooked.

to better perform my job, be able to establish IRBs where ever needed, and train others.

I think research ethics is a very interesting topics. Although I am a current student, I have thought if I pursued another graduate degree it would be in bioethics (or a closely related field). The certificate option is extremely appealing to me.

I manager an IRB office and feel it would be beneficial.

I have a position that revolves around ethics and I have been interested in this topic and learning more about it.

I would very much like to obtain a Graduate Certificate in Research Ethics as I have many years of research and regulatory experience. Research ethics is very important to both patients and researchers to ensure apporpriate actions are taken during the course of an investigationsl study.

exactly what I do every day in my scope of practice

I have 20+ years of experience in research, research ethics and compliance. This is generally not recognized on the job market and promotion without an advanced degree.

i would be interested in dining further work in the area but have little grasp of math (esp statistics)and science except in broad terms

I would be interested in a certificate program because although I'm not a researcher I am an IRB member. I do believe that a course in research ethics would be helpful in many other professional areas. Also, I just think it would be very interesting and just fun learning experience.

I am interested in international research and there is ample opportunity for learning and implementing research ethics knowledge outside the U.S.

To complement other skills that are needed to conduct clinical, human subjects research

I have been in research 16 years,and would love to be degreed.

hAVE BEEN IN RESEARCH FOR OVER A DECADE AND WOULD APPRECIATE THE OPPRUTUNITY TO ADVANCE MY DEGREE IN THE AREA I LOVE

I think an accredited program combining public health and ethics is a idea applicable to the current research environment. I have been involved in animal research the past 9 years and a better understanding of the human aspects of research ethics may allow improved communication to those utilizing animals as to the need/ appropriateness of equivalent application of principles. It would also apply to courses I give related to animal research requirements and regulatory oversight demands.

Career Advancement. I enjoy working in research. I have been a reasearch coordinator for more than 12 years, but I don't have the credentials to advance any further.

Ethics is a very interesting and integral part of research.

For people involved with research unrelated to public health the certificate would be of greater benefit as many study coordinators already possess MS degrees and are not as interested in getting one in PH. Training here at UMD and VA for coordinators is basically non existent so getting training would be beneficial to all parties involved.

I think that a research oriented degree could be very valuable to several job areas, especially health.

I have always had a strong interest in research ethics and compliance. I serve on a number of VA and University regulatory committees. I also teach part of a research ethics course required by NIH for all trainees on NIH grants. I think it would improve and validate my qualifications to teach the course, make me a better investigator and would open up other career opportunities for me.

I've done a year of graduate bioethics coursework at KennedyInst/Georgetown, but it was more theoretical and medical with little research focus. Most of the issues I face, however, are in research arena: issues both "real ethics" and "applied" (i.e. how to meet regulations, regardless of the "ethics").

I'm already more than 1/2 completed with a MS in Health Care Administration. That is why I would likely opt for the certificate program in the future.

I would like a better understanding of research ethics. Also, it directly related to my current position.

Interest in eventually becoming IRB member

I woudl like to improve my understanding of the resrach ethics in order to be more effective in the work place.

Appendix 7: Types of Online Interactivity

Student-Content Interaction

Written papers	Papers can be written on various topics. Prior to students submitting their work, papers can be checked by an anti-plagiarism service to ensure that no plagiarism is involved.
Internet research	Students can use the Internet to research questions, problems, events, etc. Prior to students submitting papers, those papers can be checked by an anti-plagiarism service to ensure that no plagiarism is involved.
Quizzes, tests/exams	Quizzes can be used in each module to make sure students completed the assigned reading and understood it. These quizzes can be "open-book", but the questions can be randomized so different students get different questions. Tests and exams should include short answer and essay questions that require higher-order thinking, along with supporting factual knowledge. The questions can be randomized so different students get different questions. Time limits can be set, backtracking can be prohibited, and students can be forced to complete the exam in one sitting.
Practice quizzes	Practice quizzes can be given periodically throughout the course so students can gauge their understanding of the content. Specifically, these ungraded practice quizzes can be given prior to the midterm and final exam. These quizzes should include only objective questions so they can be graded by the computer, enabling students to gain immediate feedback.
Journal writing	Students can maintain a journal to record reactions to topics being studied and to record personal reflections.
Mini-lectures	Written lecture material can be divided into short, readable ("chunked") sections with links to subsequent pages, if necessary. PowerPoint presentations—with or without audio narration— can be up to 5 minutes in duration but no longer than 10 minutes. Each module can contain one narrated PowerPoint presentation that covers the main points of the module. Deaf students should have access to the narration via a text transcript. Podcast lectures can be chunked and up to 5 minutes in duration but no longer than 10 minutes. Each module can contain one podcast that covers the main points of the module. Deaf students should have access to the podcast via a text transcript. All lectures are most effective when used in combination with other instructional strategies. For example, following a section of written material, you can add a practice quiz or an interactive review game (see below) to help with recall and comprehension.

Student-Instructor Interaction

Methods of interaction	Description
Email	Students can be encouraged to email the instructor with questions about the content, structure, grading, etc., of the course. Replies can be made as soon as possible.
Class discussion board	The instructor can facilitate discussions in the class discussion board. While it's impossible to reply to every student posting, the instructor can read each one and reply to selected postings. Replies can be substantive.
Announcements	Announcements can be posted to the class as often as needed. Announcements might include information on when assignments are due, changes in the syllabus, and exam schedules.
Chatroom	Chat allows the instructor to interact with students, textually and/or graphically, in real-time. The instructor can use a chat room to conduct virtual office hours.
Webconferencing	Webconferencing allows the instructor to interact with students in real-time, over the Internet and with an audio connection. The instructor can use webconferencing to conduct virtual office hours and to deliver content live to students.
Blogs	Blogs can be used as an interactive writing tool for the instructor and students to discuss and give feedback on topics relating to the course.
Journals	Journals allow students a private space where they can communicate with their instructor. The instructor can comment on the students' writing, creating an interactive dialog and an opportunity to establish a student-instructor rapport.
Comment box	The Comment box can be used to interact with students individually to answer questions, review student work, etc.

Student-Student Interaction

Email	Students can be encouraged to email each other to ask questions about the course, including assignments. They can complete at least one assignment in which they use email to facilitate a peer-editing lesson.
Class discussion board	Students can post to the discussion board in each module, answering questions posed by the instructor. They can also reply to each others' postings.
Group work	Students can work in teams to complete a group project. This project can then be shared with the rest of the class in the discussion board.
Blogs	Students can use blogs to discuss topics in the course. They can also use blogs in a writing assignment in which groups collaborate to write a paper.
Social networking	A social network can be set up for the course so everyone can communicate on any topic.
Wikis	Wikis allow students to work collaboratively to build a web site. This can be particularly useful when groups have to create a product to share with the class.
Chatroom	As an adjunct to the group discussion board, students can use the class chatroom to discuss their group project in real-time.

Appendix 8. Online Discussion Grading Rubric

Student Participation in Discussions

In this course, you are required to be a part of an online community of learners who interact through discussion. Participation in the discussion forums is critical for maximizing student learning experiences. Part of your grade for the course depends on the quality and quantity of your participation in the discussions. Generally, you are expected to attempt to answer each other's questions and further the discourse about a topic.

There are three types of discussion activities:

1. **Required Discussion Forum**: In some weeks, I will assign a required discussion forum for that week's topic. The discussion forum will be located WITHIN the module for that week. The discussion forum will be CLOSED for responses by noon of the Thursday for that class.

2. Initiation of a Discussion Forum: Throughout the course, each student is expected to initiate at least one discussion by submitting an original post, e.g., commenting on a news article relevant to public health. This discussion forum is labeled General Discussion Forum and is located on the initial module of the course.

3. Responses to Other Students. Students should respond to posts from other students. The expectation is that each student contributes approximately 10 posts throughout the course (that is, responses to other students, excluding your own initiation and excluding the required discussion forum). Having said this, the maximum number of posts that one can submit per week is 3. It is NOT required to respond to every topic initiated by other students.

Instructor Participation in Discussions

I will facilitate the discussions but will not address every single post. I might share a related idea, synthesize comments, or intervene if a discussion goes off track. I will answer questions that are addressed to me. I will check the discussions daily during the week and on the weekends.

Expectations

- Posts and responses should be thorough and thoughtful. Just posting "I agree" or "Good idea" is not adequate. Support your statements with examples, references, or links to other sources of information, giving appropriate credit when you cite the work of others.
- Make your point concisely, aim for posts in the range of 50-100 words.
- Ensure that all posts and responses address the discussion topic.
- Effective discussions rely on dialogue, so you need to build upon the posts and responses of other students to create discussion threads.
- Revisit the discussion forum frequently and reply (when necessary) to what others have posted in response to your comments.
- Write posts and responses in complete sentences that are free of grammatical and spelling errors.

Below I have listed the characteristics that I consider when assessing the quality of the post in the discussions. If you fail to submit anything to a discussion, you receive 0 points. The total point for each post is 10 points. The expectation is to submit a post.

Discussion Participation Rubric

Criteria	Unsatisfactory	Satisfactory	Exemplary
Quantity and timeliness	Submits an initial post later than the midpoint of the session or does not submit peer responses during the session. The post or response is too short or too wordy. 0-1 points	Submits at least one initial post before the midpoint of the session and submits a peer response before the end of the session. No more than one post or response is too short or too wordy. 2-3 points	Submits at least one initial post before the midpoint of the session and submits 1-2 peer responses before the midpoint of the session. Submits at least two additional peer responses before the end of the session. All posts and responses are of appropriate length. 4-6 points
Spelling and mechanics	Poor sentence structure, inadequate organization, several grammatical and spelling errors. 0-1 points	Complete sentences, comprehensible, organization could be improved to present a more coherent argument; no more than one grammatical error or spelling errors. 2-3 points	Complete sentences, well organized, grammatically correct complete sentences without any spelling errors. 4-6 points
Demonstrates knowledge and understanding of the discussion topic	Posts and responses reveal a lack of understanding or minimal understanding of the topic as evidenced by irrelevant posts. 0-1 points	Posts and responses show evidence of adequate knowledge and understanding of course content. 2-3 points	Posts and responses show evidence of knowledge and understanding of course content and include links or references to other resources that extend the learning of the community. 4-6 points
Generates learning and participation within the community	Posts do not attempt to elicit responses and reflections from other learners, or responses do not build upon the ideas of other learners. Interacts with only one or two participants. 0-1 points	Posts attempt to elicit responses and reflections from other learners, and responses build upon the ideas of other learners. Provides comments almost regularly and interacts with a few selected participants. 3 points	Posts elicit responses and reflections from a variety of other learners, and responses build upon and integrate multiple views from other learners to extend the depth of the discussion. 4-6 points

Appendix 9. Best Practice in Designing Online Courses

1. Course Overview: Detail the general course content and student responsibilities: Information, Goals and Objectives refers to the course information and expectations; overall and unit-specific goals, objectives and outcomes; pre-course requisites and assessments; academic policies and procedures; instructor information; copyright compliance; and technical requirements and support. These elements are essential to sound instructional design and provide a framework to support the learning process for optimum outcomes.	
	1.1 The welcome message is the first thing students see when they initially log into the course. Message is appropriate and tone is warm and inviting.
	1.2 Instructions make clear how to get started and where to find various course components. Contact information for technical support is provided.
	1.3 Students are introduced to the purpose and structure of the course.
	1.4 Clearly state etiquette expectations (sometimes called "netiquette") for online discussions, email, and other forms of communication.
	1.5 Provide course and/or institutional policies with which the student is expected to comply, or a link to current policies (e.g., grading policy, plagiarism, technological requirements, grading rubics).
	1.6 Clearly state the prerequisite knowledge in the discipline and/or any required competencies.
	1.7 Clearly state the minimum technical skills expected of the student.
	1.8 Acquaint students with the technology. Have the students do the following: • Introduce themselves to the class by the discussion board and are asked to post a picture • Post a message in the group discussion board with a link to a web site that will benefit the students in the class. • Post to a blog • Complete a quiz based on the syllabus
	1.9 Clearly state to the students what is required for them to succeed in an online course, including the expected weekly time commitment.
	1.10 Instructor information available to students with contact, biographical, availability and picture.
	1.11 A statement of ADA Compliance and request for special services is provided.
2. Course Organization and Design: Layout and Design refers to the course navigation, structure and organization; the use of color schemes, fonts and typefaces; and other layout and design elements that contribute to an optimum online learning environment within the course and under the course developer's control. These components shape the learning environment and make it conducive to optimum performance.	
	2.1 The course is well-organized into sections, modules or units that correspond to the course structure and syllabus.
	2.2 Course navigation is clear, functional and consistent.
	2.3 Navigation cues are present; clearly identifiable; offered in text and graphic formats; and are obvious links based upon visual cues such as color, underlining and text directions (e.g., Start here).
	2.4 Hyperlinks to other parts of the course are accurate, functional and minimize the use of pop-up windows or new windows.
	2.5 Hyperlinks to external sources (other websites outside the course) are accurate, functional and open in a new window.
	2.6 The layout is visually and functionally consistent throughout the course.
	2.7 The format is uncluttered and includes white space.
	2.8 The typeface (font) is easy to read and consistent.
	2.9 Color is used effectively and consistently.
	Im 2.10 Images (photographs, etc.) are clear and optimized for efficient loading.
	2.11 Graphic elements (pictures, animated images, etc.) illustrate information presented in the text to enhance rather than detract.
	2.12 Course design indicates a conscious effort to comply with Section 508 of the Rehabilitation Act of 1973 to make electronic and information technology accessible to persons with disabilities.
3. Learning Objectives	
	3.1 The course learning objectives describe outcomes that are measurable.
	3.2 The module learning objectives describe outcomes that are measurable and consistent with the course-level objectives.
	3.3 All learning objectives are stated clearly and written from the students' perspective.
	3.4 Instructions to students on how to meet the learning objectives are adequate and stated clearly (detail specific tasks that students will be able to complete to meet the objectives).
	3.5 The learning objectives are appropriately designed for the level of the course.
4. Instructional Materials: This refers to how content is delivered to meet a variety of learning styles, strategies and preferences; aligns with course goals, objectives and outcomes; and utilizes the learning management system's various learning activities and tools. The components are the core building blocks of an effective course for transfer and acquisition of knowledge, skills, competencies, behaviors and attitudes.	
	4.1 The instructional materials are aligned and contribute to the achievement of the stated course objectives.
	4.2 The purpose of instructional materials and how the materials are to be used for learning activities are clearly explained.
	4.3 All resources and materials used in the course are appropriately cited.
	4.4 The content is "chunked" or divided into subunits or subtopics that relate to the main topics. PowerPoints presentations should be in 5-10 minutes in duration.
	4.5 The content meets the needs of students with different learning styles. Multimedia works best to meet the needs of audio, visual, and kinesthetic learners.
	4.6 The instructional materials are current.

	4.7 The distinction between required and optional materials is clearly explained.
	4.8 A glossary is provided that defines common, unusual or technical terms used in the course.
	4.9 Audio files meet minimum standards for clarity, file length and size, and player requirements and compatibility
	4.10 Video files meet minimum standards for clarity, file length and size, written transcription or closed-captioning, and player requirements and compatibility.
	4.11 Appropriate copyright permission is obtained and displayed for all content used in the course.
	4.12 The course provides multiple activities that help learners develop critical thinking, creativity and problem-solving skills.
	4.13 Real-world applications (e.g., case studies, problem-solving scenarios, etc.) are part of the course content and activities.
	4.14 A bibliography or reference list includes a variety of material such as websites, books, journals, and multimedia.
5. Communication, Interaction and Collaboration refer to how the course design, assignments and technology effectively encourage exchanges amongst the instructor, learners and content. These components are essential to forming a dynamic community of learning in the online learning environment and aid in learner progress and retention.	
	5.1 The learning activities promote the achievement of the stated learning objectives and are aligned with the objectives.
	5.2 Learning activities provide opportunities for interaction that support active learning.
	5.3 The instructor's plan for classroom response time and feedback on assignments is clearly stated.
	5.4 The requirements for student interaction are clearly articulated.
	5.5 Activities foster student-content, student-instructor, and student-student interactions that use a variety of methods (e.g., discussion boards, chat, blog, journal, wiki, email, etc.)
	5.6. The course provides separate forums for community, course questions and content discussion.
	5.7 Expected turn-around time in responding to learners' emails (e.g., within 24 hours or between 24-48 hours, etc.) is stated.
	5.8 The course provides opportunities for learners to collaborate through group work that directly relates to course goals, objectives and outcomes.
	5.9 Guidelines for forming work groups and assigning roles within each are clearly stated.
	5.10 Benchmarks and expectations of group participation are clearly stated.
	5.11 Learners engage in peer activities, such as peer reviews, peer critiques, peer evaluations, etc.
6. Evaluation and Assessment refers to the process of determining learner achievement and quality of work through formative and summative evaluation and assessment, including the assigning of grades and processes and mechanisms to elicit feedback from learners for the purpose of course improvement and instructor performance. These components bring the instructional systems design process full-circle and reflect back upon the course goals, objectives and outcomes to demonstrate learner performance, and instructor and course effectiveness.	
	6.1 The types of assessments and evaluations are aligned with the learning objectives and are consistent with course activities and resources.
	6.2 Specific and descriptive criteria are provided for the evaluation of students' work and participation and are tied to the course grading policy.
	6.3 The assessment instruments selected are sequenced, varied, and appropriate to the student work being assessed.
	6.4 Students have multiple opportunities to measure their own learning progress (e.g., practice quizzes, study questions, etc.)
	6.5 Assessments and evaluations use multiple methods, (e.g., quizzes, tests, discussions, essays, projects, assignments, surveys, polls, etc.) appropriately to measure stated outcomes.
	6.6 Formative assessment and evaluation is used throughout the course to gauge learning and to make adjustments within the course as needed.
	6.7 Summative assessment and evaluation is used at the end of the course to gauge achievement of course goals, objectives and outcomes.
	6.8 A grading scale that defines letter grades and/or weights, if applicable, is provided.
	6.9 The instructor clearly communicates when, what type and how feedback will be provided to learners when their performance is being assessed or evaluated.
	6.10 Learners have the opportunity to provide feedback regarding the instructor and instructional strategies of the course.
	6.11 A gradebook is available so learners can check their progress.
7. Course Technology	
	7.1 The tools and media support the course learning objectives.
	7.2 Course tools and media support student engagement and guide the student to become an active learner.
	7.3 Navigation throughout the online components of the course is logical, consistent, and efficient.
	7.4 Students can readily access the technologies required in the course.
	7.5 The course technologies are current.
8. Learner Support	
	8.1 The course instructions articulate or link to a clear description of the technical support offered and how to access it.
	8.2 Course instructions articulate or link to the institution's accessibility policies and services.
	8.3 Course instructions articulate or link to an explanation of how the institution's academic support services and resources can help students succeed in the course and how students can access the services.
	8.4 Course instructions articulate or link to an explanation of how the institution's student support services can help students succeed and how students can access the services.

Adapted from Maryland Online (21) and Las Positas College Online Learning (22)

Appendix 10: Questionnaire - Is an online course right for you?

The following questions and explanations for each of the questions are shown below. These explanations will give you a good idea of what to expect from an online course. At the end you will find a link to the next section which will ask you about your computer skills.

1. The amount of time I expect to spend on my online course is:
    a) more than I would for an on campus course.
    b) the same as I would for an on campus course.
    c) less that I would for an on campus course.

If you are interested in a online course because you think that it will be less work than a traditional on campus course, then this style of learning may not be right for you. Most of our students believe that an online course is at least as much work as an on campus course. In fact, many say that their online course involved significantly more work. However, most students feel that this additional work load is more than compensated by the fact that they were able to "go to class" whenever they had the time, whether it be 2 a.m. or 6 p.m.

2. In regards to assessing my own progress and learning in a course:
    a) I feel I can gauge how well I am doing on my own, even with little instructor feedback.
    b) I need regular feedback from my instructor, but that feedback does not need to be immediate.
    c) I need frequent and immediate feedback to assess my progress.

If you answered (a) or (b) an online course will probably work fine for you. However if you answered (c) you may be disappointed with this learning format. Due to the nature of learning in this format feedback from you instructor may not be as frequent or as timely as you are used to from a traditional class. However, this can vary from course to course depending on the teaching style of your instructor. Many students feel that they actually receive more quality feedback from their instructor in this format. Many students also feel they have more consistent contact with their instructors in an online course.

3. When it comes to assignment deadlines:
    a) I usually have things done ahead of time.
    b) I usually have things done on time but sometimes need reminders of the deadline.
    c) I often turn in things late or forget that they are due if not reminded often.

One of the most important things to understand is although you are able to work on your coursework when you want to, online courses are NOT self-paced courses. They have assignment deadlines just like an on campus course. Not meeting these deadlines and falling behind in their coursework is the leading reason why online students do not succeed. Since you do not have a regular class meeting time, it is essential that you are able to keep on top of your assignments. You will not have instructors and fellow students to remind you.

4. I prefer my feedback from an instructor to be:
    a) written comments.
    b) written comments with some oral clarifications if needed.
    c) I need oral comments to understand the feedback.

If you answered (c) you may not be happy with an online style course. This style of teaching usually does not involve oral feedback. The feedback you will be receiving will almost exclusively be written comments. It is essential to you success that you be able to understand this type of feedback.

5. When given an assignment I prefer to:

a) figure out the instructions on my own with little clarification.
b) try to understand the instructions, then ask for clarification.
c) have the instructions explained to me in detail.

If you answered (c) you may have problems with this type of course. Most successful online students are those that are able to work well independently and with little direct guidance. While it is true that your instructor is there to assist you in understanding the course materials it is your responsibility to seek out this help.

6. Classroom discussion is:

a) very important to my learning style.
b) somewhat important to my learning style.
c) not important to my learning style.

There is no right or wrong answer to this question. Although there is no in person discussion in an online course, there is still discussion. The amount of discussion will depend on the structure of the individual course. This interaction will likely take the form of an online discussion group, chat, or e-mail. The thing to consider is whether or not having discussion in an electronic format will work for you. For some students electronic communication is a poor substitute for face-to-face discussion. However, many of our students actually prefer this style of discussion and feel they participate more freely than they do in an on campus setting.

7. Having face to face contact with my instructor is:

a) not important to me.
b) somewhat important to me.
c) very important to me.

In an online course there is usually little or no face to face contact with your instructor. If you answered (c) and feel that you need to see you instructor often in order to succeed then this style of learning may not be right for you. Some instructors do make arrangements for in person office hours or make special arrangements to meet students. However, you should plan on the vast majority of your contact with your instructor being via e-mail or other electronic communications.

8. My primary motivation for taking a class online is:

a) I need it for my major or I am very interested in the subject material.
b) I love the Internet and taking a class this way seems like a perfect fit for me.
c) I want to save time.

If you answered (a) you should have the necessary motivation to take an online course. The most successful online students are ones who are taking a course in which they have a personal interest or one that is necessary for their graduation. If you answered (b) then an online course may work well for you or it may not. Just because you love being online does not mean that you will like learning is this format. Some of our unsuccessful students are ones who were merely fascinated with the technology, but who had not really thought out the ramifications of taking a course in this format. If you answered (c) then an online course is probably not for you. While it is true that you will most likely not have to come to campus and that you can work on your on schedule, this in no way means you will spend less time on your online course. In fact most students feel that they spend at least as much if not more time doing work for an online course.

9. The socials aspects of the traditional on campus environment:

a) not very important to me.
b) somewhat important to me.
c) very important to me.

If you answered (c) then we do not recommend a schedule that consists solely of online courses. While there are opportunities for interaction with your classmates in an online course, this interaction may be unsatisfying for someone who needs high levels of social activity as part of their learning experience. If this is true for you, you may want to look into taking some on campus courses to supplement your online courses.

Assessment of Answers:

If you answered mostly a's:
You should be an ideal online learning student. Your answers reflect that your learning style and academic needs are in tune with the realities of taking a course online. However, this should not lead to to think that it will a seamless transition. There will surely be some adjustments you will have to make to your learning style, but these adjustments should be relatively minor.

If you answered mostly b's:
An online course should work for you, but you may need to make some adjustments to your learning style in order to be successful. You should review the explanations above too see the areas in which you will need to make those adjustments. The lower you score, the more difficult you may find it to make those changes. However, with effort you should be able to make those adjustments and have a productive online learning experience.

If you answered mostly c's:
You may want to think seriously about whether an online class is right for you. Your answers indicate that you may be unsatisfied with some elements of the online learning environment. This is not to say that for you taking an online course will surely end in disaster, but we highly recommend that you look closely at the explanations above. You will likely need to make major changes to your learning style to succeed. Use the information on this page to help you decide if those are changes you think you can make. If you decide that these changes sound like too much for you to overcome, then don't worry, online courses are not for everyone. However, if you decide to make the attempt we will gladly welcome you as a new online student.

Appendix 11: Evaluation of Course Worksheet

Category	Recommended Best Practices	Notes
Teacher Presence and Interaction	Is "Teacher Presence" clearly evident? "Teacher Presence" can be achieved in a variety of ways (these may not be applicable for all courses):	
	Are there frequent postings of announcements?	
	Are instructors responding to emails in a timely manner?	
	Are assignments being corrected in a timely manner?	
	Are grades being posted in a timely manner?	
	Is there instructor participation in discussion?	
	Are discussions being monitored?	
	Is there interaction among students?	
Gradebook		
	Is there activity in the grade book?	
	Are grades posted in a relatively short time after the assignments were due?	
	Is it clear how, where and when students will be able to view their grades?	
	Is it clear what the consequences are for late submission of assignments?	
	Are midterm grades submitted on time?	
	Are final grades submitted on time?	
Assessments		
	Are the assignments and assessments appropriate for the level of the course?	
	Are the procedures clear for submissions?	
Attendance		
	Is it clearly stated how attendance is being taken?	
Lectures		
	Are lectures fresh with current information?	
	Are lectures ADA compliant? (ex. videos have text transcript)	
	If special applications are used, such as PowerPoint, is there a link to the PowerPoint viewer?	

APPENDIX 12

Table 1: Resources
Table 2: Expenditures

TABLE 1: RESOURCES					
Resource Categories	**Year 1**	**Year 2**	**Year 3**	**Year 4**	**Year 5**
1. Reallocated Funds	$ -	$ -	$ -	$ -	$ -
2. Tuition/Fee Revenue (c + g below)					
a. Number of F/T Students	-	-	-	-	-
b. Annual Tuition/Fee Rate	$ -	$ -	$ -	$ -	$ -
c. Total F/T Revenue (a x b)	$ -	$ -	$ -	$ -	$ -
d. Number of P/T Students Resident	**6**	**9**	**10**	**12**	**16**
e. Credit Hour Rate	$ 590.00	$ 607.00	$ 626.00	$ 644.00	$ 677.00
f. Annual credit hours per P/T student	12	12	12	12	12
g. Total P/T Resident Revenue (d x e x f)	**$ 42,480**	**$ 65,556**	**$ 75,120**	**$ 92,736**	**$ 129,984**
d. Number of P/T Students Non-Resident	**4**	**5**	**6**	**8**	**8**
e. Credit Hour Rate	$ 1,030.00	$ 1,071.00	$ 1,113.00	$ 1,157.00	$ 1,203.00
f. Annual credit hours per P/T student	12	12	12	12	12
g. Total P/T Non-Resident Revenue (d x e x f)	**$ 49,440**	**$ 64,260**	**$ 80,136**	**$ 111,072**	**$ 115,488**
h. Total P/T Revenue All Students (g + g)	**$ 91,920**	**$ 129,816**	**$ 155,256**	**$ 203,808**	**$ 245,472**
3. Grants, Contracts & Other External Sources	$ -	$ -	$ -	$ -	$ -
4. Other Sources	**$ 15,000**	**$ 15,000**	**$ 15,000**	$ -	$ -
TOTAL (ADD 1 - 4)	**$ 106,920**	**$ 144,816**	**$ 170,256**	**$ 203,808**	**$ 245,472**

TABLE 2: EXPENDITURES					
Expenditure Categories	**Year 1**	**Year 2**	**Year 3**	**Year 4**	**Year 5**
1. Faculty (b +c below)	**$ 67,104**	**$ 81,437**	**$ 99,145**	**$ 124,444**	**$ 142,526**
a. #FTE	0.38	0.43	0.51	0.60	0.65
b. Total Salary	$ 54,511	$ 65,958	$ 80,398	$ 100,585	$ 115,033
c. Total Benefits	$ 12,593	$ 15,479	$ 18,747	$ 23,859	$ 27,493
2. Administrative (b + c below)	**$ -**	**$ 21,374**	**$ 28,054**	**$ 35,348**	**$ 43,301**
a. # FTE	0.00	0.20	0.25	0.30	0.35
b. Total Salary	$ -	$ 14,640	$ 19,215	$ 24,211	$ 29,658
c. Total Benefits	$ -	$ 6,734	$ 8,839	$ 11,137	$ 13,643
3. Support Staff (b + c below)	**$ 14,600**	**$ 15,330**	**$ 22,535**	**$ 27,042**	**$ 35,493**
a. # FTE	0.25	0.25	0.35	0.40	0.50
b. Total Salary	$ 10,000	$ 10,500	$ 15,435	$ 18,522	$ 24,310
c. Total Benefits	$ 4,600	$ 4,830	$ 7,100	$ 8,520	$ 11,183
4. Equipment	**$ 2,500**	**$ 2,500**	**$ 2,500**	**$ 2,500**	**$ 5,000**
5. Library	$ -	**$ -**	**$ -**	**$ -**	**$ -**
6. New or Renovated Space	$ -	$ -	$ -	**$ -**	**$ -**
7. Other Expenses	**$ 22,716**	**$ 24,175**	**$ 18,022**	**$ 14,474**	**$ 19,152**
TOTAL (ADD 1 - 7)	**$ 106,920**	**$ 144,816**	**$ 170,256**	**$ 203,808**	**$ 245,472**

APPENDIX 13
BIOSKETCHES OF TEACHING FACULTY

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors in the order listed on Form Page 2.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
Henry J. Silverman	Professor of Medicine
eRA COMMONS USER NAME (credential, e.g., agency login) hsilverm	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	YEAR(s)	FIELD OF STUDY
Rensselaer Polytechnic Institute, Troy, NY	B.S.	1974	Biomedical Engineering
Rensselaer Polytechnic Institute, Troy, NY	M.S.	1974	Biomedical Engineering
Johns Hopkins School of Medicine, Baltimore, MD	M.D.	1978	Medicine
Georgetown University, Washington, DC	M.A.	1995	Philosophy (Bioethics)

A. Positions and Honors

Positions and Employment

1981-1983 Pulmonary Fellowship: The Johns Hopkins Hospital, Baltimore, Maryland
1983-1988 Assistant Professor: Department of Medicine, University of Maryland School of Medicine
1983- 2002 Director: Medical Intensive Care Unit, University of Maryland Hospital, Baltimore
1989-1994 Associate Professor: Department of Medicine, University of Maryland School of Medicine
1996-2005 Chair: Research Ethics Committee, NIH-Sponsored ARDS Clinical Trials Network

Honors and Awards

1988 Recipient: Senior Resident's Award for Teaching, University of Maryland, Baltimore
2001 Recipient: Senior Medical Student's Award for Humanism in Medicine, The Healthcare Foundation of New Jersey
2009 Scholar, Fulbright Specialist Program

C. Selected peer-reviewed publications (Selected from 67 peer-reviewed publications)

Most Relevant to the current application (in chronological order)

1. Khalil SS, Silverman HJ, Raafat M, El-Kamary S, El-Setouhy M. Attitudes, understanding, and concerns regarding medical research amongst Egyptians: A qualitative pilot study. BMC Medical Ethics 2007 Aug 29; 8(1):9
2. Abdur Rab M, Afzal M, Abou-Zeid A, Silverman H. Ethical practices for health research in the Eastern Mediterranean region of the World Health Organization: a retrospective data analysis. PLoS ONE. 2008 May 7;3(5):e2094
3. Wazaify M, Khalil SS, Silverman HJ. Expression of therapeutic misconception amongst Egyptians: A qualitative pilot study. BMC Med Ethics. 2009 Jun 30;10:7
4. Abou-Zeid A, Silverman HJ, Shehata M. Collection, Storage, and Use of Blood Samples for Future Research: HJViews of Egyptian Patients Expressed in a Cross-Sectional Survey. 2010. Journal of Medical Ethics. Accepted for Publication.
5. Sleem H, El-Kamary S, Silverman, H. Identifying Structures, Processes, Resources and Needs of Research Ethics Committees in Egypt. BMC Medical Ethics. Accepted for publication.

Additional recent publications of importance to the field (in chronological order)

1. Silverman HJ, Hull S, Sugarman J. Degree of variability among institutional review boards on approved research practices and informed consent in the context of a multi-center clinical trial. Crit Care Med. 2001; 299:235241.

2. Silverman HJ, Miller FG. Control group selection in critical care randomized controlled trials evaluating interventional strategies: an ethical assessment. Crit Care Med. 2004; 32:852.
3. Silverman HJ, Druml C, Lemaire F, Nelson R. The European Union Directive and the protection of incapacitated subjects in research: an ethical analysis. Intensive Care Medicine 2004; 9:1723-1729.
4. Miller FG, Silverman HJ. The Ethical Relevance of the Standard of Care in the Design of Clinical Trials. Am J Resp Crit Care Med. 2005; 169:562-564.
5. Silverman HJ, Luce JM, Lanken PN, Morris AH, Harabin AL, Oldmixon CF, Thompson BT, Bernard GR, for the NHLBI Acute Respiratory Distress Syndrome Clinical Trials Network. Recommendations for informed consent forms for critical care clinical trials. Critical Care Medicine. 2005; 33:867-882
6. Silverman, HJ, et.al. HRETIE 2005 Candidates and Faculty. Enhancing Research Ethics Committees In Egypt. Guidelines for Standard Operating Procedures. The Monitor. 2006; 20:49.
7. Ramahi I, Silverman H. Clinical Research Law in Jordan: An Ethical Analysis. Dev World Bioeth. 2007, Dec. 12.
8. Abou-Zeid A, Afzal M, Silverman H. Capacity Mapping of the National Bioethics Committees in the Eastern Mediterranean Region. BMC Med Ethics. 2009 Jul 4;10:8
9. Silverman H, Ahmed B, Ajeilat S, Al-Fadil S, Al-Amad S, El-Dessouky H, El-Gendy I, El-Guindi M, El-Nimeiri M, Muzaffar R, Saleh A. Curriculum Guide for Research Ethics Workshops for Countries in the Middle East. Dev World Bioeth. 2009 Aug18
10. Riyami AA, Jaju D, Jaju S, Silverman HJ. The Adequacy of Informed Consent Forms in Genetic Research Performed in Oman: A Pilot Study. 2010. Developing World Bioethics.

C. Research Support

1 R25 TW007090-01 Silverman (PI) 6/11 – 5/16
International Research Ethics Education and Curriculum Development Award
The major goals of this project are to provide intensive training in research ethics to individuals from Egypt and other countries in the Middle East leading to career development of individuals in bioethics and enhancement of bioethics capacity in their home countries.
Role in Project: Principal Investigator (20% Salary) Amount:; $1,250,000

25TW007090-S Silverman (PI) 9/01/2009 – 8/31/2011
Fogarty Administrative Supplement for Assessment of Distance Learning programs to Determine Best Practices for Audiences Situated in Developing Countries
The goal of this supplement is to stimulate the incorporation of information and communication technologies (ICT) into the existing International Research Ethics Education and Curriculum Development Program that is situated in the Middle East. This project aims to develop and assess best practices in eleanring.

Role in Project: Principal Investigator Amount: $50,000

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors in the order listed on Form Page 2.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
Robert Wachbroit	Assistant Professor
eRA COMMONS USER NAME WACHBROIT	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	YEAR(s)	FIELD OF STUDY
Massachusetts Institute of Technology	B.S	1970	Physics
University of California, Berkeley	Ph.D.	1979	Philosophy

A. Positions and Honors

Positions and Employment

1971-73 Instructor: Department of Physics, University of San Francisco, San Francisco, California
1979-86 Assistant Professor: Department of Philosophy, University of Pennsylvania, Philadelphia, Pennsylvania
1986-present Research Scholar: Institute for Philosophy and Public Policy, University of Maryland, College Park, Maryland
1987-89 Adjunct Professor: University of Maryland School of Law, Baltimore, Maryland
1987-91 Assistant Research Scientist: Center for Public Issues in Biotechnology, Maryland, Biotechnology Institute, College Park, Maryland
1994-present Adjunct Associate Professor: Department of OB/GYN, University of Maryland School of Medicine.
1994-present Adjunct Associate Professor: Department of Philosophy, University of Maryland, Baltimore
1997-2001 Senior Research Fellow: Kennedy Institute of Ethics, Georgetown University, Washington, D.C.
2005-present Adjunct Associate Professor, Department of Epidemiology and Preventive Medicine, School of Medicine.

B. Selected 15 peer-reviewed publications (in chronological order)

1. Wachbroit, R. (1994). Rethinking confidentiality: the impact of genetics. Suffolk Law Review, 27, 501-520.
2. Wachbroit, R. (1994). Distinguishing genetic disease and genetic susceptibility. American Journal of Medical Genetics, 53, 236-40.
3. Wachbroit, R. (1995). Human Genetic Engineering, In: *The Encyclopedia of Bioethics,* 936-940. New York: Macmillan.
4. Wachbroit, R. (1998). The question not asked: the challenge of pleiotropic genetic tests. Kennedy Institute of Ethics Journal, 8, 131-44.
5. Wachbroit, R. (199). Disowning knowledge: issues in genetic testing, In: Munson, R (ed): *Intervention and Reflection: Basic Issues in Medical Ethics,* 6th Edition, Wadsworth Publishing Co.
6. Wachbroit, R. (2001). Reliance and reliability: the problem of information on the Internet. In: *Ethics and the Internet*, ed. Anton Vedders (Intersentia, Antwerp, 2001.
7. Wasserman, D. and Wachbroit, R. (eds) (2001).*Genetics and Criminal Behavior*, Cambridge University Press.
8. Wachbroit, R (2001). Understanding the genetics of violence controversy. In: *Genetics and Criminal Behavior*, ed. D. Wasserman and R.S. Wachbroit, Cambridge University Press.
9. Lichtenberg, J., Bianchi, S., Wachbroit, R., and Wasserman, D. (2002). Counting Race and Ethnicity: Revising the U.S. Census. In: *Philosophical Dimensions of Public Policy*, ed. V. Gehring and W. Galston, Transaction Publishers, New Brunswick, NJ., 133-141.
10. Vedder, A. and Wachbroit, R. (2003). Reliability of information on the Internet: some distinctions. Ethics and Information Technology, 5, 211-215.

11. Wachbroit R. and Wasserman, D. (2005). Research participation: are we subject to a duty. American Journal of Bioethics, 5, 48-9.
12. Wachbroit, R. (2006). Normality and human difference. In: *Wrestling with Behavioral Genetics: Implications for Understanding Selves and Society*, ed. Erik Parens, Audrey Chapman, and Nancy Press, Johns Hopkins University Press.
13. Wachbroit, R. (2008). The prospects for neuro-exceptionalism: transparent lies, naked minds. American Journal of Bioethics – Neuroscience, 8 (January), 3-8.
14. Wachbroit, R. (forthcoming). Human Subjects, Research Use of. In: *International Encyclopedia of Ethics*, ed. Hugh LaFollette, Wiley-Blackwell.
15. Wachbroit, R. (forthcoming). Assessing phase I clinical trials. Law, Probability, and Risk.

C. Grant Support

1 R25 TW007090-01 Silverman (PI) 6/11 – 5/16
International Research Ethics Education and Curriculum Development Award
The major goals of this project are to provide intensive training in research ethics to individuals from Egypt and other countries in the Middle East leading to career development of individuals in bioethics and enhancement of bioethics capacity in their home countries.

Role in Project: Co-Principal Investigator (7.5% Salary Support) Amount: $1,250,000

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors in the order listed on Form Page 2.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
Adil E. Shamoo	Professor of Biochemistry
eRA COMMONS USER NAME (credential, e.g., agency login)	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	MM/YY	FIELD OF STUDY
University of Baghdad, Baghdad, Iraq	B..Sc.	1962	Physics
University of Louisville, Louisville, KY	M.Sc.	1966	Physics
City University of New York, NY	Ph.D.	1970	Biophysics

A. Positions and Honors

Positions and Employment

2006 – Present Member, Defense Health Board and Chair of its Medical Ethics Subcommittee.
2006 - 2007 Member of the new Maryland Governor's Higher Education Transition Working Group.
2006 – 2007 Guest Faculty, Applied Research Ethics Program, Sarah Lawrence College, Bronxville, NY.
10/05 – 8/2006 Member, Armed Forces Epidemiological Board.
10/03 – 8/2004 Appointed to Armed Forces Epidemiological Board/DOD with a title of Ethics Consultant.
2000 – 2003 Member, National Human Research Protections Advisory Committee (NHRPAC)

2/03 – 2/2004 Chair, GlaxoSmithKline Advisory Group (Special Ethical Issues).
7/82 – Present Professor, Dept. of Biochemistry and Molecular Biology University of Maryland School of Medicine.
10/2/01- Certificate of IRB Professionals (CIP) by Council for Certification of IRB Professionals.
7/12/98 – 7/17/98 Certificate of Attendance Patent Review Course, Patent Resource Group, Inc.
6/79 – 6/82 Professor and Chairman, Dept. of Biological Chemistry, University of Maryland, School of Medicine.
7/88 – 10/88 Expert, Laboratory of Theoretical Biology, National Cancer Institute, NIH, Bethesda, MD.
1976- 1979 Established Investigator of the American Heart Association.

HONORS:

1966: Phi Kappa Phi, 1964-1965:-Graduate Fellowship-Engr. Physics Dept. of University of Louisville., 1965: Sigma Pi Sigma.,1966-1969:American Heart Association, Established Investigatorship.

JOURNALS, EDITORIALS, REVIEWS, MEMBERSHIP IN RELEVANT SOCITIES, ETC:

2005 – Present Member, Editorial Board of: Drug Information Journal.
2005 – 2007 Member, Advisory Board of : Public Library of Science, Clinical Trials (PLoS Clinical Trials).
1987 – Present Founder and Editor-in-Chief of "Accountability in Research", Gordon and Breach Science Publishers.
1996 – 2001 Member, Editorial Board of "Technology Management."
1977 – 1993 Editor-in-Chief (84-93) or Co-Editor-in-Chief (77-84), of Membrane Biochemistry," Taylor and Francis Publisher, New York.
1990 – 2004 Member, Editorial Board, Quality Assurance: Good Practice, Regulations, and Law in

Academic Press, New York, New York.
1987 – 1994 Member, Editorial Board, Molecular and Cellular Biochemistry, Martinus Nighoff Publishers.
1997 – Present Charter Member of the American Society of The Bioethics and Humanities.
1994 – Present Associate Member, Hasting Center
1988 – Present Organized twelve National and International Conferences on Research Ethics.

BOOKS
Authored, co-authored, and edited 15 books. Among them: In 2002, Ethics of the Use of Human Subjects in Research (with Dr. Felix Gyi) and in 2009, 2nd edition; Textbook on: Responsible Conduct of Research (with Dr. David Resnik).

B. Selected Peer-Reviewed Publications (in chronological order)

List of Publications 270 papers (excluding abstracts).
Selected peer-reviewed articles relevant to this application:

1. **Shamoo, A. E.**, and Resnik, D. B., **(2006**), "Ethical Issues for Clinical Research Managers", Drug Information Journal, 40: 371-383.
2. Silverman, H. et al **(…Shamoo, A. E.,…), 2006**. "Enhancing Research Ethics Committees in Egypt - Guidelines for Standard Operating Procedures", Monitor, Dec, 2005, 49 – 52
3. **Shamoo, A. E.**, and Woeckner, E. **2007.** "Ethical Flaws in the TeGenero Trial", The American Journal of Bioethics, 7:2, 90 – 92. To link to this article: DOI: 10.1080/15265160601112204 URL: http://dx.doi.org/10.1080/15265160601112204
4. **Shamoo, A. E. and Katzel, L.I., 2008.** "How Should Adverse Events Be Reported in US Clinical Trials?: Ethical Consideration", Clinical Pharmacology & Therapeutics, 27 Feb 2008), doi: 10.1038/clpt.2008.14, Ethics
5. **Shamoo, A. E., and Schwartz, J. 2007.** "Universal and Uniform Protections of Human Subjects in Research", American Journal of Bioethics, 7(12): 7-9.
6. **Shamoo, A. E. and Katzel, L.I., 2008.** "How Should Adverse Events Be Reported in US Clinical Trials?: Ethical Consideration", Clinical Pharmacology & Therapeutics, 27 Feb 2008), doi: 10.1038/clpt.2008.14, Ethics
7. Amin, S. B., McDermott, M. P., and **Shamoo, A. E. 2008.** "Clinical Trials of Drugs Used Off-Label in Neonates: Ethical Issues and Alternative Study Designs", Accountability in Research, 15:168-187.
8. **Shamoo, A. E., 2008.** "The Myth of Equipoise in Phase 1 Clinical Trials", Medscape J Med. 2008;10(11):254. ©2008 Medscape, Posted 11/05/2008 http://www.medscape.com/viewarticle/582554
9. **Shamoo, A. E., 2010.** Ethical and Regulatory Challenges in Psychophysiology and Neuroscience-Based Technology for Determining Behavior, Accountability in Research, 17:8–29, 2010

C. Research Support

1 R25 TW007090-01 Silverman (PI) 6/11 – 5/16
International Research Ethics Education and Curriculum Development Award
The major goals of this project are to provide intensive training in research ethics to individuals from Egypt and other countries in the Middle East leading to career development of individuals in bioethics and enhancement of bioethics capacity in their home countries.

Role in Project: Co-Principal Investigator (5% support) Amount:; $1,250,000

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors in the order listed on Form Page 2. Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME Adebamowo, Clement Adebayo	POSITION TITLE Director of Strategic Information and Research, Institute of Human Virology, Nigeria Associate Professor Cancer Epidemiology, UM Baltimore
eRA COMMONS USER NAME UIIBADAN	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	YEAR(s)	FIELD OF STUDY
University of Jos, Jos, Nigeria	BM ChB Hons	JUNE/1984	Medicine, Surgery
Harvard University, Boston, MA	Sc D	JUNE/2004	Nutrition Epidemiology

A. Positions and Honors.

Positions and Employment

1993 – 2001 Lecturer in Surgery, Department of Surgery, University of Ibadan, Ibadan, Oyo State, Nigeria.
2001 – 2009 Professor of Surgery Department of Surgery, University of Ibadan, Ibadan, Nigeria.
2005 – 2009 Lecturer in Nutrition Epidemiology, University of Ibadan, Ibadan, Nigeria
2005 – 2009 Lecturer in Bioethics and Director of the MSc, MPhil/PhD program in Bioethics and in Surgery, University of Ibadan, Ibadan, Nigeria
2007 – 2009 Director, Institute for Advanced Medical Research and Training, University of Ibadan
2006 – date Visiting Scientist, Department of Nutrition, Harvard School of Public Health, Boston MA
2006 – date Chairman, National Health Research Ethics Committee of Nigeria
2009 – date Associate Professor, University of Maryland School of Medicine, Baltimore, Maryland
2009 – date Executive Director, Office of Strategic Information, Research and Training, Institute of Human Virology, Nigeria
2010 – date Honorary Professor, University of Dundee, U.K.
2010 – date Coordinator of National Cancer Registration System of Nigeria

Honors, Distinctions and Awards

1 Federal Government Merit Award for Outstanding Scholarship 1981
2 Nwafor-Orizu Prize for the best Student in Academic Excellence in the University of Jos (1984)
3 Faculty Prize for the best Student in the Faculty of Medical Science (1984).
4 S.P Jain's Prize for the best student in Medical Science (1984).
5 Member, Board of Directors of the African Society for Human Genetics.
6 Chair, International Affairs Committee, American Society of Clinical Oncology, 2010 – 2011

B. LIST OF PUBLICATIONS (Selected of 115)

1. Doumatey A. P., Lashley K. S., Huang H., Zhou J., Chen G., Amoah A., Agyenim-Boateng K., Oli J., Fasanmade O., **Adebamowo C. A.,** Adeyemo A. A., Rotimi C. N. Relationships among obesity, inflammation, and insulin resistance in African Americans and West Africans. Obesity (silver spring). 2010; 18(3): 598 - 603.
2. Huo D., **Adebamowo C. A.,** Ogundiran T. O., Akang E. E. U., Campbell O., Adenipekun A., Cummings S., Fackenthal J. D., Ademuyiwa F., Ahsan H., Olopade O. I. Case-control study of body size and breast cancer risk in Nigerian women. Am. J. Epidemiol 2010; 172: 682 - 690
3. Stacey S. N., Sulem P, Zanon C., Gudjonsson S. A., Thorleifsson G., Helgason A., Jonasdottir A., Besenbacher S., Kostic J. P., Fackenthal J. D., Huo D., **Adebamowo C.,** Ogundiran T., Olson J. E., Fredericksen Z. S., Wang X., Look M. P., Sieuwerts A. M., Martens J. W., Pajares I., Garcia-Prats M. D., Ramon-Cajal J. M., de Juan A., Panadero A., Ortega E., Aben K. K., Vermeulen S. H., Asadzadeh F., van Engelenburg K. C., Margolin S., Shen C. Y., Wu P. E., Försti A., Lenner P., Henriksson R., Johansson R., Enquist K., Hallmans G., Jonsson T., Sigurdsson H., Alexiusdottir K., Gudmundsson J., Sigurdsson A., Frigge

M. L., Gudmundsson L., Kristjansson K., Halldorsson B. V., Styrkarsdottir U., Gulcher J. R,, Hemminki K., Lindblom A., Kiemeney L. A., Mayordomo J. I., Foekens J. A., Couch F. J., Olopade O. I., Gudbjartsson D. F., Thorsteinsdottir U., Rafnar T., Johannsson O. T., Stefansson K. et al Ancestry-Shift Refinement Mapping of the C6orf97-ESR1 Breast Cancer Susceptibility Locus' PLoS Genetics 2010; 6: e1001029

4. The International HapMap 3 Consortium. Integrating common and rare genetic variation in diverse human populations. Nature. 2010 2; 467(7311): 52 - 58.

5. Sumner A. E., Zhou J., Doumatey A., Imoisili O. E., Amoah A., Acheampong J., Oli J., Johnson T., **Adebamowo C.**, Rotimi C. N. Low HDL-cholesterol with normal triglyceride levels is the most common lipid pattern in West Africans and African Americans with Metabolic Syndrome: Implications for cardiovascular disease prevention. CVD Prevention and Control 2010, 5(3): 75 - 80.

6. Dalal S., Beunza J. J., Volmink J., **Adebamowo C.**, Bajunirwe F., Njelekela M., Mozaffarian D., Fawzi W., Willett W., Adami H. O., Holmes M. D. Non-communicable diseases in sub-Saharan Africa: what we know now. Int J Epidemiol. 2011; 40: 885 – 901

7. Mbulaiteye S., Bhatia K., **Adebamowo C. A.,** Sasco A. HIV and cancer in Africa: mutual collaboration between HIV and cancer programs may provide timely research and public health data Infectious Agents and Cancer 2011, 6:16

8. Fackenthal J. D., Zhang J., Zhang B., Zheng Y., Hagos F., Burrill D., Niu Q., Huo D., Sveen W. E., Ogundiran T., Adebamowo C., Olopade O. I. High prevalence of BRCA1 and BRCA2 mutations in unselected Nigerian breast cancer patients. Int J Cancer. 2011

A. Research Support

D43CA153792-01 (PI, Adebamowo) $539,964
NCI/NIH 09/01/2010-08/30/2013
IHV-UM Capacity Development for Research into AIDS Associated Malignancies (CADRE)
Role: Director of Training Program 1.8 calendar months
The Capacity Development for Research into HIV-Associated Malignancies in Nigeria (CADRE-Nigeria) training program targets development of clinical trials and cancer research expertise at the Institute of Human Virology, Nigeria (IHV-Nigeria) and its academic research partners. This research training implements four aims: clinical trials capacity, cancer registration, cancer epidemiology and general research capacity building.

2R25 TW007091-03 (PI, Adebamowo) $250,000
FIC/NIH 09/22/2004-08/30/2016
Role: Director of West African Bioethics Training Program
West African Bioethics Training Program
Role: Director of Center for Bioethics 1.8 calendar months
The goals of this project are to provide short, medium and long term training in international research ethics to biomedical researchers in West Africa

S07 TW008840-01 (PI, Adebamowo) $50,000
FIC/NIH 08/31/2010-08/30/2011
Role: Director of Program 0.6 calendar months
UMB-IRB and Nigerian NHREC Collaborative Capacity Building Initiative
The University of Maryland Baltimore Institutional Review
Board - National Health Research Ethics Committee of Nigeria (NHREC) Collaborative Capacity Building Initiative (UMBINN) is a program designed to enhance the capacity of the two ethics review committee to efficiently and effectively supervise joint research projects.

3R25 TW007091-07S1 (PI, Adebamowo) $120,000
FIC/NIH 07/01/2011-05/31/2012
Role: Director of EAGER-Africa Program
Ethics of Genomics Research in Africa
Role: Director of Center for Bioethics 0.6 calendar months
The goals of this project are to organize a consultative meeting to identify current status of research ethics in genomics in Africa; identify centers where these research are occurring and develop a roadmap for what needs to be done in eliciting knowledge about genomics and research ethics in Africa

D43TW009106-01 (PI, Adebamowo) $250,000
Fogarty International Center/NIH 08/22/2011–07/31/2016
Training Program in Nigeria for NCD Research (Traping-NCD)
Role: Director of Training 0.6 calendar months
The goals of this project are to develop the use of lifecourse epidemiology to provide advanced short, medium and long term training in epidemiology for faculty and biomedical researchers in Nigeria. "Mentor-the-Mentor" training for senior and mid-level researchers as co-mentors with the US faculty, conduct long-term degree and post-doctoral training with linkage to the "Mentor- the-Mentor", provide in-country short courses in general research capacity building, and transition trainees into productive research integrated into well-funded public health and research programs.

D43TW001041-11 (PI, Blattner) $596,825
Fogarty International Center/NIH 09/30/1998–04/30/2015
IHV-UM AIDS International Training and Research Program 0.6 calendar months
Role: Co-investigator, Nigerian Academic Coordinator
The goals of this project are to advance research training for immediate and significant impact and conduct "Mentor-the-Mentor" training for senior and mid-level researchers as co-mentors with the US faculty, conduct long-term degree and post-doctoral training with linkage to the "Mentor- the-Mentor", provide in-country short courses in general research capacity building, and transition trainees into productive research integrated into well-funded public health and research programs.

5U2GPS000651 (PI, Dakum) $24,000,000
Centers for Disease Control and Prevention 03/31/2011–03/31/2012
Global AIDS Program 1.8 calendar months
HIV/AIDS Prevention, Care & Treatment in the Federal Republic of Nigeria (PEPFAR)
Role: Director, Office of Strategic Information, Research, and Training
The goal of this project is to provide expanded coverage of HIV treatment and prevention services in Nigeria